

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	2
A. Institutional Commitments	2
B. Structure of the IRB	3
C. Responsibilities of the IRB to Provide Oversight for its Assurance Agreement	4
D. Process to Ensure that Research Does Not Commence Until the Research Has Obtained All Required Approvals	4
E. Process to Respond to Attempts to Influence the IRB or Others Responsible for the Oversight of Research	5
IV. Authority	5
V. Supportive Data and References	5
VI. History Notes	6
VII. Signature and Effective Date	6

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) to uphold its Federal-Wide Assurance of Compliance (Assurance) as filed with the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP).

II. Definitions

See DOHP 5-D5-11.1, Definitions.

III. Procedures

A. Institutional Commitments

The Department's Assurance will be maintained by the Human Research Protection Program (HRPP) Administrator and provided upon request. The Department's Assurance is based on the following commitments:

1. Safeguarding the rights and welfare of human participants in research through the creation of an IRB is a general policy established in section 381.86, Florida Statutes (F.S.). The State Surgeon General delegates his or her authority to a Department official as the Institutional Official responsible for the Department's Assurance. It is the State Surgeon General's responsibility through the designated official to exercise appropriate administrative oversight to assure the Department's policies and procedures designed for protecting the rights and welfare of human participants are effectively applied in compliance with its Assurance. The State Surgeon General is responsible for ensuring the independence of the IRB and others responsible for the oversight of research. The State Surgeon General delegates responsibility for administration of the program to the HRPP Administrator designated in the Department's Assurance. This individual is an official with sufficient standing, authority, and independence to ensure implementation and maintenance of the program.
2. Department employees, contractors, and anyone acting as an agent of the Department and which comprise its bureaus, divisions, offices, county health departments, and facilities, are subject to the Assurance and this policy when they are engaged in research under the jurisdiction of the Department IRB (see DOHP 5-D5-1.2, Activities Subject to IRB Jurisdiction).
3. The Department will uphold the ethical principles of *The Belmont Report* to all proposed research in which the Department is engaged. The ethical principles set forth in *The Belmont Report* are:

-
- a. Respect for Persons: Recognition of the personal dignity and autonomy of individuals and special protection of those persons with diminished autonomy.
 - b. Beneficence: Obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risk of harm.
 - c. Justice: Fairness in the distribution of research benefits and burdens.
 4. The Department agrees clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and are consistent with good clinical practice and applicable regulatory requirements. Clinical trials should be designed and conducted in ways that ensure the rights, safety, and well-being of participants. The rights, safety, and well-being of participants are the most important considerations and should prevail over interests of science and society.
 5. The Department adheres to all applicable laws that apply to the Department's research. This includes DHHS regulations (45 Code of Federal Regulations [CFR] 46); U.S. Food and Drug Administration Human Subject Regulations (21 CFR §§ 50, 56, 312 and 812); U.S. Environmental Protection Agency Regulations (40 CFR part 26); the Health Insurance Portability and Accountability Act of 1996 (HIPAA); and U.S. Department of Defense regulations, including 32 CFR part 219, Directive 3216.02; Directive 6200.2, Use of Investigational New Drugs for Force Health Protection (version August 1, 2000); Title 10, United States Code, section 980: Limitation on use of humans as experimental subjects; Department of the Navy, SECNAV Instruction 3900.39D.
 6. The Department follows additional state laws, such as section 381.86, F.S., and any other relevant state law relating to conduct of research with human subjects.
 7. No research in which the Department is engaged may be approved by the Department officials or others that has not been previously approved by the Department IRB.

B. Structure of the IRB

1. The IRB Committees are appointed by the State Surgeon General. As such, the IRB serves the Department as a whole, rather than a particular office, division, bureau, or county health department, and any institution for which the Department's IRB is designated as the IRB of record in an Assurance filed with OHRP with a corresponding Memorandum of Understanding (MOU).

2. The Departments Assurance presently designates two OHRP- and U.S. Food and Drug Administration-registered IRB Committees. Designation of additional IRB Committees under the Assurance requires prior notification of and approval by OHRP.

C. Responsibilities of the IRB to Provide Oversight for its Assurance Agreement

1. Approval of the IRB is required prior to the initiation of research involving human participants.
2. Through the review process, the IRB has the authority to approve, require modifications to secure approval, or disapprove research overseen by the Department.
3. The IRB has authority to suspend or terminate approval of research not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants.
4. The IRB has the authority to observe, or have a third party observe, the consent process and the conduct of research.
5. Research reviewed and approved by the IRB may be subject to review and disapproval by officials of the Department, or any institution for which the Department IRB is designated as the IRB of record in accordance with an Assurance or a signed MOU with the Department IRB.

D. Process to Ensure that Research Does Not Commence Until the Research Has Obtained All Required Approvals

As a part of the online IRB Manager application process, researchers complete or have a local county health department official complete the portion of the online application titled "Research Site and Program Support" to ensure:

1. Researchers have promulgated an application for review by the Department IRB prior to submission of grant applications; IRB review is not required prior to submission of grant applications (see IOP 57-01, Grants Management).
2. Division/office director or bureau chief approval is obtained by researchers prior to IRB review of research involving State Health Office programs.
3. A data use agreement is obtained by researchers prior to IRB review of research involving Department registries.

4. Health officer approval is obtained by researchers prior to IRB review of research involving county health departments by completing the "Research Site and Program Support" portion of the online application.
5. The Office of Budget and Revenue Management or relevant budgetary unit verifies grant funding is not released to Department researchers without IRB approval.
6. Researchers provide a copy of the contract or funding agreement prior to IRB review.

E. Process to Respond to Attempts to Influence the IRB or Others Responsible for the Oversight of Research

1. To ensure decisions of the IRB are impartial, the Department does not tolerate attempts to sway, pressure, manipulate, or otherwise influence the decisions of the IRB.
2. Persons aware of attempts to influence the IRB, or who have questions or concerns, may report this to an IRB Chair, IRB Administrator, the HRPP Administrator designated in the Department's Assurance, deputy secretary, or State Surgeon General.
3. Reports of undue influence will be investigated by the HRPP Administrator designated in the Department's Assurance, in coordination with the program attorney and senior leadership. If the allegation involves the HRPP Administrator, then a bureau chief, division/office director, or the Deputy Secretary for Health is responsible for the investigation. The Office of the Inspector General may conduct the investigation and report results to senior leadership and the State Surgeon General.

IV. Authority

Section 381.86, F.S., Institutional Review Board

V. Supportive Data and References

- A. *The Belmont Report*
- B. 45 CFR §§ 46, 160 and 164
- C. 21 CFR §§ 50, 56, 312, and 812
- D. Health Insurance Portability and Accountability Act of 1996 (HIPAA)
- E. [Terms of Assurance](#), Office of Human Research Protections, DHHS

VI. History Notes

Created: 8/28/2013
Previously Amended: 2/23/2015, 1/28/2020
Formerly: DOHP 400-1.1

VII. Signature and Effective Date



Shay Gonzalez
Interim Chief of Staff

10/28/26
Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	2
A. Review and Approval of Human Subjects Research	2
B. Scope of Authority	3
C. Review of Research Involving Data Collected for Non-Research Purposes	4
D. Failure to Submit a Project to the IRB Manager Online System for IRB Review	4
IV. Authority	5
V. Supportive Data and References	5
VI. History Notes	5
VII. Signature and Effective Date	5

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) to have jurisdiction over all human subjects research in which the Department is engaged.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

A. Review and Approval of Human Subjects Research

1. All human subjects research, and all other non-exempt research activities, which in part involve human subjects research, must be reviewed and approved by the Department IRB whenever the Department is engaged in research. The Department is engaged in non-exempt research when Department employees or agents for the purposes of research obtain data about participants in the research through intervention or interaction with them, or identifiable private information about participants in the research. Examples of when the Department is engaged in research include but are not limited to the following:
 - a. Department programs, agents, or employees receive support directly from federal agencies for non-exempt human subjects research (for example, the Department receives research funding from the Centers for Disease Control and Prevention [CDC]), even where all activities involving human subjects are carried out by agents or employees of another institution.
 - b. Department employees or agents intervene or interact for research purposes with any human subjects of the research by performing invasive or noninvasive procedures.
 - c. Department employees or agents intervene for research purposes with any human subject of the research by manipulating the environment.
 - d. Department employees or agents obtain for research purposes identifiable private information or identifiable biological specimens from any source. Obtaining includes but is not limited to: observing and/or recording private behavior and using, studying, or analyzing for research purposes identifiable private information or identifiable specimens already in the possession of the employees or agents of the institution.

-
- e. Department employees or agents are determined to be engaged in research by the Institutional Official, or the Human Research Protection Program (HRPP) Administrator designated in the Department's Federal-Wide Assurance of Compliance (Assurance), or the Director, Public Health Research, or the IRB Administrator.
 2. When conducting research, an agent of the Department refers to anyone who obtains data about living individuals for research purposes through intervention or interaction with them, or anyone who obtains individually identifiable private information for research purposes, or anyone performing institutionally designated research activities and acting on behalf of the institution or exercising institutional authority or responsibility for the conduct of research. Examples include, but are not limited to, Department employees, medical fellows and residents and others serving at Department facilities through cooperative agreements, students and interns, and persons conducting research under a contract or memorandum of understanding with Department programs (not including where the sole activity of the Department is grant-letting).
 3. No intervention or interaction with human subjects in research, including advertising, recruitment, and/or screening, may begin until the IRB has reviewed and approved the research via the online portal titled "[IRB Manager](#)."
 4. It is the responsibility of the Institutional Official, HRPP Administrator designated in the Department's Assurance, or designated HRPP staff to determine what activities constitute "human subjects research."
 5. The International Council for Harmonisation (ICH) of Technical Requirements for Pharmaceuticals for Human Use as adopted by the Food and Drug Administration includes a Guideline for Good Clinical Practice that applies to interventional clinical trials of investigational products as referenced herein.
 6. Activities where the sole involvement of the Department is grant-letting do not require review by the Department IRB unless Department employees or agents are otherwise engaged in research. Examples of grant-letting programs at the Department that do not require review by the Department IRB include the James and Esther King Biomedical Research Program, the Bankhead-Coley Program, and other similar programs where the Department's involvement is limited to grant-letting or funding.

B. Scope of Authority

The Department Assurance with the federal government defines its jurisdiction over the review of research involving human participants. The Department IRB must review all human participant research if one or more of the following apply:

1. The research is sponsored (funded) in whole or in part from federal research appropriations to the Department, even where all activities involving human subjects research are carried out by agents or employees of another institution ("pass-through funding").
2. The research is conducted by or under the direction of any employee or agent of the Department in connection with his or her official responsibilities.
3. The research is conducted using any property or facility of the Department.
4. The research involves Department clients, including recruiting participants at county health departments or other Department clients.
5. The research involves the use of non-public information maintained by the Department when released outside the Department, except as otherwise required by law.
6. The research is conducted in accordance with an Assurance filed with the Office for Human Research Protections (OHRP) in which the Department IRB is designated as the IRB of record through an established Memorandum of Understanding.

C. Review of Research Involving Data Collected for Non-Research Purposes

1. If after data are collected for non-research purposes a researcher wants to access the data with the intent of conducting research, IRB review and approval may be required prior to accessing the data for research purposes.
2. If a researcher begins a non-research project and later finds that the data gathered could contribute to generalizable knowledge, the researcher should contact the HRPP for a determination.
3. Because there are no universally accepted or completely specified criteria for determining when data collected for non-research purposes is being used for research, projects are reviewed on a case-by-case basis.

D. Failure to Submit a Project to the IRB Manager Online System for IRB Review

1. The IRB may not approve applications where the researcher has attempted to circumvent IRB policies and procedures regarding human subjects research by collecting data as non-research and then applying to use them as existing data. It is therefore in the researcher's best interest to consider carefully the likelihood that he or she will want to use the data

for research purposes in the future, and to err on the side of inclusion and seek IRB approval prior to commencing the work.

2. HRPP staff shall submit an incident report for investigation by the Office of the Inspector General if there is reason to think a researcher attempted to circumvent IRB policies.

IV. Authority

Section 381.86, Florida Statutes, Institutional Review Board

V. Supportive Data and References

- A. *The Belmont Report*
- B. 45 CFR §§ 46, 160, and 164
- C. 21 CFR §§ 50, 56, 312, and 812
- D. [Terms of Assurance](#), OHRP, Department of Health and Human Services
- E. [Guidelines for Defining Public Health Research and Public Health Non-Research](#), CDC, October 4, 1999.
- F. ICH-GCP: I., Guideline Scope

VI. History Notes

Created: 08/28/2013
Previously Amended: 01/28/2020
Formerly: DOHP 400-1.2

VII. Signature and Effective Date

Shay Gonzalez

Shay Gonzalez
Interim Chief of Staff

10/28/26
Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	2
IV. Authority	5
V. Supportive Data and References	5
VI. History Notes	5
VII. Signature and Effective Date	5

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) to review funding agreements to ensure human subject protection requirements are included.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

A. Staff responsibilities:

1. Staff review funding agreements as part of Administrative Pre-Review using the Human Subject Protection Requirements for Funding Agreements Worksheet. Inclusion of human subject protection in funding agreements generally only applies to clinical research.
2. Staff determine whether the sponsor is responsible for monitoring research; it is not necessary to require the sponsor to include human subject protection in the funding agreement if the sponsor does not monitor research.
3. Staff evaluate the risk of injury in the research conducted under its auspices and make determinations whether medical care for research-related injury might be needed.
4. Staff notify researchers when contracts and funding agreements do not contain required information. The notification and Human Subject Protection Requirements for Funding Agreements Worksheet are recorded on the network drive or application management system.
5. Staff may send for review a research study when required human subject protection information is not included in the contract or funding agreement. However, the study will not be approved until a draft contract exists that includes required human subject protection components. Contracts or funding agreements should describe the steps followed to promptly, or in a timely manner, appropriate to the level of risk involved, communicate findings from a closed research study to the researcher or organization when those findings directly affect participant safety. The contract or funding agreement will specify the time frame in which they are required to communicate the findings to the participants after closure. For such research, the staff will verify, in addition, that the researcher has provided an attestation from the entity responsible for negotiating contracts that the required information will be included in the final contract. If a contract does not include appropriate language, staff will forward sample language to the researcher.

6. When the contract is finalized, staff verify that the human subject protection language is present and provide an administrative comment to document compliance. It is not necessary to have the IRB reviewer verify contracts.
7. If the sponsor will not revise the contract to include appropriate language, Human Research Protection Program staff will contact the program attorney, or a contract attorney in the Office of the General Counsel to discuss the issue. In some cases, it is not possible to approve research without a change in the contract. For example, if the sponsor will not commit in the contract to providing data and safety monitoring reports, the IRB will have no basis to assess risk at continuing review and thus the research cannot be approved.

B. Researcher responsibilities:

1. Researchers are responsible for including human subject protection requirements in funding agreements. Funding agreements must specify the following human subject protection components before research starts:
 - a. Confirm who will provide medical care to participants in clinical research and who will be responsible for covering the cost. The Department does not require any particular entity to be responsible for providing care, only that the funding agreement and informed consent process make it clear to participants who will provide medical care and who will be responsible for covering the cost of that care.
 - b. Assurance that the sponsor will promptly report to the researcher any findings that could affect the safety of participants or influence the conduct of the study, when sponsors are responsible for monitoring the progress of the study. Researchers are responsible for promptly submitting copies of monitoring reports that contain findings that could affect the safety of participants or influence the conduct of the study to the IRB using the Problems Requiring Prompt Reporting to the IRB form located on the online application system titled "IRB Manager."
 - c. Contracts or other funding agreements must specify that data and safety monitoring plans are provided prior to IRB prior to approval of the research, and that contracts or other funding agreements specify the time frame for providing routine and urgent data and safety monitoring reports to the IRB.

- d. Sponsors should follow Department policies regarding dissemination of research findings for programs at the Department that have such policies.
 - e. Sponsors must notify the researcher when participant safety could be directly affected by study results after the study has ended (normally for a period of two years). Researchers will notify the IRB using the Problems Requiring Prompt Reporting to the IRB form. The IRB will determine whether the researcher should inform participants.
 - f. When the contract is finalized, the researcher emails the final contract to staff.
 - 2. Researchers should review expectations for human subject protection in contracts and funding agreements, and verify the information is included, using the Human Subject Protection Requirements for Funding Agreements Worksheet.
 - 3. Researchers are responsible for ensuring human subject protection components are included in contracts. Failure to include this information will result in delays in approval of research.
- C.** Researchers following International Council for Harmonisation Good Clinical Practice (ICH-GCP) as adopted by the United States Food and Drug Administration must:
 - 1. Ensure that during and following participation in a trial, adequate medical care is provided to a participant for any adverse events, including clinically significant laboratory values related to the trial.
 - 2. Inform a participant when medical care is needed for intercurrent illness(es) of which the researcher becomes aware.
 - 3. Make a reasonable effort to ascertain a participant's reason for withdrawing prematurely from a clinical trial, while fully respecting the participant's rights since a participant is not obliged to give his or her reasons to the researcher.
- D.** Contract requirements must:
 - 1. Include a description of who will provide care and who is responsible for covering the cost of that care.
 - 2. Require the sponsor to promptly report to the Department any findings that could affect the safety of participants or influence the conduct of the study.

3. Require the sponsor to send data and safety monitoring reports to the Department and specify the time frame for sending routine and urgent data and safety monitoring reports to the Department.
4. Require that sponsors communicate findings from a closed research study when those findings directly affect participant safety and specify a time frame (such as two years), when appropriate.

IV. Authority

Section 381.86, Florida Statutes, Institutional Review Board

V. Supportive Data and References

- A. Association for Accreditation of Human Research Protection Programs Standard I-8
- B. ICH-GCP: III.2.7., III.2.7.1., III.2.8, III.2.9.

VI. History Notes

Created: 08/23/2013
Previously Amended: 02/17/2015, 01/28/2020
Formerly: DOHP 400-1.3

VII. Signature and Effective Date

Shay Gonzalez

Shay Gonzalez
Interim Chief of Staff

10/28/26
Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	2
IV. Authority	7
V. Supportive Data and References	8
VI. History Notes	8
VII. Signature and Effective Date	8

I. Policy Statements

The State Surgeon General or Department of Health (Department) Human Research Protection Program (HRPP) Administrator has authority to determine when activities covered by the HRPP constitute research involving human participants. Researchers do not have the authority to make an independent determination.

II. Definitions

See DOHP 5-D5-11.1, "Definitions"

III. Procedures

A. Criteria used to make determinations of whether activity involves research

1. The applicable regulations under which research determinations are made are 45 CFR part 46 (Department of Health and Human Services [DHHS] regulations), 21 CFR part 56 (Food and Drug Administration [FDA] regulations), and 45 CFR part 116 (Health Insurance Portability and Accountability Act [HIPAA] regulations). When research is not covered by regulation, the Department follows the definition used in DHHS regulations.
2. Research is defined at 45 CFR § 46.102(e); to make the regulatory definition more precise, where applicable, the Department further specifies the following:
 - a. "Investigation" means an inquiry, examination, or search for facts, usually involving the formulation or testing of a hypothesis.
 - b. "Systematic" means conducted according to a plan, organized method, or procedure for testing or formulating a question or hypothesis and interpreting results.
 - c. "Designed" means planned, purposed, or conducted to apply to phenomena outside the observed data, or to contribute to generalizable knowledge.
 - d. "Generalizable knowledge" means observations, findings, information, or results that have been demonstrated with enough confidence and significance to confirm or alter the consensus within the professional norms of a community or discipline.
3. A "human subject" is defined at 45 CFR § 46.102(e).
4. A "clinical investigation" is defined at 21 CFR § 50.3(c).
5. "Human subject" is defined 21 CFR § 50.3(g).

6. Criteria when the Department is engaged in research and the jurisdiction of the IRB are specified in DOHP 5-D5-1.2, Activities Subject to IRB Jurisdiction.
 7. The International Council for Harmonisation (ICH) of Technical Requirements for Pharmaceuticals for Human Use as adopted by the FDA includes a Guideline for Good Clinical Practice that applies to interventional clinical trials of investigational products as referenced herein.
- B.** Common examples of activities requiring determination of research involving human participants
1. Public health practice
 - a. To make determinations, the Department relies upon criteria specified in [Public Health Practice vs. Research: A Report for Public Health Practitioners Including Cases and Guidance for Making Distinctions](#), Hodge and Gostin, et al. 2004.
 - b. Criteria used to make determinations and examples are provided in the “Human Subject Research Determination” application available on the IRB online application management system titled “IRB Manager.”
 - c. Public health investigations, when authorized and required by statute, such as investigations into acute or chronic infectious diseases, conditions, or environmental hazards, and activities explicitly required by statute, are generally not research involving human participants. However, a statute may require both public health reporting and also authorize use of information for research (such as the Florida Cancer Registry and Florida Vital Statistics).
 - d. Public health surveillance activities conducted by a public health authority, limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance.
 - (1) Including the collection and testing of information or biospecimens conducted, supported, requested, ordered, required, or authorized by a public health authority.
 - (2) Including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products.

-
- (3) Including those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or manmade disasters).
 - (4) Including a description of who may be designated a public health authority – for example, whether this is limited to Department employees or agents, or whether it may extend to external researchers.
 - e. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
 - f. Authorized operational activities (as determined by the relevant federal agency) in support of intelligence, homeland security, defense, or other national security missions.
2. Quality improvement and program evaluation activities
- a. To make determinations, the Department relies upon criteria specified in Lynn J, Baily MA, Jennings B et al. The Ethics of Using QI Methods to Improve Health Care Quality and Safety. Annals of Internal Medicine 2007; 146, 666-673.
 - b. Criteria used to make determinations and examples are provided in the “Human Subject Research Determination” application.
 - c. Quality assurance activities conducted as an ongoing part of program operations using a standard framework such as Sterling, Plan-Do-Check-Act, Six-Sigma, and similar framework are generally not research involving human participants.
3. Activities involving residents, interns, and student volunteers
- a. Residents, interns, and student volunteers may not use data or information obtained through work for research without prior IRB approval. If there is a desire to potentially use information or the results of analysis (for example, results of secondary analysis of data conducted while employed by the Department) as part of academic degree programs, a request for review by the IRB should be submitted. Projects used as part of doctoral degrees, residencies, and master’s programs are normally considered research.

- b. Residents, interns, and student volunteers may not remove confidential data from the Department to research other activities without first seeking review by the IRB.
- C. Criteria used to make determinations of whether research involves human subjects
 - 1. Activities do not involve human participants as defined by DHHS regulations if they do not involve the researcher gathering information about living individuals through intervention or interaction with individual participants and they do not involve the researcher gathering identifiable private information about living individuals.
 - 2. Information is considered “not identifiable” if the identity of the participant is not or may not readily be ascertained by the researcher or associated with the information. For example, population-level registry data published by the Department is considered “not identifiable.”
 - 3. When following FDA regulations, a “human subject” means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. For medical device studies involving in vitro diagnostics and unidentified tissue specimens, the FDA defines the unidentified tissue specimens as human subjects.
 - 4. When the researcher receives private information or specimens with no code or link that would allow a researcher to establish identity, this would not involve human subjects, unless the research falls under FDA regulations, as defined by DHHS regulations. For example, a publicly available, unidentifiable, non-linked cell line qualifies as not involving human subjects.
 - 5. The researcher may receive coded private information or specimens and qualify for non-human subjects as defined by the DHHS regulations if all the following conditions are met:
 - a. The research is not covered by FDA regulations.
 - b. The code is not derived from or related to the HIPAA identifiers that must be stripped from private health information (e.g., patient medical record number and the last four digits of an individual’s Social Security number).
 - c. The private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals.

- d. The researcher cannot readily ascertain the identity of the individuals to whom the coded private information or specimens pertain due to any of the following:
 - (1) The key to decipher the code is destroyed before the research begins.
 - (2) The researcher and the holder of the key enter into an agreement prohibiting the release of the key to the researcher under any circumstances, until the individuals are deceased.
 - (3) The private information is received from an IRB-approved repository or data management center that includes written operating procedures that prohibit the release of the key to the researcher under any circumstances, until the individuals are deceased.
 - (4) There are other legal requirements prohibiting the release of the key to the researcher until the individuals are deceased.

D. Process for making determinations

- 1. The State Surgeon General or HRPP Administrator has authority to determine whether an activity covered by the HRPP represents “human subject research.” Department program managers, consultants, contractors, and researchers do not have authority to make an independent determination.
- 2. Anyone may request a consultation about whether an activity is research involving human participants using the online IRB application management system titled “IRB Manager.” Normally requests come from the person responsible for the activity, such as a researcher or program manager.
- 3. The applicant provides sufficient information for the Department to make a determination by submitting an application in the IRB Manager system.
- 4. Determinations of whether activities covered by the HRPP are considered to be research involving human participants are made by the HRPP Administrator designated in the Department’s Federal-Wide Assurance of Compliance or other HRPP staff. If the HRPP Administrator has direct involvement in the activity, then another person without direct involvement will make the determination. Normally this is an IRB Chair. If the IRB Chair has a conflict, another IRB Chair or the State Surgeon General will make a determination. Determinations are made using criteria in the “Human Subject Research Determination” application.

5. Determinations are communicated to the applicant via email through the online application system.

6. Determinations are normally made in less than one month.

E. Process for providing guidance about activities that sometimes are and sometimes are not research involving human participants

1. The program website provides examples and specifies how program managers and researchers can request a consultation to determine whether an activity is considered research involving human subjects.

2. The HRPP provides guidance through regular presentations tailored to specific public health programs.

3. Guidance is available through the program website.

F. Modifications

Any change that might disqualify the activity from a “Non-Human Subject” or “Non-Research” status must be reported to the IRB for review and verification prior to implementation.

G. Additional Requirements

1. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information that focus directly on the specific individuals about whom the information is collected are not considered research.

2. Activities that are not research involving human participants must meet the Department’s ethical standards. These include acceptable risk-benefit relationship, equitable participant selection, consent where appropriate, protections of privacy interests of participants and the confidentiality of their data (under state law) where appropriate, transparency about the research process, proportionality, and where applicable, community involvement in quality improvement and public health efforts.

IV. Authority

Section 381.86, Florida Statutes, Institutional Review Board

V. Supportive Data and References

- A. 45 CFR part 46
- B. 21 CFR parts 50 and 56
- C. OHRP Guidance on Research Involving Coded Private Information or Specimen Use in Research, (2008)
- D. [Public Health Practice vs. Research: A Report for Public Health Practitioners Including Cases and Guidance for Making Distinctions](#). Hodge and Gostin, et al. 2004.
- E. Lynn J, Baily MA, Jennings B et al. The Ethics of Using QI Methods to Improve Health Care Quality and Safety. Annals of Internal Medicine 2007; 146, 666-673
- F. ICH-GCP: I., Guideline Scope

VI. History Notes

Created: 08/23/2013

Previously Amended: 02/22/2015, 01/28/2020

Formerly DOHP 400-4.6, Human Subjects Research/Non Research Determination,
DOHP 400-1.4

VII. Signature and Effective Date



Shay Gonzalez
Interim Chief of Staff

10/28/26
Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	2
A. Exempt Eligibility	2
B. Amendments	14
C. Other Considerations Concerning Exempt Research	14
IV. Authority	14
V. Supportive Data and References	14
VI. History Notes	15
VII. Signature and Effective Date	15

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) that all human subject research activities under its jurisdiction be reviewed to determine whether the research meets one or more of the exemption categories described in the federal regulations and complies with the Department's ethical standards.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

A. Exempt Eligibility

1. Categories of exempt research are defined in 45 CFR § 46.101(b) and 21 CFR § 56.104(d); when not covered by federal regulations the Department applies federal exempt categories. When research is regulated by the Department of Health and Human Services, the Food and Drug Administration (FDA) or other federal agencies, the IRB may not create new categories of exempt research, but the Department may create new exempt categories when research is not covered by federal regulations and doing so results in increased efficiency and effectiveness of the human research protection program (HRPP).
2. The HRPP Administrator designated in the Department's Federal-Wide Assurance of Compliance provides an authoritative decision about whether research is exempt from regulation and may authorize an IRB analyst to make exemption determinations under supervision. Researchers do not have the authority to make an independent determination that research involving human subjects is exempt and must contact the HRPP concerning the status of proposed research or changes in ongoing research. A researcher may request a particular category of exemption, but the final determination of applicability will be made by Department staff.
3. Researchers complete an application for determination of whether research meets one or more exemption categories or by submitting an application in the Department's online review system titled "IRB Manager."
4. Staff use a checklist to determine if research meets one or more exemption criteria and generally make a determination in less than one month.
5. Exemption determinations are communicated to researchers using email via the online review system.

-
6. Research must not be granted an exemption when one or more of the following conditions are present:
 - a. The research involves prisoners as participants.
 - b. For categories 1 through 5: The research is subject to FDA regulation.
 - c. The research involves deception.
 - d. The research involves greater than minimal risk to participants.
 - e. The research is classified.
 - f. The project involves significant physical invasions or intrusions upon the privacy of participants.
 7. Limited Review
 - a. The Department IRB uses the limited review process to review all research activities that are considered exempt activities under 45 CFR § 46.104 for which limited IRB review is a condition of exemption:
 - (1) § 46.104(d)(2)(iii)
Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: The information obtained is recorded by the researcher in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).
 - (2) § 46.104 (d)(3)(i)(C)
Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: The information obtained is recorded by the researcher in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

- (3) § 46.104 (d)(7)
Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).
- (4) § 46.104 (d)(8)
Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
 - (a) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d).
 - (b) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117.
 - (c) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8) of this section.
 - (d) The researcher does not include returning individual research results to subjects as part of the study plan. This provision does not prevent a researcher from abiding by any legal requirements to return individual research results.
- b. The limited review process for initial applications follows the expedited review process (see DOHP 5-D5-4.3, Review of Human Subjects Research: Initial Review).
- c. If a study has been approved by an IRB member using the limited review process, that study is not required to submit continuing review applications, and may submit annual check-ins (see DOHP 5-D5-4.4, Review of Human Subjects Research: Continuing Review) unless:

- (1) The study has reported a problem or unanticipated event that affects the privacy and/or confidentiality of the participants; or
 - (2) The study has submitted an application to modify which provides information that un-exempts the research from IRB review.
 - d. When conducting a limited review, the IRB member shall review the proposed study to verify that the research contains appropriate provisions to protect the privacy and confidentiality of participants consistent with federal and state law and regulation.
 - e. When conducting a limited review for exemption categories 104(d)(7) and (d)(8), the IRB member shall review the broad consent protocol proposed by the study team to verify that broad consent procedures have been followed as appropriate.
- 8. Research may be granted exempt status by the HRPP Administrator or authorized IRB analyst if all research activities involve procedures listed in one or more of the specific categories under 45 CFR § 46.101(b).
Note: Under federal regulations these categories do not apply to research involving prisoners. Under Department policies and procedures these categories do not apply to research involving deception. Also, categories 1-5 do not apply to FDA-regulated research. Categories in 45 CFR § 46.101(b) permitting exemptions are:
 - a. 45 CFR § 46.104(d)(1): Research conducted in established or commonly accepted educational settings involving normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction, such as:
 - (1) Research on regular and special education instructional strategies.
 - (2) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
 - b. 45 CFR § 46.104(d)(2): Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

-
- (1) Information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects.
 - (2) Any disclosure of the human subjects' responses outside of the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.
 - (3) The information is recorded by the researcher in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited review to make the determination required by [§ 46.111\(a\)\(7\)](#).
 - (4) If the research involves children as participants, the research must be limited to educational tests (cognitive, diagnostic, aptitude, achievement), and observation of public behavior when the researcher(s) do not participate in the activities being observed. Research that uses survey procedures, interview procedures, or observation of public behavior when the researcher(s) participate in the activities being observed cannot be granted an exemption.
- c. 45 CFR § 46.104(d)(3): Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
- (1) The information obtained is recorded by the researcher in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
 - (2) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
 - (3) The information obtained is recorded by the researcher in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7).

- (4) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the researcher has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
 - (5) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.
- d. 45 CFR § 46.104(d)(4): Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
 - (1) The identifiable private information or identifiable biospecimens are publicly available;
 - (2) Information, which may include information about biospecimens, is recorded by the researcher in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the researcher does not contact the subjects, and the researcher will not re-identify subjects;
 - (3) The research involves only information collection and analysis involving the researcher's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR § 164.501 or for "public health activities and purposes" as described under 45 CFR § 164.512(b); or
 - (4) The research is conducted by, or on behalf of, a federal department or agency using government-generated or government-collected information obtained for non-

research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501. Note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. § 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. § 3501 et seq.

- (5) Example: Researcher A wishes to screen blood samples at a rural hospital for incidence of HIV infection. She does not want to draw specimens specifically for this purpose; rather she proposes to use specimens that were drawn for some other purpose, but which remain in the hospital laboratory. If researcher A proposes to use specimens that had been drawn prior to the initiation of her research and are, for some reason, "on the shelf," the protocol may qualify as exempt, assuming the other requirements are met (i.e., the sources are either publicly available or the information is recorded by the researcher in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects).
 - (6) Under this exemption, a researcher (with proper institutional authorization) may inspect private, identifiable records, but may only record information in a non-identifiable manner. The data must be permanently and completely de-linked at the time of extraction. A code may be used to organize data as it is collected. However, the code may not be a means of re-linking the data set to the original data source.
 - (7) Example: Researcher B wishes to examine court records of involuntary commitments to psychological institutions. If he uses court records that were on file before the initiation of his research, the protocol may qualify as exempt.
- e. 45 CFR § 46.104(d)(5): Research and demonstration projects that are conducted or supported by a federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or

services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

- (1) Each federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.
- (2) Public benefit or service programs; this exemption is for federally supported projects and is most appropriately invoked with authorization or concurrence by the funding agency. The following criteria must be satisfied to invoke the exemption for research and demonstration projects examining “public benefit or service programs”:
 - (a) The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services under the Older Americans Act).
 - (b) The research or demonstration project must be conducted pursuant to specific federal statutory authority.
 - (c) There must be no statutory requirements that the project be reviewed by an IRB.
 - (d) The project must not involve significant physical invasions or intrusions upon the privacy of participants.
- (3) This exemption is for projects conducted by or subject to approval of federal agencies and requires authorization or concurrence by the funding agency.

- f. 45 CFR § 46.104(d)(6) and 21 CFR § 56.104(d): Taste and food quality evaluation and consumer acceptance studies:
 - (1) If wholesome foods without additives are consumed.
 - (2) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
- g. 45 CFR § 46.104(d)(7): Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8). For purpose of conducting the limited IRB review, the IRB must determine:
 - (1) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained;
 - (2) The researcher obtains the legally effective broad consent of the participant or the participant's legally acceptable representative.
 - (3) The researcher must provide the prospective participant or legally acceptable representative sufficient opportunity to discuss and consider whether or not to participate and minimize the possibility of coercion or undue influence.
 - (4) The information that is given to the participant or the legally acceptable representative must be in language understandable to the participant or the legally acceptable representative.
 - (5) The prospective participant or legally acceptable representative must be provided with the information a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
 - (6) No broad consent may include any exculpatory language through which the participant or the legally acceptable representative is made to waive or appear to waive any of

the participant's legal rights, or releases or appears to release the researcher, the sponsor, the organization, or its agents from liability for negligence.

- (7) Broad consent must include the following information:
- (a) A description of any reasonably foreseeable risks or discomforts to the participant.
 - (b) A description of any benefits to the participant or to others that may reasonably be expected from the research.
 - (c) A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained.
 - (d) A statement that participation is voluntary.
 - (e) A statement that refusal to participate will involve no penalty or loss of benefits to which a participant is otherwise entitled.
 - (f) A statement that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
 - (g) When appropriate, a statement that the participant's biospecimens (even if the identifiers are removed) may be used for commercial profit and whether the participant will or will not share in this commercial profit.
 - (h) When appropriate, for research involving biospecimens, a statement indicating whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).
 - (i) A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the

broad consent would permit the types of research conducted.

- (j) A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens.
 - (k) A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which could be indefinite).
 - (l) Unless the participant or legally acceptable representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the participant's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies.
 - (m) Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the participant in all circumstances, a statement that such results may not be disclosed to the participant.
 - (n) An explanation of whom to contact for answers to questions about the participant's rights and about storage and use of the participant's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.
- (8) Documentation of broad consent or waiver of documentation of consent is obtained.

- (9) If there is a change made for research purposes in the way identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy interests of participants and the confidentiality of the data.
 - (10) When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these participants.
- h. 45 CFR § 46.104(d)(8): Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
 - (1) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d).
 - (2) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117.
 - (3) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d). The researcher does not include returning individual research results to subjects as part of the study plan. This provision does not prevent a researcher from abiding by any legal requirements to return individual research results.
 - (4) The research has undergone limited IRB review by an IRB member, who determines:
 - (a) There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.
 - (b) The research to be conducted is within the scope of the broad consent for storage, maintenance, and

secondary research use of identifiable private information or identifiable biospecimens.

- (c) When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these participants, when appropriate.

B. Amendments

If there is a change in research such that it would change the exempt status, then regardless of the time period, the researcher must submit a new research determination.

C. Other Considerations Concerning Exempt Research

1. All research conducted under exempt review is subject to all applicable Department institutional and IRB policies and procedures.
2. Exempt research activities are subject to the same subject protections and ethical standards as outlined in *The Belmont Report*.
3. Exemption determinations are typically made within 14 business days of receiving a complete application from the researcher.

IV. Authority

Section 381.86, Florida Statutes, Institutional Review Board

V. Supportive Data and References

- A.** 45 CFR §§ 46.101(b)(1-6)
- B.** 45 CFR § 46.301(a)
- C.** Office for Human Research Protections (OHRP) Guidance at 45 CFR § 46.101(b)(5): Exemption for Research and Demonstration Projects on Public Benefit and Service Programs, OHRP Guidance on the Involvement of Prisoners in Research, May 23, 2003, Federal Register, Vol. 48, pp. 9266-9270, March 4, 1983
- D.** 21 CFR § 56.104(c)-(d)

- E.** DOHP 5-D5-1.4, Differentiating Research from Public Health Practice and Quality Improvement
- F.** OHRP Compliance Activities: Common Findings and Guidance -7/10/2002 Item #30
- G.** OHRP Guidance: Coded Private Information - 8/10/2004

VI. History Notes

Created: 08/23/2013
Previously Amended: 06/10/2020
Formerly: DOHP 400-4.3-08, DOHP 400-1.5

VII. Signature and Effective Date

Shay Gonzalez

Shay Gonzalez
Interim Chief of Staff

10/28/26

Effective Date

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) that all researchers meet the following requirements to conduct research involving human participants under the jurisdiction of the IRB.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

- A.** As described in DOHP 5-D5-1.1, Institutional Oversight of Assurance, the Department's Federal-Wide Assurance of Compliance with the federal government specifies that all human subjects research that is conducted by or under the direction of any employee or agent of the Department or covered entity in connection with his or her institutional responsibilities must be reviewed by the IRB.
- B.** All Department employees or agents of the Department engaged in research will have reviewed the ethical principles of *The Belmont Report*, federal and state laws and regulations, institutional policies and procedures, Department IRB policies and procedures, and if applicable, Good Clinical Practice standards when conducting human subjects research. Additionally, they will have completed the required training (initial and continuing education) for the ethical conduct of human subjects research (see DOHP 5-D5-9.1, Research Ethics Education and Training).
- C.** Conflict of Interest: The protection of human research participants requires objectivity in communicating risks, selecting subjects, promoting informed consent, and gathering, analyzing and reporting data. Therefore, the IRB will consider conflict of interest issues in its deliberations of applications. See DOHP 5-D5-2.3, Identifying, Evaluating, and Managing Researcher and Research Staff Conflicts of Interest, for the full procedure regarding conflicts of interest.
- D.** All individuals conducting human subjects research must be adequately qualified and, if necessary, licensed relevant to the scope and complexity of the research conducted. Qualifications will be documented through a completed bio sketch or curriculum vitae and reviewed by the IRB members.

IV. Authority

Section 381.86, Florida Statutes, Institutional Review Board

V. Supportive Data and References

- A.** DOHP 5-D5-1.1, Institutional Oversight of Assurance

- B.** DOHP 5-D5-1.2, Activities Subject to IRB Jurisdiction
- C.** DOHP 5-D5-2.3, Identifying, Evaluating and Managing Researcher and Research Staff Conflicts of Interests

VI. History Notes

Created 08/23/2013
Previously Amended: 01/28/2020
Formerly: DOHP 400-2.1-07

VII. Signature and Effective Date



Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/28/26

Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	2
A. Human Subjects Protection	2
B. Researcher Training	3
C. Researcher and Key Study Personnel Conflicts of Interest	3
D. Congruence with Funding Proposals	4
E. Supervision and Auditing of Research Process	4
F. Confidentiality	4
G. Additional Requirements for Activities Involving Vulnerable Populations	5
H. Amendments and Requests for Changes in IRB Application	6
I. Informed Consent	6
J. Unanticipated Problems Involving Risk to Participants or Others	7
K. Continuing Reviews	7
L. Research Records	7
M. Use of Investigational Drugs and/or Investigational Devices	8
N. Additional Institutional Committee/Institution Approvals	8
O. Federal-Wide Assurances of Compliance (Assurances), Memorandums of Understanding (MOU), Other IRB Approvals, and Letters of Cooperation	8
IV. Authority	9
V. Supportive Data and References	9
VI. History Notes	9
VII. Signature and Effective Date	9

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) that researchers conduct human subjects research in accordance with federal, state, and institutional rules, regulations, and policies, and IRB policies and procedures.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

A. Human Subjects Protection

1. The Department IRB policies and procedures are designed to protect the rights and safety of human research participants based on the ethical principles of *The Belmont Report*.
2. It is the researcher's responsibility to disclose any interests specified in the online application and, if applicable, complete the researcher and research staff conflict of interest portion of the online application. See DOHP 5-D5-2.3, Identifying, Evaluating, and Managing Researcher and Research Staff Conflicts of Interests.
3. The researcher assumes responsibility for compliance with all federal, state, and local laws, institutional rules, regulations and policies, and Department IRB policies and procedures related to research involving humans and the [Good Clinical Practice Guidelines](#) as adopted by the Food and Drug Administration (FDA).
4. The researcher is the ultimate protector of the participant's rights and safety. Each researcher is obligated to be personally certain that each participant is adequately informed and freely consents to participate in the research. The researcher must personally ensure that every reasonable precaution is taken to reduce risk to the participants.
5. The researcher may not initiate any research involving humans without prior IRB review and approval. In addition, the researcher may not amend or change an approved protocol without prior IRB review and approval, except where necessary to eliminate apparent immediate hazard to the participant.
6. The researcher is responsible for designing research studies that are sound enough to demonstrate the research outcome, minimize risks, and ensure that risks are reasonable in relation to anticipated benefits, if any. The researcher shall demonstrate adequate resources to protect participants in the research. To this end researchers shall provide the IRB with the following information to evaluate whether the researcher has minimized risks:

- a. The purpose of the research
- b. The scientific or scholarly rationale
- c. The procedures to be performed
- d. A description of the procedures being performed already for diagnostic or treatment purposes
- e. The risks and potential benefits of the research to participants, considering physical, psychological, social, economic, and legal risks
- f. Description of the time for the researchers to conduct and complete the research
- g. Description of the number and qualifications of staff
- h. Description of research facilities
- i. Whether the researcher has access to a population that will allow recruitment of the necessary number of participants. If the Department determines the researcher does not have access to the target population or community, the Department will provide situationally appropriate resources to assist the researcher in reaching the targeted population or community.
- j. Description of the availability of medical or psychosocial resources that participants may need as a consequence of the research

B. Researcher Training

- 1. It is the responsibility of each researcher to complete research ethics training consistent with requirements in DOHP 5-D5-9.1, Research Ethics Education and Training.
- 2. It is the responsibility of each researcher to ensure that other researchers and key study personnel who are responsible for the design and conduct of the research are adequately trained in human research protections and ensure completion of continuing education requirements.

C. Researcher and Key Study Personnel Conflicts of Interest

- 1. It is the researcher's responsibility to disclose all actual or perceived conflicts of interest as defined by institutional policy to the IRB for review to ensure full disclosure to participants in human subjects research of the potential conflict.

2. It is the researcher's responsibility to ensure that all actual or perceived conflicts of interest as defined by institutional policy are reviewed and a determination rendered by an ethics committee and that the outcome of such review is submitted to the IRB prior to initiation of the research.

D. Congruence with Funding Proposals

1. It is the responsibility of the researcher to ensure that the online IRB application is consistent with the proposal for funding for extramural or intramural support.
2. The researcher should act as a liaison between the IRB and the research sponsor.

E. Supervision and Auditing of Research Process

1. It is the responsibility of each researcher to ensure that all procedures associated with the research are performed, with the appropriate level of supervision, only by individuals who are licensed or otherwise qualified to perform them under the laws of Florida and the policies of the Department. The researcher must ensure adherence to the study protocol and monitor the informed consent process. The researcher must also ensure there are appropriate facilities and resources to conduct the research.
2. It is the responsibility of the researcher to regularly review his or her research processes and address any deficiencies identified.
3. It is the responsibility of the researcher to conduct and document auditing of research activities on a regular basis.
4. It is the responsibility of the researcher to audit external performance sites routinely, assuring adequate staff, resources, and pharmacy practices.

F. Confidentiality

1. The conditions for maintaining confidentiality of the participants' research records, as determined by any relevant data use agreements, are required for the life of the data.
2. Research conducted with FDA regulated articles must be kept in accordance with current FDA regulations.
3. The researcher must also ensure participant privacy and confidentiality according to Health Insurance Portability and Accountability Act (HIPAA) guidelines, and institutional and IRB policies and procedures.

G. Additional Requirements for Activities Involving Vulnerable Populations

1. The IRB must review and approve the use of a vulnerable population in research activities. Special considerations are provided in the federal regulations and the Department IRB policies and procedures for the following populations:
 - a. Pregnant Women, Human Fetuses, Neonates, and Transplantation of Fetal Tissue: For research activities involving pregnant women, human fetuses, neonates, and transplantation of fetal tissue, the researcher must ensure that all requirements are satisfied, and adequate provisions have been made for monitoring the informed consent process. See DOHP 5-D5-6.1, Research Involving Pregnant Women, Fetuses, Neonates.
 - b. Prisoners: If a participant becomes a prisoner after enrolling in a research study that the IRB did not approve for inclusion of prisoners, the researcher is responsible for immediately reporting this situation using the IRB online management system to report problems requiring prompt reporting. The researcher must cease all interactions or interventions with the prisoner-participant until approval has been received from the IRB and the Office for Human Research Protections (OHRP). If the researcher wants to enroll prisoners in research, then the researcher needs to request an amendment. All research activities conducted or supported by the U.S. Department of Health and Human Services involving the use of prisoners as participants require both IRB approval and OHRP approval. See DOHP 5-D5-6.2, Research Involving Prisoners.
 - c. Children: For research activities involving children, the researcher must ensure that all requirements in 45 CFR part 46 Subpart D are satisfied, or equivalent protections. The researcher is responsible for ensuring parental consent, as well as child assent/dissent, in accordance with the determinations of the IRB. See DOHP 5-D5-6.3, Research Involving Children.
 - d. Cognitively Impaired: Individuals who are or who may become cognitively impaired may have diminished autonomy that may limit their capacity to provide consent. Therefore, the researcher is responsible for ensuring that informed consent is conducted in accordance with the determinations of the IRB. See DOHP 5-D5-6.4, Research Involving Cognitively Impaired Persons.
2. The IRB may also determine that other target populations identified in the research proposal are “vulnerable” in particular types of research and may impose additional protections not outlined in the federal regulations.

H. Amendments and Requests for Changes in IRB Application

It is the responsibility of the researcher to not deviate from the IRB-approved research activities until the researcher has received written approval from the IRB except when necessary to eliminate apparent immediate hazards to the participant. Such changes must be reported promptly to the IRB.

I. Informed Consent

1. The researcher must ensure that the performance of the informed consent process is congruent with Department IRB policy and federal regulations.
2. The researcher may delegate obtaining informed consent to a member of his or her study team. However, the researcher is responsible for monitoring the informed consent process and ensuring copies of the consent documents have been provided to participants while keeping the original on file.
3. 45 CFR § 46.116(h) outlines the requirements for posting clinical trial consent forms. Based on those requirements, a study team must comply with the following:
 - a. Any study that is federally funded is required to provide a sample consent form to a federal department or agency on a website specified by the U.S. federal government after the study is closed to recruitment, but no later than 60 calendar days after the last study visit by any participant, as required by the protocol.
 - b. There are currently two (2) websites that can be used for posting the sample consent form: [ClinicalTrials.gov](https://www.clinicaltrials.gov) and [Regulations.gov](https://www.fda.gov/regulatory-information/about-fda-regulations).
 - c. The study team is responsible for complying with the federal department or agency instructions for posting the consent form as required by federal regulation. Once the study staff has posted the consent form, they must inform the IRB within five (5) business days.
 - d. The IRB will go to the website specified by the study team and verify that the consent form has been posted. A note documenting the date and internet location of the consent form post will be added to the study's electronic file.
 - e. If a study team believes that the study meets an exception to the federal posting requirement, the study team is responsible for reaching out to the federal funding agency to request such. The study team is also responsible for following all exception and/or redaction protocol as required by the federal funding agency.

- f. Upon approval of exception, the study team must submit notice from the federal funding agency to the IRB, notifying the IRB of the exception, within five (5) business days of receipt of the notice. Such notice will be added to the study's electronic file on the online "IRB Manager" study management system.

J. Unanticipated Problems Involving Risk to Participants or Others

The researcher must report to the IRB, Data and Safety Monitoring Boards, sponsors, and appropriate federal agencies any problems requiring prompt reporting to the IRB. See DOHP 5-D5-4.6, Problems Requiring Prompt Reporting to the IRB.

K. Continuing Reviews

1. Certain approved research proposals that qualify in accordance with the 2024 update to 45 CFR part 46 (the "Common Rule") may be exempt from applying for continuing review as determined by the IRB.
2. For those research studies that do not qualify, continuing review must be conducted not less than once per year. The researcher must ensure that continuing review applications are submitted to the online IRB application system titled "IRB Manager" not less than six (6) weeks prior to expiration of the research study's approval date. The researcher acknowledges that the federal regulations do not allow a grace period.
3. Continuing review must be substantive and meaningful. Therefore, the researcher must submit a comprehensive summary of the research activities and progress since the last continuing review, which would include a summary of adverse events and unanticipated problems, amendments, results of literature searches, publications, etc. The researcher is responsible for being aware of the current literature in his/her field of study to ensure participants are no longer placed at risk if additional risks have been identified or no benefit has been proven.
4. Failure to timely submit an application for continuing review via the online system "IRB Manager" will result in the closure of the study until such time as the researcher submits a new application for IRB review. The researcher acknowledges this by and through his or her application for IRB review.

L. Research Records

1. At a minimum, researchers must maintain research records for at least three (3) years from the date the research is closed with the IRB.
2. All research records must be accessible for inspection and copying by authorized representatives of the IRB, federal regulatory agency representatives, and the department or agency supporting the research.

3. Beyond three (3) years, requirements for record retention vary with the type of research conducted and provisions of the researcher's funding source. It is the researcher's responsibility to have a clear understanding of the retention requirements of a sponsor.
4. All HIPAA related documentation must be maintained for at least six (6) years from the date of the last use or disclosure of the protected health information.
5. If for any reason there is a change in principal investigator on a protocol, the IRB must be notified. The researcher may either have another researcher assume principal investigator responsibilities, close any research studies with the IRB, or take the research studies to the new location. The researcher must also notify in writing to the IRB the plan for either destroying the data or transferring the data to another principal investigator.

M. Use of Investigational Drugs and/or Investigational Devices

The researcher is responsible for obtaining the investigational new drug (IND) exception or investigational device exemption (IDE) from the FDA in accordance with federal regulations.

N. Additional Institutional Committee/Institution Approvals

It is the responsibility of the researcher to seek review and approval from any other required State Health Office programs, county health departments, or other institutions (universities, hospitals, school districts) as required and provide documentation to the IRB using the "Research Site and Program Support" portion of the initial application prior to the initiation of any research.

O. Federal-Wide Assurances of Compliance (Assurances), Memorandums of Understanding (MOU), Other IRB Approvals, and Letters of Cooperation

1. It is the researcher's responsibility to ensure that the proper approvals and agreements are in place prior to the commencement of research. This includes research at performance sites, "engaged" or "not engaged," that are not a legal entity of the Department or covered entity.
2. The researcher is responsible for submitting copies of all IRB approvals or letters of cooperation, whichever is applicable, for all performance sites indicated in the IRB application that are not a legal entity of the Department or covered entity.
3. The researcher must ensure that each performance site indicated in the IRB application as "engaged" in research, has a **current** Assurance and IRB approval, not just initially but throughout the conduct of the research.

-
4. If the IRB has agreed to serve as the IRB of record for a performance site “engaged” in research as evidenced by an executed MOU, it is the researcher’s responsibility to ensure that the MOU is current and that he/she upholds the terms and conditions defined within the MOU.

IV. Authority

Section 381.86, Florida Statutes, Institutional Review Board

V. Supportive Data and References

- A. *The Belmont Report*
- B. 45 CFR part 46
- C. ICH-GCP: III.2.2.

VI. History Notes

Created: 08/23/2013
Previously Amended: 01/28/2020
Formerly: DOHP 400-2.2-07

VII. Signature and Effective Date



Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/28/26
Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	2
IV. Authority	7
V. Supportive Data and References	7
VI. History Notes	7
VII. Signature and Effective Date	7

I. Policy Statements

It is the policy of the Department of Health (Department) that financial interests related to research are disclosed, evaluated, and managed or eliminated to prevent financial interests from adversely affecting the protection of participants or the credibility of the Human Research Protection Program (HRPP) at the Department.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

- A.** Researchers and all research personnel whose institutional responsibilities include the design, conduct, or reporting of research, or service on research-related Department committees such as the Institutional Review Board (IRB), must report financial interests related to the research, including interests of their immediate family, as defined in this policy.
 - 1. “Related to the research” means a financial interest in the sponsor, product or service being tested, or in a product or service that competes with the product or service being tested.
 - 2. “Immediate family” means spouse, domestic partner, and dependent children.
- B.** Researchers and others covered by this policy must complete financial conflicts of interest training at least every three (3) years, and immediately upon joining the Department, or when the Department’s financial conflicts of interest policies are revised in a way that changes researcher requirements, or when there is non-compliance with financial conflicts of interest policies and procedures. Education is available through required IRB researcher training.
 - 1. Education will occur through completion of the Conflict of Interest module in the Collaborative Institutional Training Initiative (CITI) training program. CITI training is required every three (3) years, and prior to commencing research.
 - 2. When a researcher informs HRPP staff of a change in reportable interests, HRPP staff will inform them of the need to re-take the CITI conflict of interest education module.
- C.** Researchers must disclose the following financial interests using a Researcher and Research Staff Conflict of Interest Disclosure form on the online IRB system titled “IRB Manager” when requesting initial review by the IRB, when requesting to continue research (continuing review by the IRB), and must report within 30 calendar days of discovering (e.g., through inheritance or marriage) any new financial interest related to the research during the research. Researchers should

contact the HRP Administrator if there are questions about whether a financial interest must be reported. Reportable financial Interests may include:

1. Compensation or payments for services (e.g., consulting fees, lecture payments, bonus, royalties, paid authorship, honoraria, gifts, or in-kind products or services) related to the research of any value, except as otherwise excluded by this policy.
2. Compensation or payments for services where an arrangement has been entered into such that the amount of compensation will be affected by the outcome of the research.
3. Equity interests (stocks, stock options, security, or other ownership interests) related to the research of any value.
4. Equity interest related to the research in a non-publicly traded corporation of any value by the individual or a member of the individual's immediate family.
5. Equity interest related to the research of any amount to the researcher or any member of the researcher's immediate family where an arrangement has been entered into such that the amount of compensation will be affected by the outcome of the research.
6. Intellectual property rights and interests (patents, copyrights, royalties, licensing agreements, and any other proprietary interest) related to the research.
7. Board or executive relationship related to the research, regardless of compensation.
8. Any other interest that could be affected by the outcome of the research.
9. Travel related to the research, including the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration.

D. Non-reportable interests include:

1. Publicly-traded mutual funds, including the Florida Retirement System.
2. Salary from the Department or a university.
3. Income from seminars, lectures, or teaching engagements sponsored by federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

-
4. Income from service on advisory committees or review panels for federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education (e.g., Centers for Disease Control and Prevention).
 5. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the individual does not directly control the investment decisions made in these vehicles.
- E.** Financial interest meeting any of the following criteria are significant financial interests and development of a management plan is required:
1. Compensation or payments for services (e.g., consulting fees, lecture payments, bonus, royalties, paid authorship, honoraria, gifts, or in-kind products or services) related to the research in excess of \$5,000, except as otherwise excluded by this policy.
 2. Compensation or payments for services where an arrangement has been entered into such that the amount of compensation will be affected by the outcome of the research.
 3. Equity interests (stocks, stock options, security, or other ownership interests) related to the research in excess of \$5,000.
 4. Equity interest related to the research in a non-publicly traded corporation of any value by the individual or a member of the individual's immediate family.
 5. Equity interest related to the research of any amount to the researcher or any member of the researcher's immediate family where an arrangement has been entered into such that the amount of compensation will be affected by the outcome of the research.
 6. Intellectual property rights and interests (patents, copyrights, royalties, licensing agreements, and any other proprietary interest) related to the research.
 7. Board or executive relationship related to the research, regardless of compensation.
 8. When the interest concerns an officer or employee of the Department, any interest defined as a conflict of interest under Florida law.
 9. Any other interest that could be affected by the outcome of the research.
- F.** The HRPP Administrator designated in the Department's Federal-Wide Assurance of Compliance, or the Department's Ethics Officer will determine if a

reported interest is related to the research and if the financial interest is a significant financial interest requiring review by a conflict of interest committee.

1. If the interest is a non-reportable interest, the individual is informed via email or through the online IRB system ("IRB Manager") that no further action is required under this policy.
2. If the interest is not related to the research or the person's institutional responsibilities, the individual is informed via email through IRB Manager that no further action is required under this policy.
3. If the interest is related to the research, but not a significant financial interest, the individual is informed via email through IRB Manager that no further action is required under this policy.

- G.** The HRPP Administrator will inform the researcher within 14 business days that a significant financial interest related to the research exists and provide the researcher an opportunity to propose a management plan to prevent the financial interest from interfering with the design, conduct, or reporting of the research, including interfering with the protection of participants, and submit this information for review by the convened IRB using the IRB Manager. The convened IRB has final authority to determine whether the management plan is adequate.
- H.** The HRPP Administrator is responsible for convening a conflict of interest review committee within 14 business days, to be composed of the HRPP Administrator, Ethics Officer, program attorney, and one or more IRB chairs. Committee members read the researcher's application and all supporting materials such as the sponsor protocol, consent document, and advertisements, and the disclosure form describing significant financial interests. The conflict of interest committee will review the reportable interests and will be provided the application for IRB review of research.
- I.** The conflict of interest committee must develop a draft management plan within 30 calendar days of being convened, confirm the researcher's agreement to the management plan, and develop a plan to monitor the research to ensure compliance. The committee will consider the value of the financial interest, the scope of the relationship, and the person's role in the research. Examples of management actions include:
1. Not conducting the research at the Department.
 2. Severing the relationship that created the financial conflict.
 3. Reducing or eliminating the financial interest (e.g., sale of an equity interest) or other interests (not just those related to a particular research study).

4. Changing personnel or responsibilities, or removing personnel from all or some part of the project.
 5. Identifying an independent researcher who can obtain informed consent from research participants.
 6. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias.
 7. More frequent continuing review.
 8. Public disclosure of the financial interest, e.g., when publishing or presenting the results of the research, to the Department's IRB or directly to participants in a clinical trial.
 9. Management may include a retrospective review and a mitigation report if necessary.
- J.** The researcher is given 14 business days to comment on the draft management plan and confirm agreement. If the researcher does not agree to the proposed management plan, the research will not occur.
- K.** The HRPP Administrator provides the plan drafted by the conflict of interest committee to a deputy secretary or other senior leadership for review within 14 calendar days, which is then sent to the convened IRB.
- L.** The convened IRB reviews the draft management plan, but not the details of the disclosed interests. Research may not be approved prior to the IRB's approval of a management plan. The convened IRB may require a more stringent plan than the draft management plan submitted for review. The IRB has final authority to determine whether a management plan is adequate, including a management plan developed by a researcher's organization, when the researcher is outside of the Department. When researchers come from organizations that use personnel and committees external to the IRB to evaluate and manage financial conflicts of interest, researchers are required to report these determinations as part of the IRB application. For example, if a researcher's university has a conflict of interest committee, then the determinations of this committee must be submitted to the IRB as part of the application for review.
- M.** The convened IRB's determination is communicated to the researcher via email through the IRB Manager.
- N.** If the agreed upon management plan is not followed by the researcher, the IRB Coordinator will consult with leadership, up to the State Surgeon General, and the IRB committee to determine appropriate action, including but not limited to suspension or termination of approval, increased supervision or monitoring, and increased training requirements.

- O. Researchers found to have not reported required interests are referred to the Office of the Inspector General.
- P. Records of financial interest disclosures are maintained for at least three (3) years from completion of the research.

IV. Authority

- A. Section 381.86, Florida Statutes, Institutional Review Board
- B. 42 CFR part 50 Subpart F
- C. 21 CFR §54.2(a)-(d), 21 CFR §54.2(f), 21 CFR, §54.4(a)(3), 21 CFR §54.4(b)

V. Supportive Data and References

- A. DOHP 5-D5-1.1, Institutional Oversight of Assurance
- B. DOHP 5-D5-1.2, Activities Subject to IRB Jurisdiction
- C. DOHP 5-D5-3.2, Committee Member, Consultant and Staff Conflicts of Interest
- D. 45 CFR part 46

VI. History Notes

Created: 08/23/2013

Previously Amended: 02/25/2015, 01/28/2020

Formerly: DOHP 400-2.3-07, Investigator and Key Study Personnel Conflicting Interests

VII. Signature and Effective Date

Shay Gonzalez

Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/28/26
Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	2
IV. Authority	6
V. Supportive Data and References	6
VI. History Notes	6
VII. Signature and Effective Date	6

I. Policy Statements

It is the policy of the Department of Health Institutional Review Board (IRB) that each research application submitted through the online IRB management system (IRB Manager), excluding “exempt” research, to the IRB for review include a plan to ensure the safety and welfare of its participants.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

A. Researcher Responsibility for Data and Safety Monitoring

The principal investigator should develop a data monitoring plan, which may include a Data Safety Monitor (DSM) or Data Safety Monitoring Board (DSMB) for his or her study as appropriate for the size, complexity, and level of risk involved in the research. This requirement does not apply to industry-sponsored research, where the sponsor is responsible for safety monitoring.

B. Research Activities that Should Include a DSM or DSMB

1. The study is intended to provide definitive information about the effectiveness and/or safety of a medical intervention.
2. Prior data suggest that the intervention under study has the potential to induce a potentially unacceptable toxicity.
3. The study is evaluating mortality or another major endpoint, such that inferiority of one treatment arm has safety as well as effectiveness implications.
4. It would be ethically important for the study to stop early if the primary question addressed has been definitively answered, even if secondary questions or complete safety information were not yet fully addressed.

C. DSMB Composition

1. The DSMB should have multidisciplinary representation, including physicians from relevant medical specialties and biostatisticians. This may include other experts such as bioethicists, epidemiologists, and basic scientists.
2. The DSMB should have membership limited to individuals free of apparent significant conflicts of interest, whether they are financial, intellectual, professional, or regulatory in nature.

3. The appropriate size depends on the type of study and types of expertise needed.

D. DSM or DSMB Responsibilities

1. The primary responsibility of the DSM or DSMB is to safeguard the interests of study participants. Therefore, the DSM or DSMB will review the safety measures in the protocol:
 - a. To preserve the study integrity and credibility; and
 - b. To facilitate the availability of timely as well as reliable findings to the broader clinical community.
2. The DSM or DSMB should provide written documentation confirming that they have read the protocol and agree with the study design and the data safety monitoring plan (DSMP).
3. The DSM or DSMB will review the progress of the study carefully and diligently.
4. Each enrolled subject's research chart should be reviewed on a risk-based frequency, as determined by the researcher, for side effects and tolerability of the investigational drug.
5. The DSM or DSMB will ensure that all problems requiring prompt reporting to the IRB (see DOHP 5-D5-4.6, Problems Requiring Prompt Reporting to the IRB), are reported to the IRB according to policies and procedures.
6. The DSM or DSMB will be available to the researcher for consultation concerning any untoward study events or any questions regarding consent issues.
7. The DSM or DSMB will provide a letter of predefined frequency to the IRB, through the researcher, summarizing the oversight activities of the DSM or DSMB during the monitoring period which should include:
 - a. Results of the chart reviews
 - b. Summary of consultations with the researcher
 - c. Concerns, if any, regarding subject safety or study drug tolerability

E. DSM or DSMB Charter

1. The DSM or DSMB Charter should include the following:

-
- a. A detailed presentation of the membership composition, including qualifications and experience.
 - b. Roles and responsibilities of the DSM or DSMB and if relevant, of Steering Committee members.
 - c. The authority of the DSM or DSMB (e.g. advisory to the sponsor, principal investigator)
 - d. The timing and purpose of DSMB meetings
 - e. The procedures for maintaining confidentiality
 - f. The format, content, and frequency of DSM or DSMB reports
 - g. Statistical procedures including monitoring guidelines, which will be used to monitor the identified primary, secondary, and safety outcome variables
 - h. Plans for changing frequency of interim analysis as well as procedures for recommending protocol changes
2. A copy of this Charter should be maintained with the research study files.

F. DSM or DSMB Tasks

Tasks may include, but not be limited to, the following:

1. Conduct initial review of the proposed research to ensure quality study conduct.
2. Review procedures to ensure quality of study conduct including data management and quality control procedures.
3. Evaluate the quality of ongoing study conduct by evaluating the study accrual, compliance with eligibility, participant adherence to study requirements, and accuracy and completeness of data.
4. Consider factors external to the study when relevant information becomes available, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the study.
5. Recommend early termination based on efficacy results.
6. Recommend termination due to unfavorable benefit-to-risk or inability to answer study questions.
7. Recommend continuation of ongoing studies.

8. Consider the overall picture using primary and secondary analysis.
9. Modify sample sizes based on ongoing assessment of event rates.
10. Review final results.

G. DSMP

A detailed plan is required for all research that is not “exempt” under federal regulations. The level of detail in the plan should be based on the degree of risk entailed by the research participants. Low risk studies may have simple plans, but the plan must contain at a minimum the following:

1. Identification of a DSM or DSMB
2. A description of the general DSMP
3. A description of the plan to monitor progress and safety:
 - a. This may include a plan for safety review either by an assigned board, committee, or monitor at predetermined intervals relevant to the complexity of the research.
 - b. Depending on the complexity of the research, the plan may include assessments of data quality, timeliness, participant recruitment, accrual, and retention.
4. A description of the plan to ensure compliance with Food and Drug Administration (FDA) regulations and reporting of adverse events, and Department of Health and Human Services regulations concerning problems that may represent unanticipated problems involving risk to participants or others. This may include:
 - a. A description of the process for detecting and reporting adverse events that requires reporting according to the data and safety monitoring plan and reporting problems that may represent unanticipated problems involving risk to participants or others.
 - b. A description of who will be monitoring and collecting problems requiring prompt reporting (e.g., principal investigator, research nurse, etc.).
 - c. Specification of who will be notified of problems requiring prompt reporting (e.g., IRB, National Institutes of Health (NIH), FDA, principal investigator, etc.).
 - d. A reporting plan indicating the timing of reports.

- e. A plan for annual reporting of problems requiring prompt reporting if study longer than one (1) year.
- f. A description of the plan to ensure that suspensions of funded trials are reported to the grants program director.
- g. A description of the plan to ensure data accuracy and protocol compliance.

IV. Authority

Section 381.86, Florida Statutes, Institutional Review Board

V. Supportive Data and References

- A. NIH/NIAMS "DSMB Charter"
- B. *Data Monitoring Committees in Clinical Trials*. Ellenberg, Susan S., Thomas R. Fleming, and David L. DeMets; 2003 John Wiley and Sons, LTD
- C. [AAHRPP Tip Sheet: Following the Guideline of the International Conference on Harmonisation – Good Clinical Practice \(E6\)](#)

VI. History Notes

Created: 08/23/2013
Previously Amended: 01/28/2020
Formerly: DOHP 400-2.4

VII. Signature and Effective Date



Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/28/26
Effective Date

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) to ensure that privacy and confidentiality protections are adequate for all research participants, which may include requesting the researcher to secure a Certificate of Confidentiality.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

A. Circumstances When a Certificate of Confidentiality May be Indicated

Data collection about sensitive issues (such as illegal behavior, alcohol or drug use, or sexual practices or preferences) requires the protection of confidentiality beyond preventing accidental disclosures. Under federal law, researchers can obtain an advance grant of confidentiality, known as a Certificate of Confidentiality, that will provide protection against compulsory disclosure, such as a subpoena, for research data. The researcher should describe in the IRB application any conditions under which confidential information might be disclosed and create an informed consent document that accurately reflects those conditions, including any voluntary disclosure by the researcher. The IRB is required to determine whether the risks to subjects are minimized, informed consent is appropriate, and privacy and confidentiality protections are adequate.

B. Eligibility for a Certificate of Confidentiality

Federal funding is not a prerequisite for requesting a Certificate of Confidentiality. Any research that collects personally identifiable, sensitive information and that has been approved by an IRB is eligible for a certificate.

C. Protections Provided by a Certificate of Confidentiality

A Certificate of Confidentiality provides protection for the researcher and the participants against compelled disclosure of identifying information about participants of biomedical, behavioral, clinical, and other research (Public Health Service Act '301(d), 42 U.S.C. '241(d)). Under this act, the Secretary of Health and Human Services may authorize persons engaged in research to protect the privacy of participants by withholding from all persons not connected with the conduct of the research the names or other identifying characteristics of the participant. This means researchers may not be compelled in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings to identify their participants.

1. The protection is available only when the research is of a sensitive nature where the protection is judged necessary to achieve the research objectives.

2. Research can be considered sensitive if it involves the collection of information in the following categories:
 - a. Research on HIV, AIDS, and other sexually transmitted diseases
 - b. Information relating to sexual attitudes, preferences, or practices
 - c. Information relating to the use of alcohol, drugs, or other addictive products
 - d. Information pertaining to illegal conduct
 - e. Information that if released could reasonably be damaging to an individual's financial standing, employability, or reputation within the community
 - f. Information that might lead to social stigmatization or discrimination if it were disclosed
 - g. Information pertaining to an individual's psychological wellbeing or mental health
 - h. Research on behavioral interventions and epidemiologic studies
 - i. Genetic information
3. Examples of studies that would not qualify for a Certificate of Confidentiality are:
 - a. Projects that are not research based
 - c. Projects that are not approved by an IRB in accordance with the National Institutes of Health (NIH) guidelines governing Certificates of Confidentiality
 - c. Projects that do not collect sensitive information or information that might harm the research participants
 - d. Projects that do not collect personally identifiable information

D. Limitations of a Certificate of Confidentiality

The Certificate of Confidentiality does not govern the voluntary disclosure of identifying characteristics of research participants but only protects participants from compelled disclosure of identifying characteristics by the researcher. Researchers, therefore, are not prevented from the voluntary disclosure of matters such as child abuse or a subject's threatened violence to self or others. However, if a researcher intends to make such voluntary disclosures, the consent

form must clearly indicate this.

E. Researcher Responsibility for Ensuring Confidentiality

Researchers are responsible for ensuring confidentiality of research data. If the researcher is conducting research involving sensitive information, the IRB may require the researcher to obtain a Certificate of Confidentiality. The researcher is responsible for submitting a request for the Certificate of Confidentiality to the NIH. Additional information and submission instructions are located on the [NIH website](#).

- F.** Researchers must inform participants when information is recorded in the medical record.

IV. Authority

Section 381.86, Florida Statutes, Institutional Review Board

V. Supportive Data and References

- A.** NIH Frequently Asked Questions on Certificates of Confidentiality, Web Posting: October 1, 2017
- B.** Public Health Service Act 301(d), 42 U.S.C. 241(d)
- C.** Office for Human Research Protections, "Guidance on Certificates of Confidentiality," February 25, 2003
- D.** ICH-GCP: II.1.6., III.2.12.7.

VI. History Notes

Created: 08/23/2013
Previously Amended: 01/28/2020
Formerly: DOHP 400-2.5-08

VII. Signature and Effective Date



Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/28/26
Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	2
A. Composition of Institutional Review Boards	2
B. Membership Selection	2
C. Number of Members	3
D. Alternates	3
E. Qualifications of IRB Members	4
F. Annual Review of Membership Needs	4
G. Term of Service	5
H. Required Expertise for Review of Research Involving Vulnerable Populations	6
I. Additional Appropriate Expert Consultants	7
J. IRB Member, Chair, and Staff Performance Evaluations	7
K. Reporting Changes in IRB Membership	8
IV. Authority	8
V. Supportive Data and References	8
VI. History Notes	8
VII. Signature and Effective Date	8

I. Policy Statements

It is the policy of the Department of Health (Department) that the composition of all Department Institutional Review Boards (IRBs) be in accordance with federal regulations.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

A. Composition of Institutional Review Boards

1. Each IRB must have members with varying backgrounds as described in section III.B. below to promote complete and adequate review of research commonly conducted by the Department.
2. Consultants, Ex Officio, and Administrative Members
 - a. Consultants, ex officio members, administrative members, invited guests, or expert consultants do not vote.
 - b. Ex officio and administrative members on the IRB may include the following:
 - (1) Persons who are automatically members by virtue of the position held
 - (2) Persons necessary to the IRB by virtue of special knowledge or area of expertise (e.g., expert consultant)

B. Membership Selection

Selections for IRB member voting positions and Chairs for the IRBs are made by the State Surgeon General based upon recommendations from the Human Research Protection Program (HRPP) Administrator. Recommendations are based on an assessment of the qualifications and expertise of the IRB members and to ensure the diversity of IRB members, including consideration of race, gender, cultural background, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

1. The HRPP Administrator designated in the Department's Federal-Wide Assurance of Compliance (Assurance) recruits volunteers as needed, seeking advice from IRB Chairs, IRB members, division directors, bureau chiefs, senior leadership, researchers, and others in making recommendations to the State Surgeon General.

2. Decisions for selecting IRB members are made to ensure the membership of IRBs include appropriate qualifications and expertise and retain diversity while maintaining regulations for required individuals to serve on the IRB.
3. IRB Chairs and Vice Chairs are selected as highly respected individuals from within or outside the institution, fully capable of managing the IRB and matters brought before it with fairness and impartiality.

C. Number of Members

IRBs must have a minimum of five (5) members each, with varying backgrounds and expertise to provide complete and thorough review of research activities commonly conducted by the Department or involving Department resources or clients. Each IRB must include at least one member whose primary interests are in a scientific area, one member whose primary interests are in a non-scientific area, and one member who is not affiliated with the Department and who is not part of the immediate family of a person who is affiliated with the Department (i.e. not an employee, not recently retired, not a contractor or vendor providing goods or services, or a family member or spouse of an employee). The unaffiliated member, the member representing the general perspective of subjects, and the non-scientific member may be the same person or they may be represented by two or three different persons. The IRB must include at least one member who represents the perspective of research participants, such as a former or current research participant or a research participant advocate. No IRB has members who are all males or all females or has members who represent a single profession.

D. Alternates

Alternate IRB members, if appointed, are designated for a specific member or members. Generally, members from one IRB are appointed and designated to serve as alternates for current members of another IRB. If not already appointed as IRB members, alternate members are appointed by the State Surgeon General.

1. Alternate members function in the same capacity as regular IRB members in terms of their review responsibilities. In some cases, members are appointed as alternate members because of specific qualifications and expertise, such as knowledge of prisons, or knowledge of certain state data registry systems.
2. Meeting minutes must notate when an alternate member replaces a voting member. If both the alternate IRB member and the primary IRB member attend a meeting, only one of these two may vote.

3. The IRB roster identifies the primary members or class of primary members for whom each alternate member can substitute.
4. Alternate members receive and review the same material the primary members receive.

E. Qualifications of IRB Members

1. The IRB membership must be:
 - a. Knowledgeable with sufficient expertise and sufficiently qualified through the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel; and
 - b. Able to ascertain the acceptability of proposed research in terms of institutional commitments, regulations, applicable law, and standards of professional conduct and practice.
2. Additionally, IRB members and Chairs must:
 - a. Be committed to the workload.
 - b. Understand the required time commitment.
 - c. Come to meetings prepared for discussion.
 - d. Be committed to the institution's goals for human research protections.
 - e. Possess good communication skills.
 - f. Be able to act as a facilitator.
 - g. Be willing to contact researchers to discuss issues and initiate solutions prior to the meeting.
 - h. When applicable have:
 - (1) Strong clinical expertise; and/or
 - (2) Research experience

F. Annual Review of Membership Needs

Composition of the membership of the IRB should be adequate in light of the anticipated scope and complexity of research activities, the types of subject

populations likely to be involved, and the size and available resources of the Department. The HRPP Administrator designated in the Department's Assurance conducts an annual review of IRB membership to meet regulatory and organizational requirements.

G. Term of Service

1. IRB Members

- a. IRB members are requested to serve a minimum of two years.
- b. IRB members are requested to serve as an alternate member for a minimum of one year at the completion of their term.

2. IRB Chairs

- a. IRB Chairs are respected, active members of the IRB who are well-informed in regulations relevant to the use of human subjects in research. IRB Chairs normally include individuals from State Health Office programs and county health departments.
- b. Candidates for IRB Chairs are selected by the HRPP Administrator designated in the Department's Assurance and the director of the Public Health Research Unit based on their experience in human research protections, professional discipline(s) and achievements, educational background, and their availability to commit the appropriate amount of time and effort to the Department IRB.
- c. The State Surgeon General appoints the Chair(s) based on their experience in human research protections, professional discipline(s) and achievements, educational background, and their availability to commit the appropriate amount of time and effort to the Department IRB.
- d. Chairs are normally requested to serve one year as an IRB member prior to assuming the role of Chair.
- e. Chairs are requested to serve a minimum of three years including a minimum of one year as Chair.
- f. Chairs are requested to serve an additional year as an IRB member at the completion of their term to serve as a mentor for the newly selected Chair to promote consistency and continuity. In addition, this will provide a resource for the newly selected Chair and IRB members on historical perspectives, rationale for decisions made regarding policy, and meeting facilitation skills.

- g. Chairs are requested to serve as a regular or alternate member at the completion of their term.

H. Required Expertise for Review of Research Involving Vulnerable Populations

1. Research Involving Children

The IRB considering a protocol involving children as participants should:

- a. Assess its needs for pediatric expertise among the IRB voting membership to ensure it possesses the professional competence necessary to review the specific research activities.
- b. Include one or more individuals who are knowledgeable about and experienced in working with children, or request review by an expert with such knowledge or experience. To fulfill this requirement, the IRB may invite nonvoting individuals to assist in the review of issues which require expertise beyond, or in addition to, that available among voting IRB members.
- c. When reviewing proposed research on children with disabilities or people with mental health disabilities sponsored by the US Department of Education, the Department IRB must also include a member with expertise in the area of this population.

2. Research Involving Prisoners

Federal regulations require the IRB membership be modified if it is to review research involving prisoners. Therefore, if any IRB reviews research involving prisoners, at least one voting member of the IRB present at the meeting shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity.

3. Research Involving Pregnant Women and Neonates Representative

The IRB considers all applicable federal regulations regarding research with this population, requires at least one IRB member present at the meeting to be knowledgeable or experienced in working with this population, or requests review by an expert with such knowledge or experience.

4. Research Involving Cognitively Impaired Participants

The IRB includes at least one member with expertise in the area of the cognitively impaired population when reviewing studies with this population or studies in which the participants may become cognitively impaired throughout the course of the research, or requests review by an

expert with such knowledge or experience.

I. Additional Appropriate Expert Consultants

On a case-by-case basis, the IRB or staff may request review by an individual with competence in an area not represented by the IRB membership. The HRPP Administrator designated in the Department's Assurance is responsible for identifying a consultant.

1. Consultants do not vote.
2. If HRPP staff determine a consultant is needed to supplement the IRB's review, staff identify persons with relevant qualifications and expertise by seeking suggestions from persons including, but not limited to, IRB members and Chairs, relevant Department subject matter experts, Department bureau chiefs and division directors, federal partners such as the Centers for Disease Control and Prevention, university partners, or through a literature search.
3. For example, when the IRB reviews community-based participatory research, the IRB will include one or more members with appropriate qualifications and expertise in this area, or the Department will obtain a consultant. Relevant qualifications and experience include prior research of this type or experience participating as a member of a community advisory board, or other relevant experience. Members or the consultant will consider the criteria above when reviewing this research (including but not limited to considering community advisory boards, patient advocacy groups, and the other criteria above). IRB membership qualifications apply to initial review, review of modifications, continuing review of research, and review of unanticipated problems and non-compliance.

J. IRB Member, Chair, and Staff Performance Evaluations

1. IRB members and Chairs complete a self-evaluation annually which includes the following:
 - a. Knowledge and application of the federal regulations
 - b. Knowledge and application of IRB policies and procedures
 - c. Participation in IRB meeting discussions
 - d. Interaction with researchers and study contacts
 - e. Completion of educational requirements
2. The HRPP Administrator designated in the Department's Assurance and

other staff shall perform an ongoing assessment of IRB members and Chairs based on observations made during the IRB meetings, and provide feedback individually to the member to enhance and promote growth in their performance as an IRB member.

3. Staff are evaluated at least annually. The IRB Coordinator is evaluated by the HRPP Administrator designated in the Department's Assurance, who in turn is evaluated by the director of the Public Health Research Unit.

K. Reporting Changes in IRB Membership

HRPP staff are responsible for reporting any amendments or changes to the IRB roster to the Office of Human Research Protections (OHRP) within 90 calendar days of the initiation of such changes.

IV. Authority

Section 381.86, Florida Statutes, Institutional Review Board

V. Supportive Data and References

- A. 45 CFR § 46.107
- B. 21 CFR part 56
- C. OHRP IRB Guidebook
- D. International Council for Harmonisation – Good Clinical Practice: III.1.3.1., III.1.3.3., III.1.3.4., III.1.3.5., III.1.3.6., III.1.4.1.

VI. History Notes

Created: 08/23/2013
Previously Amended: 01/28/2020
Formerly: DOHP 400-3.1

VII. Signature and Effective Date



Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/28/26
Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	2
IV. Authority	4
V. Supportive Data and References	5
VI. History Notes	5
VII. Signature and Effective Date	5

I. Policy Statements

It is the policy of the Department of Health (Department) that Institutional Review Board (IRB) Chairs, board members, consultants, and staff disclose reportable interests, and that conflicts of interest are managed by requiring that IRB members, consultants, and staff with conflicts not participate in any portion of the review of research activities except to provide information requested by the IRB, and by requiring that persons with conflicts leave the meeting room for discussion and voting.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

- A.** Individuals involved in promotion of the Department's research enterprise, including but not limited to grant writers and members of the budget program, shall not serve as members of the IRB and shall not carry out the day-to-day operations of the review process.
- B.** IRB members and staff are required to disclose reportable interests (and interests of their immediate family, including spouse or partner and dependent children) annually using a signed reporting form.
- C.** IRB members with a conflict of interest shall not participate in the review of or vote on protocols in which they have a conflict, except to provide information as requested by the IRB. If an alternate is available, they can vote in place of the IRB member with the conflict. Staff do not conduct administrative review of research when they have a conflict. The Department does not allow consultants who have disclosed a reportable interest to serve as consultants.
- D.** IRB members and staff with a conflict of interest must leave the meeting room for discussion and voting on matters to which they have a conflict.
- E.** IRB members and staff with a conflict of interest are documented in the minutes as being absent from the room with an indication that a conflict of interest was the reason for the absence. Members reporting a conflict of interest are not counted in the quorum for that particular study only.
- F.** IRB members and staff must report any financial or non-financial interest related to the research when they are assigned a study, and at the beginning of each IRB meeting. If all staff have a conflict of interest in the research, administrative review will be conducted by other Department staff or an IRB Chair.
- G.** IRB members and staff must disclose the following reportable interests related to the research. An interest is "related to the research" when it involves the sponsor or product or service being evaluated in the research, or a competitor to a

product or service being tested in the research, or where the interest is related to the IRB member's or staff's work at the Department as follows:

1. Compensation or payments for services (e.g., consulting fees, lecture payments, bonus, royalties, paid authorship, honoraria, gifts, or in-kind products or services) related to the research of any value, except as otherwise excluded by this policy.
2. Compensation or payments for services where an arrangement has been entered into such that the amount of compensation will be affected by the outcome of the research.
3. Equity interests (stocks, stock options, security, or other ownership interests) related to the research of any value.
4. Equity interests whose value, when aggregated for the individual and the individual's immediate family, represents more than a 5% ownership interest in any single entity.
5. Equity interest related to the research in a non-publicly traded corporation of any value by the individual or a member of the individual's immediate family.
6. Equity interest related to the research of any amount to the researcher or any member of the researcher's immediate family where an arrangement has been entered into such that the amount of compensation will be affected by the outcome of the research.
7. Intellectual property rights and interests (patents, copyrights, royalties, licensing agreements, and any other proprietary interest) related to the research.
8. Board or executive relationship related to the research, regardless of compensation.
9. Involvement or participation in the design, conduct, or reporting of the research, including providing advice on Department registry data systems.
10. Serving as the immediate supervisor of a researcher within the last year.
11. Any other interest that the IRB member believes would interfere with his or her ability to objectively review a protocol.
12. Any travel related to the research.

H. Non-reportable interests include:

DOHP 5-D5-3.2

1. Publicly-traded mutual funds, including the Florida Retirement System.
 2. Salary from the Department or a university.
 3. Income from seminars, lectures, or teaching engagements sponsored by federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
 4. Income from service on advisory committees or review panels for federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education (e.g., Centers for Disease Control and Prevention).
 5. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the individual does not directly control the investment decisions made in these vehicles.
- I.** This policy applies to all reviews including:
1. Administrative pre-review by staff
 2. Review by a convened IRB
 3. Review using the expedited procedure
 4. Initial review, continuing review, and review of modifications
 5. Review of unanticipated problems involving risks to participants or others
 6. Review of non-compliance with the regulations or the requirements of the IRB
 7. Investigation of allegations of non-compliance or problem reports
- J.** Questions about whether a conflict of interest exists will be determined by the IRB Chair, or Human Research Protection Program Administrator designated in the Department's Federal-Wide Assurance of Compliance, or by consulting legal counsel, who may seek an opinion from the Department's Ethics Officer.

IV. Authority

Section 381.86, Florida Statutes, Institutional Review Board

V. Supportive Data and References

- A. OHRP Guidance, "Conflict of Interest"
- B. ICH-GCP(E6)(R3): III.1.3.1

VI. History Notes

Created: 08/23/2013
Previously Amended: 02/24/2015, 01/28/2020
Formerly: DOHP 400-3.2-08

VII. Signature and Effective Date



Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/28/26

Effective Date

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) that members review all research involving human participants under the Department's jurisdiction through the online IRB system (IRB Manager).

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

A. Institutional Review Board Members

The mission of the Department IRB is to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under its jurisdiction (see DOHP 5-D5-1.2, Activities Subject to IRB Jurisdiction) through ethically responsible and scientifically valid research, continuous education of the research community, monitoring of research activities, and compliance with the federal regulations and institutional policies and procedures.

1. IRB members have an understanding of basic ethical principles, the regulatory requirements, and the mechanics of serving on the IRB.
2. IRB members conduct prospective and continuing review of proposed research activities according to Department of Health and Human Services regulations 45 CFR part 46, Food and Drug Administration (FDA) regulations 21 CFR parts 50 and 56 and when applicable, other federal, state, and local laws, and institutional policies and procedures including the IRB policies and procedures.
3. IRB members identify any conflicts of interest prior to the review of research activities and bring this to the attention of staff for reassignment.
4. IRB members obtain guidance or additional information in order to conduct an adequate study evaluation. This may include the request of an additional reviewer or consultant with expertise in the area of research under review. To support an appropriate review of community-based participatory research projects, the Department will offer, as needed, training to IRB members that covers topics related to the design, implementation, and dissemination of results of such research. The training may include presentation of pertinent information (e.g., principles of community-based participatory research, policy and checklist requirements for reviewing such research), articles covering aspects of this methodology, as well as requirements to complete relevant course modules or to attend presentations by Department staff or subject matter experts. In addition, the Department will include IRB members and/or consultants with expertise in community-based participatory research by

identifying and recruiting local researchers and community members whose credentials reflect such knowledge and experience.

B. Consultants and Ad Hoc Reviewers

1. Consultants and ad hoc reviewers are held to the same standards as those described above. Consultants who report a conflict of interest are not allowed to serve.
2. A consultant may serve as an ad hoc reviewer when expertise in a specific area is needed. The consultant may not be able to attend the meeting but is expected to provide a written review of the research. This could be a narrative or could be captured on the reviewer's comment form.
3. The consultant may attend the meeting to participate in the review and discussion, however; the consultant may not count toward quorum or vote.
4. An IRB member or administrative staff may request a written review from an expert consultant and may also request they attend the meeting for participation in the discussion.

C. To reduce risk to participants and determine if risks to participants are reasonable in relation to benefits, board members evaluate the research proposal for both scientific and scholarly merit to determine if it is sound enough to justify human subjects' participation. The focus should be on the risks associated with study participation. The evaluation occurs during review by the convened IRB and when conducting reviews using an expedited procedure. Reviewers must determine the science is sound enough to accomplish the research outcomes. Review of scientific validity includes consideration of the background, rationale, design, aims or hypotheses, procedures, and involvement of human participants. In order to approve research, board members must determine the research uses procedures consistent with sound research design, and the research design is sound enough to yield the expected knowledge.

D. For studies following the International Council for Harmonization Good Clinical Practice (ICH-GCP) as adopted by FDA, the available nonclinical and clinical information on an investigational product (s) should be adequate to support the proposed clinical trial.

1. Clinical trials should be scientifically sound and reflect the state of knowledge and experience with investigational products, including, if applicable,
 - a. The condition to be treated, diagnosed, or prevented
 - b. The current understanding of the biological mechanism (of both

the condition and the investigational product)

- c. The population for which the investigational product is intended
- 2. For clinical trials involving patients, the focus should be on risks that go beyond those associated with usual medical care. The risks relating to test articles or investigational products that have a marketing authorization when used in the clinical trial context may differ from the usual care of patients and should be taken into consideration.
- 3. The IRB will ensure periodic review of current scientific knowledge and approaches to determine whether modifications to the trial are needed, since new or unanticipated information may arise once the trial has begun. The scientific goal and purpose should be carefully considered so as not to unnecessarily exclude particular participant populations.
- E. Some programs in the Department conduct scientific review, such as the Florida Cancer Registry Data System. If a program conducts scientific review, the researcher must provide the results with the application prior to review by the IRB. The IRB can consider a review conducted by a program, but the IRB conducts its own independent evaluation of the scientific validity and whether the procedures are sound enough to yield the expected knowledge.

IV. Authority

Section 381.86, Florida Statutes, Institutional Review Board

V. Supportive Data and References

- A. 45 CFR part 46
- B. 21 CFR parts 50, 56
- C. ICH-GCP: III.1.3.1, II.1.4., II.4., II.4.1., II.4.2., II.4.3., II.6., II.7., II.7.1., II.7.2., II.7.3., II.7.4., II.8.

VI. History Notes

Created: 08/23/2013
Previously Amended: 02/23/2015, 01/29/2020
Formerly: DOHP 400-4.1

VII. Signature and Effective Date

Shay Gonzalez

Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/29/26
Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	2
A. Development of the Agenda	2
B. Quorum Required for Convened IRB Review	4
C. Presentations by Researchers	6
D. Voting	6
E. Motions	6
IV. Authority	8
V. Supportive Data and References	8
VI. History Notes	8
VII. Signature and Effective Date	8

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) to conduct regularly scheduled meetings based on the volume of research to be reviewed in order to allow adequate time for discussion and for effective and consistent review according to applicable laws, regulations, codes, and guidance and Department policies and procedures.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

A. Development of the Agenda

1. The Human Research Protection Program (HRPP) Administrator or other designated HRPP staff creates an agenda and saves the agenda to the program's network drive or online management system (IRB Manager). Protocols are added to an agenda once HRPP staff determines the application for review of research is complete.
2. HRPP staff limit the number of protocols for review at a convened meeting to allow for adequate time for discussion of all items on the agenda. The limit for items on the convened agenda is not more than 12 items for a 90-minute meeting but is normally not more than 10 items for a 90-minute meeting.
3. HRPP staff prioritize the inclusion of items on agendas in the following order:
 - a. Unanticipated problems involving risks to participants or others, and non-compliance
 - b. Requests to modify research and requests to continue research
 - c. New applications for review of research
4. HRPP staff consult with the IRB Chair when there are questions about whether an item should be on the agenda for a particular meeting.
5. Two primary reviewers are assigned to present the study. HRPP staff assigns primary reviewers using authority delegated by the IRB Chair. Staff ensure at least one person with appropriate scientific or scholarly expertise conduct an in-depth review of the research.
6. HRPP staff, in consultation with an IRB Chair when necessary, evaluate each study and determine whether there is sufficient expertise or

knowledge to review the research or whether additional expertise is needed to supplement the IRB's review. Staff base their evaluation of whether board members have sufficient qualifications and expertise on information provided in each member's curriculum vitae and, when appropriate, by confirming with members they are sufficiently knowledgeable to review a particular study. If no members are qualified, staff reassigns a study to a later meeting or obtains a consultant. IRB Chairs or members may also request a consultant. Reviews are not conducted when members do not have sufficient expertise or knowledge.

- a. If HRPP staff determines a consultant is needed to supplement the IRB's review, they identify persons with relevant qualifications and expertise by seeking suggestions from persons including, but not limited to, IRB members and Chairs, relevant Department subject matter experts, Department bureau chiefs and division directors, federal partners such as the Centers for Disease Control and Prevention, university partners, or through a literature search.
 - b. The HRPP Administrator has the consultant complete the IRB Member and Staff Conflict of Interest Disclosure Worksheet. If there are no conflicts, the consultant is assigned to the study. Consultants with a conflict do not review research. Consultants provide information to the IRB by completing a reviewer comment form in the online management system (IRB Manager). In addition, consultants may also present information to the convened IRB by attending a meeting. However, when a consultant attends a meeting, the consultant does not vote.
7. Each IRB meets monthly for between 90 and 120 minutes. Staff notify board members using email via the IRB Manager that the agenda is complete approximately seven calendar days in advance of convened meetings, but no less than three calendar days in advance of each IRB's monthly meeting. In addition, the notice contains the checklist on what materials IRB members should review, member education and application materials, reviewer forms, conflict of interest disclosure form or where to obtain these using the IRB Manager.
8. The Department anticipates in exceptional circumstances, such as a declared public health emergency, the IRB may need to meet on an emergency basis for review of a specific study. The agenda would be provided to reviewers as soon as practical prior to the meeting, but not less than 24 hours in advance.
9. The IRB agenda is used to inform IRB members of research protocols approved using the expedited procedure, and applications that qualify for exemption or applications that are not research involving human participants, such as public health practice and quality improvement.

10. The IRB agenda may be used to distribute information for continuing education of IRB members.

B. Quorum Required for Convened IRB Review

1. The IRB may only review proposed research at a convened meeting at which a quorum is present. A majority of the voting members of the IRB must be present, including at least one member whose primary interests are in nonscientific areas, at least one member whose primary interest is in a scientific area, and at least one member who is not affiliated with the Department. Although not required for quorum, at least one member who represents the general perspective of research participants must be present at least 10 of 12 meetings per year. Chairs are voting members. The unaffiliated member, the member representing the general perspective of subjects, and the non-scientific member may be the same person, or they may be represented by two or three different persons. A voice vote is taken for each action being reviewed by the IRB; votes are recorded by staff for inclusion in meeting minutes.
2. IRB meetings are not convened if a member whose primary interests are in nonscientific areas, at least one member whose primary interest is in a scientific area, at least one member who is not affiliated with the Department are not present.
3. For research to be approved it has to receive the approval of a majority of members present at the meeting in person or via conference call. No official actions take place at a meeting where a majority of the voting members are not present.
4. If quorum is lost during a meeting (e.g., those with conflicts being excused, early departures, loss of all non-scientists), the IRB cannot take votes until the quorum is restored. If required members (e.g. non-scientific) leave the room and quorum is lost, votes cannot be taken until the quorum is restored, even if the majority of the members are still present.
5. Wherever possible, IRB meetings take place with all participating IRB members physically present. When members participate via video conference, web conference system, or conference call, each participating IRB member:
 - a. Has received all pertinent material prior to the meeting to allow adequate time for review and the request of additional information, if needed; and
 - b. Can actively and equally participate in the discussion of all protocols (i.e., each member can hear and be heard by all other participating members).

- c. The minutes of such meetings clearly document these two conditions have been satisfied in addition to the usual regulatory requirements (e.g., attendance; initial and continued presence of a majority of members, including at least one nonscientist member; actions taken by the IRB; the vote on such actions; discussion and resolution of controverted issues).
6. When the IRB reviews research involving prisoners, a prisoner representative is present.
7. If the IRB reviews research that involves categories of participants vulnerable to coercion or undue influence, one or more individuals who are knowledgeable about or experienced in working with such participants are present.
8. No IRB member may participate in any review by the IRB, including review of a project's initial submission, amendments, continuing review, reports of unanticipated problems involving risks to participants or others, or reports of non-compliance in which the member has a conflict of interest. If a conflict exists, the IRB member can provide information requested by the IRB but cannot be present for the discussion and the vote and must leave the room. If they are present via video conference or conference call, they must leave the call.
9. HRPP staff are responsible for determining that a quorum is established and maintained during the meeting. Staff use the roster to document quorum during the meeting, and this information is recorded in the minutes for each meeting.
10. IRB members are encouraged to print out the reviewer comment worksheets, which contain the criteria for approval, and bring them to convened meetings. Video projections and video conference technology may be used to view specific parts of an application during the discussion of a study, such as the informed consent document, and projection may be used to project the criteria for approval.
11. Chairs review the agenda prior to each meeting, and the assignment of reviewers. IRB staff provide notes to Chairs prior to meetings. Chair notes may include protocol-specific information, such as the fact that a reviewer was not able to approve a study using the expedited procedure or requested a consultant. Staff distribute minutes to all IRB members via email to allow members to comment. The Chair reviews and approves the minutes within 48 hours after staff draft the minutes. Chairs are responsible for ensuring the IRB's discussion of the study provides opportunities for members to ask questions, seek more information, and generally facilitate discussion among all members.

C. Presentations by Researchers

1. Researchers are encouraged to present a summary of the research and answer questions from IRB members.
2. Researchers may not be present for the IRB's discussion and subsequent vote and must leave the room or hang up if present on a conference call.

D. Voting

1. Members must vote either in favor (affirmative) or against (negative) regarding a protocol. Per Chapter 119, Florida Statutes, a vote of "abstention" can only be recorded if there is a conflict of interest. Under federal regulations IRB members with a conflicting interest may not participate in the IRBs' review of any protocol, except to provide information requested by the IRBs. Department IRB members with a conflict of interest should absent themselves from the meeting room during the IRBs' deliberative discussion and vote on the affected research and the remaining members must vote either in favor or against the protocol.
2. Votes are taken by voice vote. An affirmative vote represents the decision of the majority of members present. Chairs are voting members.
3. HRPP staff take votes during the meeting and record them as part of the minutes of the meeting.
4. HRPP staff are responsible for assuring consultants do not have conflicts of interest at the time they are retained.

E. Motions

1. Approval with no changes

Approval is granted if the research activity meets the criteria for approval as defined in federal regulations and no changes to the research application are recommended.
2. Approved pending verification of changes by the Chair or his/her designee
 - a. Substantive changes or requirements, requests for more information for IRB consideration, and other issues related to the criteria for approval require review and approval by the convened IRB. For example, if the IRB needs more information about the plans for recruitment, or clarification about protections for confidentiality, the convened IRB needs to review those changes.

- b. Minor or prescriptive changes or requirements may be reviewed for approval by the IRB, or by the IRB Chair or designee. Minor or prescriptive changes are those that can be verified as having been made or not. For example, “drop the control arm” is a specific prescriptive change; the confirmation or verification of whether or not the specific prescriptive change was made can be done by the Chair. Similarly, “confirm that education materials are provided to everyone, not just those in the intervention arm” is a prescriptive change that can be verified by the Chair.
- c. The date of approval is the date the conditions were determined to be met.

3. Deferred

- a. A deferral is granted if the study does not meet the criteria for approval as defined in federal regulations or the IRB recommends substantial revisions to the IRB application, sponsor’s protocol, informed consent document(s), or other pertinent documents rendering it unable to assess the risk/benefit ratio without the completed revisions.
- b. Studies are also deferred when the information provided in the application or protocol is insufficient for the convened IRB to conduct an adequate review, or when the convened IRB requires additional expertise, or when the IRB does not have adequate time to conduct an appropriate review.

4. Suspension of IRB approval

Suspension of IRB approval occurs when evidence of a possible increase in risk to participants or non-compliance by the researcher has been determined by the IRB. Suspensions are made under full IRB review procedures.

5. Termination of IRB approval

IRB approval of a currently approved study may be terminated if the study is not being conducted in accordance with the IRB policies, is not in compliance with federal regulations, and/or has been associated with unexpected serious harm to participants. Terminations of IRB approval are made under full IRB review procedures.

6. Disapproval

Disapproval of new protocols is granted if the convened IRB determines the protocol does not meet the criteria for approval, or if the researcher is

unable to revise the protocol to meet the criteria for approval as defined in federal regulation.

IV. Authority

Section 381.86, Florida Statutes, Institutional Review Board

V. Supportive Data and References

- A. 45 CFR § 46.108(b)
- B. OHRP Guidance on Written Institutional Review Board (IRB) Procedures
- C. 21 CFR § 56.108
- D. ICH-GCP: III.1.3., III.1.4., III.1.3.1, III.1.3.5., III.1.3.6.

VI. History Notes

Created: 08/23/2013
Previously Amended: 01/29/2020
Formerly: DOHP 400-4.2, incorporates "IRB Determinations and Motions"

VII. Signature and Effective Date



Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/29/26
Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	2
IV. Authority	7
V. Supportive Data and References	7
VI. History Notes	7
VII. Signature and Effective Date	7

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) that all research involving human participants under its jurisdiction be reviewed according to criteria for approval in federal regulations (45 CFR § 46.111 and 21 CFR § 56.111). Further, the Department must manage IRB activities through the use of an online management system (IRB Manager).

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

A. Process for administrative screening by staff and assigning reviewers

1. Staff check applications for completeness using a staff review form. Incomplete applications are returned to the researcher with comments so the researcher can revise and submit a complete application.
2. Certain organizational entities of the Department may require researchers to obtain further approval of research, where applicable. Examples include State Health Office divisions and bureaus, public health laboratories, and county health departments. These organizational entities may not approve research that has not been approved by the IRB, but may require further approval, such as formal permission to conduct research. When additional programmatic permission to conduct research contingent upon IRB approval is not present, staff return applications to researchers to provide documentation of permission to conduct research. Programmatic review may occur in parallel, when the programmatic review does not involve review of scientific validity or other topics that impact the criteria for approval, but IRB staff will not release a study without programmatic approval.
3. When applications are complete, staff assign reviewers using authority delegated from the IRB Chair to assign reviewers based on the qualifications and expertise listed in the IRB membership roster, and to ensure that at least one member with appropriate scientific expertise and knowledge reviews the research. When a study involves vulnerable populations, staff assign a reviewer with appropriate expertise in the specific vulnerable population. If staff are unsure, they consult with an IRB Chair.
4. Applications are added to the agenda of the next available IRB meeting that has reviewers possessing necessary qualifications and expertise. Applications are normally assigned to the next agenda, unless that IRB does not have relevant qualifications and expertise. For example, if the application involves a vulnerable population such as prisoners, the

application is assigned to the next meeting that a prisoner representative is in attendance.

5. If the reviewer has a conflict of interest, the reviewer will contact the Human Research Protection Program Administrator or IRB staff and recuse themselves from the review (see DOHP 5-D5-3.2, IRB Member, Consultant, and Staff Conflicting Interests).

B. Process for review of applications for initial review by the convened IRB

1. The IRB uses a primary reviewer system for all review of research by the convened IRB. Staff email materials to reviewers via the IRB Manager to provide members access to all materials. All members (including alternate members) are provided access to all materials. All members are provided and review applications for initial review, which contain the relevant information to determine whether the proposed research fulfills the criteria for approval. All members review the proposed consent and assent documents (and Department of Health and Human Services [DHHS]-approved sample consent and assent documents) and recruitment materials.
2. One or more primary reviewers are expected to conduct an in-depth review of all materials, which include the complete protocol (DHHS-approved protocol when one exists), any relevant grant applications or contracts, and scientific review materials. At least one member reviews the researcher brochure, when one exists, and any other materials submitted with the application. IRB members are provided a checklist with the agenda listing documents everyone needs to review and additional materials the primary reviewers must read.
3. Reviewers use an online form to provide comments and to ensure all regulatory requirements are met. One or more primary reviewers use the form to present the study to other board members, and to ensure there is sufficient discussion by the convened IRB to ensure the regulatory criteria for approval are met.
4. IRB members may request a consultant to supplement the IRB's review (see DOHP 5-D5-3.1, Composition of the IRB).
5. IRB members determine whether continuing review should occur at an interval less than one year, at an interval of one year, or if the study in question is eligible for exemption from the continuing review requirement based on information about anticipated risks posed by the research. Absent other compelling reasons, the convened IRB will require review more often than annually whenever the research involves one or more of:
 - a. Phase I research

- b. Involvement of recombinant DNA or other types of gene transfer protocols
 - c. Classified research
 - d. Research for which participants would be exposed to additional risks, e.g. breach of confidentiality, phase I studies, disproportionate number or severity of adverse events
 - e. Previous suspensions or termination of approval of the research due to compliance, record-keeping or other concerns, failure to obtain approval to continue research prior to expiration of approval
 - f. Recommendations from other Department committees
 - 6. When the convened IRB requests substantive clarifications or modifications that are directly relevant to the determinations required by the IRB, the clarifications or modifications must be reviewed by the convened IRB and may not be verified by the Chair or designee. Examples of substantive clarifications or modifications include, "Explain why participants younger than 18 years of age will be allowed to participate", "Provide additional justification for the use of placebo" and "Clarify whether participants will be offered counseling services at the end of the study."
 - 7. Requests by the IRB for the researcher to make a prescriptive or minor change may be verified by the Chair or designee. A minor change is one where the Chair or designee simply verifies the change was made as specified by the IRB. If the change is not made as specified, the application is returned to the convened IRB for review. For example, "Delete the duplicate contact information for the IRB (last page, bottom paragraph)" or "Drop the placebo-controlled arm of this study." The date of approval is the date the conditions were determined to be met.
 - 8. The range of possible actions the IRB is allowed to take is described in policy (see DOHP 5-D5-4.2, Conduct of Meetings by the Convened IRB).
 - 9. The date of approval is the date the conditions were determined to be met.
- C.** Process for review of applications for initial review using the expedited procedure
- 1. Applications for initial review that are eligible for review using the expedited procedure are assigned to one or more experienced reviewers from the designated IRB for review and approval. An experienced IRB member normally means a voting member or alternate voting member with appropriate qualifications and expertise who has received training

relative to the expedited review categories, and possesses the expertise needed to review the proposed research.

2. The reviewer assigned will have expertise in the area of the research adequate to the scope and complexity of the research. The reviewer may request a second reviewer, request review by an expert consultant to the IRB, or refer the study to the convened IRB for determination. In the case of multiple reviewers, all reviewers must determine the criteria for approval are met for it to be approved. If any reviewer determines the criteria for approval has not been met or is unsure, the study is referred to the convened IRB. In the absence of consensus, the application is submitted to the convened IRB. However, the determination of disapproval can only be made by the convened IRB.
3. The reviewer using the expedited procedure is provided with and reviews the same materials as primary reviewers for the convened IRB.
4. The criteria for approval using the expedited procedure are the same as those for review by a convened IRB.
5. Reviewers use a reviewer comment form to ensure all regulatory requirements are met. The criteria for eligibility for initial review using the expedited procedure are listed on the "Expedited Procedure Eligibility" form that is used by the reviewer to determine whether research meets one or more expedited categories and other requirements to undergo continuing review using the expedited procedure.
6. If a reviewer using the expedited procedure determines the continuing review period for a study would be less than one year, the study should be referred to the convened IRB for review.
7. The reviewer using the expedited procedure may approve research or require changes. However, the reviewer may not disapprove the research; if the reviewer is unable to approve research, it is referred to the full IRB.

D. Process for notifying researchers and organization officials

1. The convened IRB is notified of the findings and actions of research applications that have been approved through the expedited procedure using the IRB agenda.
2. IRB staff must distribute to the Human Research Protection Program Administrator designated in the Department's Federal-Wide Assurance of Compliance, a bureau chief, division director, deputy secretary, and if requested, the State Surgeon General, a notification of the findings of the IRB by sending a copy of the approved minutes. Staff include these

officials when distributing minutes of meetings of the convened IRB to members of the IRB.

3. Researchers are notified of the IRB's decision to approve, disapprove, or require modifications to secure approval through email via the IRB Manager.
 - a. The communication through the IRB Manager includes modifications or clarifications required as a condition for IRB approval.
 - b. If the IRB disapproves a proposed research study, researchers are informed through email via the IRB Manager of the IRB's reasons for the decision and how the researcher may respond in person or in writing.
4. Researchers are notified of the approval period for research through email via the IRB Manager. If the study is reviewed at the convened IRB meeting and approved with minor changes, the Chair shall review and verify the changes. Once the minor changes required by the convened IRB have been made, the approval period begins with the date of the convened meeting. If the study is reviewed at the convened IRB meeting, and the convened IRB requires substantial changes and defers the study, it is returned to the researcher. When the researcher re-submits the application, the study is reviewed again by the convened IRB (normally the same IRB). If the convened IRB approves, the approval date is the date of the meeting where the substantial changes were reviewed and approved. The expiration date is the last date the protocol is approved in Eastern Time. For example, if a study is approved through June 10, authorization to conduct research expires at 11:59 p.m. Eastern Time on June 10.

E. Process for managing expiration of IRB Approval

1. There is no grace period extending authorization to conduct research beyond the expiration date of IRB approval. If the IRB does not re-approve the research by the specified expiration date, all study activities must cease including recruitment, enrollment, interventions and interactions, collection of private identifiable data, and analysis of identifiable information, pending re-approval of the research by the IRB. If the IRB requires changes to the research at continuing review, this does not extend the expiration period. Expiration of authorization to conduct research is automatic and requires no decision, determination, or action by an IRB. Such expirations of approval are not suspensions of IRB approval, terminations of IRB approval, or administrative holds.
2. Staff notify the researcher via email through the IRB Manager that authorization and approval to conduct research has expired. The

researcher must immediately provide documentation to staff that all research has stopped.

3. Once notified of the expiration, the researcher must immediately submit to the IRB Chair a list of research subjects for whom expiration of the research would cause harm, if any. The IRB Chair reviews this list and allows individual participants to continue participating in the research interventions or interactions only when the IRB finds an overriding safety concern or ethical issue involved such that it is in the best interests of individual participants to continue participating. The convened IRB is informed of the Chair's decision using the agenda for the next meeting.
4. Enrollment of new subjects shall not occur on or after the expiration of IRB approval.

IV. Authority

- A. Section 381.86, Florida Statutes, Institutional Review Board
- B. Rule 64H-2.002, Institutional Review Board Applications, Florida Administrative Code

V. Supportive Data and References

- A. 45 CFR § 46.109(e)
- B. 45 CFR § 46.110
- C. 21 CFR § 56.109
- D. ICH-GCP: III.3, III.1.3.1, III.1.3.5., III.1.3.6, III.1.4

VI. History Notes

Created: 08/23/2013
Previously Amended: 02/23/2019, 01/29/2020
Formerly: DOHP 400-4.3

VII. Signature and Effective Date



Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/29/26
Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	2
IV. Authority	11
V. Supportive Data and References	11
VI. History Notes	11
VII. Signature and Effective Date	11

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) that research activities receive regularly scheduled complete reappraisals at intervals appropriate to the degree of risk. Continuing review must be substantive and meaningful. To approve research, the convened IRB or reviewer using the expedited procedure must find that the Department of Health and Human Services (DHHS) or Food and Drug Administration criteria for approval (45 CFR § 46.111 and 21 CFR § 56.111) are met. If continuing review is required, it must occur as long as research involving human participants continues, including analysis of private identifiable information.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

- A.** Researchers must submit all materials detailed in the application available on the online management system (IRB Manager) for continuing review at least six (6) weeks prior to the expiration of the IRB's authorization to conduct research. The expiration date is the last date that the protocol is approved.
- B.** Staff conduct pre-review and assign reviewers based on authority designated by the IRB Chair(s):
 - 1. Staff conduct pre-review of applications for completeness using the staff review form on the IRB Manager. Incomplete applications are returned with instructions for the researcher to revise and submit a complete application.
 - 2. Staff verify that researchers have obtained permission to conduct research and return applications to researchers to provide documentation of permission when organizational entities of the Department require researchers to obtain further approval of research. Examples include State Health Office divisions and bureaus, public health laboratories, and county health departments. These organizational entities may not approve research that has not been approved by the IRB, but may require further approval, where applicable, such as formal permission to conduct research.
 - 3. When applications are complete, staff assign reviewers using authority delegated from the IRB Chair(s) to assign reviewers based on the qualifications and expertise listed in the IRB membership roster. When a study involves vulnerable populations, staff assign a reviewer with appropriate expertise in the specific vulnerable population. If staff are unsure, they consult an IRB Chair.

4. Human Research Protection Program (HRPP) staff, in consultation with an IRB Chair, when necessary, evaluate each study and determine whether there is sufficient expertise or knowledge to review the research. Applications are added to the agenda of the next available IRB meeting that will include reviewers possessing necessary qualifications and expertise. Applications are normally assigned to the next agenda, unless that IRB does not have relevant qualifications and expertise. For example, if the application involves a vulnerable population such as prisoners, the application is assigned to the next meeting that a prisoner representative is in attendance.
 - a. If HRPP staff determine a consultant is needed, they identify persons with relevant qualifications and expertise by seeking suggestions from persons including, but not limited to, IRB members and Chairs, relevant Department subject matter experts, Department bureau chiefs and division directors, federal partners such as the Centers for Disease Control and Prevention, university partners, or through a literature search.
 - b. Consultants provide information to the IRB by the same online review forms used by IRB members. In addition, consultants may also present information to the convened IRB by attending a meeting. However, when a consultant attends a meeting, the consultant does not vote.
5. If the reviewer has a conflict of interest, the reviewer will contact the HRPP Administrator or IRB staff and recuse themselves from the review (see DOHP 5-D5-3.2, IRB Member, Consultant, and Staff Conflicting Interests).

C. Continuing review by the convened IRB:

1. The Department uses a primary reviewer system for all reviews of research by the convened IRB. The IRB Manager provides members access to all materials. Reviewers are provided with and review information necessary to determine whether the proposed research continues to fulfill the criteria for approval. One or more primary reviewers are expected to conduct an in-depth review of all materials, including:
 - a. The application for continuing review of research, which includes a status report
 - b. The complete, full protocol (including the DHHS-approved protocol when one exists)
 - c. All study documents approved by the IRB during the previous approval period

DOHP 5-D5-4.4

- d. Any protocol modifications previously approved by the IRB
 - e. The researcher brochure
 - f. The current consent document (including the DHHS-approved consent, when one exists)
 - g. Any newly proposed consent document (including the DHHS-approved revisions to the consent document, when they exist)
 - h. Any findings from conflict of interest committees (for example, when a university conflict of interest committee determines a researcher has a conflict with the research, so the IRB can determine whether a management plan is appropriate.)
2. All other members of the IRB (including alternate members) are provided access to all materials but are expected to review the application for continuing review, which includes a status report and provides the relevant information to determine whether the proposed research fulfills the criteria for approval. In addition, all members read the current consent document and review any newly proposed consent document.
3. Reviewers complete or discuss in detail at the convened IRB meeting a form designed to ensure all regulatory requirements are met. One or more primary reviewers use the form to present the study to other board members, and to ensure there is sufficient discussion by the convened IRB to ensure the regulatory criteria for approval are met.
4. IRB members may request a consultant to supplement the IRB's review (see DOHP 5-D5-3.1, Composition of the IRB).
5. Review of the currently approved informed consent document must ensure the information is still accurate and complete.
6. Any significant new findings that may relate to the participant's willingness to continue participation should be provided to the participant in an updated informed consent document. Review of currently approved or proposed informed consent documents occurs during the scheduled continuing review by the IRB but may be done more frequently if new information becomes available.
7. IRB members determine whether protocols need verification from sources other than the IRB on a case-by-case basis and according to the following criteria:
 - a. Protocols randomly selected by the HRPP

- b. Complex protocols involving unusual levels or types of risks to participants
 - c. Protocols conducted by researchers who previously have failed to comply with federal regulations or the requirements or determinations of the IRB
 - d. Protocols where concerns about possible material changes occurring without IRB approval have been raised based on information provided in continuing review reports or from other sources
- 8. IRB members determine whether continuing review should occur at an interval less than one year, at intervals of one year, or whether the research in question is eligible for exemption from continuing review based on information about anticipated risks posed by the research and any new information including reports of non-compliance, complaints, or other unanticipated problems. Absent other compelling reasons, the convened IRB will require review more often than annually whenever the research involves one or more of:
 - a. Phase I research
 - b. Involvement of recombinant DNA or other types of gene transfer protocols
 - c. Classified research
 - d. Research for which participants would be exposed to additional risks, e.g. breach of confidentiality, phase I studies, disproportionate number or severity of adverse events
 - e. Previous administrative holds or suspensions of the research due to compliance, record-keeping, or other concerns
 - f. Recommendations from other Department committees
- 9. When the convened IRB requests substantive clarifications or modifications that are directly relevant to the determinations required by the IRB, the clarifications or modifications must be reviewed by the convened IRB and may not be verified by the Chair or designee. Examples of substantive clarifications or modifications include, "Explain why participants younger than 18 years of age will be allowed to participate", "Provide additional justification for the use of placebo" and "Clarify whether participants will be offered counseling services at the end of the study."

10. Requests by the IRB for the researcher to make a minor change may be verified by the Chair or designee. A minor change is one where the Chair or designee verifies the change was made as specified by the IRB. If the change is not made as specified, the application is returned to the convened IRB for review. For example, "Delete the duplicate contact information for the IRB (last page, bottom paragraph)", "Drop the placebo-controlled arm of this study" and "Participants must be 18 years or older."
 11. The range of possible actions that the IRB is allowed to take is described in policy (see DOHP 5-D5-4.2, Conduct of Meetings by the Convened IRB).
- D.** Process for review of applications for continuing review using the expedited procedure:
1. Applications for continuing review that are eligible for review using the expedited procedure are assigned to one or more experienced reviewers from the designated IRB for review and approval. Only experienced IRB members may conduct reviews using the expedited procedure. An experienced IRB member means a voting member or alternate voting member with appropriate qualifications and expertise who has received training in the expedited review categories, and possesses the expertise needed to review the proposed research. Normally reviewers serve on the IRB at least three (3) months before being designated as experienced reviewers.
 2. When continuing review by an IRB member is no longer required, the researcher completes an annual check-in form on the IRB Manager that is reviewed by IRB staff.
 3. The mechanism for maintaining ongoing oversight of all open studies includes the continuing review process, and the annual check-in form for studies that are not required to have continuing reviews.
 4. The reviewer assigned will have expertise in the area of the research adequate to the scope and complexity of the research. The reviewer may request a second reviewer, request review by an expert consultant to the IRB, or refer the study to the full IRB for determination. In the case of multiple reviewers, decisions are made by consensus of the reviewers. In the absence of consensus, the application is submitted to the convened IRB. However, the determination of disapproval can only be made by the convened IRB.
 5. The reviewer using the expedited procedure is provided with and reviews the same materials as the primary reviewers for the convened IRB.
 6. The criteria for approval using the expedited procedure are the same as those for review by a convened IRB.

7. Reviewers use a form to ensure all regulatory requirements are met. The criteria for eligibility for continuing review using the expedited procedure are listed on the Expedited Procedure Eligibility form available on the IRB Manager. The reviewer uses this form to determine whether research meets one or more expedited categories and other requirements to undergo continuing review using the expedited procedure, and/or whether the research is appropriate for an exemption from the continuing review process.
8. The reviewer must include his or her rationale for determination of whether a continuing review of research is not required in the IRB expedited review eligibility worksheet.
9. Review of the currently approved informed consent document must ensure the information is still accurate and complete.
10. The reviewer considers any significant new findings that may relate to the participant's willingness to continue participation and whether they should be provided to the participant in an updated informed consent document. Review of a currently approved or proposed informed consent document occurs during the scheduled continuing review by the IRB but may be done more frequently if new information becomes available. If a reviewer using the expedited procedure identifies significant new findings, the application should be sent for review by the convened IRB.
11. IRB members determine whether continuing review should occur at an interval less than one year, at intervals of one year, or whether the research in question is eligible for exemption from continuing review based on information about anticipated risks posed by the research and any new information including reports of non-compliance, complaints, or other unanticipated problems. If a reviewer using the expedited procedure determines a shortened continuing review interval would be indicated, the application should be sent for review by the convened IRB.
12. The reviewer using the expedited procedure may approve research or require changes. However, the reviewer may not disapprove; if the reviewer is unable to approve research, it is referred to the convened IRB.
13. If an ongoing study has been approved by an IRB member using the limited review process, that study is not required to submit continuing review applications, and may submit annual check-ins unless:
 - a. The study has reported a problem or unanticipated event that affects the privacy and/or confidentiality of the participants; or
 - b. The study has submitted an application to modify which provides information that un-exempts the research from IRB review.

- E.** Annual Check-In as an Alternative to Continuing Review: Organizations are permitted, but not required, to eliminate the requirement for continuing review of research originally approved through the expedited review. Written materials specify that continuing review by the IRB or an expedited reviewer is not required when:
1. Research meets one or more expedited review categories.
 2. Research has progressed to the point that it involves only one or both of the following:
 - a. Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
 - b. Accessing follow-up clinical data from procedures that participants would undergo as part of clinical care.
 3. The annual check-in process may not be used without the researcher first submitting a continuing review application and the IRB then determining continuing review is not required for that particular study.
 4. At that point, the IRB will distribute to the researcher a letter informing the researcher of the change from continuing review to annual check-in. The check-in form may be accessed on the IRB Manager.
 5. Once a study has been approved for annual check-in, the researcher must submit the annual check-in document every year not less than 60 calendar days prior to the date their previous annual check-in was approved by the IRB or, if they have not completed an annual check-in previously, not less than 60 calendar days prior to the date the previous continuing review application was approved by the IRB.
 6. When a study has already been approved for annual check-ins, the study team must continue to update the IRB regarding:
 - a. Any problems, unanticipated events, or other issues that may change the type of review that a study is eligible for.
 - b. Any modification of the study protocol, study staff, principal researcher, or conflicts of interest information.
 - c. The closure of the research study. When submitting for closure of the research study, the study staff is required to follow those procedures outlined for closing a study below.
- F.** Process used by staff to notify the IRB, researchers, and organization officials of the results of reviews:

1. The convened IRB is notified of the findings and actions of research applications that have been approved through the expedited procedure with the IRB agenda.
2. The HRPP Administrator designated in the Department's Federal-wide Assurance, and the director of the Public Health Research Unit, are the organization officials notified of the findings of the IRB. Staff include these officials when distributing draft minutes of meetings of the convened IRB to members of the IRB.
3. Researchers are notified of the IRB's decision to approve, disapprove, or require modifications to secure approval through email via the IRB Manager.
 - a. The communication from email via the IRB Manager includes modifications or clarifications required as a condition for IRB approval.
 - b. If the IRB disapproves a proposed research study, researchers are informed through email via the IRB Manager of the IRB's reasons for the decision and how the researcher may respond in person or in writing.
4. Researchers are notified of the approval period for research through email via the IRB Manager. If the study is reviewed at the convened IRB meeting and approved with minor changes, the Chair will review and verify the changes. Once the required changes by the convened IRB have been made, the approval period begins with the date of the convened meeting. If the study is reviewed at the convened IRB meeting, and the convened IRB requires substantial changes and defers the study, it is returned to the researcher. When the researcher re-submits the application, the study is reviewed again by the convened IRB (normally the same IRB). If the convened IRB approves, the approval date is the date of the meeting where the changes were reviewed and approved. The expiration date is the last date that the protocol is approved. For example, if a study is approved through June 10, authorization to conduct research expires at 11:59 p.m. Eastern Time on June 10.

G. Process for managing expiration of IRB approval:

1. There is no grace period extending authorization to conduct research beyond the expiration date of IRB approval. If the researcher has not provided continuing review information to the IRB or the IRB has not approved the research by the specified expiration date, all interactions and interventions on current participants must stop, unless the IRB Chair finds an overriding safety concern or ethical issue involved such that it is in the best interests of study participants to continue. If the IRB requires

changes to the research at continuing review, this does not extend the expiration period. Expiration of authorization to conduct research is automatic and requires no decision, determination, or action by an IRB. Such expirations of approval are not suspensions of IRB approval, terminations of IRB approval, or administrative holds. Allowing a protocol to expire is considered non-compliance and is reviewed for such (see DOHP 5-D5-10.1, Investigating Any Noncompliance, Serious or Continuing Noncompliance).

2. The researcher must immediately provide documentation to IRB staff that all research has stopped.
3. Once notified of the expiration, the researcher must immediately submit to the IRB Chair a list of research subjects for whom expiration of the research would cause harm, where applicable. An IRB Chair reviews this list and allows individual participants to continue participating in the research interventions or interactions only when the IRB Chair finds an overriding safety concern or ethical issue involved such that it is in the best interests of individual participants to continue participating. The convened IRB is informed.
4. Enrollment of new subjects cannot occur on or after the expiration of IRB approval.

H. Closures of research:

1. Researchers must submit a continuing review form to notify the Department that research is completed, and the study is closed. Researchers must submit a continuing review application to receive notification that continued IRB oversight is no longer required. Failure to submit a continuing review form at the closure of research is reviewed as non-compliance.
2. Staff verify the activity no longer includes research involving human participants, including but not limited to data analysis or private identifiable information.
3. If staff determine the activity no longer involves research involving human participants, the researcher is notified via email through the IRB Manager confirming the study is closed and no further action is required.
4. If staff determine research involving human participants continues, for example, if the researcher continues to analyze private identifiable information, the researcher is notified within 14 calendar days that the study requires ongoing review as long as research involving human participants continues and must submit a complete application to continue research.

5. Staff may request advice from an IRB Chair whether research involving human participants continues. However, closing a study is an administrative action by staff, is not a type of IRB approval, and does not require review by the IRB.

IV. Authority

- A. Section 381.86, Florida Statutes, Institutional Review Board
- B. Rule 64H-2.002, Institutional Review Board Applications, Florida Administrative Code
- C. ICH-GCP: III.1.3, III.1.3.5., III.1.3.6, III.1.4

V. Supportive Data and References

- A. 45 CFR § 46.109(e)
- B. 45 CFR § 46.110
- C. Guidance on Continuing Review, Office for Human Research Protections
- D. 21 CFR § 56.109

VI. History Notes

Created: 08/23/2013
Previously Amended: 01/29/2020
Formerly: DOHP 400-4.4, replaces DOHP 400-4.8, "Review of Human Subjects: Continuing Review"

VII. Signature and Effective Date



Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/29/26
Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	2
IV. Authority	6
V. Supportive Data and References	6
VI. History Notes	7
VII. Signature and Effective Date	7

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) that changes in approved research are not implemented without prior IRB approval, except to eliminate immediate hazards to participants.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

A. Researchers submit applications via the online management system (IRB Manager) to request approval to modify or amend an approved research study.

1. Researchers must submit the exact text of an amendment or other revision to the protocol and any proposed changes to the consent document to the IRB, and a summary of the changes. Revised documents must be submitted both with the changes highlighted, and as clean versions.
2. Modifications to the informed consent document must take into account both prospective research subjects and, if applicable, research subjects already enrolled in the study.
3. The researcher may make a modification to research activities to avoid an immediate hazard to the participant but must report this to the IRB as soon as possible, but must be within five (5) business days (see DOHP 5-D5-4.6, Problems Requiring Prompt Reporting to the IRB).
4. Any changes made to research without prior IRB approval, except to avoid an immediate hazard, will be evaluated using DOHP 5-D5-10.1, Investigating any Non-Compliance, Serious or Continuing Non-Compliance.

B. Staff conduct pre-review and assign reviewers based on authority designated by the IRB Chairs.

1. Staff conducts pre-review of applications for completeness using the staff review form on the IRB Manager. Incomplete applications are returned with instructions for the researcher to revise and submit a complete application.
2. When applications are complete, staff assign reviewers using authority delegated from the IRB Chairs to assign reviewers based on the qualifications and expertise listed in the IRB membership roster. When a study involves vulnerable populations, staff assign a reviewer with

appropriate expertise in the specific vulnerable population. If staff are unsure, they consult an IRB Chair.

3. Human Research Protection Program (HRPP) staff, in consultation with an IRB Chair, when necessary, evaluate each study and determine whether there is sufficient expertise or knowledge to review the research. Applications are added to the agenda of the next available IRB meeting that has reviewers possessing necessary qualifications and expertise. Applications are normally assigned to the next agenda, unless that IRB does not have relevant qualifications and expertise. For example, if the application involves a vulnerable population such as prisoners, the application is assigned to the next meeting where a prisoner representative is in attendance.
 - a. If HRPP staff determine a consultant is needed, they identify persons with relevant qualifications and expertise by seeking suggestions from persons including but not limited to IRB members and Chairs, relevant Department subject matter experts, Department bureau chiefs and division directors, federal partners such as the Centers for Disease Control and Prevention, university partners, or through a literature search.
 - b. Consultants provide information to the IRB by completing the same reviewer comment forms used by IRB members. In addition, consultants may also present information to the convened IRB by attending a meeting. However, when a consultant attends a meeting, the consultant does not vote.
4. If the reviewer has a conflict of interest, the reviewer will contact the HRPP Administrator; or, in the case of an IRB staff having a conflict of interest, IRB staff recuse themselves from the review (see DOHP 5-D5-3.2, IRB Member, Consultant, and Staff Conflicting Interests).

C. Review of Amendments by the Convened IRB

1. The Department uses a primary reviewer system for all reviews of research by the convened IRB. IRB Manager provides IRB members access to all materials. Reviewers are provided with and review all modified documents.
2. Reviewers complete or discuss in detail at the convened IRB meeting a form to ensure all regulatory requirements are met when the modifications affect one or more criteria. One or more primary reviewers use the form to present the study to other board members, and to ensure there is sufficient discussion by the convened IRB to ensure the regulatory criteria for approval are met.

3. IRB members may request a consultant to supplement the IRB's review (see DOHP 5-D5-3.1, Composition of the IRB).
4. Reviewers determine whether any significant new findings that may relate to the participant's willingness to continue participation should be provided to a current research participant in an updated informed consent document.
5. Major changes in research shall be reviewed by the convened IRB. The convened IRB may also review minor changes.

D. Review of Amendments by a Reviewer Using the Expedited Procedure

1. Applications involving requests to make minor changes to the research that are eligible for review using the expedited procedure are assigned to one or more experienced reviewers from the designated IRB for review and approval. Only experienced IRB members may conduct reviews using the expedited procedure. An experienced IRB member means a voting member or alternate voting member with appropriate qualifications and expertise who has received training in the expedited review categories, and possesses the expertise needed to review the proposed research. Normally reviewers serve on the IRB at least three (3) months before being designated as experienced reviewers.
2. The reviewer assigned will have expertise in the area of the research adequate to the scope and complexity of the research. The reviewer may request a second reviewer, request review by an expert consultant to the IRB, or refer the study to the full IRB for determination. In the case of multiple reviewers, decisions are made by consensus of the reviewers. In the absence of consensus, the application is submitted to the convened IRB. However, the determination of disapproval can only be made by the convened IRB.
3. The reviewer using the expedited procedure is provided with and reviews the same materials as the primary reviewers for the convened IRB.
4. The criteria for approval using the expedited procedure are the same as those for review by a convened IRB.
5. Reviewers use a form to ensure all regulatory requirements are met. The criteria for eligibility for continuing review using the expedited procedure are listed on the Expedited Procedure Eligibility form used by the reviewer to determine whether research meets one or more expedited categories and other requirements to undergo review using the expedited procedure.
6. The reviewer using the expedited procedure may approve research or require changes. However, the reviewer may not disapprove; if the reviewer is unable to approve research, it is referred to the convened IRB.

E. Minor Amendments

1. Minor changes pose no more than minimal risk. Proposed minor changes to previously approved research may be reviewed in an expedited manner. Examples of minor modifications may include, but are not limited to, the following:
 - a. The addition of research activities that would be considered exempt or expedited if considered independent from the main research protocol.
 - b. Decreasing the number or volume of biological sample collections, provided that such a change does not affect the collection of information related to safety evaluations.
 - c. An increase in the length of confinement or number of study visits for the purpose of increased safety monitoring.
 - d. A decrease in the length of confinement or number of study visits, provided that such a decrease does not affect the collection of information related to safety evaluations.
 - e. Alterations in human research participant payment or liberalization of the payment schedule with proper justification.
 - f. Changes to improve the clarity of statements or to correct typographical errors, provided that such a change does not alter the content or intent of the statement.
 - g. The addition or deletion of qualified researchers.
 - h. A change in funding source.
2. Minor changes must meet one or more of the categories eligible for expedited review listed in the Expedited Procedure Eligibility form on the IRB Manager.

F. Major Amendments

1. If the study was approved using the expedited procedure, and the change is not minor, it may be reviewed using the expedited procedure if it continues to meet one or more expedite categories.
2. When a proposed change in a research study is not minor, then the full IRB must review and approve changes at a convened meeting before changes can be implemented. Examples of major modifications may include, but are not limited to, the following:

- a. Broadening the range of inclusion criteria
- b. Narrowing the range of exclusion criteria
- c. Alterations in the dosage or route of administration of an administered drug
- d. Extending substantially the duration of exposure to the test material or intervention
- e. Alterations in the dosage form (e.g., tablet to capsule or oral liquid) of an administered drug, provided the dose and route of administration remain constant
- f. The deletion of laboratory tests, monitoring procedures, or study visits directed at the collection of information for safety evaluations
- g. The addition of investigative or research sites
- h. The addition of serious, unexpected adverse events or other significant risks to the Informed Consent Document
- i. Changes which, in the opinion of the IRB Chair or his/her designee, do not meet the criteria or intent of a minor modification

IV. Authority

- A.** Chapter 381.86, Florida Statutes, Institutional Review Board
- B.** Rule 64H-2.002, Institutional Review Board Applications, Florida Administrative Code

V. Supportive Data and References

- A.** 45 CFR § 46.109
- B.** 21 CFR § 56.108(a), 21 CFR § 46.109
- C.** Office for Human Research Protections Guidance on Written Institutional Review Board (IRB) Procedures
- D.** ICH-GCP: III.1.3, III.1.3.5., III.1.3.6, III.1.4.

VI. History Notes

Created: 08/23/2013

Previously Amended: 01/29/2020

Formerly: DOHP 400-4.7, Amendments to Approved or Exempt Research, DOHP 400-4.5

VII. Signature and Effective Date



Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/29/26

Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	2
IV. Authority	7
V. Supportive Data and References	7
VI. History Notes	7
VII. Signature and Effective Date	7

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) that researchers will report to the IRB as soon as possible all problems defined in this policy.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

A. Requirements for reporting:

Researchers must report the following problems to the IRB using a reporting form via the online management system (IRB Manager) as soon as possible, but in all cases within five (5) business days of any of the following:

1. Adverse event (regardless of whether the event was internal (onsite) or external (offsite) and regardless of whether the event meets the Food and Drug Administration (FDA) definition of "serious adverse event"), which in the opinion of the principal researcher are both unexpected and related. Adverse events not meeting these criteria do not need to be reported.
2. Information that changes the risks or potential benefits of the research. For example:
 - a. Any interim analysis or safety monitoring report indicating the frequency or magnitude of harms or benefits may be different than initially presented to the IRB.
 - b. Any paper published from another study that shows the risks or potential benefits of the research may be different than initially presented to the IRB.
3. Any breach of confidentiality.
4. Any change in FDA labelling or withdrawal from marketing of a drug, device, or biologic used in a research protocol.
5. Any change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research participant.
6. Any incarceration of a participant in a protocol not approved to enroll prisoners.
7. Any event that requires prompt reporting to the sponsor.

8. Any sponsor-imposed suspension for risk.
9. Any complaint of a participant when the complaint indicates unexpected risks or cannot be resolved by the research team.
10. Any protocol violation (meaning an accidental or unintentional change to the IRB-approved protocol) that harmed participants or others or that indicates participants or others may be at increased risk of harm or has the potential to recur.
11. Any unanticipated adverse device effect (any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application, including a supplementary plan or application, or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects).
12. Any non-compliance identified by Department audit or monitoring.
13. Any investigation by the FDA or the Office for Human Research Protections (OHRP) or other federal agency of research (not just including this study) by any researcher on the study.
14. Any loss of license or hospital privileges by any researcher on the study. Researchers following the International Council for Harmonization Good Clinical Practice (ICH-GCP) guideline as adopted by the FDA must also report to the IRB:
 - a. Deviations from the protocol to eliminate immediate hazards to the trial participants.
 - b. Changes increasing the risk to participants and/or significantly affecting the conduct of the trial.
 - c. All suspected unexpected serious adverse reactions in accordance with applicable regulatory requirements.
 - d. New information that may adversely affect the safety of the participants or the conduct of the trial.
15. Researchers are required to report to all IRBs with jurisdiction over the research and provide documentation of their determinations to the Department.
16. Reportable problems should be reported regardless of whether they occur during the study, after study completion, or after participant withdrawal or completion. For example, if the researcher learns during data analysis of

a breach in confidentiality that occurred during the recruitment phase, this information should still be reported to the IRB.

B. Criteria used for reviewing unanticipated problems involving risks to participants or others:

1. Reviewers determine whether the report meets the definition of “unanticipated problem involving risks to participants or others” by evaluating whether the problem is:
 - a. Unexpected (in terms of nature, severity or frequency) given (1) the research procedures, and (2) the characteristics of the participant population being studied.
 - b. Related or possibly related to participation in the research (possibly related means there is a reasonable possibility the incident, experience, or outcome may have been caused by participation in the research).
 - c. Suggestive that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.
2. These criteria will be applied to evaluate each item of information reported by researchers.

C. Process for administrative screening of each reported problem:

1. The IRB staff, when necessary, in coordination with the IRB Chair or an IRB member with relevant subject matter expertise, conducts an administrative pre-review to screen all reports and assess if the problem involves unanticipated problems involving risks to participants or others. If IRB staff determines the event is not unexpected, not related, and does not suggest that participants or others are placed at greater risk of harm, then the problem is documented in records on the IRB Manager as “no further action” with justification. No further action is taken, unless the problem involves non-compliance. See DOHP 5-D5-10.1, Investigating Any Non-compliance, Serious and Continuing Non-Compliance.
2. If staff are unable to make a determination or are unsure, the report is forwarded to an IRB Chair.

D. Process for review of unanticipated problems by the Chair:

1. The Chair reviews the report to determine if the problem is an unanticipated problem involving risk to participants or others. If the Chair determines the event is not unexpected, not related, and does not suggest that participants or others are at greater risk of harm, then the

problem is documented in records in the IRB Manager as “no further action” with justification. No further action is taken, unless the problem involves non-compliance. See DOHP 5-D5-10.1, Investigating Any Non-Compliance, Serious and Continuing Non-Compliance.

2. If the Chair determines the event is an unanticipated problem involving risks to participants or others, and the problem is not greater than minimal risks to participants or others, then the Chair may review and notify the IRB and report per DOHP 5-D5-10.1, Investigating Any Non-Compliance, Serious or Continuing Non-Compliance.
3. If the Chair or subject matter expert are unable to make a determination, the report is forwarded for review by the convened IRB. The convened IRB reviews all problem reports where the IRB staff or Chair or subject matter expert is unable to determine the problem report is not an unanticipated problem involving risks to participants or others or not noncompliance. See DOHP 5-D5-10.1, Investigating Any Non-Compliance, Serious or Continuing Non-Compliance.

E. Process for IRB review of reported problems by the convened IRB:

1. The convened IRB reviews problem reports using a primary and secondary reviewer system to determine if the problem involves unanticipated problems involving risks to participants.
 - a. Reviewers are assigned by the IRB staff, where necessary in consultation with the IRB Chair. Where possible, the report will be reviewed by the primary and secondary reviewers who conducted the most recent review of the protocol. Reviewers will have relevant subject matter expertise and may request additional expertise.
 - b. All IRB members have access to the report and supporting documents submitted with the report (including but not limited to safety monitoring board reports and sponsor reports). In addition, all IRB members have access to all documents reflecting the current IRB-approved state of the protocol, including but not limited to the protocol, consent document, and supplemental information.
 - c. One or more primary reviewers will review the report, all supporting documents, and all the documents reflecting the current IRB-approved state of the protocol.
 - d. All other IRB members will review the report, the initial IRB application updated with any changes, any supporting documents, and the consent document.

2. The IRB will determine whether the report meets the definition of "unanticipated problem involving risks to participants or others" using the criteria specified in section III.B. above.
 3. If the IRB determines the problem is not an unanticipated problem involving risks to participants, no further action will be taken if the problem does not involve noncompliance.
 4. If the IRB determines the problem is an unanticipated problem involving risks to participants, then the IRB will determine which of the following actions are appropriate regarding the protocol:
 - a. Modification of the protocol
 - b. Modification of the information disclosed during the consent process
 - c. Providing additional information to past participants
 - d. Notification of current participants when such information might relate to participants' willingness to continue to take part in the research
 - e. Requirement that current participants re-consent to participation
 - f. Modification of the continuing review schedule
 - g. Monitoring of the research
 - h. Monitoring of the consent
 - i. Suspension of the research
 - j. Termination of the research
 - k. Referral to other organizational entities (legal counsel, county health department health officer, division director, deputy secretary, and State Surgeon General in the role of Institutional Official)
 5. The IRB's discussion is documented in minutes, including discussion of controverted issues, if any, and their resolution.
 6. The researcher is informed of the IRB's determination by staff through email via the IRB Manager.
- F.** Any unanticipated problems involving risks to participants or others will be reported to regulatory agencies and institutional officials or others following the

Department's reporting policy. See DOHP 5-D5-10.3, Reporting to Institutional Officials, Department or Agency Heads.

- G.** Requests for information. Questions about the trial should be answered to the satisfaction of the participant or the participant's legally acceptable representative.

IV. Authority

Section 381.86, Florida Statutes, Institutional Review Board

V. Supportive Data and References

- A.** 45 CFR §46.103(b)(5)(i)
- B.** 45 CFR §46.116(b)(5)
- C.** 21 CFR §50.25(b)(5)
- D.** 21 CFR §56.108(b)(1)
- E.** 21 CFR §812.150(a)(1)
- F.** OHRP Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events
- G.** OHRP Guidance on Reporting Incidents to OHRP
- H.** FDA Information Sheets: Continuing Review After Study Approval
- I.** ICH-GCP: III.2.8.6.

VI. History Notes

Created: 08/23/2013
Previously Amended: 01/29/2020
Formerly: DOHP 400-4.9-07, DOHP 400-4.6

VII. Signature and Effective Date



Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/29/26
Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	2
IV. Authority	7
V. Supportive Data and References	7
VI. History Notes	8
VII. Signature and Effective Date	8

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) to review and approve all recruitment materials for participants in research conducted under its jurisdiction.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

- A.** All recruiting and advertising materials included in study protocols must be approved by the IRB. The IRB must ensure that appropriate safeguards exist to protect the rights and welfare of research participants and prospective research participants. In fulfilling these responsibilities, the IRB must review all of the research documents and activities that bear directly on the rights and welfare of the participants of proposed research, including the methods and materials that researchers propose to use to recruit participants.
1. The researcher must obtain IRB approval in advance for all television, radio, videotape or print advertisements, email solicitations, internet websites, and other recruitment methods and materials intended for the recruitment of prospective research participants. All methods of advertisement utilized require prior written approval from the facility where research is conducted (for example, the county health department health officer, if research is conducted at a county health department) or a deputy secretary, or the State Surgeon General. All methods of advertisement require approval from the IRB prior to their use.
 2. The following examples do not qualify and are excluded as an advertisement:
 - a. Communications intended only to be seen or heard by health professionals, such as “dear doctor” letters and doctor-to-doctor letters.
 - b. News stories, so long as they are not intended for recruitment purposes (e.g. a news story would not include a phone number at the end to contact for more information to participate in a particular study, full details of inclusion/exclusion criteria of a particular study, etc.).
 - c. Publicity intended for other audiences (e.g., media releases regarding types of services available or offered by a particular clinic, institute, or physician).

-
3. Soliciting for study participants is the start of the informed consent process and subject selection process. When the researcher decides after the initial approval to advertise for participants or to change the advertisement, the new advertising or changes to approved advertising is considered an amendment to the ongoing study. The IRB reviews the advertising to ensure it is free from undue inducements and does not promise a certainty of cure beyond what is outlined in the consent and the protocol. This is especially critical when a study may involve participants who are likely to be vulnerable to undue influence.
 4. When advertising is to be used, the IRB must review the information contained in the advertisement and the mode of its communication, to determine that:
 - a. The procedure for recruiting participants is not coercive and does not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.
 - b. Advertising materials do not include exculpatory language.
 - c. Advertising materials do not emphasize the payment or the amount to be paid, by such means as larger or bold type.
 5. The IRB must review the final printer-ready draft copy of printed advertisements before they are sent to a printer to evaluate the relative size of type used and other visual effects. When advertisements are to be taped for broadcast, the IRB must review the final audio or video tape. For websites and social media, the IRB must review the final versions of materials. The IRB may review and approve the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording. The review of the final taped message prepared from IRB-approved text may be accomplished through expedited procedures.
- B.** Any advertisement to recruit participants should be limited to the information the prospective participants need to determine their eligibility and interest. When appropriately worded, the following items may be included in advertisements:
1. The name, address, and facility or institution of the researcher or study coordinator (e.g. Florida Department of Health).
 2. If applicable, include “investigational, meaning non-Food and Drug Administration (FDA) approved.”
 3. The condition under study and the purpose of the research.

4. In summary form, the criteria that will be used to determine eligibility for the study.
5. A brief list of participation benefits, if any (e.g., a no-cost health examination).
6. The time or other commitment required of the participants.
7. The location of the research and the person or office to contact for further information.

C. Advertising materials should not include the following:

1. Claims, either explicitly or implicitly, that the drug, biologic, device, or other type of intervention is safe or effective for the purposes under investigation.
2. Claims, either explicitly or implicitly, that the test article is known to be equivalent or superior to any other drug, biologic, device, or intervention.
3. Terms such as "new treatment," "new medication," or "new drug" without explaining the test article is investigational, meaning non FDA-approved.
4. Promises of "free medical treatment," when the intent is only to say participants will not be charged for taking part in the investigation.
5. Compensation for participation in a trial offered by a sponsor to include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.

D. The IRB must review payments to determine:

1. The amount of payment and the proposed method of all payments and timing of disbursement is neither coercive nor presents undue influence.
2. Credit for payment accrues as the study progresses and is not contingent upon the participant completing the entire study.
3. Any amount paid as a bonus for completion is reasonable and not so large as to unduly induce participants to stay in the study when they would otherwise have withdrawn.
4. All information concerning payment, including the amount and schedule of payments, is set forth in the consent document.

E. Additional requirements for researchers required to follow the International Council for Harmonization Good Clinical Practice (ICH-GCP) guideline as adopted by the FDA:

-
1. If the trial participants are compensated for their participation in the trial, the IRB should review both the amount and method of payment to participants to ensure neither presents problems of coercion or undue influence on the trial participants.
 - a. Payments to a participant should be timely, prorated, and not wholly contingent on completion of the trial by the participant.
 - b. Reasonable reimbursement of expenses incurred by participants, such as for travel and lodging, is not coercive.
 2. The IRB should ensure information regarding payment to participants, including the methods, amounts and schedule of payment to trial participants, is set forth in the informed consent materials and any other information to be provided to participants.
 3. The IRB should ensure the participant selection process is representative of the population groups the investigational product is intended to benefit, once authorized, to allow for generalizing the results across the broader population.
- F.** Receptionist Scripts. The first contact prospective study participants make is often with a receptionist who follows a script to determine basic eligibility for the specific study. The IRB must review the script and procedures to ensure they adequately protect the rights and welfare of the prospective participants. The IRB must have assurance that any information collected about prospective participants will be appropriately handled.
- G.** Internet Recruitment. All advertisements and recruitment methods must be reviewed and approved by the IRB prior to implementation except for two specific clinical trial listing services which do not require prospective IRB approval as determined by the FDA. These include the National Cancer Institute's cancer clinical trial listing (PDQ), and the government sponsored AIDS Clinical Trials Information Service (ACTIS). For other internet recruitment sites, IRB review and approval is required to ensure the information does not promise or imply a certainty of cure or other benefit beyond what is contained in the protocol and the informed consent document. In addition, the researcher must ensure the information shared for internet recruitment is in accordance with their signed clinical trial agreement or grant.
- H.** Department Mass Communication Email. Advertising submitted through mass email solicitation at the Department should be simple, readable, and understandable. It should meaningfully and respectfully convey a message to a broad spectrum of the Department community. It should be text-based and written in paragraphs. The following format is recommended when utilizing this method of recruitment or advertisement:
1. A headline that describes the study and volunteers needed

-
2. Use sentences and paragraphs
 3. Paragraph 1 – include enough information to help readers self-select
 4. Paragraph 2 – purpose of the study
 5. Paragraph 3 – requirements of participation
 6. Paragraph 4 – benefit to the participant or a statement there is no benefit
 7. Paragraph 5 – a contact person “for more information”
- I.** Students as Participants. The IRB should exercise oversight with the use of students as participants in research.
- J.** Database/Primary Care Physician (PCP) Recruitment. Oftentimes researchers request to use search methods of particular databases looking for potential participants that may be eligible for their research projects (e.g., disease, age, sex, etc.), or they request to contact PCPs for access to potential participants from the PCP’s patient population. These recruitment methods require IRB approval prior to initiation.
- K.** Inclusion of Women, Children and Minorities. The inclusion of women, children, and minorities in research is important, both to ensure they receive an appropriate share of the benefits of research and that they do not bear a disproportionate burden. To the extent that participation in research offers direct benefits to the participants, under-representation of children, women, or minorities denies them the opportunity to benefit. Moreover, for purposes of generalizing research results, researchers must include the widest possible range of population groups.
- L.** Involvement of Humans in Research. Researchers must provide the IRB details of the proposed involvement of humans in their research protocols, including the characteristics of the subject population, anticipated numbers, age ranges, and health statuses. The proposed research should specify the gender and racial/ethnic composition of the subject population, as well as criteria for inclusion or exclusion of any subpopulation. If ethnic, racial, and gender estimates and continuing review numbers are not included in the background data for a protocol, the researchers must provide a clear rationale for exclusion of this information.
- M.** Finder’s Fees and Bonus Payments. Research sponsors may offer to pay researchers or study personnel an additional fee to encourage participant recruitment efforts and the timely or accelerated opening of research studies. Finder’s fees and bonus payments are not allowed.
- N.** Legal Implications
1. The Council on Ethical and Judicial Affairs of the American Medical

Association denounced the practice of finder's fees in December 1994.

2. The federal anti-kickback statute can also be implicated by this practice.
 3. For physicians, Florida Statutes (F.S.) may prohibit certain recruitment incentives and may be subject to disciplinary action. See for example, section 458.331, F.S.
- O.** During the process of recruiting Department clients or using a Department facility to recruit participants, the researcher must provide information on how a prospective research participant can contact the Department Human Research Protection Program, including the toll-free telephone number or, if applicable, the county health department medical director to voice concerns or ask questions.

IV. Authority

Section 381.86, F.S., Institutional Review Board

V. Supportive Data and References

- A.** 21 CFR § 56.107(a)
- B.** 21 CFR § 56.111(a)(3)
- C.** 21 CFR § 56.111(b)
- D.** 21 CFR § 50.20
- E.** 21 CFR § 50.25
- F.** 21 CFR § 812.20(b)(11)
- G.** U.S. Food and Drug Administration Information Sheets: "Recruiting Study Subjects," 1998 Update Clarification of Ethics Opinion 6.03, 65. Finder's Fees: Payment for the Referral of Patients to Clinical Research Studies
- H.** 42 U.S.C. §§ 1320a-7b(b)
- I.** Section 458.331, F.S., Grounds for disciplinary action; action by the board and department.

VI. History Notes

Created 08/23/2013
Previously Amended: 01/29/2020
Formerly: DOHP 400-5.6-07, DOHP 400-4.7

VII. Signature and Effective Date



Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/29/26

Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	2
IV. Authority	5
V. Supportive Data and References	5
VI. History Notes	6
VII. Signature and Effective Date	6

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) to determine if a specific research project requires the additional safeguard of a monitor to observe the consent process or serve as an advocate for the research participants to ensure the protection of the health and safety of participants.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

A. The convened IRB will determine if a specific research project requires the additional safeguard of a monitor to observe the consent process or serve as an advocate for the research subjects to ensure the protection of the rights and welfare of the subjects. This may include but is not limited to the following:

1. Situations where participation in research is the only available medical option and no standard of care is available or proven effective.
2. Subjects who, due to their illness or their hope at the prospect of receiving relief or “treatment” through research, may be too willing to participate (not make a voluntary decision) or give due consideration to the range of options, some of which may not include research.
3. Research where the risk is such that a second party (i.e., consent monitor) functions as a subject advocate to enhance the informed consent process.
4. Potential subjects may include vulnerable populations. Examples include but are not limited to the following:
 - a. Subjects with limited or no resources
 - b. Subject population (e.g., runaway minors, refugees) where sensitive surveys, interviews, interactions, and/or interventions may pose more than minimal risk
 - c. Subjects with diminished decision-making capabilities
5. Situations where the IRB is concerned about the conduct of the study or the process of obtaining informed consent. Examples include but are not limited to the following:
 - a. Complaints from subjects or others regarding the conduct of the study

- b. Complaints from subjects or others regarding the consent process with the researchers
 - c. Audit report to the IRB identifying problems with the execution of the consent process and document
 - d. Audit review of violations or events of non-compliance identifying problems with the consent process or conduct of the study
- 6. Situations where the convened IRB requires the additional safeguard of a consent monitor are distinct from quality improvement monitoring activities (see DOHP 5-D5-10.1, Investigating Any Non-Compliance, Serious or Continuing Non-compliance).
- B.** The convened IRB may determine at any stage of the research review process the need for a consent monitor and may require the researcher to provide resources for monitoring.
- C.** The determination to remove the requirement of a consent monitor for specified research will be made by the convened IRB. Reports from the consent monitor of the observations made during the consent process and/or "Summary of Consent Monitoring for Research" documents will be provided to the IRB.
- D.** Formal correspondence to the principal investigator will describe the IRB's determination of the need and reasons for the requirement to use a consent monitor for the respective research project.
 - 1. Correspondence will indicate the IRB's determination of whether the principal investigator or the IRB will identify a consent monitor. The IRB may seek the researcher's involvement in identifying a consent monitor; however, the selection of the consent monitor is ultimately the IRB's decision.
 - 2. Correspondence will indicate the time frame for the response from the principal investigator and that the researcher must approve the suggested consent monitor candidate.
 - 3. The Human Research Protection Program Administrator may serve as a consent monitor.
 - 4. Approval letters will include language specifying that research may only be conducted under the terms of the IRB's specified monitoring requirements.
- E.** All potential consent monitor candidates will receive training from the Ethics and Human Research Protection Program. Training will include a review of the following:

1. Roles and responsibilities of the consent monitor
2. Evaluation to sign a consent form for research
3. Reporting consent monitoring for research to the IRB

F. Consent Monitoring Process

1. The principal investigator or designee will contact the consent monitor in advance of a consent session with a potential subject.
2. The principal investigator or designee will provide, in advance, a copy of the current approved informed consent document to the consent monitor.
3. The consent monitor has five (5) principal duties:
 - a. Listen: The consent monitor should listen to the consent process and exchange between the researcher and the subject and the subject's family.
 - b. Observe: The consent monitor should closely observe the communication between the researcher and the subject. The monitor should use her/his knowledge of the consent document and be prepared to ask questions of the researcher or the subject if it appears things are not clear.
 - c. Ask Questions: The consent monitor should be prepared to ask questions in order to facilitate comprehension on the part of the subject. In order to understand whether the subject fully comprehends the research and is making a knowledgeable decision about participation, questions should elicit a response from the subject that requires some deliberation and thought about the research rather than yes/no questions.
 - d. Document: Document the interactions, questions, answers, and the decision-making process.
 - e. Decide: Decide with the researcher and the subject whether the subject should be enrolled in the research, provided additional time to consider participation in the research, or should not be enrolled. The consent monitor may determine whether a subject does not understand the consent process or the research and request the researcher re-review the materials with the subject. If the monitor does not think the subject understands the research or all items of the consent document, then the subject should not be enrolled in the research.

4. The researcher will introduce the consent monitor to the potential subject and provide an explanation for the consent monitor's presence.
5. The consent monitor will utilize a copy of the approved informed consent document during the consent process to ensure all elements of the consent document are addressed by the researcher. At any time during the consent session, the consent monitor may request the researcher review or clarify information for the potential subject and/or seek clarification of comprehension from the potential subject.
6. At the end of the consent session, the consent monitor will utilize a checklist to assess the potential subject's comprehension of the consent process.
 - a. The potential subject will be asked the questions on the evaluation form by the consent monitor.
 - b. The consent monitor may ask additional questions as necessary.
7. The consent monitor will prepare a summary for IRB review. The summary will be maintained in the specific IRB research protocol file on the online IRB management system (IRB Manager).
8. The summary will be reviewed by the convened IRB at an identified interval (e.g., every five subjects) as determined by the convened IRB.

IV. Authority

- A. Section 381.86, Florida Statutes, Institutional Review Board
- B. 45 CFR § 46.109(e)
- C. 45 CFR § 46.111(b)
- D. 21 CFR § 109.7(f)
- E. 21 CFR § 56.111(b)

V. Supportive Data and References

Office for Human Research Protections' [Protecting Human Research Subjects Guidebook](#) (1993).

VI. History Notes

Created: 08/23/2013
Previously Amended: 01/29/2020
Formerly: DOHP 400-4.8

VII. Signature and Effective Date

Shay Gonzalez

Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/29/26

Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	2
IV. Authority	7
V. Supportive Data and References	7
VI. History Notes	7
VII. Signature and Effective Date	7

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) that all requests for reliance agreements be reviewed according to criteria for approval in federal regulations (45 CFR § 46.111 and 21 CFR § 56.111) and section 381.86, Florida Statutes (F.S.).

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

A. Process for administrative screening by staff, IRB Chair review, and Public Health Research Unit director approval:

1. Upon receipt of an application that includes a reliance request, staff check the application for completeness, along with the request to cede or establish the Department as the relying institution, using a staff review form. Incomplete applications are returned to the researcher with comments so the researcher can revise and submit a complete application.
2. Certain organizational entities of the Department may require researchers to obtain further approval of research, where applicable. Examples include State Health Office divisions and bureaus, public health laboratories, and county health departments. These organizational entities may not approve research that has not been approved by the Department IRB, but may require further approval, such as formal permission to conduct research. When additional programmatic permission to conduct research contingent upon IRB approval is not present, staff will return applications to researchers for them to provide documentation of permission to conduct research. Programmatic review may occur in parallel when the programmatic review does not involve review of scientific validity or other topics that impact the criteria for approval, but IRB staff will not release a study without programmatic approval.
3. When an application is determined to be complete, staff sends it to the IRB Chair(s) (and an additional member if needed) to ensure the request to cede or establish the Department as the relying institution is consistent with all federal, state, and Department rules and regulations.
4. Once the IRB Chair(s) has made recommendations on whether to cede, or become the relying institution, or deny the request, the application is passed on to the director of biomedical research for approval.

-
5. If approval by the director of biomedical research is obtained, the application is passed on to the director of the Public Health Research Unit for final approval. If approval by the director of biomedical research is denied, the other institution will have to decide whether and/or how to move forward. Applications may be re-submitted for IRB review or withdrawn.
 6. If approval by the director of the Public Health Research Unit is obtained, both institutions will either sign and approve a SMART IRB Master Agreement or draft a reliance agreement with the assistance of legal counsel. If approval by the director is denied, the other institution will have to decide whether and/or how to move forward. Applications may be re-submitted for IRB review or withdrawn.
 7. Once approval has been granted for the Department to become the reviewing institution, all Department IRB policies apply. The Department will promptly notify the principal investigator, site investigator(s), and the relying institution(s) of its determinations (e.g., exemption) or review decisions regarding research (e.g., approval, disapproval, required modifications); of changes in the research that are reviewed and approved by the reviewing IRB after initial approval; and of lapses in IRB approval of the research and any applicable corrective action plans; of applicable review decisions, findings, and actions (including any suspension or termination of IRB approval of research and required corrective actions) with respect to (i) any unanticipated problems involving risks to human subjects or others or significant research participant complaints (e.g., those that could affect the conduct of the research) involving research participants enrolled by the relying institution; and (ii) such events involving research participants enrolled by any other relying institution if such events relate to or may affect the conduct of the research by or the safety, rights or welfare of research participants enrolled in the research. Such notifications may be made through the reviewing IRB/reviewing IRB institution or their designee, if agreed by the relevant relying institution(s) in connection with the instance of research.

B. Conditions for the Department becoming the relying institution or the IRB of record:

1. The study is funded by the National Institutes of Health (NIH) and is submitted after the implementation of the 2018 Common Rules Revision. Research applications submitted prior to the implementation date will not be automatically granted approval to cede review.
2. As of January 20, 2020, the Department IRB is required to cede review for **all** federally funded applications that are multicenter site studies or “cooperative research.”

-
3. The IRB of record must maintain a Federal-Wide Assurance of Compliance (Assurance).
 4. The IRB of record must ensure the researchers are conducting their research in accordance with the terms and conditions specified in the authorization agreement and the IRB's Assurance.
 5. A reviewing IRB will consider any local considerations, other considerations, and other local information communicated to it.
 6. The IRB of record must be Association for the Accreditation of Human Research Protection Programs (AAHRPP) accredited. However, this policy is only applicable if the study is not a federally funded multicenter site study.
 7. The principal investigator must provide all necessary information pertaining to local research activities conducted at external sites in accordance with Department IRB policies and procedures.
 8. Prior to agreeing to serve as the relying organization, the Department will conduct a ceded reliance review as detailed in section III.A.1-4. Prior to agreeing to serve as the relying organization, the Department will perform its own conflict of interest analysis under its relevant policies and will provide to the reviewing IRB any resulting conflict of interest determinations, prohibitions, and management plans as well as any updates to such prohibitions, determinations, or plans the Department has determined to be necessary for the conduct by and approval of the research on behalf of the relying institution under such policies. If the reviewing IRB and the Department are not able to identify a mutually agreeable approach, the research will be withdrawn from ceded review (without an IRB approval or disapproval) with respect to the Department.
 9. The Department IRB will communicate with the researcher and the researcher's reviewing organization to determine a communication plan regarding point of contact, study actions, study status changes, relevant policies, IRB records, and other necessary information. The reviewing IRB's policies pertaining to possible unanticipated problems, participant complaints, protocol deviations, and other events will be applied to the research.
 10. The principal investigator will abide by all Department IRB policies and procedures.
 11. Principal investigators will comply with all oversight activities deemed appropriate by the Department IRB, federal oversight agencies, and/or federal funding agencies at all sites (e.g., monitoring, auditing).

C. Process for Sharing Oversight of Research

1. When sharing oversight of research, the Department IRB will communicate with the researcher and the researcher's reviewing organization to determine a communication plan regarding point of contact, study actions, study status changes, relevant policies, IRB records, and other necessary information.
 2. The researcher's organization will be responsible for providing education to researchers and research staff.
 3. Scientific review will be first conducted at the researcher's organization, and the findings will be communicated to the partner IRB. If the findings are disputed, scientific review will then be conducted at the partner IRB.
 4. In the case of noncompliance, the researcher must first notify their organization, and the partner IRBs will coordinate the plan of action, including but not limited to auditing, creating a management plan, and enforcing a management plan.
 5. The researcher's organization will perform a conflict of interest analysis under its relevant policies and will provide to the partner IRB any resulting conflict of interest determinations, prohibitions, and management plans as well as any updates to such prohibitions, determinations, or plans the researcher's organization has determined to be necessary for the conduct by and approval of the research.
 6. In the event of a termination of shared oversight, the researcher's organization will continue oversight of active studies until closure or a mutually agreed upon transfer of the studies.
- D. Process for Conducting Studies Following Department of Health and Human Services (DHHS) and FDA Requirements**
1. The reviewing IRB/reviewing IRB institution will maintain current registration of its IRB(s) with DHHS.
 2. The reviewing IRB will uphold its Assurance as filed with the DHHS Office for Human Research Protections.
 3. The reviewing IRB/reviewing IRB institution will obtain any additional approvals from DHHS when the research involves pregnant women, fetuses, neonates, children, or prisoners.
 4. The reviewing IRB/reviewing IRB institution will apply its relevant policies in the instance of serious or continuing noncompliance; unanticipated problems involving risks to participants or others; and suspensions or terminations of IRB approval. The reviewing IRB will provide to the relying

IRB any determinations, prohibitions, and management plans as well as any updates to such prohibitions, determinations, or plans.

E. Process for Conducting Studies Following the NIH Policy on Single IRB Reviews

1. Unless other requirements must be met under a specific federal agency's policy and/or guidelines, the Department will follow the NIH policy and guidance regarding a single IRB.
2. The Department will use the SMART IRB Master Agreement to document the single IRB. The respective responsibilities of the two institutions will be described. When ceding review to another IRB, a ceded reliance review will be conducted as detailed in section III.A.1-6.
3. The reviewing IRB will be responsible for ensuring multi-site approval has been received, according to its relevant policies.
4. The reviewing IRB will be responsible for ensuring the following approvals have been received, if applicable:
 - a. If (a) the research involves pregnant women, fetuses, neonates, children, or prisoners, and (b) DHHS or FDA regulations are applicable, additional approvals have been obtained from DHHS.
 - b. If the research is funded by NIH and involves genomic data, requirements of the NIH Genomic Data Sharing Policy are met.
 - c. If the research is funded by other government agencies (e.g., U.S. Department of Defense, U.S. Department of Justice, or U.S. Department of Veterans Affairs), the requirements of the applicable agencies are met.
5. The reviewing IRB will provide to the relying IRB any determinations, prohibitions, and management plans as well as any updates to such prohibitions, determinations, or plans.

F. Process for Additional Reviews Relevant to the Human Research Protection Program Conducted by External Organizations

1. Additional reviews, including but not limited to biosafety review, radiation safety review, recombinant DNA research review, human stem cell research review, and conflict of interest review will be documented according to the policies of the reviewing IRB. The reviewing IRB will provide to the relying IRB any determinations, prohibitions, and management plans as well as any updates to such prohibitions, determinations, or plans. The relying IRB will communicate with the principal investigator, site investigator(s), and the reviewing institution of

circumstances when the external review must consider additional regulatory requirements, as applicable.

2. The reviews will be conducted according to the relevant policies of the external organizations. Researchers will be provided with education on these policies and reviews by the reviewing IRB.

IV. Authority

- A. Section 381.86, F.S., Institutional Review Board
- B. Rule 64H-2.002, Institutional Review Board Applications, Florida Administrative Code

V. Supportive Data and References

- A. 45 CFR § 46.103
- B. [AAHRPP Tip Sheet: Following the Guideline of the International Conference on Harmonisation – Good Clinical Practice \(E6\)](#)

VI. History Notes

This is a new policy not previously covered by any other policy.

VII. Signature and Effective Date



Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/29/26
Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	3
A. Risk Assessment and Planning	3
B. Continuity of IRB Operations During Emergency	3
C. Research Participant Safety Protocols	4
D. Communication and Training	5
IV. Authority	6
V. Supportive Data and References	6
VI. History Notes	6
VII. Signature and Effective Date	6

I. Policy Statements

- A. It is the policy of the Department of Health (Department) to maintain a comprehensive Human Research Protection Program (HRPP) emergency preparedness and response plan to ensure the protection of research participants' rights and welfare during emergencies. The Department recognizes various emergencies may create challenges to Institutional Review Board (IRB) operations, research conduct, and the safety of research participants. This policy establishes procedures for the continuity of operations during emergency situations.
- B. This policy applies to all research activities under the jurisdiction of the HRPP, including all IRB members, staff, researchers, research staff, and other personnel involved in human subjects research.

II. Definitions

Biological Emergencies: Conditions or diseases of significant public health concern that result in economic loss and require substantial response efforts by the Department.

Continuity of Operations: The capability to continue essential HRPP functions during an emergency through pre-planned procedures and alternate methods.

Cyber Security Incident: Any event that results in unauthorized access to, disruption of, or compromise of information systems, data, or technology infrastructure supporting HRPP operations.

Emergency: Any natural disaster, extreme weather event, man-made disaster, biological emergency, cyber security incident, public health emergency, or other unforeseen event that may impact HRPP operations, research conduct, or the safety and welfare of research participants.

Extreme Weather Events: Meteorological events that pose a barrier to typical daily functions and services.

Man-made Disasters: Human-induced circumstances that result in the loss of property or life.

Natural Disaster: Meteorological or geological events that result in the loss of property or life.

Risk Assessment: The systematic evaluation of potential emergencies and their likely impact on HRPP operations and research participant safety.

See also DOHP 5-D5-11.1, Definitions

III. Procedures

A. Risk Assessment and Planning

The HRPP director, IRB coordinator, and institutional official, in collaboration with the Department's Division of Emergency Preparedness and Community Support, shall conduct an annual risk assessment to identify potential emergencies that may affect HRPP operations.

1. The risk assessment shall evaluate the likelihood and potential impact of each identified hazard on:
 - a. IRB meeting operations and review processes
 - b. Research participant safety and welfare
 - c. HRPP staff availability and facility access
 - d. Data security and recordkeeping systems
 - e. Communication capabilities with researchers and participants
2. Risk assessment results shall inform the development and update of any required emergency response procedures and resource allocation decisions in the HRPP Plan.
3. Conduct annual emergency tabletop exercises to test emergency response procedures as outlined in the HRPP Plan. Conduct after-action reviews and document any finds from the tabletop exercises and update the plan as required.

B. Continuity of IRB Operations During Emergency

1. Consult the HRPP Plan for procedures on continuing operations and assess if the emergency may impact IRB operations.
2. If operations are impacted, follow procedures related to meeting continuity such as scheduling any meetings virtually, using expedited review procedures for time-sensitive protocols when full board meetings cannot be convened, and establishing a mutual reliance agreement with an external IRB for back-up review capacity during emergencies.
 - a. Maintain written procedures for how quorum and voting will be established and conducted during emergencies.
 - b. Prioritize review of research that directly benefits participants and expedite safety-related protocol modifications and adverse event

reports. Postpone other reviews that do not meet the above criteria during resource-limited periods.

- c. Ensure there are data management, backup, and recovery procedures, including during a cyber security incident, and consult with the Department's Office of Information Technology for immediate assistance.

C. Research Participant Safety Protocols

1. If the disaster or emergency that is imminent or has occurred would impact the ability of a researcher to complete their research, conduct an immediate safety assessment of specific studies to require researchers to assess any immediate risks to study enrolled participants.
 - a. If required, implement protocols for emergency contact with participants at high risk.
 - b. If necessary, establish and implement procedures for the emergency unblinding when participant safety is at risk.
2. Maintain a protocol that provides for modifications to study protocols during emergencies.
 - a. Allow temporary protocol modifications to eliminate immediate hazards without prior IRB approval but reportable to the IRB within five business days.
 - b. Require all researchers to document all emergency-related protocol deviations.
 - c. Strictly prohibit any study modifications that may increase risk or compromise scientific integrity without IRB review.
 - d. For alternative research procedures, support remote consent procedures when in-person contact is not safe or feasible. Allow for virtual study procedures and for the immediate provision of the emergency delivery of any investigational products if necessary.
3. Suspension of research will be necessary if the study meets the following criteria:
 - a. Research that competes for essential emergency response resources.
 - b. Studies that increase risk to participants during emergency situations.

- c. Research that requires in-person procedures when such contact may pose safety risks.
- 4. When the disaster or emergency no longer poses a risk to life or property, the IRB coordinator will notify the researchers and the IRB Chair(s) and members that normal operations have resumed.
- 5. Studies may be resumed following assessment of the emergency situation. If the situation has been resolved, restart protocols may be implemented. All study modifications must follow IRB review requirements.
 - a. Researchers must implement re-contract procedures for any affected participants during study suspension.
 - b. Researchers must submit any protocol amendments per IRB requirements for resumed research.

D. Communication and Training

- 1. The HRPP administrator will:
 - a. Establish any primary and alternative contact methods for all HRPP personnel and will maintain updated contact information for all team members, IRB Chair(s), and members.
 - b. Establish a communication schedule and status report, documenting all emergency-related decisions and communications.
 - c. Ensure cross-training of IRB staff to ensure essential functions of the HRPP and IRB can be performed.
 - (1) Provide emergency response protocols and training annually to all IRB members and Chair(s).
 - (2) Conduct annual emergency tabletop exercises to test emergency response procedures.
 - (3) Provide a copy of the HRPP Plan and any other emergency response protocols.
- 2. The IRB coordinator will ensure timely research community notifications during an emergency situation.
 - a. Provide timely notifications on emergency procedures and expectations for researchers.

- b. Provide guidance on study protocol modification requirements and reporting procedures.
- c. Establish dedicated emergency communication channels.
- d. Notify any regulatory agencies if emergency situations warrant.
- e. Report any significant protocol deviations or adverse events.
- f. Maintain documentation for post-emergency after-action reports and update the HRPP Plan as required.

IV. Authority

Section 381.86, Florida Statutes, Institutional Review Board

V. Supportive Data and References

- A. Department of Health Emergency Preparedness Plan
- B. 45 CFR Part 46, Protection of Human Subjects
- C. 21 CFR Parts 50 and 56, Protection of Human Subjects and IRB Regulations
- D. Effects of Disasters on Human Research Protections Programs Guidance (May 14, 2008), Department of Health and Human Services
- E. Considerations for the Conduct of Clinical Trials During Major Disruptions (September 2023), Food and Drug Administration

VI. History Notes

This is a new policy not covered by any existing policy.

VII. Signature and Effective Date



Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/29/26

Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	2
IV. Authority	4
V. Supportive Data and References	4
VI. History Notes	5
VII. Signature and Effective Date	5

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) to ensure provisions are made to obtain legally acceptable informed consent prospectively from each research participant or permission from his or her legally acceptable representative.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

A. Presumption of Consent in Research

The IRB ensures provisions are made to obtain legally effective informed consent prospectively from each research participant, or permission from his/her legally acceptable representative. However, there are circumstances in which the IRB may grant a waiver of informed consent in accordance with federal regulations.

B. Presumption Informed Consent Will Be Documented

Documentation of consent is obtained unless alternate procedures are approved by the IRB. The IRB reviews all consent documents to ensure the adequacy of the information contained in the consent document, and adherence to federal regulations regarding the required elements of informed consent.

C. Presumption Consent Will Be Obtained Prior to Research

Consent is obtained from the participant or permission from a legally acceptable representative prior to initiating research activities. This includes recruitment and screening procedures.

1. Children. For subjects who meet the Food and Drug Administration (FDA) and Department of Health and Human Services definition of "children," as defined in 21 CFR § 50.3 and 45 CFR § 46.402, their parents or guardians are the legally acceptable representatives who may grant permission for their participation in research. Parental permission and minor assent must be obtained per DOHP 5-D5-6.3, Research Involving Children.
2. Adults unable to consent. If a researcher intends to enroll adult subjects who lack the capacity to consent, legal counsel will be consulted on a protocol-by-protocol basis to determine who is authorized to grant permission for participation in research prior to IRB approval. Permission from legally acceptable representatives will be obtained per DOHP 5-D5-6.4, Research Involving Cognitively Impaired Persons.

3. Research over extended periods. Studies involving subjects who are decisionally impaired, or subjects who have a diminished capacity to understand the risks and benefits for participation in research, may take place over extended periods of time. The IRB considers whether and when periodic reconsenting of individuals is required to ensure a subject's continued involvement is voluntary. The IRB may require the researcher to re consent subjects after taking into account the study's anticipated length and the condition of the individuals to be included (e.g., subjects with progressive neurological disorders). Additionally, the IRB considers whether and when to require a reassessment of decision-making capacity.
- D.** For researchers required to follow the International Council for Harmonisation Good Clinical Practice (ICH-GCP) as adopted by the FDA, consent documents must include the following ICH-GCP elements of disclosure:
1. The informed consent process should take into consideration relevant aspects of the trial, such as the characteristics of the participants, the trial design, the anticipated benefits and risks of medical intervention(s), the setting and context in which the trial will be conducted (e.g., trials in emergency situations), and the potential use of technology to inform participants (or their legally acceptable representatives) and obtain informed consent.
 2. The information should be as clear and concise as possible, use simple language, and avoid unnecessary volume and complexity.
 3. For potential participants unable to provide informed consent, their legally acceptable representatives, acting in the participants' best interest, should provide consent prior to clinical trial participation. These potential participants should be informed about the trial in a manner that facilitates their understanding and, if capable, the participant should sign and date the informed consent form or assent form as appropriate.
 4. The process and information provided should be designed to achieve the primary objective of enabling potential trial participants to evaluate the benefits, risks, and burden of participating in the trial and to make an informed decision on whether or not to participate in the trial. The information provided during the informed consent process should be clear and concise so as to be understandable by potential participants or legally acceptable representatives.
 5. When computerized systems are used to obtain informed consent, trial participants may be given the option to use a paper-based approach as an alternative.
 6. Whether the informed consent process takes place in person or remotely, the researcher should assure themselves of the identity of the participant

(or legally acceptable representative) in accordance with applicable regulatory requirements.

7. Prior to a participant's participation in the trial, the written consent document should be signed and personally dated by the participant or by the participant's legally acceptable representative.
8. Prior to a participant's participation in the trial, the written consent document should be signed and personally dated by the researcher or delegated researcher site staff who conducted the informed consent discussion.
9. If a participant is unable to read or if a legally acceptable representative is unable to read, an impartial witness should be present (remotely or in-person) during the entire informed consent discussion.
 - a. After the written consent document and any other written information to be provided to participants is read and explained to the participant or the participant's legally acceptable representative, and after the participant or the participant's legally acceptable representative has orally consented to the participant's participation in the trial and, if capable of doing so, has signed and personally dated the consent document, the witness should sign and personally date the consent document.
 - b. By signing the consent document, the witness attests the information in the consent document, and any other written information was accurately explained to, and apparently understood by, the participant or the participant's legally acceptable representative, and consent was freely given by the participant or the participant's legally acceptable representative.
10. Prior to participation in the trial, the participant or the participant's legally acceptable representative should receive a copy (paper or electronic) of the signed and dated written consent document and informed consent materials provided in accordance with applicable regulatory requirements.

IV. Authority

Section 381.86, Florida Statutes, Institutional Review Board

V. Supportive Data and References

- A. 45 CFR § 46.111
- B. 45 CFR §§ 46.116 and 46.117
- C. 45 CFR § 46.402

- D. 21 CFR § 50.3
- E. 21 CFR §§ 50.24, 50.25 and 50.55
- F. 38 CFR Parts 16 and 17
- G. Office for Human Research Protections Guidance Document: Informed Consent, Legally Effective and Prospectively Obtained (OPRR REPORTS 93-3)
- H. ICH-GCP: III.2.8., III.2.8.10., III.2.8.1.13.

VI. History Notes

Created: 08/23/2013
Previously Amended: 01/29/2020
Formerly: DOHP 400-5.1

VII. Signature and Effective Date



Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/29/26

Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	2
IV. Authority	7
V. Supportive Data and References	7
VI. History Notes	8
VII. Signature and Effective Date	8

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) that informed consent be documented in writing as determined in the IRB review and approval process.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

A. The IRB evaluation of the research consent process includes a description of the consent process that encompasses:

1. The person who will conduct the consent interview
2. The person who will provide consent or permission
3. Any waiting period between informing the prospective participant and obtaining consent
4. Steps taken to minimize the possibility of coercion or undue influence
5. The language used by those obtaining consent
6. The language understood by the prospective participant or the legally acceptable representative
7. The information to be communicated to the prospective participant or the legally acceptable representative
8. The medium through which informed consent is conducted and potential technology used

B. All documentation of consent shall include for participants or prospective participants and their representatives the following pieces of contact information for persons to voice concerns, ask questions, or obtain information about their rights as a research participant:

1. The principal investigator or a senior research team member and a contact email
2. The telephone number and email for the principal investigator's local IRB if it is not the Department IRB
3. Where to go and whom to contact in the event of a research-related injury

4. The Department IRB, including the email address IRB@flhealth.gov and the Department toll-free telephone number
5. If the research site is at a county health department facility, contact information (email address at a minimum) for the director, administrator, or medical director of the facility

C. Three Options for Documentation of Informed Consent

1. The IRB may approve procedures for documentation of consent involving either:
 - a. A written consent form signed by the participant
 - b. A short form written consent with oral presentation
 - c. In limited circumstances, a waiver of the signed written consent form

Each of these options is described in detail below.

2. It is the responsibility of the IRB to determine which of the procedures described below is appropriate for documenting informed consent in the research applications it reviews. Generally, only Option One (a written, signed consent form) will be appropriate.

D. Option One: Written Consent Form Signed by the Participant or Legally Acceptable Representative

1. In most circumstances, the IRB should require that consent is documented through the use of a written consent form approved by the IRB and signed and dated by the participant or the participant's legally acceptable representative.
2. This consent form must embody the required elements of informed consent, as well as any additional applicable elements that are required by federal regulation. This form may be read to the participant or the participant's legally acceptable representative. However, the principal investigator should allow the participant or the legally acceptable representative adequate opportunity to read and consider the consent document before it is signed. A copy of the signed and dated document must be given to the person signing the form.
 - a. The written informed consent document should embody, in language understandable to the participant, all the required elements necessary for legally effective informed consent (see DOHP 5-D5-5.1, Legally Effective and Prospectively Obtained

Informed Consent).

- b. Participants who do not speak English should be presented with an informed consent document written in a language understandable to them.

E. Option Two: Oral Presentation Using the Short Form

1. As an alternative to standard written informed consent documents, oral presentation of informed consent information may be used and documented using the short form consent document. The short form consent document should generally only be used when the research involves no more than minimal risk to subjects or, if the research involves more than minimal risk, presents the prospect of direct benefit to individual subjects. The short form consent document attests that the elements of consent have been presented orally. In such cases, the participant must be provided with both:
 - a. A short form written consent document stating the required basic and appropriate additional elements of consent (see DOHP 5-D5-5.1, Legally Effective and Prospectively Obtained Informed Consent) have been presented orally to the participant or the participant's legally acceptable representative.
 - b. A signed and dated copy of the written summary of the information, approved by the IRB, that is presented orally to the participant or the participant's legally acceptable representative.
2. Witness Required: A witness to the oral presentation is required. For participants who do not speak English, the witness must be conversant in both English and the language of the participant.
3. The participant or the legally acceptable representative must sign and date the short form written consent document.
4. The witness must sign and date both the short form written informed consent document and a copy of the written summary.
5. The person obtaining consent (e.g., the principal investigator) must sign and date a copy of the written summary of the information that is presented orally. The person obtaining consent may not be the witness to the consent.
6. A copy of the signed summary must be given to the participant or participant's legally acceptable representative.
7. Participants Who Do Not Speak English

-
- a. It is preferable that the written informed consent documents for non-English speaking participants embody, in a language understandable to the participant, all the required elements necessary for legally effective informed consent.
 - b. Alternatively, the regulations permit oral presentation of informed consent information in conjunction with a short form written consent document (stating that the elements of consent have been presented orally) and a written summary of what is presented orally. A witness to the oral presentation is required, and the participant must be given signed and dated copies of the short form informed consent document and the summary. When this procedure is used with participants who do not speak English, the following are required:
 - (1) The oral presentation and the short form written informed consent document should be in a language understandable to the participant.
 - (2) The IRB-approved English language informed consent document may serve as the summary.
 - (3) A witness who is fluent in both English and the language of the participant must be present.
 - c. The IRB must review and approve all foreign language versions of the informed consent document, or the short form informed consent documents prior to use.
 - d. Expedited review of these versions is acceptable if the convened IRB has already approved the research study, the full English language informed consent document, and the English language version of the short form document.
- F.** Option Three: Waiver of Documentation; see DOHP 5-D5-5.3, Waiver and Alteration of Informed Consent.
- G.** No Verbal Consent: Verbal agreement to participate in a research study is not permitted unless the documentation or process of informed consent is waived by the IRB.
- H.** Use of Facsimile, Mail, Email, or Online Web Document to Document Informed Consent
- 1. The IRB may approve a process allowing the consent document to be delivered by mail or facsimile to the potential participant or the potential participant's legally acceptable representative and to conduct the consent

interview by telephone when the participant or the legally acceptable representative can read the consent document as it is discussed. A document may also be sent as an attachment via email for the participant to print out and sign and return. Finally, a consent document may be presented to the potential participants via an online form, as long as the potential participant receives a physical copy of the consent document they signed (or have opportunity to sign) through an online form.

2. All other applicable conditions for documentation of consent must also be met when using this procedure.
- I. When following International Council for Harmonisation Good Clinical Practices (ICH-GCP) as adopted by the Food and Drug Administration, informed consent must address the following additional ICH-GCP elements of disclosure:
1. The informed consent process should take into consideration relevant aspects of the trial, such as the characteristics of the participants, the trial design, the anticipated benefits and risks of medical intervention(s), the setting and context in which the trial will be conducted (e.g., trials in emergency situations), and the potential use of technology to inform participants (or their legally acceptable representatives) and obtain informed consent.
 2. The information should be as clear and concise as possible, use simple language, and avoid unnecessary volume and complexity.
 3. For potential participants unable to provide informed consent, their legally acceptable representatives, acting in the participants' best interest, should provide consent prior to clinical trial participation. These potential participants should be informed about the trial in a manner that facilitates their understanding and, if capable, the participant should sign and date the informed consent form or assent form as appropriate.
 4. The process and information provided should be designed to achieve the primary objective of enabling potential trial participants to evaluate the benefits, risks, and burden of participating in the trial and to make an informed decision on whether or not to participate in the trial. The information provided during the informed consent process should be clear and concise so as to be understandable by potential participants or legally acceptable representatives.
 5. When computerized systems are used to obtain informed consent, trial participants may be given the option to use a paper-based approach as an alternative.
 6. Whether the informed consent process takes place in person or remotely, the principal investigator should assure themselves of the identity of the participant (or legally acceptable representative) in accordance with applicable regulatory requirements.

7. Prior to a participant's participation in the trial, the written consent document should be signed and personally dated by the participant or by the participant's legally acceptable representative.
8. Prior to a participant's participation in the trial, the written consent document should be signed and personally dated by the principal investigator or delegated investigator site staff who conducted the informed consent discussion.
9. If a participant is unable to read or if a legally acceptable representative is unable to read, an impartial witness should be present (remotely or in-person) during the entire informed consent discussion.
 - a. After the written consent document and any other written information to be provided to participants is read and explained to the participant or the participant's legally acceptable representative, and after the participant or the participant's legally acceptable representative has orally consented to the participant's participation in the trial and, if capable of doing so, has signed and personally dated the consent document, the witness should sign and personally date the consent document.
 - b. By signing the consent document, the witness attests the information in the consent document, and any other written information was accurately explained to, and apparently understood by, the participant or the participant's legally acceptable representative, and that consent was freely given by the participant or the participant's legally acceptable representative.
10. Prior to participation in the trial, the participant or the participant's legally acceptable representative should receive a copy (paper or electronic) of the signed and dated written consent document and informed consent materials provided, in accordance with applicable regulatory requirements.

IV. Authority

Section 381.86, Institutional Review Board, Florida Statutes

V. Supportive Data and References

- A. 45 Code of Federal Regulations (C.F.R.) §§ 46.111, 46.116, and 46.117
- B. 21 C.F.R. §§ 50.24, 50.25 and 50.55
- C. 38 C.F.R. Parts 16 and 17
- D. Office for Human Research Protections Guidance Document: Informed Consent, Legally Effective and Prospectively Obtained (OPRR REPORTS 93-3)

E. ICH-GCP: III.1.3.1, III.1.4.1., III.2.8., III.2.8.10., III.2.8.1.13.

VI. History Notes

Created: 8/23/2013
Previously Amended: 1/29/2020
Formerly: DOHP 400-5.2

VII. Signature and Effective Date



Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/29/26
Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	2
IV. Authority	6
V. Supportive Data and References	6
VI. History Notes	7
VII. Signature and Effective Date	7

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) to grant a waiver from informed consent for research or an exception from informed consent for qualifying emergency research in congruence with federal regulation and Department IRB policies and procedures.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

- A. The Department IRB follows the criteria in 45 Code of Federal Regulations (CFR) §§ 46.116(e-f), 45 CFR § 46.117, 21 CFR § 56.109(c)(1), and 21 CFR § 56.109(d) to determine whether the IRB can waive the requirement to obtain written documentation of the consent process.
- B. The IRB follows the criteria in 45 CFR §§ 46.116(c-f), 45 CFR § 46.117, and 21 CFR § 56.109(c)(1), and 21 CFR § 56.109(d) determines whether the IRB can waive or alter the consent process.
- C. Procedures for waiving or altering the process and documentation of parental permission and minor assent are described in DOHP 5-D5-6.3, Research Involving Children.
- D. Exception from Informed Consent Requirements for Emergency Research Subject to Food and Drug Administration (FDA) Regulation

Important Note: Do not confuse with emergency use of FDA regulated products. See DOHP 5-D5-7.6, Emergency Use of FDA Regulated Products and Emergency Use Authorizations.

The IRB may review and approve a clinical investigation without requiring prospective informed consent of **all** research subjects if the IRB (with the concurrence of a licensed physician who is a member of or consultant to the IRB and who is not otherwise participating in the clinical investigation) finds and documents each of the following:

- 1. The target population for the research is in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.
- 2. Obtaining informed consent is not feasible because:

- a. The subjects will not be able to give their informed consent as a result of their medical condition;
 - b. The intervention under investigation must be administered before consent from the subjects' legally acceptable representative is feasible; and
 - c. There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.
3. Participation in the research holds out the prospect of direct benefit to the subjects because:
 - a. The subjects are facing a life-threatening situation that necessitates intervention;
 - b. Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence supports the potential for the intervention to provide a direct benefit to the individual subjects; and
 - c. The risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of subjects and the risks and benefits of the proposed intervention or activity.
4. The clinical investigation could not practicably be carried out without the waiver.
5. The proposed investigational plan defines the length of the potential therapeutic window based on scientific evidence, and the researcher has committed to attempting to contact a legally acceptable representative for each subject within that window of time and, if feasible, to asking the legally acceptable representative contacted for consent within that window rather than proceeding without consent. The researcher must agree to summarize efforts made to contact legally acceptable representatives and make this information available to the IRB at the time of continuing review.
6. The IRB has reviewed and approved informed consent procedures and an informed consent document consistent with federal regulations and IRB policies and procedures. The informed consent procedures and the informed consent document are to be used with subjects or their legally acceptable representatives in situations where use of such procedures and documents is feasible.

7. Additional protections of the rights and welfare of the subjects will be provided, including, at least:
 - a. Consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn.
 - b. Prior to the initiation of the clinical investigation, public disclosure to the communities in which the clinical investigation will be conducted and from which the subjects will be drawn of plans for the investigation and its risks and expected benefits.
 - c. At the completion of the clinical investigation there are plans for public disclosure of sufficient information to apprise the community and researchers of the study. The information must include the demographic characteristics of the research population and results of the clinical investigation.
 - d. Establishment of an independent data and safety monitoring committee to exercise oversight of the clinical investigation.
 - e. If obtaining informed consent is not feasible and a legally acceptable representative is not reasonably available, the researcher must commit to attempting to contact within the therapeutic window the subject's family member who is not a legally acceptable representative and asking whether he/she objects to the subject's participation in the clinical investigation. The researcher will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.
8. Procedures must be in place to inform, at the earliest feasible opportunity, each subject, or if the subject remains incapacitated, a legally acceptable representative of the subject, or if such a representative is not reasonably available, a family member, of the subject's inclusion in the clinical investigation, the details of the investigation and other information contained in the informed consent document, specifically that the subject, the legally acceptable representative, or the family member may discontinue the subject's participation at any time without penalty or loss of benefits of which the subject is otherwise entitled.
9. If a legally acceptable representative or family member is told about the clinical investigation and the subject's condition improves, the subject is also to be informed as soon as feasible.
10. If a subject is entered into a clinical investigation with waived consent and the subject dies before a legally acceptable representative or family

member can be contacted, information about the clinical investigation is to be provided to the subject's legally acceptable representative or family member, if feasible.

11. All clinical investigation records, including regulatory files, must be maintained for at least three (3) years after the completion of the clinical investigation and must be accessible for inspection and copying by the regulatory authorities, as applicable.
12. Clinical investigations that are granted an exception to the informed consent requirement under this section must be performed under a separate investigational new drug (IND) application or investigational device exemption (IDE) that clearly identifies the clinical investigation may include subjects who are unable to consent. The submission of these clinical investigations to the FDA for a separate IND or IDE is required even if an IND for the same drug product or an IDE for the same device already exists. Applications for this IND or IDE may not be submitted as an amendment to the existing IND or IDE.
13. If the IRB determines it cannot approve a request for exception from informed consent requirements in emergency research because the clinical investigation does not meet the criteria according to federal regulations, IRB policies and procedures, or other relevant ethical concerns, the IRB must document its findings and provide these findings promptly in writing to the clinical researcher who will forward to the sponsor of the clinical investigation.

E. Emergency Research Not Subject to FDA Regulation

The IRB review finds:

1. The research activity is not subject to FDA regulations in 21 CFR Part 50 or will not be carried out under an FDA IND or an FDA IDE, the application for which has clearly identified the protocols that would include participants who are unable to consent; and
2. Items III.D.1-10. as stated above are met.

F. The Department does not permit planned emergency research requesting a waiver of informed consent to enroll:

1. Pregnant women and fetuses
2. Prisoners
3. Children

G. No Deferred Consent or Unapproved Waivers of Informed Consent

Informed consent procedures that provide for other than legally acceptable and prospectively obtained consent fail to constitute informed consent under federal regulations for the protection of human subjects in research. Therefore, waiving informed consent using a method other than those described in this policy is a violation of IRB policy and federal regulations and is subject to reporting to the appropriate federal, state, and institutional officials.

H. An exception from consent in emergency medicine research is prohibited unless a waiver is obtained from the Secretary of Defense.

IV. Authority

Section 381.86, Florida Statutes, Institutional Review Board

V. Supportive Data and References

- A.** 45 CFR Part 46
- B.** 45 CFR § 46.116
- C.** 21 CFR Parts 50 and 56
- D.** 21 CFR § 50.24
- E.** Office for Human Research Protections Guidance Document; Informed Consent Requirements in Emergency Research (OPRR 97-01)
- F.** 45 CFR Part 46 Waiver of Informed Consent Requirements in Certain Emergency Research (Federal Register, Vol. 61, No. 192, pp. 51531-51533, October 2, 1996)
- G.** FDA Guidance for IRBs, Clinical Investigators, and Sponsors, August 2023
- H.** DOHP 5-D5-5.1, Legally Effective and Prospectively Obtained Informed Consent
- I.** DOHP 5-D5-7.6, Emergency Use of FDA Regulated Products and Emergency Use Authorizations
- J.** International Council for Harmonisation - Good Clinical Practice: III.2.8., III.2.8.10., III.2.8.1.13.

VI. History Notes

Created: 04/20/2010
Previously Amended: 08/23/2013, 01/29/2020
Formerly: DOHP 400-5.3

VII. Signature and Effective Date



Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/29/26

Effective Date

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) to ensure that adequate provisions are made for soliciting the assent and dissent of children and cognitively impaired adults who lack decision-making capacity.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

- A.** In instances where the participant is not legally capable of giving informed consent (e.g., minors) or where the participant is cognitively impaired, the IRB must find that adequate provisions are made for soliciting the assent of the participant when, in the judgment of the IRB, the participant is capable of providing assent.
- B.** In determining whether participants are capable of assenting, the IRB shall take into account the age, maturity, and psychological state of the participant involved. This judgment may be made for all participants to be involved in research under a particular protocol, or for each participant, as the IRB deems appropriate. If the IRB determines the capability of some or all of the participants is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or wellbeing of the participant and is available only in the context of the research, the assent of the participant is not a necessary condition for proceeding with the research. Even when the IRB determines the participants are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accordance with IRB policy.
- C.** When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

IV. Authority

Section 381.86, Florida Statutes, Institutional Review Board

V. Supportive Data and References

- A.** *The Belmont Report*
- B.** 45 CFR Part 46, Subpart D
- C.** 21 CFR Part 50, Subpart D
- D.** DOHP 5-D5-5.1, Legally Effective and Prospectively Obtained Informed Consent

DOHP 5-D5-5.4

- E. DOHP 5-D5-6.3, Research Involving Children
- F. International Council for Harmonisation - Good Clinical Practice: II.2., III.1.2.6., III.1.2.7., III.2.8.

VI. History Notes

Created: 05/15/2010
Previously Amended: 08/23/2013, 01/29/2020
Formerly: DOHP 400-5.4

VII. Signature and Effective Date



Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/29/26
Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	2
IV. Authority	7
V. Supportive Data and References	7
VI. History Notes	7
VII. Signature and Effective Date	7

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) to review research in compliance with applicable regulations to ensure, when research involves pregnant women who are vulnerable to coercion or undue influence, safeguards are included in the research design to protect the rights and welfare of participants in research.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

A. IRB Review and Approval of Research Involving Pregnant Women

Research involving women who are or may become pregnant shall receive special attention from the IRB because of women's additional health concerns during pregnancy and because of the need to avoid unnecessary risk to the fetus. Further, in the case of a pregnant woman, the IRB must determine when informed consent of the father is required for research. Special attention is justified because of the involvement of a third party (the fetus) who may be affected but cannot give consent and because of the need to prevent harm or injury to future members of society. Procedural protections beyond the basic requirements for participant protection are prescribed in the federal regulations for research involving pregnant women.

B. Florida law specifies that experimentation on a fetus is prohibited, except as necessary to protect or preserve the life and health of such fetus or premature infant (section 390.0111(6), Florida Statutes (F.S.)).

C. Research Involving Pregnant Women

Pregnant women may be involved in research when all of the following conditions are met:

1. Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses.
2. The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or when there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important knowledge (for research conducted or supported by federal funds, the knowledge is limited to biomedical knowledge) which cannot be obtained by any other means.

3. Any risk is the least possible for achieving the objectives of the research.
4. When the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important knowledge (or, when the research is federally funded, important biomedical knowledge) that cannot be obtained by any other means, the woman's consent is obtained in accordance with the informed consent provisions of 45 CFR Part 46 Subpart A.
5. When the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accordance with the informed consent provisions of 45 CFR Part 46 Subpart A, except the father's consent need not be obtained when he is unable to consent because of unavailability, incompetence, or temporary incapacity, or the pregnancy resulted from rape or incest.
6. Each individual providing consent under 4. or 5. above, is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.
7. For children as defined in 45 CFR § 46.402(a) who are pregnant, assent and permission are obtained in accordance with the provisions of 45 CFR Part 46 Subpart D (see DOHP 5-D5-6.3, Research Involving Children).
8. No inducements, monetary or otherwise, will be offered to terminate a pregnancy.
9. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.
10. Individuals engaged in the research will have no part in determining the viability of a neonate.

D. Research Involving Neonates

1. The Department does not participate in research involving interactions or interventions with neonates of uncertain viability or non-viable neonates. However, it is possible that research may be conducted involving data (surveillance or otherwise state reporting data) concerning neonates of uncertain viability and nonviable neonates. The following conditions must be satisfied:
 - a. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential

risks to neonates.

- b. Each individual providing consent under 45 CFR § 46.205(b)(2) is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
- c. Individuals engaged in the research will have no part in determining the viability of the neonate.
- d. The requirements of 45 CFR § 46.205(b)(2) have been met as applicable.
- e. Experimentation on a fetus is prohibited, except as necessary to protect or preserve the life and health of such fetus or premature infant (section 390.0111(6), F.S.).

2. Neonates of uncertain viability

Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this policy unless the following additional conditions have been met:

- a. The IRB must determine:
 - (1) The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective; or
 - (2) The purpose of the research is the development of important knowledge (or, when the research is federally funded, important biomedical knowledge) which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research.
- b. The legally effective informed consent of either parent of the neonate, or when neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally acceptable representative is obtained in accordance with 45 CFR Part 46 Subpart A, except the consent of the father or his legally acceptable representative need not be obtained when the pregnancy resulted from rape or incest.
- c. Experimentation on a fetus is prohibited, except as necessary to protect or preserve the life and health of such fetus or premature infant (section 390.0111(6), F.S.).

3. Viable neonates

When a neonate is judged viable (i.e., being able, after delivery, to survive, given the benefit of available medical therapy, to the point of independently maintaining heartbeat and respiration) the neonate is then called an infant and should be treated as a child for purpose of research participation. A neonate, after delivery, who has been determined to be viable may be included in research only to the extent permitted by and in accordance with the requirements of 45 CFR Part 46 Subparts A and D.

- E. Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus is prohibited under Florida law.
- F. Research Not Otherwise Approvable Which Presents an Opportunity to Understand, Prevent, or Alleviate a Serious Problem Affecting the Health or Welfare of Pregnant Women, Fetuses, or Neonates

Per federal regulations, the Secretary of the Department of Health and Human Services (DHHS) will conduct or fund research the IRB does not believe meets the requirements of 45 CFR § 46.204 or 45 CFR § 46.205 only when:

- 1. The IRB finds the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates; and
- 2. Per federal regulations, the Secretary of DHHS, after consultation with a panel of experts in pertinent disciplines (e.g., science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the *Federal Register*, has determined either:
 - a. The research, in fact, satisfies the conditions of 45 CFR § 46.204, as applicable; or
 - b. The following:
 - (1) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates;
 - (2) The research will be conducted in accordance with sound ethical principles; and
 - (3) Informed consent will be obtained in accordance with the informed consent provisions of 45 CFR Part 46 Subpart A and other applicable subparts of 45 CFR Part 46.

3. Modification or Waiver of Specific Requirements. Per federal regulations, upon the request of the researcher (with the approval of the IRB), the Secretary of DHHS may modify or waive any of the above requirements of this policy.

G. Studies in Which Pregnancy is Coincidental to Subject Selection

1. Any study in which women of childbearing potential are possible subjects may inadvertently include pregnant women. Federal regulations require, when appropriate, subjects be provided a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, when the subject is or may become pregnant) which are currently unforeseeable as part of the informed consent process.
2. The IRB must judge whether the mother's participation would pose any risk to the fetus or nursing infant. In some studies, the IRB may need to ensure non-pregnant subjects are advised to avoid pregnancy or nursing for a time during or following the research. Furthermore, where appropriate, subjects should be advised to notify the researcher immediately should they become pregnant. In some instances, there may be potential risk sufficient to justify requiring pregnant women either be specifically excluded from the research or studied separately.

H. Exemption from Review

The exemptions from IRB review listed at 45 CFR §§ 46.104(b) and 46.104(d)(1-8) may be applied to research involving pregnant women, human fetuses, and neonates in accordance with 45 CFR § 46.201(b).

I. Research Funded by the Environmental Protection Agency (EPA)

1. For research conducted or supported by the EPA, or for research not conducted or supported by any federal agency that has regulations for protecting human research participants but where the intention of the research is submission to the EPA, research involving the intentional exposure of pregnant women, nursing women, or children to any substance is prohibited.
2. For observational research involving children that does not involve greater than minimal risk, the IRB may approve such research only if the IRB finds adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in 40 CFR § 26.406.
3. The IRB shall review observational research involving pregnant women and fetuses using 40 CFR Part 26 and 45 CFR Part 46 Subpart B.

-
- J.** Equivalent protections for review of research involving pregnant women that is not conducted or supported by DHHS
1. Researchers provide the same information for review by the IRB regardless of source of funding.
 2. IRB members review the same materials regardless of source of funding.
 3. IRB members make the same protocol-specific determinations concerning research involving pregnant women, fetuses, or neonates regardless of funding.
 4. When research involves secondary analysis of data from state registries, such as a registry about pregnancy and premature births, the Department may assign a reviewer whose expertise is more appropriate for review of research involving secondary analysis of existing data, such as a statistician, instead of a reviewer with expertise in research involving pregnant women.

IV. Authority

Section 381.86, F.S., Institutional Review Board

V. Supportive Data and References

- A.** 45 CFR Part 46
- B.** 21 CFR § 56.111(b)
- C.** 40 CFR § 26.304, 40 CFR §§ 26.404-.405
- D.** Section 390.0111(6) F.S., Experimentation on Fetus Prohibited; exception
- E.** ICH-GCP: II.2., III.1.2.6., III.1.2.7., III.2.8.

VI. History Notes

Created: 08/23/2013
Previously Amended: 02/14/2015, 01/30/2020
Formerly: DOHP 400-6.1-09

VII. Signature and Effective Date

Shay Gonzalez

Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/28/26
Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	2
IV. Authority	9
V. Supportive Data and References	9
VI. History Notes	9
VII. Signature and Effective Date	9

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) to review and approve all research involving prisoners with additional ethical and regulatory considerations applicable to prisoners under 45 CFR Part 46, Subpart C, "Additional Department of Health and Human Services (DHHS) Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects."

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

A. IRB Review and Approval of Research Involving Prisoners

The special vulnerability of prisoners makes consideration of involving them as research subjects particularly important. Prisoners may be under constraints because of their incarceration, which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations apply for reviewing research involving prisoners. Therefore, when a protocol involves the use of prisoners as participants, both the general IRB policies and procedures apply, and the additional ones outlined in this policy. The IRB may approve research involving prisoners only when these special provisions are met.

1. Research involving prisoners as participants must be reviewed and approved by Department IRB policies and procedures, and additional considerations for prisoners as determined by federal, state, county, and local regulations.
2. For research involving prisoners, the definition of minimal risk differs from the definition of minimal risk in the Common Rule (45 C.F.R. 46). The definition for prisoners requires reference to physical or psychological harm, as opposed to harm or discomfort, to risks normally encountered in the daily lives, or routine medical, dental, or psychological examination of healthy persons. See DOHP 5-D5-11.1, Definitions.
3. The Department IRB must review research in which prisoners are the target population, the participant is a prisoner at the time of enrollment, or when a currently enrolled participant becomes incarcerated and research interventions and interactions would occur during the incarceration period or when identifiable private information will be obtained during the incarceration period.

-
4. Persons who are released on parole in the community, or in community-based alternate settings, such as “half-way houses,” are not considered prisoners.
 5. Persons confined by civil commitment proceedings are not prisoners. However, the IRB shall consider their special circumstances.
 6. When the IRB is reviewing a protocol in which a prisoner is a participant, the convened IRB committee or reviewer using the expedited procedure must make, in addition to requirements under 45 CFR Part 46, Subpart A, seven (7) additional findings under 45 CFR § 46.305(a), as follows:
 - a. The research under review represents one of the following categories of research permissible under 45 CFR § 46.306(a)(2):
 - (1) A study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided the study presents no more than minimal risk and no more than inconvenience to the participants.
 - (2) A study of prisons as institutional structures or of prisoners as incarcerated persons, provided the study presents no more than minimal risk and no more than inconvenience to the participants.
 - (3) Research on conditions particularly affecting prisoners as a class (e.g., vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided the study may proceed only after the DHHS Secretary (through the Office for Human Research Protections [OHRP]) has consulted with appropriate experts including experts in penology, medicine, and ethics and published notice in the *Federal Register* of his or her intent to approve such research.
 - (4) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the DHHS Secretary (through OHRP) has consulted with appropriate experts including experts in penology, medicine, and ethics and published notice in the *Federal Register* of his or her intent to approve such research.

- b. Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages where the limited choice environment of the prisoner is impaired.
- c. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers.
- d. Procedures for the selection of participants within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides the IRB justification in writing for following some other procedures, control participants must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project.
- e. The information is presented in language which is understandable to the participant population.
- f. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole.
- g. Where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.
- h. For certain epidemiological research conducted or supported by DHHS the sole purpose of which is to describe the incidence or prevalence of a disease by identifying all cases or to study risk factors associated with a disease, and where the Department certifies to OHRP the research presents no more than minimal risk and no more than minimal inconvenience to the prisoner-subjects and prisoners are not a particular focus of the research.

B. Composition of IRB when Prisoners are Involved in Research

- 1. When reviewing research involving prisoners, special composition requirements for IRB membership exist. This section describes additional

requirements for the composition of the IRB in addition to those listed in DOHP 5-D5-4.2, Review of Human Subjects Research: Conduct of Meetings by the Convened IRB. See 45 CFR §§ 46.304 (a) and (b).

- a. A majority of the IRB (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the IRB.
- b. When reviewing research involving prisoners, at least one member of the IRB must be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity. The prisoner representative must have a close working knowledge, understanding, and appreciation of prison conditions from the perspective of a prisoner. Suitable individuals could include present or former prisoners, prison chaplains, prison psychologists, prison social workers, or other prison service providers, persons who have conducted advocacy for the rights of prisoners, or individuals who are qualified to represent the rights and welfare of prisoners by virtue of appropriate background and experience.
- c. Inclusion of a prisoner representative is not required if another IRB satisfying this requirement has already approved the research under 45 CFR Part 46 Subpart C.
- d. The IRB must meet the special composition requirements for all types of review for the protocol: initial review, continuing review, review of protocol amendments, review of problems requiring prompt reporting to the IRB (see DOHP 5-D5-4.6, Problems Requiring Prompt Reporting to the IRB), or in the event an individual becomes a prisoner while participating in a research protocol.

2. Initial review by the convened IRB when research involves prisoners

When an IRB reviews a protocol involving prisoners as participants, the composition of the IRB must satisfy the following requirements:

- a. The prisoner representative must be a voting member of the IRB. The prisoner representative may be listed as an alternative member who becomes a voting member when needed.
- b. The prisoner representative must review research involving prisoners.
- c. The prisoner representative must be assigned as a primary reviewer and must receive all materials pertaining to the research.

- d. The prisoner representative must be present at a convened meeting when the research involving prisoners is reviewed. If the prisoner representative is not present, research involving prisoners cannot be reviewed or approved. The prisoner representative may attend the meeting via conference call, but the prisoner representative must receive all materials pertaining to the research.
 - e. The prisoner representative must provide a written review using a reviewer comment form, and present his/her review orally at the convened meeting of the IRB when the research involving prisoners is reviewed.
- 3. Initial review using the expedited procedure for certain research involving prisoners
 - a. Research involving interaction with prisoners (including obtaining consent from prisoners) may be reviewed by the expedited procedure if a determination is made the research is minimal risk for the prison population being studied or included.
 - (1) The prisoner representative must concur with the determination of minimal risk.
 - (2) The prisoner representative must review the research as a reviewer designated by the IRB Chair. This may be as the sole reviewer or in addition to another reviewer. The prisoner representative must provide a written review using a reviewer comment form available on the online IRB system (IRB Manager).
 - b. Research involving prisoners that does not involve interaction with prisoners (for example, research involving existing data or record review, including epidemiological research involving prisoners) may be reviewed by the expedited procedure if a determination is made the research is minimal risk for the prison population being studied or included.
 - c. The prisoner representative may review the research in this select subcategory of prisoner research as a reviewer if designated by the IRB Chair, but review by the prisoner representative is not required.
- 4. Review of amendments when research involves prisoners
 - a. Substantial modifications reviewed by the convened IRBs must use the same procedures for initial review including the responsibility of the prisoner representative.

- b. Minor modifications to previously approved research may be reviewed using either of the two procedures described above in sections III.B.3.a or III.B.3.b, based on the type of modification.
 - c. Review of amendments must use the same procedures for initial review using the expedited procedure including the responsibility of the prisoner representative.
 - 5. Continuing review when research involves prisoners
 - a. Continuing review by the convened IRB must use the same procedures for initial review including the responsibility of the prisoner representative.
 - b. For continuing review of studies involving prisoners that meet criteria for expedited review, the continuing review may be reviewed using either of the two procedures described above for initial review using the expedited procedure at sections III.B.3.a or III.B.3.b above.
 - c. Continuing review of studies must use the same procedures for initial review using the expedited procedure including the responsibility of the prisoner representative.
- C. Measures to be Taken When a Current Research Participant Becomes a Prisoner
 - 1. When a participant becomes a prisoner after enrolling in a research study, the researcher is responsible for **immediately** reporting the event using the Problems Requiring Prompt Reporting form. This is not required when the study was previously approved by the IRB for prisoner participation.
 - 2. When research interactions and interventions or obtaining identifiable private information will not occur during the incarceration, IRB review and approval under 45 CFR Part 46 Subpart C is not required.
 - 3. When the study was not previously reviewed and approved by the IRB in accordance with the requirements of Subpart C, all research interactions and interventions with, as well as obtaining identifiable private information, **must cease** until the requirements of 45 CFR Part 46 Subpart C (for DHHS-funded research) or equivalent protections are satisfied.
 - 4. Review must meet requirements described in sections III.B.2. and III.B.3. above.

D. Research Conducted or Supported by DHHS

1. For research conducted or supported by DHHS to involve prisoners, two (2) actions must occur:
 - a. The institution engaged in the research must certify to the DHHS Secretary (through OHRP) the IRB designated under its Federal-Wide Assurance of Compliance (Assurance) has reviewed and approved the research under 45 CFR § 46.305.
 - b. The DHHS Secretary (through OHRP) must determine the proposed research falls within the categories of research permissible under 45 CFR § 46.306(a)(2).
2. When a researcher wishes to engage in non-DHHS supported research, certification is not required. However, the IRB applies the standards of this policy and the federal regulations when reviewing the research.
3. When either of the following are true, the research should only proceed after the IRB has consulted with the appropriate experts, as determined by the IRB:
 - a. The research involves conditions particularly affecting prisoners as a class as explained in section III.A.6.a.(1) above.
 - b. The research does not satisfy the stipulations in section III.A.6.a above.
4. The Human Research Protection Program Administrator designated in the Department's Assurance is responsible for certifying to OHRP the duties of the IRB have been fulfilled.

E. Additional Approvals

The Federal Bureau of Prisons places special restrictions on research that takes place within the Bureau of Prisons under 28 CFR Part 512. The provisions under 28 CFR Part 512 specify additional requirements for prospective researchers (both employees and non-employees) to obtain approval to conduct research within the Bureau of Prisons and responsibilities of Bureau of Prisons staff in processing proposals and monitoring research projects.

F. Additional Considerations

1. When a prisoner is also a child (e.g., an adolescent detained in a juvenile detention facility), DOHP 5-D5-6.3, Research Involving Children, will also apply.

2. Exemption from review of research involving prisoners is not allowed. Research that would otherwise be exempt from the requirement that it receive IRB approval is not exempt when the research involves prisoners.
- G.** Equivalent protections for review of research involving prisoners that is not conducted or supported by DHHS:
 1. Researchers provide the same information for review by the IRB regardless of source of funding.
 2. IRB members review the same materials regardless of source of funding.
 3. IRB members make the same protocol-specific determinations concerning research involving prisoners.

IV. Authority

Section 381.86, Florida Statutes, Institutional Review Board

V. Supportive Data and References

- A.** 45 CFR Part 46 Subpart C
- B.** 28 CFR Part 512
- C.** "OHRP Guidance on Involvement of Prisoners in Research," May 23, 2003
- D.** Waiver of the Applicability of Certain Provisions of Department of Health and Human Services Regulations for Protection of Human Research Subjects for Department of Health and Human Services Conducted or Supported Epidemiologic Research Involving Prisoners as Subjects, *Federal Register* (October 7, 2002) (67 FR 62432)
- E.** ICH-GCP: II.2., III.1.2.6., III.1.2.7., III.2.8.

VI. History Notes

Created: 07/8/2010

Previously Amended: 08/23/2013, 02/14/2015, 01/30/2020

Formerly: DOHP 400-6.2-09

VII. Signature and Effective Date



Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/28/26
Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	2
A. Procedure for Determining When Research Involves Children	2
B. Procedure for Determining Who is a Guardian	3
C. IRB Review and Approval of Research Involving Children	3
D. Categories of Research Involving Children	3
E. Requirements for Permission by Parents or Guardians and for Assent by Children	5
F. Adequate Provisions for Parents' or Guardians' Permission	6
G. Waiver of Parents' or Guardians' Permission	7
H. Wards of the State or Other Agency	8
I. Pediatric Expertise on IRB Committee	8
J. Research Funded by the Environmental Protection Agency	8
K. Equivalent Protections for Review of Research Involving Children That Is Not Conducted or Supported by DHHS	9
IV. Authority	9
V. Supportive Data and References	9
VI. History Notes	10
VII. Signature and Effective Date	10

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) to review research in compliance with applicable regulations to ensure, when research involves children who are vulnerable to coercion or undue influence, safeguards are included in the research design to protect the rights and welfare of children.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

A. Procedure for Determining When Research Involves Children

1. Persons under the age of 18 years are children as defined in Department of Health and Human Services (DHHS) regulation, regardless of whether the research is funded or supported by DHHS, except as provided elsewhere in Florida law:
 - a. A person under the age of 18 years who has had the disability of nonage removed by a circuit court is no longer a child and may consent to treatments and procedures in research (section 743.015, Florida Statutes [F.S.]).
 - b. A person under the age of 18 years who is married or has been married, including one whose marriage is dissolved, or who is widowed or widowed is no longer a child and may consent to treatments and procedures in research (section 743.01, F.S.).
 - c. An unwed pregnant person under the age of 18 years may consent to the performance of medical or surgical care or services relating to her pregnancy, or relation to her child, including not greater than minimal risk research relating to her pregnancy or her child, and such consent is valid and binding as if she had achieved her majority (section 743.065, F.S.).
 - d. A person under the age of 18 years seeking medical care or services related to sexually transmitted disease may consent to such treatments and procedures, including not greater than minimal risk research related to sexually transmitted diseases, and the consent of the parents or guardians of such a minor is not a prerequisite (section 384.30, F.S.).
2. If IRB staff are uncertain whether the researcher's proposed plans to enroll in research persons who are less than 18 years of age involve children, the IRB staff will consult with legal counsel to determine whether the research involves children under DHHS regulations, regardless of

whether the research is funded or supported by DHHS. IRB staff will convey findings of legal counsel to the convened IRB or reviewer using the expedited procedure.

3. When the research involves children, it will be reviewed under 45 CFR Part 46 Subpart D, or equivalent protections.
4. When individuals less than 18 years of age can consent to the procedures or treatment in research under Florida law, then the research will not be reviewed under 45 CFR Part 46 Subpart D.

B. Procedure for Determining Who is a Guardian

1. The only individuals who may provide permission for children to participate in research under Florida law are:
 - a. A natural or adoptive parent; or
 - b. A guardian appointed by a court, having granted specific authority to the guardian to enroll the child in research.
2. Legally acceptable representatives may not give permission for research involving children unless they are a guardian appointed by a court, having granted specific authority to the guardian to enroll the child in research.
3. If IRB staff are uncertain who may serve as a guardian, the IRB staff will consult with legal counsel to determine who may serve as a guardian for the protocol. IRB staff will convey findings of legal counsel to the IRB or representative.

C. IRB Review and Approval of Research Involving Children

The special vulnerability of children and adolescents makes consideration of involving them as research participants particularly important. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations apply for reviewing research involving children. The IRB may approve research involving children only when special provisions are met. The IRB must classify research involving children into one of four categories and document their discussions of the risks and benefits of the research study. The four categories of research involving children that may be approved by the IRB committee are based on degree of risk and benefit to individual subjects.

D. Categories of Research Involving Children

1. Category 404: Research Not Involving Greater than Minimal Risk to Children (45 CFR § 46.404). When the IRB finds that no greater than minimal risk to children is presented, the IRB may approve the research

only when the IRB finds adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth below.

2. Category 405: Research Involving Greater than Minimal Risk but Presenting the Prospect of Direct Benefit to the Individual Subjects (45 CFR § 46.405). When the IRB finds more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or involves a monitoring procedure that is likely to contribute to the subject's wellbeing, the IRB may approve the research only when the IRB finds:
 - a. The risk is justified by the anticipated benefit to the participants;
 - b. The relation of the anticipated benefit to the risk presented by the study is at least as favorable to the participants as that provided by available alternative approaches; and
 - c. Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth below.
3. Category 406: Research Involving Greater than Minimal Risk and No Prospect of Direct Benefit to the Individual Child, but Likely to Yield Generalizable Knowledge about the Child's Disorder or Condition (45 CFR § 46.406). When the IRB finds more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or involves a monitoring procedure which is not likely to contribute to the wellbeing of the subject, the IRB may approve the research only when the IRB finds:
 - a. The risk represents a minor increase over minimal risk;
 - b. The intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
 - c. The intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance for the understanding or amelioration of the participants' disorder or condition; and
 - d. Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth below.
4. Research Not Otherwise Approvable, which Presents an Opportunity to Understand, Prevent, or Alleviate a Serious Problem Affecting the Health

or Welfare of Children (45 CFR 46.407). When the IRB finds the research does not meet the requirements set forth in categories 46.404, 46.405 or 46.406 as described above, the IRB may approve the research only when:

- a. The IRB finds the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and
- b. When federally funded, the Secretary of DHHS, after consultation with a panel of experts in pertinent disciplines (e.g., science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:
 - (1) The research in fact satisfies the conditions of categories 46.404, 46.405, or 46.406; or
 - (2) The following:
 - (a) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
 - (b) The research will be conducted in accordance with sound ethical principles; and
 - (c) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth below in section III.F.

E. Requirements for Permission by Parents or Guardians and for Assent by Children

1. Adequate Provisions for Child's Assent

- a. The IRB must find adequate provisions are made for soliciting the assent of child participants when in the judgment of the IRB the children are capable of providing assent.
- b. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. The child should be given an explanation of the proposed research procedures in a language

that is appropriate to the child's age, experience, maturity, and condition.

2. Waiver of Assent

When the IRB determines either of the following to be true, then the assent of the children is not a necessary condition for proceeding with the research:

- a. The capability of the children is so limited they cannot reasonably be consulted; or
- b. The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or wellbeing of the children and is available only in the context of the research.
 - (1) Therefore, when the research offers the child the possibility of a direct benefit that is important to the health or wellbeing of the child and is available only in the context of the research, the IRB may determine the assent of the child is not necessary.
 - (2) Additionally, in such circumstances, a child's dissent, which should normally be respected, may be overruled by the child's parents at the IRB's discretion. When research involves the provision of experimental therapies for life-threatening diseases such as cancer, however, the IRB should be sensitive to the fact that parents may wish to try anything, even when the likelihood of success is marginal and the probability of extreme discomfort is high. Should the child not wish to undertake such experimental therapy, difficult decisions may have to be made. In general, when the child is a mature adolescent and death is imminent, the child's wishes should be respected.
 - (3) Finally, even where the IRB determines the child participants are capable of assenting, the IRB may still waive or alter the assent requirement under circumstances in which consent may be waived or altered for adults in accordance with DOHP 5-D5-5.3, Waiver and Alteration of Informed Consent, regarding waiver or alteration of informed consent generally.

F. Adequate Provisions for Parents' or Guardians' Permission

The IRB must ensure adequate provisions are made for soliciting the permission of each child's parents or guardians.

1. Research not involving greater than minimal risk to children or research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child. The IRB must determine whether:
 - a. The permission of both parents is required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child; or
 - b. The permission of one parent is sufficient.
2. Research involving greater than minimal risk and no prospect of direct benefit to the individual child, but likely to yield generalizable knowledge about the child's disorder or condition. The IRB must determine the permission of both parents is required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
3. Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. When the research is approved under section III.D.4 above and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

G. Waiver of Parents' or Guardians' Permission

When the IRB determines a research protocol is designed for conditions or for a participant population for which parental or guardian permission is not a reasonable requirement to protect the participants (e.g., neglected or abused children), it may waive the consent requirements described above, provided all of the following are true:

1. An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted.
2. The waiver is not inconsistent with federal, state, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research participants, and their age, maturity, status, and condition.
3. The research is not subject to Food and Drug Administration regulation.

H. Wards of the State or Other Agency

Children who are wards of the state or any other agency, institution, or entity can be included in research in categories 45 CFR § 46.406 or 45 CFR § 46.407 approved under sections III.G. (permission of guardian), or III.F. (waiver of consent/assent) above, only if the IRB finds and documents such research is:

1. Related to their status as wards; or
2. Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as participants are not wards.
3. If the research is approved under 45 CFR § 46.406 or 45 CFR § 46.407, the IRB must require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as representative, guardian or *in loco parentis*. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the researchers, or the guardian organization.

I. Pediatric Expertise on IRB Committee

An IRB committee considering a protocol involving children as participants shall:

1. Assess its needs for pediatric expertise among the IRB voting membership to ensure it possesses the professional competence necessary to review the specific research activities; and
2. Include one or more individuals who are knowledgeable about and experienced in working with children. To fulfill this requirement, the IRB committee may invite nonvoting individuals to assist in the review of issues which require expertise beyond, or in addition to, that available among voting IRB members.

J. Research Funded by the Environmental Protection Agency

1. For research conducted or supported by the EPA, or for research not conducted or supported by any federal agency that has regulations for protecting human research participants but where the intention of the research is submission to the EPA, research involving the intentional exposure of pregnant women, nursing women, or children to any substance is prohibited.
2. For observational research involving children that does not involve greater than minimal risk, the IRB may approve such research only if the

IRB finds adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in 40 CFR § 26.406.

3. For observational research involving children that presents greater than minimal risk but presents the prospect of direct benefit to the individual participants, the IRB may approve only if the IRB finds and documents:
 - a. The intervention or procedure holds out the prospect of direct benefit to the individual participant or is likely to contribute to the participant's wellbeing.
 - b. The risk is justified by the anticipated benefit to the participants.
 - c. The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches.
 - d. Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in 40 CFR § 26.406.

K. Equivalent Protections for Review of Research Involving Children That Is Not Conducted or Supported by DHHS

1. Researchers provide the same information for review by the IRB regardless of source of funding.
2. IRB members review the same materials regardless of source of funding.
3. IRB members make the same protocol-specific determinations concerning research involving children.
4. When research involves secondary analysis of data from state registries, such as an immunization registry, the Department may assign a reviewer whose expertise is more appropriate, such as a statistician or reviewer familiar with the database, instead of a reviewer with expertise in research involving children.

IV. Authority

Section 381.86, F.S., Institutional Review Board

V. Supportive Data and References

- A.** 45 CFR §§ 46.101(e)-(f)
- B.** 45 CFR § 46.102(c)

- C. 45 CFR §§ 46.402(d)-(e)
- D. 21 CFR § 50.3(l)
- E. 21 CFR § 50.3(o)
- F. 21 CFR § 50.3(s)
- G. 21 CFR § 56.103(c)
- H. 40 CFR Part 26 Subpart D
- I. OHRP Report 98-03, NIH Policy Guidance on the Inclusion of Children in Research
- J. OHRP Guidance, [Children Involved as Subjects in Research: Guidance on the DHHS 45 CFR 46.407 \("407"\) Review Process](#)
- K. OHRP IRB Guidebook Online, Chapter 6, Section C, "[Children and Minors](#)"
- L. DOHP 5-D5-5.1, Legally Effective and Prospectively Obtained Informed Consent
- M. DOHP 5-D5-5.2, Documentation of Informed Consent
- N. ICH-GCP: II.2., III.1.2.6., III.1.2.7., III.2.8.

VI. History Notes

Created: 06/20/2010
Previously Amended: 08/23/2013, 01/30/2020
Formerly: DOHP 400-6.3-09

VII. Signature and Effective Date



Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/28/26
Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	2
A. IRB Review and Approval of Research Involving Adults Unable to Consent	2
B. Requirements for Evaluating Decision-Making Capacity for Cognitively Impaired Participants	2
C. Determination of Capacity to Consent or Ability to Withdraw	3
D. Procedure for Determining Who is a Legally Acceptable Representative	3
E. Institutionalized Participants	5
F. Composition of IRB When Cognitively Impaired Participants Are Involved in Research	5
IV. Authority	5
V. Supportive Data and References	6
VI. History Notes	6
VII. Signature and Effective Date	6

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) to review, approve, and provide guidance on the special ethical considerations when adults unable to consent are involved in human subjects research.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

A. IRB Review and Approval of Research Involving Adults Unable to Consent

1. Adults may be temporarily or permanently unable to give consent due to injury, illness, or other cognitive impairment. When the IRB reviews research involving adults unable to consent, it ensures participants are provided additional safeguards, including the use of a legally acceptable representative. The IRB should consider recommendations in *The Belmont Report*.
2. The IRB must review all research in which adults unable to consent will be considered as participants to ensure the researcher has provided additional safeguards to protect the rights and welfare of this vulnerable population.
3. The IRB must consider the degree of cognitive impairment of the participant, the level of risk, and the potential benefit to the individual participant.

B. Requirements for Evaluating Decision-Making Capacity for Cognitively Impaired Participants

The IRB must find appropriate provisions are made for determining the participant's ability to provide consent or their ability to withdraw, through evidence of one or more of the following pertaining to the individual:

1. The ability to make a choice.
2. The ability to understand relevant information.
3. The ability to appreciate the situation and its likely consequences.
4. The ability to manipulate information rationally.

C. Determination of Capacity to Consent or Ability to Withdraw

The determination of capacity to consent or ability to withdraw may be made through a standardized measure or consultation with another qualified professional. The IRB must approve the process used by the researcher for making such a determination and consider whether the researcher needs to assess capacity to consent during the course of the research if the research involves participants with fluctuating decision-making capacity.

1. Because the capacity to consent or the ability to withdraw may fluctuate, the IRB must evaluate the process for continued verification of understanding and willingness to participate.
 - a. The consent procedures should describe a plan for protecting individuals who may lose their capacity to provide consent or their ability to withdraw while participating in research activities (e.g., use of an ombudsman).
 - b. The IRB may require an outside witness observe and confirm the consenting process.
2. For participants who lack decision-making capacity, the permission of the individual's legally acceptable representative is required, and assent should be obtained from the participant (see DOHP 5-D5-5.1, Legally Effective and Prospectively Obtained Informed Consent).
3. In research situations where there is the potential for direct benefit to the participant, the IRB may waive the requirement to obtain assent. However, permission from the legally acceptable representative must be obtained.
4. Even when the IRB determines the individuals are capable of consenting or withdrawing, the IRB may still waive the consent requirements under the circumstances described in DOHP 5-D5-5.1, Legally Effective and Prospectively Obtained Informed Consent.
5. The IRB must also review and approve the appropriate consent documents with the required elements of consent written in a language understandable to the participant.

D. Procedure for Determining Who is a Legally Acceptable Representative

1. Under Chapter 765, Florida Statutes (F.S.), several classes of persons can consent for incapacitated adults. They are listed below in order of priority. Consent must be sought first from the person at the top of the list. Only if that option is not reasonably available, willing, or competent to consent, does the next option apply, and so on down the list. If the first

reasonably available person refuses consent, however, that refusal is final.

- a. Health care surrogate: Any competent adult expressly designated to make health care decisions for a particular incapacitated individual. The designation must be in writing in accordance with Florida law.
- b. Attorney in fact ("power of attorney"): A competent adult to whom the subject has delegated authority to make health care decisions by means of a validly executed durable power of attorney.
- c. Judicially appointed guardian (in the absence of a surrogate or where a court revokes the authority of the surrogate). All persons who have been adjudged incompetent should have a judicially appointed guardian.
- d. Proxy: Under section 765.401, F.S., a proxy (substitute decision maker) may consent (where the participant has not executed an advanced directive, or designated a surrogate to make health care decisions, or a court has not appointed a guardian) to experimental treatment, provided the experimental treatment has been approved by an IRB and the proxy reasonably believes the patient would have made the decision under the circumstances.
- e. If none of the above are reasonably available, then a competent adult who has not been expressly designated to make health care decisions for a particular incapacitated individual, but who is available, willing, and competent to act is the next option for consent. The following possible proxies should be sought, again in order of priority, working down the list when an option is not reasonably available, or is unwilling or incompetent to act as proxy:
 - (1) The subject's spouse.
 - (2) An adult child of the subject. If the subject has more than one adult child, then obtain permission from a majority of the adult children who are reasonably available.
 - (3) A parent of the subject.
 - (4) The adult sibling of the subject. If the subject has more than one adult sibling, then obtain permission from a majority of the adult siblings who are reasonably available.
 - (5) An adult relative of the subject who has exhibited special care and concern for the subject and who has maintained

regular contact with the subject and who is familiar with the subject's activities, health, and religious or moral beliefs.

- (6) A close, personal friend 18 years of age or older who has exhibited special care and concern for the patient.
2. If Human Research Protection Program staff are uncertain who may serve as a legally acceptable representative for an incapacitated adult, the IRB staff will consult with legal counsel to determine who may serve as a legally acceptable representative for the protocol. IRB staff will convey findings of legal counsel to the IRB or representative.
3. When it is determined by the researcher the participant lacks decision-making capacity, the IRB must find appropriate provisions are made for soliciting the permission of each individual's legally acceptable representative unless the criteria are met to approve a waiver of informed consent (see DOHP 5-D5-5.1, Legally Effective and Prospectively Obtained Informed Consent).

E. Institutionalized Participants

1. The IRB must consider the rationale and justification for involvement of institutionalized participants, including an explanation as to why non-institutionalized individuals could not be used.
2. Research proposals where involuntarily institutionalized participants are to be included shall also be reviewed consistent with additional criteria as specified in DOHP 5-D5-6.2, Research Involving Prisoners.

F. Composition of IRB When Cognitively Impaired Participants Are Involved in Research

1. When reviewing research involving cognitively impaired participants, the IRB committee must include in its composition one or more individuals who are knowledgeable about and experienced in working with the cognitively impaired.
2. When the study requires review by the full IRB committee, it must meet the special composition requirements when conducting reviews for initial review, continuing review, protocol amendments, and problems requiring prompt reporting to the IRB when the research involves cognitively impaired individuals.

IV. Authority

Section 381.86, F.S., Institutional Review Board

V. Supportive Data and References

- A. The *Belmont Report*
- B. Am J Psychiatry 155:11, November 1998, "Guidelines for Assessing the Decision-Making Capacities of Potential Research Subjects with Cognitive Impairment"
- C. The Office of Human Subjects Research, National Institutes of Health, Information Sheet #7, "Research Involving Cognitively Impaired Subjects: A Review of Some Ethical Considerations"
- D. ICH-GCP: II.2., III.1.2.6., III.1.2.7., III.2.8.

VI. History Notes

Created: 07/18/2010
Previously Amended: 08/23/2013, 02/25/2015, 01/30/2020
Formerly: DOHP 400-6.4-08

VII. Signature and Effective Date



Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/28/26

Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	2
IV. Authority	4
V. Supportive Data and References	4
VI. History Notes	5
VII. Signature and Effective Date	5

I. Policy Statements

It is the policy of the Department of Health Institutional Review Board (IRB) that human participant research involving the use of investigational articles (drugs or medical devices) complies with regulations governing investigational articles.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

- A.** When research involves the use of a drug other than a marketed drug in the course of medical practice, or when research is conducted to evaluate the safety or effectiveness of a device:
1. When the sponsor holds the investigational new drug (IND) exception, researchers are responsible for providing the sponsor-held IND exception or providing information in the IRB application sufficient for the Human Research Protection Program (HRPP) to determine exemptions from regulatory requirements (21 CFR § 312.2(b)) are met.
 2. When the sponsor holds the investigational device exemption (IDE), researchers are responsible for providing the sponsor-held IDE or providing information in the IRB application sufficient for the HRPP to determine the research use of a device meets requirements for an IDE (21 CFR § 812.2(b)(1)) or is exempt from the requirement for an IDE (21 CFR § 812.2(c)).
 3. For investigator-initiated research, where the researcher holds the IND exception or the IDE, the researcher is responsible for arranging to have a contract research organization (CRO) accredited by the Association for Accreditation of Human Research Protection Programs (AAHRPP) ensure all regulatory requirements are met. The IRB may approve investigator-initiated research by university researchers if documentation is provided that the university is responsible for ensuring all regulatory requirements are met, and the university human research protection program is accredited by AAHRPP. Researchers shall not conduct United States Food and Drug Administration (FDA)-regulated investigator-initiated research that is not monitored by a sponsor or CRO.
- B.** Process to confirm the test article has an IND exception or an IDE, or the protocol meets one of the FDA exemptions from the requirement to have an IND exception or an IDE:
1. Staff confirm the drug has an IND exception, or the drug meets the criteria to have an IND exception (21 CFR § 312.2(b)) using the Reviewer Worksheet Drugs form on the online IRB system (IRB Manager).

Acceptable forms of documentation are the presence of an IND exception on the sponsor protocol, communication from the sponsor, or communication from the FDA. Staff may require the sponsor to provide documentation from the FDA that an IND exception is not required.

2. Staff confirm the IDE is valid, or the device meets requirements for an abbreviated IDE (21 CFR § 812.2(b)(1)) or is exempt from the requirement for an IDE (21 CFR § 812.2(c)) using the Reviewer Worksheet Devices form on the IRB Manager. Acceptable forms of documentation are the presence of an IDE on the sponsor protocol, communication from the sponsor, or communication from the FDA. Staff may require the sponsor to provide documentation from the FDA that an IDE is not required.
 3. For investigator-initiated research, staff confirm an AAHRPP-accredited contract research organization will ensure compliance, or that a university with a human research protection program accredited by AAHRPP will ensure compliance.
 4. The completed Reviewer Worksheet Drugs or Reviewer Worksheet Devices form is stored on the IRB Manager and is available to the IRB as documentation of the validity of the IND exception or the IDE.
- C.** IRB review of the use of an investigational drug is conducted using the Reviewer Worksheet Drugs form completed by the primary reviewer.
- D.** IRB review of the use of an investigational device is conducted using the Reviewer Worksheet Devices form completed by the primary reviewer.
- E.** IRB review of the use of an investigational device is conducted in accordance with International Council for Harmonisation Good Clinical Practice (ICH-GCP) as adopted by the FDA to include the following:
1. Investigational products used in a clinical trial should be manufactured in accordance with applicable Good Manufacturing Practice (GMP) standards and be managed in accordance with the product specifications and the trial protocol.
 2. Responsibility for investigational product(s) management, including accountability, handling, dispensing, administration, and return rests with the researcher/institution.
 3. When the researcher/institution delegates some or all of their activities for investigational product(s) management to a pharmacist or another individual in accordance with local regulatory requirements, the delegated individual should be under the oversight of the researcher/institution.
 4. The researcher/institution and/or a pharmacist or other appropriate individual should maintain records of the product's delivery, the inventory,

the use by each participant (including documenting the participants were provided the doses specified by the protocol) and the return to the sponsor and destruction or alternative disposition of unused product(s). These records should include dates, quantities, batch/serial numbers, expiration dates (if applicable), and the unique code numbers assigned to the investigational product(s) and trial participants. For authorized medicinal products, alternative approaches to the aforementioned may be considered, in accordance with local regulatory requirements.

5. The investigational product(s) should be stored as specified by the sponsor and in accordance with applicable regulatory requirement(s).
6. The researcher should ensure the investigational product(s) are used only in accordance with the approved protocol.
7. Where applicable, the researcher or a person designated by the researcher/institution should explain the correct use of the investigational product(s).
8. The investigational product may be shipped to the participant's location or supplied to/dispensed at a location closer to the participant (e.g., at a local pharmacy or a local health care center).
9. The investigational product may be administered at the participant's location by researcher site staff, the participant themselves, a caregiver or a health care professional.

IV. Authority

Section 381.86, Florida Statutes, Institutional Review Board

V. Supportive Data and References

- A. 21 CFR Part 11, 21 CFR Part 54, 21 CFR Part 210, 21 CFR Part 211, 21 CFR Part 312, 21 CFR Part 314, 21 CFR Part 320, 21 CFR Part 330, 21 CFR Part 601, 21 CFR Part 807, 21 CFR Part 812, 21 CFR Part 814, 21 CFR Part 820, and 21 CFR Part 860
- B. FDA Information Sheets Related to IRB Review and Investigational Articles
- C. [AAHRPP Tip Sheet: Following the Guideline of the International Conference on Harmonisation – Good Clinical Practice \(E6\)](#)

VI. History Notes

Created: 08/28/2013
Previously Amended: 02/17/2015, 01/30/2020
Formerly: DOHP 400-7.1

VII. Signature and Effective Date



Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/28/26
Effective Date

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) that all investigational drugs and devices are used only in approved research protocols and under the direction of approved researchers in accordance with applicable laws and regulations.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

A. Control of Investigational Drugs and Devices

The IRB conducts protocol-by-protocol review and approval of the researcher's plans to control investigational articles via use of the online management system (IRB Manager). Acceptable methods include:

1. For research at county health departments, control may be provided by the pharmacy or by the researcher in the research clinic consistent with all legal requirements.
2. For research involving in vitro diagnostic devices, control may be provided by the researcher in the laboratory consistent with all legal requirements.
3. For other settings, control may be provided by the researcher consistent with all legal requirements.

B. Storage of Investigational Drugs and Devices

1. For research where investigational drugs are stored in a county health department pharmacy, it is the responsibility of a licensed pharmacist to comply with all institutional, state, and federal law regarding storage of investigational drugs, including controlled substances.
2. When not controlled by a pharmacy, it is the personal responsibility of the researcher to comply with all institutional, state, and federal law regarding storage of investigational drugs.
3. When not controlled by a pharmacy, investigational drugs used in the context of research must be stored in areas under the direct supervision of the researcher and in accordance with the sponsor protocol, when applicable.
4. Investigational agent storage facilities must be in compliance with institutional, state, and federal (including the Food and Drug

Administration [FDA]) laws. Pharmacy monitoring may be incorporated into the IRB auditing process as needed to ensure compliance.

C. Dispensing of Investigational Drugs

1. Investigational drugs administered to research participants may be provided to research participants through a pharmacy, or by the researcher in a research clinic, or by a nurse in a research clinic.
2. It is the responsibility of the researcher to ensure dispensing is in accordance with all institutional, state, and federal requirements.

D. The researcher is responsible for the tracking and oversight of FDA-regulated devices in research and must meet the following requirements in order to use an investigational device in research conducted under the jurisdiction of the IRB:

1. The investigational device must be used only by the researcher and/or under his or her direct supervision;
2. The investigational device must be used only as approved by the FDA and as described in the currently approved IRB documents;
3. The researcher must not supply the investigational device to persons not authorized under the investigational device exemption (IDE); and
4. Informed consent from the participant or the participant's legally acceptable representative must be prospectively obtained.

E. Investigations of issues related to the potential mishandling of investigational drugs will be conducted by the Office of the Inspector General, which will refer to other Department offices or divisions or other agencies with responsibility for compliance. The office or agency responsible for enforcing compliance will promptly report any mishandling to the IRB within seven (7) business days.

IV. Authority

Section 381.86, Florida Statutes, Institutional Review Board

V. Supportive Data and References

A. 45 CFR Part 46

B. 21 CFR § 312.61, 21 CFR § 312.62, 21 CFR § 312.69, 21 CFR § 812.100, 21 CFR § 812.110, 21 CFR § 812.140(a)

VI. History Notes

Created: 05/09/2010

Previously Amended: 08/23/2013, 02/17/2015, 01/30/2020

Formerly DOHP 400-7.1-09

VII. Signature and Effective Date



Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/28/26
Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	2
A. Significant Risk versus Non-Significant Risk Devices	2
B. Exemptions From Investigational Device Exemption Requirements	2
C. Department Institutional Review Board Approval of the Use of an Investigational Device	3
D. Advertising or Recruitment for Studies That Involve an Investigational Device Exemption	4
E. Informed Consent in Research That Involves an Investigational Device Exemption	5
F. Additional Reporting Requirements	5
IV. Authority	6
V. Supportive Data and References	6
VI. History Notes	6
VII. Signature and Effective Date	6

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) that all investigational device use be reviewed and approved by the IRB in accordance with applicable laws and regulations.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

A. Significant Risk versus Non-Significant Risk Devices

1. Unless exempt by the investigational device exemption (IDE) regulations, an investigational device must be categorized as either a significant risk (SR) device or a non-significant risk (NSR) device. The initial risk assessment is determined by the sponsor, but the IRB must make a formal determination during a convened meeting regarding the appropriate SR/NSR category. See section III.C. below.
2. Research involving the use of an SR device must be conducted in accordance with the full requirements of the Food and Drug Administration (FDA) and must have an approved IDE from the FDA.
3. Research involving the use of an NSR device must be conducted in accordance with the "abbreviated" requirements of the FDA as described in 21 CFR § 812.2(b). In some cases, the FDA may notify the sponsor it does not agree with the NSR determination and will require the submission of an IDE.

B. Exemptions From Investigational Device Exemption Requirements

1. The device can be exempt from the IDE requirements. A claim that the device is exempt must reference the exemption category being claimed. There are seven exemption categories that may be claimed. The first two categories pertain to devices that were either manufactured before 1976 or similar products manufactured after 1976. Categories three and four are the most commonly applied for exemptions. Categories five and six are pertinent to the use of devices in animals. Category seven pertains to custom devices and is rarely utilized. Full information regarding the seven exemption categories that may be claimed can be found in the FDA regulations 21 CFR § 812.2(c).
2. The exemption category most commonly claimed is 21 CFR § 812.2(c)(3). In addition to the sponsor's compliance with applicable requirements in 21 CFR 809.10(c), the device testing must comply with the following requirements:

- a. Is noninvasive;
 - b. Does not require an invasive sampling procedure that presents significant risk;
 - c. Does not by design or intention introduce energy into a participant; and
 - d. Is not used as a diagnostic procedure without confirmation of the diagnosis by another medically established diagnostic product or procedure.
3. Another common exemption category claimed is 21 CFR § 812(c)(4). To qualify for this exemption, the device testing must not be for the purposes of determining safety and effectiveness and must not put participants at risk. The device testing must be limited to the following:
 - a. Consumer preference testing;
 - b. Testing of a modification; or
 - c. Testing of a combination of two or more devices in commercial distribution.
4. It is the sponsor's responsibility to provide sufficient justification to support the exemption category being claimed.
5. An exemption from the IDE requirement is not an exemption from the requirement for prospective IRB review or informed consent.

C. Department Institutional Review Board Approval of the Use of an Investigational Device

1. Where a protocol is subject to be reviewed under more than one department or agency's regulations, the requirements of each set of regulations must be met. This situation may arise, for example, with IDEs where both the FDA and the Department of Health and Human Services have jurisdiction over the research. The use of an unapproved SR IDE requires an FDA IDE.
2. The IRB must determine whether it is in agreement with the rendering of the decision by the sponsor of the device being an NSR or an SR device. When the IRB is in agreement with the sponsor's determination of NSR, no report to the FDA is required until the data is submitted. However, the sponsor must be notified when the IRB disagrees with the sponsor's NSR determination.

-
3. The IRB may approve or disapprove the proposed research based on local context and its responsibilities to protect human participants in research even when approval of the device has been granted by the FDA.
 4. The researcher is responsible for the tracking and oversight of FDA-regulated devices in research and must meet the following requirements in order to use an investigational device in research conducted under the jurisdiction of the Department IRB:
 - a. The investigational device must be used only by the researcher or under his or her direct supervision;
 - b. The investigational device must be used only as approved by the FDA and as described in the currently approved IRB documents;
 - c. The researcher must not supply the investigational device to persons not authorized under the IDE; and
 - d. Informed consent from the participant or the participant's legally acceptable representative must be prospectively obtained.
 5. Research using an investigational device must be conducted under applicable Department IRB policies and procedures.

D. Advertising or Recruitment for Studies That Involve an Investigational Device Exemption

1. Advertisements or recruiting tools must not include the term "new treatment," without explaining the IDE is "investigational, meaning non-FDA approved." A phrase such as "receive new treatment" implies that study participants will be receiving newly marketed products of proven worth. It is not a treatment because its effectiveness has not been proven or established. The term "new" is misleading as it gives the participant hope of a new intervention when the outcome is unknown. This could be viewed as coercive.
2. Advertisements or recruiting tools must not include the promise of "free medical treatment" when the intent is only to say that participants will not be charged for taking part in the investigation or experimental intervention (e.g., device). The use of the word "free" could be viewed as coercive as it may entice someone to participate in a study for the perceived benefits.

See DOHP 5-D5-4.7, Recruitment and Advertising

E. Informed Consent in Research That Involves an Investigational Device Exemption

1. Informed consent must meet the requirements outlined in the applicable IRB policies (see DOHP 5-D5-5.1 – 5.4);
2. No claims are to be made which state or imply, directly or indirectly, the IDE is safe or effective for the purposes under investigation or the device is in any way superior to any other device;
3. The informed consent document must contain a statement that the IDE is “investigational, meaning non-FDA approved”;
4. The informed consent document must contain a statement that the FDA may have access to the participant’s medical records as they pertain to the study; and
5. The researcher must ensure that throughout the consenting process and study participation the participant understands the IDE is experimental, and its benefits for the condition under study are unproven.

F. Additional Reporting Requirements

1. Devices may have an unanticipated adverse device effect on participants or others. A researcher must submit to the sponsor and to the Department IRB any problems requiring prompt reporting to the IRB (see DOHP 5-D5-4.6, Problems Requiring Prompt Reporting to the IRB) occurring during an investigation as soon as possible, but no later than five (5) business days after the researcher first learns of the effect. Should the IRB determine the new information gained in the adverse effect report changes its risk assessment, the IRB has the ability to reconsider its prior NSR decision and ask for FDA review.
2. A sponsor must immediately conduct an evaluation of any unanticipated adverse device effect on participants or others.
 - a. A sponsor who determines an unanticipated adverse device effect presents an unreasonable risk to participants must terminate or suspend all investigations or parts of investigations presenting that risk as soon as possible. Termination or suspension must occur no later than five (5) business days after the sponsor makes this determination and no later than 15 business days after the sponsor first received notice of the effect.
 - b. When the device is an SR device, a sponsor may not resume a terminated or suspended investigation without IRB and FDA approval. When the device is not an SR device, a sponsor may not resume a terminated or suspended investigation without IRB

approval and, when the investigation was terminated or suspended for an unanticipated adverse device effect that presented an unreasonable risk to participants or others, FDA approval.

3. Within 90 calendar days after termination or completion of the investigation or the researcher's part of the investigation, the researcher must submit a final report to the sponsor and the Department IRB.

IV. Authority

Section 381.86, Florida Statutes, Institutional Review Board

V. Supportive Data and References

- A. 45 CFR Part 46
- B. 21 CFR Parts 50 and 56
- C. 21 CFR Part 812
- D. [ICH-GCP Guideline for Good Clinical Practice](#)

VI. History Notes

Created: 05/15/2010
Previously Amended: 08/23/2013, 01/30/2020
Formerly: DOHP 400-7.2

VII. Signature and Effective Date

Shay Gonzalez

Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/28/26
Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	2
A. IRB Requirements for the Use of an Investigational Drug, Agent, or Biologic	2
B. Use of an Investigational Drug, Agent, or Biologic by a Researcher	5
C. Advertising or Recruitment for Studies Involving Investigational Drugs, Agents, or Biologics	7
D. Informed Consent in Research That Involves an Investigational Drug, Agent, or Biologic	8
IV. Authority	8
V. Supportive Data and References	8
VI. History Notes	9
VII. Signature and Effective Date	9

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) that the use of investigational drugs, agents, and/or biologics be reviewed and approved for use in accordance with federal regulations.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

A. IRB Requirements for the Use of an Investigational Drug, Agent, or Biologic

1. The IRB will ensure:
 - a. The available nonclinical and clinical information on an investigational product(s) is adequate to support the proposed clinical trial.
 - b. Clinical trials are scientifically sound and reflect the state of knowledge and experience with the investigational product(s), including, if applicable:
 - (1) The condition to be treated, diagnosed, or prevented;
 - (2) The current understanding of the underlying biological mechanism (of both the condition and the investigational product); and
 - (3) The population for which the investigational product is intended.
 - c. Periodic reviews of current scientific knowledge and approaches are considered to determine whether modifications to the trial are needed, since new or unanticipated information may arise once the trial has begun.
 - d. Careful consideration of the scientific goal and purpose are carefully considered so as not to unnecessarily exclude particular participant populations.
2. The IRB will conduct initial approval and ongoing monitoring of investigational drugs, agents, and biologics used in human subjects research under its jurisdiction. Included in this process is a review by a pharmacist on the IRB committee. Prospective IRB review is required even when a waiver from IRB regulations has been granted by the Food

and Drug Administration (FDA) for use of the investigational drug, agent, or biologic.

3. FDA regulations allow certain individuals not enrolled in clinical trials to obtain expanded access to investigational drugs, agents, or biologics through the following methods:
 - a. Compassionate use: The term “compassionate use” is erroneously used to refer to the provision of investigational drugs outside of an ongoing clinical trial to a limited number of patients who are desperately ill and for whom no standard alternative therapies are available. The term “compassionate use” does not, however, appear in FDA or Department of Health and Human Services (DHHS) regulations. It is preferable, instead, to use the names of the specific access programs when discussing the use of investigational articles outside of formal clinical trials.
 - b. Group C treatment investigational new drug (IND): A means for the distribution of investigational drugs, agents, or biologics to oncologists for the treatment of cancer under protocols outside controlled clinical trials. Group C drugs, agents, or biologics usually have shown evidence of relative and reproducible efficacy in a specific tumor type. Although the FDA typically grants a waiver for most drugs used in Group C treatment IND protocols, the IRB requires prospective IRB review and approval.
 - c. Open label protocol: A study designed to obtain additional safety data, typically done when the controlled trial has ended and treatment continues. The purpose of such a study is to allow participants to continue to receive the benefits of the investigational drug, agent, or biologic until marketing approval is obtained. When open label studies are conducted involving the Department, prospective IRB review and approval is required.
 - d. Parallel track: A method approved by the FDA that expands the availability of investigational drugs, agents, or biologics as quickly as possible to persons with AIDS and other HIV-related diseases. These drugs, agents, or biologics are utilized in separate protocols that “parallel” the controlled clinical trials and are essential to establish their safety and effectiveness. Although the Secretary of DHHS may, on a protocol-by-protocol basis, waive the provisions of 45 CFR Part 46 where adequate protections are provided through other mechanisms, when these studies are conducted involving the Department, prospective IRB review and approval is required by the IRB.
 - e. Treatment IND or biologics: A mechanism for providing eligible participants with investigational drugs (as early in the drug

development process as possible) for the treatment of serious and life-threatening illnesses for which there are no satisfactory alternative treatments. The FDA defines an immediately life-threatening disease as a stage of a disease in which there is a reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment. The FDA will permit an investigational drug to be used under a treatment IND after sufficient data have been collected to show the drug “may be effective” and does not have unreasonable risks. When these studies are conducted involving the Department, prospective IRB review and approval is required.

- f. There are four requirements that must be met before a treatment IND can be issued:
 - (1) The drug is intended to treat a serious or immediately life-threatening disease;
 - (2) There is no satisfactory alternative treatment available;
 - (3) The drug is already under investigation or trials have been completed; and
 - (4) The trial sponsor is actively pursuing marketing approval.
- g. The FDA identifies two special considerations when a patient is to be treated under a treatment IND:
 - (1) Informed consent: Informed consent is especially important in treatment IND situations because the participants are desperately ill and particularly vulnerable. They will be receiving medications which have not been proven either safe or effective in a clinical setting. Both the setting and their desperation may work against their ability to make an informed assessment of the risk involved. Therefore, the IRB should ensure potential participants are fully aware of the risks involved.
 - (2) Charging for treatment INDs: The FDA permits charging for the drug, agent, or biologic when used in a treatment IND. Therefore, the IRB committee should pay particular attention to treatment INDs in which the participants will be charged for the cost of the drugs. When participants are charged for the use of the test article, economically disadvantaged persons will likely be excluded from participation. Charging for participation may preclude economically disadvantaged persons as a class from receiving access to test articles. The IRB should balance

this interest against the possibility that unless the sponsor can charge for the drug, it will not be available for treatment use until it receives full FDA approval.

- h. Single-patient use: The use of an investigational drug outside of a controlled clinical trial for a patient, usually in a desperate situation, who is unresponsive to other therapies or in a situation where no approved or generally recognized treatment is available. There is usually little evidence the proposed therapy is useful but may be plausible on theoretical grounds or anecdotes of success. Access to investigational drugs for use by a single, identified patient may be gained either through the sponsor under a treatment protocol, or through the FDA, by first obtaining the drug from the sponsor and then submitting a treatment IND to the FDA requesting authorization to use the investigational drug for treatment use. When these studies are conducted involving the Department, prospective IRB review and approval is required (see III.B.3. below). For example, the Department's system for tuberculosis care provides clofazimine for tuberculosis and other mycobacterium diseases, and this drug can be provided under a single-patient use IND.
 - i. Emergency IND: The emergency use of an unapproved investigational drug, agent, or biologic requires an emergency IND. The FDA has established mechanisms and guidance for obtaining an emergency IND for the use of investigational drugs, agents, or biologics. Additional IRB guidance regarding emergency IND is provided in DOHP 5-D5-7.6, Emergency Use of FDA-Regulated Products and Emergency Use Authorizations.
- 4. Where the protocol is subject to review under more than one department or agency's regulations, the requirements of each set of regulations must be met. This situation may arise, for example with treatment INDs, where both the FDA and DHHS have jurisdiction over the research. The use of an unapproved investigational drug, agent, or biologic requires an FDA IND.

B. Use of an Investigational Drug, Agent, or Biologic by a Researcher

- 1. In order for an investigational drug, agent, or biologic to be used in clinical research at the Department, an IND must be on file with the FDA and an IND number granted, or the appropriate exemption granted. Exemptions can be granted when research involves the use of a drug other than the use of a marketed drug in the course of medical practice. Some exemption categories are below:
 - a. IND Exemption 2

-
- (1) A clinical investigation is for an in vitro diagnostic biological product that involves one or more of the following:
 - (a) Blood grouping serum
 - (b) Reagent red blood cells
 - (c) Anti-human globulin
 - (2) The diagnostic test is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure.
 - (3) The diagnostic test is shipped in compliance with 21 CFR § 312.160.
 - b. IND Exemption 4: A clinical investigation involving use of a placebo if the investigation does not otherwise require submission of an IND.
 2. Clinical investigations of a drug, agent, or biologic that is lawfully marketed in the United States are exempt from the requirements of an IND when the following conditions are met:
 - a. Use of the investigational drug, agent, or biologic is not intended to be reported to the FDA in support of a new indication for use nor support any significant change in labeling for the product;
 - b. The use of the investigational drug, agent, or biologic is not intended to support a significant change in the advertising of the product;
 - c. The use of the product does not involve a route of administration, dosage level, and/or use in a subpopulation, or other factors that significantly increase the risks, or decrease the acceptability of the risks associated with the use of the drug, agent, or biologic;
 - d. The use will be conducted in compliance with the IRB approval and informed consent procedures;
 - e. The use will be conducted in compliance with the requirements concerning the promotion and sale of the drug, agent, or biologic as described in FDA regulations 21 CFR § 312.7; and
 - f. The use does not intend to invoke exception from informed consent requirements for emergency use.

-
- g. When a researcher asserts a study does not require an IND, the Department will require the researcher to contact the FDA for a formal determination.
 - 3. Research involving combinations of FDA-approved drugs, agents, or biologics that are currently approved as single use do not require an IND. However, use of these drugs, agents, or biologics in research must still be prospectively reviewed and approved by the IRB.
 - 4. The researcher administering an investigational drug, agent, or biologic must meet the following requirements in order to use an investigational drug, agent, or biologic in research conducted under the jurisdiction of the IRB.
 - a. The drug, agent, or biologic must be used only in accordance with the plan of investigation as described by the FDA-approved IND application and the IRB-approved protocol;
 - b. If an IND exemption has been obtained, the drug, agent, or biologic must be used only in accordance with the plan of investigation as described by the IRB-approved protocol;
 - c. The drug, agent, or biologic may only be used in participants under the researcher's personal supervision or under the supervision of physicians who are directly responsible to the researcher; and
 - d. Informed consent from the participant or the participant's legally acceptable representative is prospectively obtained, unless a waiver of consent has been approved by the IRB.
 - 5. Research involving an investigational drug, agent, or biologic must be conducted in accordance with Department IRB policies.

C. Advertising or Recruitment for Studies Involving Investigational Drugs, Agents, or Biologics

- 1. Advertisements or recruiting tools must not include the term "new treatment," without explaining the drug, agent, or biologic is "investigational, meaning non-FDA approved." A phrase, such as "receive new treatment" implies study participants will be receiving newly marketed products of proven worth. It is not a treatment because its effectiveness has not been proven or established. The term "new" is misleading as it gives the participant hope of a new intervention when the outcome is unknown. This could be viewed as coercive.
- 2. Advertisements or recruiting tools must not include the promise of "free medical treatment" when the intent is only to say participants will not be

charged for taking part in the investigation or experimental intervention (e.g., drug, agent, biologic.) The use of the word “free” could be an undue inducement to participate in a study for the perceived benefits.

See DOHP 5-D5-4.7, Recruitment and Advertising

D. Informed Consent in Research That Involves an Investigational Drug, Agent, or Biologic

1. Informed consent must meet the requirements outlined in the Department IRB informed consent policies (see DOHP 5-D5-5.1–5.4);
2. No claims are to be made which state or imply, directly or indirectly, the investigational drug, agent, or biologic is safe or effective for the purposes under investigation or the drug is in any way superior to another drug;
3. The informed consent document must contain a statement that the drug, agent, or biologic is “investigational, meaning non-FDA approved”;
4. The informed consent document must contain a statement that the FDA may have access to the participant’s medical records as they pertain to the study; and
5. The researcher must ensure throughout the consenting process and study participation the participant understands the investigational drug, agent, or biologic is under investigation, and its benefits for the condition under study are unproven.
6. For Phase I studies, the informed consent document must disclose the purpose of the research includes examining the drug’s safety. For Phase II and Phase III studies, the informed consent document must disclose the purpose of the research includes examining the drug’s safety and efficacy.

IV. Authority

Section 381.86, Florida Statutes, Institutional Review Board

V. Supportive Data and References

- A.** 21 CFR Parts 50, 56, 312, and 509
- B.** FDA Information Sheet: Investigational Use of Marketed Drugs, Biologics and Medical Devices, 1998.

VI. History Notes

Created: 09/23/2009
Previously Amended: 08/23/2013, 01/30/2020
Formerly: DOHP 400-7.4

VII. Signature and Effective Date



Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/28/26
Effective Date

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) to review and approve the use of all humanitarian use devices (HUDs).

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

A. IRB Review of Humanitarian Use Device Use

1. In order for a HUD to be used in treatment, diagnosis, or research at the Department, the IRB and the Food and Drug Administration (FDA) must approve it, and a humanitarian device exemption be issued.
 - a. The IRB approval must verify the use of the HUD, as proposed, is congruent with current labeling of the device, and does not exceed the scope of the FDA-approved indication.
 - b. The IRB may impose more stringent restrictions for use of the HUD as a means of additional protections, as deemed necessary.
2. The initial review of a HUD is to be completed by the full IRB committee. The full committee may make the determination at initial review that subsequent continuing reviews meet expedited criteria.
3. The physician utilizing the HUD for treatment, diagnosis, or research must use the HUD only in accordance with the labeling of the device, intended purpose, and in the designated population for which the FDA approved its use.
 - a. Only the holder of the HUD agreement with the FDA must use the HUD; and
 - b. Informed consent is required from a patient prior to the use of a HUD when:
 - (1) The HUD is the subject of a clinical investigation; or
 - (2) The IRB requires use of informed consent.

B. Considerations for Prompt Reporting

1. Whenever the physician or health care provider receives or otherwise becomes aware of information, from any source, that reasonably suggests a HUD has or may have caused or contributed to the death or

serious injury of a patient, the physician or health care provider must report such findings to the FDA and the IRB as soon as possible, but no later than five business days after the researcher first learns of the effect or problem (see DOHP 5-D5-4.6 Problems Requiring Prompt Reporting to the IRB). This reporting is in addition to, not a substitute for, FDA and/or manufacturer reporting requirements in accordance with 21 CFR § 803.30.

2. The physician or health care provider shall promptly report FDA action(s) regarding the HUD to the IRB.
3. Modifications to the HUD or the clinical use of the HUD are to be promptly reported to the IRB in accordance with DOHP 5-D5-4.5, Amendments and Modifications of Approved Research.

IV. Authority

Section 381.86, Florida Statutes, Institutional Review Board

V. Supportive Data and References

- A. 21 CFR § 803.30, 21 CFR Part 814
- B. FDA Device Exemptions Regulation: Questions and Answers; Final Guidance for Industry, July 12, 2001.
- C. FDA Device Regulations, June 26, 1996.

VI. History Notes

Created: 09/30/2009
Previously Amended: 08/23/2013, 01/30/2020
Formerly: DOHP 400-7.5

VII. Signature and Effective Date

Shay Gonzalez

Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/28/26
Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	2
IV. Authority	6
V. Supportive Data and References	6
VI. History Notes	7
VII. Signature and Effective Date	7

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) to recognize the provisions found in the Food and Drug Administration (FDA) regulations for the emergency use of investigational drugs, biologics, agents, or devices.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

- A.** Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care for patients who need such care, to the extent the physician is permitted to do so under FDA regulation and other applicable law.
- B.** Emergency use of a test article is not human research subject to Department of Health and Human Services (DHHS) regulations (45 CFR Part 46). Data from an emergency use may not be reported in a way that implies the activity was a prospectively planned, systematic investigation designed to develop or contribute to generalizable knowledge.
- C.** Emergency use of a test article is research involving human subjects subject to FDA regulation. The patient given the investigational article is a participant in FDA-regulated research. The FDA may require data from an emergency use to be reported in a marketing application. The IRB may allow data from an emergency use to be published in a retrospective report and all other uses required by FDA. If the FDA-regulated research involves an investigational drug, the FDA must issue an investigational new drug (IND).
- D.** The emergency use provision in the FDA regulations (21 CFR § 56.104(c)) is an exemption from prior review and approval by the IRB when it meets several conditions. To ensure emergency use is consistent with regulation, researchers should notify the Human Research Protection Program (HRPP) Administrator designated in the Department's Federal-Wide Assurance of Compliance (Assurance), HRPP staff, or an IRB Chair first. A licensed physician must make the required determinations.
 - 1. The HRPP Administrator designated in the Department's Assurance or IRB Chair or IRB member who is a licensed physician will review the situation with the researcher to make sure the criteria allowing exemption from IRB review under FDA regulation and Department policy concerning emergency use are met:
 - a. The patient is in a life-threatening or severely debilitating situation necessitating the use of the test article.
 - b. No standard acceptable treatment is available.

- c. There is not sufficient time to obtain IRB approval.
 - d. The use is reported to the IRB within five (5) business days by the researcher administering the investigational article.
 - e. Informed consent will be obtained and documented in accordance with 21 CFR Part 50 or the situation meets the waiver criteria in 21 CFR § 50.23 or informed consent will not be obtained because the following are true:
 - (1) The participant is confronted by a life-threatening situation necessitating the use of the test article.
 - (2) Informed consent cannot be obtained from the participant because of an inability to communicate with, or obtain legally effective consent from, the participant.
 - (3) Time is not sufficient to obtain consent from the participant's legal representative.
 - (4) There is no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the participant.
 - f. The emergency use of an unapproved investigational drug or biologic requires an IND. If the subject does not meet the criteria of an existing approved protocol, the researcher should contact the manufacturer of the drug/biologic to determine if it can be provided under an existing IND or, if not available through the manufacturer, contact the FDA for an emergency IND.
 - g. Permission of the sponsor exists prior to use.
 - h. The activity does not meet the DHHS definition of "research" involving "human subjects" as defined by DHHS.
 - i. Any subsequent use of the test article is subject to IRB review.
 - 2. Documentation that the situation is a life-threatening emergency should be provided both in the patient's medical record and in a letter to the IRB.
- E.** If there is no time to contact the HRPP Administrator or IRB Chair prior to use, the HRPP Administrator or IRB Chair or IRB member who is a licensed physician will make the determination retrospectively based on the report that is provided within five (5) business days and issue a letter indicating whether the activity met the exemption requirements at 21 CFR § 56.103(c).

-
- F.** Notification of the HRPP Administrator or IRB Chair should not be construed as IRB approval. The researcher is required to submit notification within five business days, and notification of the HRPP Administrator or IRB Chair is used to initiate tracking and ensure the researcher files this report as required in FDA regulation (21 CFR § 56.104(c)).
- G.** If the Chair or IRB member who is a licensed physician determines, based on retrospective evaluation, the activity does not meet the exemption requirements at 21 CFR § 56.103(c) the issue will be handled according to DOHP 5-D5-10.1, Investigating Any Non-Compliance, Serious or Continuing Non-Compliance.
- H.** Not all emergency use requires exemption from prior IRB review. If there is sufficient time to allow IRB review, researchers will complete a new IRB application which will be scheduled for review at the next possible meeting. FDA regulations (21 CFR § 56.102(d)) permit one emergency use, but any subsequent use must have prior IRB review and approval (21 CFR § 56.104(c)). If a researcher anticipates the possible subsequent use of the agent will occur, the researcher should complete an IRB application.
- I.** Manufacturers or sponsors that agree to allow the use of the investigational drug, agent, biologic, or device, but will not ship without “an IRB approval letter,” will be provided a written statement the IRB is aware of the proposed use and based on the information it has been provided by the researcher the proposed use meets the requirements of 21 CFR § 56.102(d).
- J.** During a public health emergency, it may be necessary to give a test article to more than one patient. The Project BioShield Act of 2004 provided a mechanism for population-level emergency use of unapproved medical products. Emergency use authorizations (EUAs) represent a different mechanism for authorizing shipment and use of unapproved medical products than INDs and investigational device exemptions (IDEs). An EUA allows the use of drugs, biologics, and medical devices that are not approved, licensed, or cleared respectively (unapproved medical products) in an emergency to diagnose, treat, or prevent a serious or life-threatening disease or condition when there are no adequate, approved, or available alternatives.
- K.** Review by the IRB is not required for EUAs. However, the HRPP may assist in providing information and guidance to local hospitals about why IRB review is not required.
- L.** Procedure for EUAs
1. Declaration of an emergency
 - a. The Secretary of Homeland Security determines there is a domestic emergency, or significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiologic, or nuclear agent or agents;

- b. The Secretary of Defense determines there is a military emergency, or a significant potential for a military emergency, involving a heightened risk of attack on U.S. military forces with a specified biological, chemical, radiologic, or nuclear agent or agents;
 - c. The Secretary of DHHS determines there is a public health emergency that affects or involves a significant biological, chemical, radiologic, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents.
 - d. A declaration of emergency is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.
- 2. A declaration of emergency is then issued under section 564 of the Food, Drug, and Cosmetic Act. This allows for the potential use of a product under an EUA provided the FDA Commissioner certifies to the Secretary of DHHS that:
 - a. The agent specified in the declaration of emergency can cause a serious or life-threatening disease or condition;
 - b. Based on the totality of scientific evidence available, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition; or a serious or life-threatening disease or condition caused by a product authorized under section 564, or approved, cleared, or licensed under the Food, Drug, and Cosmetic Act or Public Health Service Act, for diagnosing, treating, or preventing a disease or condition and caused by the agent specified in the declaration of emergency;
 - c. The known and potential benefits outweigh the known and potential risks of the product when used to diagnose, prevent, or treat the serious or life-threatening disease or condition that is the subject of the declaration; and
 - d. There is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such serious or life-threatening disease or condition.
- 3. FDA guidance specifies the information that should be submitted to FDA for consideration of an EUA.

4. The FDA Commissioner may establish conditions on the use of a product under an EUA. The provider may be required by the FDA to:
 - a. Inform patients the FDA Commissioner has authorized the emergency use of the product.
 - b. Inform patients of the risks and benefits of the drug.
 - c. Inform patients of any alternative therapies available.
 - d. Inform patients they may refuse administration of the unapproved product.
5. An EUA will be in effect for the duration of the declaration under which it was issued, unless the EUA is revoked because the criteria of issuance are no longer met or revocation is appropriate to protect public health or safety.
6. The terms and conditions of an EUA preempt state laws governing the dispensing, administration, or labeling of unapproved medical products or approved medical products for unapproved uses.

IV. Authority

Section 381.86, Florida Statutes, Institutional Review Board

V. Supportive Data and References

- A. 21 CFR § 50.23
- B. 21 CFR § 50.24
- C. 21 CFR § 50.25(d)
- D. 21 CFR § 56.102(d)
- E. 21 CFR § 56.104(c)
- F. FDA Information Sheets, Frequently Asked Questions: IRB Procedures
- G. FDA Information Sheets, Emergency Use of an Investigation Drug or Biologic, Emergency Use of Unapproved Medical Devices
- H. [FDA Guidance: Emergency Use Authorization of Medical Products](#)
- I. Section 564 of the Food, Drug, and Cosmetic Act
- J. Project BioShield Act of 2004, Public Law 108–276

- K. [Emergency Use Authorization \(EUA\) to Enable Use of Needed Products in Civilian and Military Emergencies, United States](#)
- L. [ICH-GCP Guideline](#)
- M. ICH-GCP: II.2.4., III.1.2.6., III.2.8.8.

VI. History Notes

Created: 6/16/2010
Previously Amended: 08/23/2013, 01/31/2020
Formerly: DOHP 400-7.6

VII. Signature and Effective Date



Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/28/26
Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	2
IV. Authority	5
V. Supportive Data and References	5
VI. History Notes	6
VII. Signature and Effective Date	6

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) to follow legal requirements to allow reconstruction of a complete history of all IRB actions related to the review of research under its jurisdiction.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

- A.** Records shall be maintained in a manner that contains a complete history of all IRB actions related to review and approval of a research protocol.
- B.** Records regarding research are maintained in electronic form on the secure online IRB system (IRB Manager) meeting Department information security requirements, and shall be retained indefinitely when practical, but for at least three (3) years after completion of the research. If the protocol is cancelled without participant enrollment, IRB records are retained indefinitely when practical but maintained for at least three (3) years after cancellation. Records are retained for six (6) years after the research is completed when the research is covered under the Health Insurance Portability and Accountability Act.
- C.** Records are accessible for inspection and copying by authorized representatives of any regulatory oversight agency or sponsor at reasonable times and in a reasonable manner. IRB records are public records under Florida law.
- D.** The Human Research Protection Program Administrator specified in the Department's Federal-Wide Assurance of Compliance is responsible for ensuring appropriate records are maintained.
- E.** The IRB will maintain written policies and procedures which will be reviewed at least annually by the Human Research Protection Program Administrator.
- F.** The IRB roster and record of appointments to the IRB will be maintained in electronic form indefinitely on the IRB Manager. IRB rosters contain documentation of:
 - 1. Names
 - 2. Earned degrees
 - 3. Representative capacities
 - 4. Scientific/nonscientific status
 - 5. Affiliation status (whether the IRB member or an immediate family

member of the IRB member is affiliated with the organization)

6. Indications of experience sufficient to describe each IRB member's chief anticipated contributions
7. Employment or other relationship between each IRB member and the organization
8. Alternate members
9. The primary members or class of primary members for whom each alternate member can substitute

G. Records of research protocols include at minimum:

1. Copies of all research applications reviewed, including protocols or research plans, research brochure, scientific and scholarly evaluations, if any, consent documents and approved sample consent documents, recruitment materials, data safety monitoring board/committee reports, progress reports submitted by the researcher, and reports of adverse events, unanticipated problems to participants or others (see DOHP 5-D5-4.6, Problems Requiring Prompt Reporting to the IRB, for more information), reports of significant new findings, reports of injuries to participants, and review of allegations and findings of non-compliance. Records also include continuing review activities and modifications to approved research. In lieu of a research brochure, protocol may include current scientific information, such as a basic product information brochure (e.g., summary of product characteristics, package leaflet, or labelling), as appropriate, including their updates.
2. All correspondence between the IRB and researchers.
3. When conducting continuing review on research that otherwise would not require continuing review, the rationale for why such review was conducted.
4. When conducting reviews by the expedited procedure, justification for using the expedited procedure (citation of expedited categories), description of actions, and determinations by the reviewer as required by law. Results of reviews using the expedited procedure are communicated to IRB members regularly.
5. The rationale for an expedited reviewer's determination that research appearing on the expedited review list is more than minimal risk.
6. Justification for exemption determinations.
7. Justification for determinations that activities do not constitute research

involving human subjects (public health practice, quality improvement, research not involving human subjects).

8. Determination required by Food and Drug Administration (FDA) regulations, including but not limited to verification of the validity of investigational new drug exceptions and investigational device exemptions.
9. Documentation of researcher qualifications, including a curriculum vitae or resume, verification of license when appropriate, and record of research ethics education.
10. Documentation specifying the responsibilities that a relying organization and an organization operating an IRB will each undertake to ensure compliance with the requirements of the [Common Rule](#).

H. IRB minutes recording IRB deliberations and determinations include at minimum:

1. Actions taken by the IRB.
2. Separate deliberations for each action.
3. Votes for each protocol as numbers for, against, or abstaining.
4. Attendance at the meeting, including record of when an alternate member replaces a primary member. Record of members or alternate members who participate through videoconference or teleconference, and documentation that those members received all pertinent material before the meeting and were able to actively and equally participate in all discussions.
5. The basis for requiring changes in research.
6. The basis for disapproving research.
7. A written summary of the discussion of controverted issues and their resolution.
8. For initial and continuing review, the approval period, if applicable.
9. The names of IRB members who leave the meeting because of a conflict of interest along with the fact a conflict of interest is the reason for the absence.
10. Required determinations and protocol-specific findings justifying those determinations for:
 - a. Waiver or alteration of the consent process

- b. Research involving pregnant women and neonates; section 390.0111(6), Florida Statutes (F.S.), provides no person shall use any live fetus or live, premature infant for any type of scientific, research, laboratory, or other kind of experimentation either prior to or subsequent to any termination of pregnancy procedure except as necessary to protect or preserve the life and health of such fetus or premature infant.
 - c. Research involving prisoners
 - d. Research involving children
 - e. Research involving adults unable to consent
 - f. Justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the Department of Health and Human Services (DHHS)-approved sample consent document, when following DHHS regulations.
 - g. Documentation of the rationale for significant risk/non-significant risk device determinations, when following FDA regulations.
11. Record of any training and education activities conducted at meetings of the convened IRB.

IV. Authority

Section 381.86, F.S., Institutional Review Board

V. Supportive Data and References

- A. 45 CFR Part 46
- B. 45 CFR § 46.115(a)-(b), Office for Human Research Protections, Guidance on Written IRB Procedures
- C. Institutional Review Boards Frequently Asked Questions, [FDA Information Sheets, IV. IRB Records](#)
- D. 21 CFR § 56.115, IRB records
- E. ICH-GCP: III.1.3.1., III.1.3.3., III.1.3.4., III.1.4.1., III.1.5., III.1.5.1., III.1.5.2., III.2.4, III.2.12.

VI. History Notes

Created: 06/28/2010
Previously Amended: 08/23/2013, 01/31/2020
Formerly: DOHP 400-8.1

VII. Signature and Effective Date



Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/28/26
Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	2
IV. Authority	4
V. Supportive Data and References	4
VI. History Notes	5
VII. Signature and Effective Date	5

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) that all researchers and key study personnel conducting human subjects research under the jurisdiction of IRB complete initial and annual human research protections training.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

A. All Department researchers and key study personnel must complete initial research ethics education and compliance training prior to research commencing and re-certify every three (3) years. Individuals engaged in research must provide certification of completion to the IRB:

1. Training via the Collaborative IRB Training Initiative (CITI). This internet-based course in human subjects research protection and research ethics is available at no cost and designed specifically for all personnel who have significant involvement in the planning, conduct, and analysis of any scientific activity that employs human research participants. The course consists of training modules that are divided into two tracks: biomedical research and social/behavioral research. The learning objectives of the CITI course are:
 - a. To provide an understanding of the historical perspectives, ethical principles, and federal regulations associated with the conduct of research with human participants.
 - b. To provide a clear understanding of what constitutes informed consent and how it must be applied in research involving humans.
 - c. To provide basic information on the regulations and policies governing research with investigational drugs, biologics, and devices.
 - d. To provide a clear understanding of the ethical issues and federal regulations in force during the conduct of social/behavioral research, records-based research, and genetics research with human participants.
 - e. To provide researchers conducting research at U.S. Veterans Affairs facilities a clear understanding of the special procedural and regulatory policies for human research at U.S. Veterans Affairs research facilities.

2. Human Research Protection Program (HRPP) staff monitor education requirements by checking on the completion of the CITI course when new applications are submitted and checking the dates of CITI course completion at continuing review or by reviewing a report from the CITI program. HRPP staff are responsible for ensuring certification of training is documented in the online IRB system (IRB Manager).
 3. The IRB may not approve research without CITI certification present for all researchers and key study personnel. For ongoing studies, if education is required, that research study must stop until education requirements are completed.
- B.** A [Researcher Guide](#) will serve as a resource manual for all study personnel that will assist researchers in smoothly navigating the IRB process and adhering to the federal regulations and IRB policies related to human research protections.
- C.** All researchers and key study personnel conducting research involving human participants at the Department are encouraged to review the core training materials including the Department Federal-Wide Assurance of Compliance, the Department IRB policies and procedures, the *Belmont Report*, and the federal regulations including 45 CFR Part 46 and 21 CFR Parts 50 and 56. Links to this information plus links to other federal agencies (e.g., National Institutes of Health [NIH], Food and Drug Administration [FDA], Office of Human Research Protections) governing human subjects research are available on the [Department IRB website](#).
- D.** Research studies are not approved until all researchers and study personnel complete research ethics education and training. Applications may be reviewed; however, the IRB will defer approval until education is complete. Verification that researchers and staff completed education requirements represents a minor change to the study and may be reviewed using the expedited procedure.
- E.** IRB members must complete initial research ethics education and compliance training prior to research commencing and must re-certify every three (3) years or as required by CITI. New IRB members receive training on the IRB Manager.
- F.** New members observe at least one (1) meeting, and do not vote. In their second meeting they may vote but are not assigned as a primary reviewer. In their third meeting they may be assigned as a primary reviewer but may not take the lead in presenting a study. New members' understanding is assessed by HRPP staff, and individual feedback is provided.
- G.** The IRB will send mass email notifications, limited to a mailing list of all researchers and key study personnel who have active studies, to alert them of pertinent IRB issues or decisions that may impact their research.

-
- H.** When following the International Council for Harmonisation Good Clinical Practice (ICH-GCP) guideline as adopted by the FDA, the researcher and research staff must be knowledgeable about the following responsibilities:
1. The researcher provides evidence of his or her qualifications through up-to-date curriculum vitae or other relevant documentation requested by the sponsor, the IRB or ethics committee (EC), or the regulatory authority.
 2. The researcher is familiar with the appropriate use of the investigational product as described in the protocol in the current researcher brochure, in the product information, and in other information sources provided by the sponsor.
 3. A qualified physician (or dentist, when appropriate), who is a researcher or a co-researcher for the clinical trial, is responsible for all clinical trial-related medical (or dental) decisions (not applicable to independent IRBs or ECs).
 4. During and following a participant's participation in a clinical trial, the researcher ensures adequate medical care is provided to a participant for any adverse events, including clinically significant laboratory values, related to the clinical trial (not applicable to independent IRBs or ECs).
 5. The researcher ensures the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor.

IV. Authority

Section 381.86, Florida Statutes, Institutional Review Board

V. Supportive Data and References

- A.** NIH, ["Required Education in the Protection of Human Research Participants"](#) June 5, 2000 (Revised August 25, 2000)
- B.** CITI Training
- C.** ICH-GCP: II.5.1., III.2.1.1.

VI. History Notes

Created: 06/16/2010

Previously Amended: 08/23/2013, 02/22/2015, 01/31/2020

Formerly: DOHP 400-9.1

VII. Signature and Effective Date



Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/28/26

Effective Date

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) to provide information to the public regarding the rights of research participants.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

- A.** The IRB will provide a toll-free contact number for Human Research Protection Program (HRPP) staff. The number provides prospective participants, participants in research, and former participants a way to contact HRPP staff and discuss problems, concerns, or make a complaint; ask questions; obtain information; or offer input about how the Department can improve the process of participating in research.
- B.** HRPP staff, when conducting administrative screening of applications, ensure the toll-free number appears on every informed consent document following a statement about whom the participant may contact independent of the research regarding questions or for additional information concerning the rights of participants in research.
- C.** The HRPP will maintain a mechanism to receive complaints from participants or others in a confidential manner. Complaints may be communicated via the toll-free number or by using a web-based form.
- D.** HRPP staff will be available to provide presentations to community groups and at Department conferences involving public outreach to provide information and increase awareness of human research protections.
- E.** The HRPP Administrator designated in the Department's Federal-Wide Assurance of Compliance is responsible for annually evaluating outreach activities and making improvements to these activities, as needed. During this annual evaluation, the HRPP Administrator will seek input from the IRB coordinator, and IRB Chairs for feedback on how outreach activities may be improved.

IV. Authority

Section 381.86, Florida Statute, Institutional Review Board

V. Supportive Data and References

[Department IRB Website](#)

VI. History Notes

Created: 07/07/2010
Previously Amended: 08/23/2013, 01/31/2020
Formerly: DOHP 400-9.4, DOHP 400-9.2

VII. Signature and Effective Date



Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/28/26

Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	2
IV. Authority	6
V. Supportive Data and References	6
VI. History Notes	7
VII. Signature and Effective Date	7

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) to investigate allegations and manage findings of non-compliance with Human Research Protection Program (HRPP) requirements.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

A. Requirements for reporting allegations of non-compliance:

Information regarding non-compliance in human subjects research may come to the attention of the IRB through several pathways:

1. Researchers, study team members, sponsors, IRB members, and IRB staff, and those with direct supervision of researchers are required to report complaints, protocol deviations, results of sponsor audits, or audits from sponsors or other Department investigations, and other non-compliance.
2. Reports may also come from any source such as a participant or their family members, institutional personnel, other institutional committees, the media, anonymous sources, or the public.
3. Reports are made to the HRPP Administrator designated in the Department's Federal-Wide Assurance of Compliance (Assurance) via phone or email.
4. Normally reports are made using the online IRB system (IRB Manager), but reports may also come via telephone, email, or letter.
5. The following types of information should be submitted, with as much information provided as possible, so allegations of non-compliance can be assessed:
 - a. Description of what happened, including the time and persons involved
 - b. Name of the researcher
 - c. Name of the study
 - d. Location of the research
6. Researchers are required to report non-compliance to all IRBs with

jurisdiction over the research and provide documentation of their determinations to the Department.

7. Non-compliance should be reported regardless of whether it may have occurred during the study, after study completion, or after participant withdrawal or completion.

B. Process for investigation of each allegation of non-compliance:

1. The IRB staff conduct an investigation of all reports of alleged non-compliance to determine whether each allegation has a basis in fact. If the allegation of non-compliance is found not to have a basis in fact, then no further action is taken, unless the event involves an unanticipated problem involving risks to participants or others. See DOHP 5-D5-4.6, Problems Requiring Prompt Reporting to the IRB.
2. If the IRB staff find an allegation of non-compliance has a basis in fact, or if staff is uncertain, then the alleged non-compliance is referred to the IRB Chair for determination, normally the IRB Chair of the IRB that reviewed and approved the research.
2. The IRB Chair investigates the allegation of non-compliance and determines whether the allegation is non-compliance. If the IRB Chair determines the allegation of non-compliance has no basis in fact, then no further action is taken, unless the event involves unanticipated problem involving risks to participants or others. See DOHP 5-D5-4.6 Problems Requiring Prompt Reporting to the IRB.
4. If an allegation of non-compliance is found not to have a basis in fact by staff or the IRB Chair, an administrative comment is filed in the IRB Manager documenting the reasons and the researcher is informed through the IRB Manager.

C. Process for handling non-compliance found to have a basis in fact that is neither serious nor continuing:

1. The IRB Chair evaluates each instance of non-compliance and determines whether it is serious, whether it is continuing, and whether the non-compliance involves unanticipated problems involving risks to participants or others. See DOHP 5-D5-4.6 Problems Requiring Prompt Reporting to the IRB.
2. If the IRB Chair determines the non-compliance is neither serious nor continuing, then the IRB Chair, when appropriate, reviews a draft of the corrective action plan provided by the researcher and determines whether it is acceptable. Staff shall include the information on an IRB agenda as an information item.

-
3. The IRB Chair may refer non-compliance that is neither serious nor continuing to the full IRB for review.
 4. If the IRB Chair determines the non-compliance is serious or continuing or is uncertain, the IRB Chair must refer to the full IRB for review.
- D.** Process for handling non-compliance found to have a basis in fact that is serious or continuing:
1. The convened IRB reviews all allegations of serious or continuing non-compliance using a primary reviewer system.
 - a. Reviewers are assigned by the IRB staff, where necessary in consultation with the IRB Chair. Where possible, non-compliance will be reviewed by one or more primary reviewers who conducted the most recent review of the protocol. Reviewers will have relevant subject matter expertise and may request additional expertise. See DOHP 5-D5-4.3, Review of Human Subjects Research: Initial Review.
 - b. All IRB members have access to the allegation of non-compliance and supporting documents (including but not limited to safety monitoring board reports and sponsor reports). In addition, all IRB members have access to all documents reflecting the current IRB-approved state of the protocol, including but not limited to the protocol, consent document, and supplemental information.
 - c. One or more primary reviewers will review the report of non-compliance, all supporting documents, and all the documents reflecting the current IRB-approved state of the protocol.
 - d. All other IRB members will review the report, the initial IRB application updated with any changes, any supporting documents, and the consent document.
 2. The IRB will determine whether non-compliance is serious or continuing.
 3. If the IRB determines non-compliance is not serious or continuing, no further action will be taken if the problem does not involve a problem requiring prompt reporting to the IRB. See DOHP 5-D5-4.6, Problems Requiring Prompt Reporting to the IRB.
 4. If the IRB determines non-compliance is serious or continuing, then the IRB will determine which of the following actions are appropriate regarding the protocol:
 - a. Modification of the protocol

- b. Modification of the information disclosed during the consent process
 - c. The provision of additional information to past participants
 - d. Notification of current participants when such information might relate to participants' willingness to continue to take part in the research
 - e. A requirement that current participants re-consent to participation
 - f. Modification of the continuing review schedule
 - g. Monitoring of the research
 - h. Monitoring of the consent
 - i. Suspension of IRB approval of the research. Suspension means all interventions or interactions with living individuals cease until the IRB determines research may commence, except when the suspension of study drugs or other interventions would place participants at risk.
 - j. Termination of IRB approval of the research. Termination means all interventions or interactions with living individuals cease. When terminating research would place participants at risks of harm, the IRB will work with the researcher to transition patients to a new study or other appropriate action.
 - k. Referral to other organizational entities (legal counsel, county health department health officer, division director, Deputy Secretary for Health, and State Surgeon General in the role of Institutional Official).
- 5. The IRB discussion is documented in minutes, including discussion of controverted issues, if any, and their resolution.
- 6. The researcher is informed of the IRB's determination using the IRB Manager.
- E.** Any non-compliance that is serious and continuing is reported to regulatory agencies and institutional officials or others following DOHP 5-D5-10.3, Reporting to Institutional Official, Department or Agency Heads.
 - 1. The report of non-compliance will be distributed to the IRB, the HRPP Administrator designated in the Department's Assurance, the Deputy Secretary for Health, the State Surgeon General, and the Office for Human Research Protections (OHRP), if research is covered by

Department of Health and Human Services regulations, and other federal agencies when the research is overseen by those agencies and they require reporting separate from OHRP, and the Food and Drug Administration (FDA) when research is FDA-regulated.

2. Reporting of non-compliance will take place in accordance with DOHP 5-D5-10.3, Reporting to Institutional Official, Department or Agency Heads.

F. Attempts to unduly influence an IRB member or IRB staff are research misconduct:

1. IRB members or staff who believe they have been subject to undue influence must report this to the HRPP Administrator designated in the Department's Assurance or the Deputy Secretary for Health or State Surgeon General. IRB members or staff may also report to the Office of the Inspector General. The HRPP Administrator will notify the Deputy Secretary for Health as soon as possible but within five (5) calendar days that a report of undue influence has been made and an investigation has started.
2. The HRPP Administrator designated in the Department's Assurance investigates allegations of undue influence or refers the investigation to the Office of the Inspector General. If the HRPP Administrator is the subject of an allegation, the immediate supervisor or Office of the Inspector General investigates and takes corrective action. If an allegation is found not to have a basis in fact, no further action is taken.
3. If an allegation is found to have a basis in fact, the HRPP Administrator will provide a report of the investigation to the Deputy Secretary for Health and State Surgeon General within 10 business days; said official will address with the employee's supervisor. If the undue influence is due to a researcher not employed by the Department, the Institutional Official or the HRPP Administrator designated in the Department's Assurance will report all attempts of undue influence of the IRB process to the Institutional Official of the researcher's university.

IV. Authority

Section 381.86, Florida Statutes, Institutional Review Board

V. Supportive Data and References

- A.** 45 CFR § 46.103(b)(5)(i)
- B.** 45 CFR § 46.116(b)(5)
- C.** 21 CFR § 50.25(b)(5)

- D.** 21 CFR § 56.108(b)(2)
- E.** DOHP 5-D5-4.6, Problems Requiring Prompt Reporting to the IRB
- F.** DOHP 5-D5-10.2, Suspension or Termination of IRB Approval
- G.** DOHP 5-D5-10.3, Reporting to Institutional Official, Department or Agency Heads
- H.** ICH-GCP: III.2.6, III.2.10

VI. History Notes

Created: 07/06/2010
Previously Amended: 08/23/2013, 01/31/2020
Formerly: DOHP 400-10.1

VII. Signature and Effective Date



Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/29/26

Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Procedures	2
A. Sponsor-Imposed Suspensions	2
B. Study Expiration is Not a Suspension or Termination	2
C. Suspension and Termination of IRB Approval	3
D. Procedure for Reporting Suspension and Termination	4
IV. Authority	5
V. Supportive Data and References	5
VI. History Notes	5
VII. Signature and Effective Date	5

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) that all currently approved research is subject to modification or change in approval status, as deemed necessary by the IRB, to protect participants in research. The IRB may suspend or terminate its approval of research if the research is not being conducted in accordance with IRB requirements, federal regulations, or if it has been associated with unexpected serious harm to participants. Examples where approval of research may be suspended or terminated include but are not limited to:

- A.** Inappropriate involvement of human subjects in research
- B.** Inhibition of the rights or welfare of participants
- C.** Serious non-compliance, or continuing non-compliance with federal regulations or IRB policies
- D.** New information regarding increased risk to human participants

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

A. Sponsor-Imposed Suspensions

Notification of suspension by a sponsor for whatever reason is reviewed as an unanticipated problem. See DOHP 5-D5-4.6, Problems Requiring Prompt Reporting to the IRB.

B. Study Expiration is Not a Suspension or Termination

1. If a researcher has failed to provide continuing review information to the IRB, or the IRB has not reviewed and approved a research study by the specified continuing review expiration date, authorization to conduct the study expires. All research, including enrollment of new participants, cannot occur after the expiration of IRB approval and all research activities must stop including recruitment, enrollment, interventions, interactions, and collection of private identifiable data.
2. The Human Research Protection Program (HRPP) Administrator will notify the researcher that authorization to conduct research has expired. Once notified of the expiration, the researcher must confirm all research has stopped or immediately submit to the IRB Chair a list of research participants for whom cessation of the research would cause harm.

- a. For research that is not greater than minimal risk, research stops, but the researcher does not need to submit a list of participants.
 - b. The full IRB reviews this list and allows individual participants to continue participating in the research interventions or interactions only when the IRB determines it is in their best interest.
3. The IRB notifies the researcher in writing of the study expiration.
 - a. The letter indicates that after the expiration date:
 - (1) Enrollment of new participants must stop.
 - (2) All research activities must stop.
 - (3) Any continuation of research activity is a violation of federal regulations.
 - b. The letter also indicates the researcher must immediately submit to the IRB a list of research participants for whom cessation of the research would cause harm. If the research is not greater than minimal risk, then the letter does not require the researcher to provide this information.
4. Research studies where approval has expired and the researcher has confirmed research has stopped may be closed administratively. Normally researchers complete a continuing review form to close the study, but staff may close the study administratively if this is not possible (e.g., due to illness of a researcher). Reinstatement of the research requires submission of a research protocol for initial review.

C. Suspension and Termination of IRB Approval

1. The convened IRB is authorized to suspend its approval of research.
2. If IRB approval of research needs to be suspended in an urgent manner to protect research participants, an IRB Chair or the HRPP Administrator designated in the Department's Federal-Wide Assurance of Compliance or the State Surgeon General may suspend research. When research is suspended by someone other than the convened IRB, IRB Chair(s) will be notified as soon as possible, and the convened IRB will be notified at the next meeting. In addition to notifying the convened IRB, the Deputy Secretary for Health and State Surgeon General will be notified. They may require additional action, such as reporting to the Office of the Inspector General.
3. Only the convened IRB may terminate IRB-approved research.

4. The convened IRB considers actions to protect the rights and welfare of currently enrolled participants.
5. The convened IRB considers whether procedures for withdrawal of enrolled participants take into account their rights and welfare (e.g., making arrangements for medical care outside of a research study, transfer to another researcher, and/or continuation in the research under independent monitoring).
6. The convened IRB will consider whether to inform current participants of the termination or suspension.
7. When someone other than the convened IRB suspends research, the person reports any adverse outcomes or events in the research to the convened IRB.

D. Procedure for Reporting Suspension and Termination

1. The IRB promptly reports all suspensions to the researcher in writing. The letter:
 - a. Includes a statement of the reasons for the IRB's action.
 - b. Requires the researcher to submit to the IRB proposed procedures for withdrawal of currently enrolled subjects that consider their rights and welfare. The IRB reviews the proposed procedures. The IRB may mandate oversight or transfer responsibility to another researcher to ensure implementation of these procedures.
 - c. Requires the researcher to submit to the IRB a proposed script or letter notifying all currently enrolled participants that are affected by the suspension. The IRB reviews the proposed script or letter. If follow-up of subjects for safety reasons is permitted/required by the IRB, participants should be so informed. The IRB may directly contact participants to fulfill this notification.
 - d. Requires the researcher to report any events to the IRB or sponsor that would have required reporting had the former participants continued to be enrolled in the research. The IRB may mandate oversight or transfer responsibility to another researcher to ensure implementation of these procedures.
2. There is no need for the IRB to consider whether recurrent suspensions or terminations alone are serious or continuing non-compliance because all non-compliance that leads to a suspension or termination will be evaluated according to DOHP 5-D5-10.1, Investigating Any Non-Compliance, Serious or Continuing Non-Compliance.

3. All suspensions and terminations will be reported according to DOHP 5-D5-10.3, Reporting to Institutional Officials, Department or Agency Heads.
4. When suspending research, the IRB or other authorized individual shall consider actions to protect the health and safety of research participants, in addition to recommendations from the researcher, such as:
 - a. Transferring participants to another researcher.
 - b. Arranging for clinical care outside of research.
 - c. Allowing the continuation of some research activities under the supervision of an independent monitor.

IV. Authority

Section 381.86, Florida Statutes, Institutional Review Board

V. Supportive Data and References

- A. 45 CFR § 46.113
- B. 42 CFR Part 50 Subpart A
- C. Office for Human Research Protections, "Guidance on Continuing Review," dated July 11, 2002
- D. DOHP 5-D5-10.1, Investigating Any Non-Compliance, Serious or Continuing Non-Compliance
- E. DOHP 5-D5-4.4, Review of Human Subjects Research: Continuing Review
- F. ICH-GCP: III.2.6, III.2.10.

VI. History Notes

Created: 5/28/2010
Previously Amended: 08/23/2013, 01/31/2020
Formerly: DOHP 400-10.2

VII. Signature and Effective Date



Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/29/26
Effective Date

I. Policy Statements

It is the responsibility of the Department of Health (Department) Institutional Review Board (IRB) and Human Research Protection Program (HRPP) to ensure reporting occurs according to federal regulations and Department policy.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

A. This procedure will be followed whenever any of the following occurs:

1. Any determination by an IRB that a problem is an unanticipated problem involving risk to participants or others.
2. Any determination by an IRB that an incident of noncompliance is serious non-compliance, or continuing non-compliance with this policy or the requirements or determinations of the IRB.
3. Any suspension or termination of IRB approval.

B. Process for reporting unanticipated problems involving risks to participants or others, non-compliance determined to be serious or continuing, and suspensions or terminations of research.

1. The HRPP Administrator designated in the Department's Federal-Wide Assurance of Compliance is responsible for preparing materials within 30 calendar days of the completion of an investigation or determination for reporting to organizational officials.
2. Reports are made to the following organizational officials at the Department:
 - a. Bureau chief or division director
 - b. Deputy Secretary for Health
 - c. State Surgeon General
3. Reports are made to the researcher's organization and any other IRBs the researcher reported in the IRB application at the initial and continuing review as having jurisdiction over the research.
4. The Department will attempt to work collaboratively with other IRBs to coordinate reporting when more than one IRB is reporting.

- C.** Reporting to federal officials will generally take place within 60 calendar days of the completion of an investigation and/or determination.
1. When research involves a drug or device regulated by the Food and Drug Administration (FDA), the following will be reported to the FDA:
 - a. Unanticipated problems involving risks to participants or others
 - b. Non-compliance determined to be serious or continuing
 - c. Suspensions or termination of research
 2. When research is sponsored or supported by the Department of Health and Human Services (DHHS), the following will be reported to the Office for Human Research Protections (OHRP):
 - a. Unanticipated problems involving risks to participants or others
 - b. Non-compliance determined to be serious or continuing
 - c. Suspensions or termination of research
 3. When research is sponsored or supported by the Department of Defense, the following will be reported to the Department of Defense human research protection officer:
 - a. Unanticipated problems involving risks to participants or others
 - b. Non-compliance determined to be serious or continuing
 - c. Suspensions or termination of research
- D.** Generally, the maximum time allowed between the recognition of a reportable event and fulfilling reporting requirements is 90 calendar days.
- E.** Any concerns regarding data integrity outside of the jurisdiction of the IRB will be referred to the Office of the Inspector General, Office of the General Counsel, Deputy Secretary for Health, and State Surgeon General for further consideration or action.

IV. Authority

Section 381.86, Florida Statutes, Institutional Review Board

V. Supportive Data and References

- A.** DHHS: 45 CFR §46.103(b)(5)(ii), 45 CFR §46.113, OHRP Guidance on Reporting Incidents to OHRP
- B.** FDA: 21 CFR §56.108(b)(3), 21 CFR §56.113, FDA Information Sheets: Continuing Review After Study Approval
- C.** ICH-GCP: III.2.6, III.2.10

VI. History Notes

Previously Amended: 08/23/2013, 02/28/2015, 01/31/2020
Created: 07/07/2010
Formerly: DOHP 400-10.3

VII. Signature and Effective Date



Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/29/26

Effective Date

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) to maintain a safe, confidential, and reliable channel for current, prospective, or past research participants to report problems and concerns, obtain information, and offer input; to respond to questions; and to investigate all complaints received regarding human subjects research conducted under its jurisdiction.

II. Definitions

See DOHP 5-D5-11.1, Definitions

III. Procedures

- A.** The Department provides multiple mechanisms, including a webpage, template language in consent documents, and a toll-free phone number, for participants, researchers, members of the public, and others to ask questions, discuss problems or concerns or file a complaint, request information, or offer suggestions.
- B.** The Human Research Protection Program (HRPP) Administrator designated in the Department's Federal-Wide Assurance of Compliance or other HRPP staff will respond to questions and provide information generally within two (2) business days. If contacted with a concern or complaint, it is referred to the HRPP Administrator.
- C.** The HRPP Administrator shall investigate all complaints received regarding human subjects in research under the IRB's jurisdiction. The level of investigation will depend on the seriousness of the situation and the potential risk to participants. Complaints may come from any source including IRB members, researchers, participants and their families, institutional personnel, other institutional committees, the media, anonymous sources, or the public.
- D.** Complaints may come from any category of research reviewed and may include anyone involved or not directly involved in the research process/study.
- E.** Investigations should result in finding a suitable resolution and response to the complainant in a timely manner.
- F.** All complaints will be handled in a confidential manner. This includes any individual involved in notifying the IRB of an alleged violation of researcher compliance.
- G.** Complaints of a sensitive nature may be brought to the IRB Chair(s) for discussion and recommendation.
- H.** After completion of the investigation, all complaints processed under this policy will also be processed under DOHP 5-D5-4.6, Problems Requiring Prompt

Reporting to the IRB, as a potential unanticipated problem involving risks to participants or others.

- I. All complaints processed under this policy that involve non-compliance or allegations of non-compliance will also be processed under DOHP 5-D5-10.1, Investigating Any Non-Compliance, Serious or Continuing Non-Compliance.

IV. Authority

Section 381.86, Florida Statutes, Institutional Review Board

V. Supportive Data and References

- A. 45 CFR Part 46
- B. ICH-GCP: III.2.10.

VI. History Notes

Created: 05/25/2010
Previously Amended: 08/23/2013, 02/21/2015, 01/31/2020
Formerly: DOHP 400-10.4

VII. Signature and Effective Date



Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/29/26
Effective Date

TABLE OF CONTENTS

Section	Page
I. Policy Statements	2
II. Definitions	2
III. Authority	15
IV. History Notes	16
V. Signature and Effective Date	16

I. Policy Statements

It is the policy of the Department of Health (Department) Institutional Review Board (IRB) that to improve consistency and ease maintenance of other policies, the definitions listed in this policy will be used throughout all Human Research Protection Program (HRPP) policies.

II. Definitions

Administrative Rule: Each agency statement of general applicability that implements, interprets, or prescribes law or policy or describes the procedure or practice requirements of an agency and includes any form which imposes any requirement or solicits any information not specifically required by statute or by an existing rule. The term also includes the amendment or repeal of a rule (see section 120.55, Florida Statutes [F.S.]). Rules comprise the Florida Administrative Code.

Adverse Event: Any harm experienced by a participant regardless of whether the event was internal (onsite) or external (offsite) and regardless of whether the event meets the Food and Drug Administration (FDA) definition of "serious adverse event," which in the opinion of the principal investigator is both unexpected and related. "Adverse events" not meeting these criteria should not be reported. See "related" and "unexpected."

Advertising: A public announcement usually by a printed notice or voice or data broadcast that describes a research study including contact information. This is typically used for recruitment purposes for a research study.

Agent: Any individual (employee or contractor) authorized to act on behalf of the Department.

Allegation of Non-compliance: Written or verbal report of possible non-compliance concerning research under the oversight of the Department.

Alternate Member: Individuals appointed by the institutional official to substitute for IRB members with the same responsibilities and authority. Counts toward a quorum in the absence of an IRB member whose expertise the alternate member is replacing. If the member and alternate are both present at a meeting, only one may vote.

Amendment: Any change to an IRB-approved study protocol regardless of the level of review it receives initially (see also minor amendment and major amendment).

Appearance of a Conflict of Interest: If a reasonable person with knowledge of the relevant facts would question the impartiality of researchers, study personnel, IRB members, consultants, or IRB staff, or would question the regard for the public duty or interest of researchers, study personnel, IRB members, consultants, or IRB staff, then an appearance of a conflict of interest exists.

Assent: A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Bonus Payment: Prohibited compensation tied to the rate or timing of recruitment. Examples of bonus payments include but are not limited to the following: the sponsor announces the highest enrolling site in the nation will receive a \$10,000 bonus; the sponsor offers to pay an additional \$10,000 to any site that enrolls five participants within a week; the sponsor offers to pay an additional \$10,000 to any site that fulfills its recruitment target by the end of the month; the sponsor offers to pay an additional \$1,000 for any subject who agrees to enroll within one calendar day of initial contact.

Certificate of Confidentiality: A document that provides additional protection of data from legal subpoena. The certificate provides protection against compelled disclosure of identifying information or other identifying characteristics of a research participant enrolled in biomedical, behavioural, clinical, and other forms of sensitive research.

Children: Individuals who have not attained the legal age for consent to treatments or procedures involved in the research or clinical investigation, under the applicable laws of Florida, and as a result are unable to consent to the treatments or procedures in the research. A person under the age of 18 years who has had the disability of nonage removed by a circuit court is no longer a child and may consent to treatments and procedures in research; §743.015 F.S.; A person under the age of 18 years who is married or has been married, including one whose marriage is dissolved, or who is a widow or widower is no longer a child and may consent to treatments and procedures in research; §743.01, F.S. An unwed pregnant person under the age of 18 years of age may consent to the performance of medical or surgical care or services relating to her pregnancy, or relation to her child, including not greater than minimal risk research relating to her pregnancy or her child, and such consent is valid and binding as if she had achieved her majority; §743.065, F.S. A person under the age of 18 years seeking medical care or services related to sexually transmitted disease may consent to such treatments and procedures, including not greater than minimal risk research related to sexually transmitted diseases, and the consent of the parents or guardians of a minor is not a prerequisite, §384.30, F.S.

Clinical Investigation: Any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, or need not meet the requirements for prior submission to the FDA under these sections of the Federal Food, Drug, and Cosmetic Act, but the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations (21 Code of Federal Regulations [CFR] § 50.3(c), 21 CFR § 56.102(c)).

Clinical Trial: A research study in which one or more human participants are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioural health-related outcomes.

Coded Information: For the purposes of this policy, identifying information that would

enable the researcher to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof and a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

Cognitively Impaired: Having a psychiatric disorder (e.g., psychosis, neurosis, personality or behaviour disorder), an organic impairment (e.g., dementia), or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished as determined by reasonable medical judgment. Others, including individuals under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and individuals with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interest.

Collaborative IRB Training Initiative (CITI): An internet-based set of educational modules on the protection of human participants in research. It is sponsored by a consortium of IRB professionals and researchers from universities and medical schools across the country and is administered by the University of Miami.

Conflict of Interest: IRB members, consultants, and IRB administrators are considered to have a conflicting interest if they or a member of their immediate family has any financial interests related to the research where they have any role in the design, conduct, or reporting of the research, or other individual conflict of interest. See DOHP 5-D5-3.2, IRB Member, Consultant, and Staff Conflicting Interests.

Continuing Non-compliance: A pattern of repeated actions or omissions taken by a researcher that indicates a deficiency in the ability or willingness of a researcher to comply with federal and state regulations, IRB policy, or determinations or requirements of the IRB.

Continuous Quality Improvement (CQI): A methodology employed to improve existing processes by identifying the root cause of a problem, developing and implementing an action plan, and evaluating the outcome to ensure problem resolution. The PDSA cycle incorporates the following process: Plan, Do, Study, Act.

Continuing Review: Periodic review of research activities necessary to determine whether the risk/benefit ratio has changed, whether there are unanticipated findings involving risks to participants or others, and whether any new information regarding the risks and benefits should be provided to participants.

Data and Safety Monitor (DSM): An individual assigned to conduct interim monitoring of accumulating data from research activities to ensure the continuing safety of research participants, relevance of the study question, appropriateness of the study, and integrity of the accumulating data. The individual should have expertise in the relevant medical, ethical, safety, and scientific issues.

Data and Safety Monitoring Board (DSMB): A formally appointed independent group

consisting of at least three (3) members assigned to conduct interim monitoring of accumulating data from research activities to ensure the continuing safety of research participants, relevance of the study question, appropriateness of the study, and integrity of the accumulating data. Membership should include expertise in the relevant field of study, statistics, and research study design.

Data and Safety Monitoring Committee (DSMC): Another term for DSMB.

Data and Safety Monitoring Plan (DSMP): Describes how the researcher plans to oversee the research participant's safety and welfare and how adverse events will be characterized and reported. The intensity and frequency of monitoring should be tailored to fit the expected risk level, complexity, and size of the study.

Dead Fetus: A fetus that exhibits none of the following: heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord (if still attached).

Delivery: Complete separation of the fetus from the woman by expulsion or extraction or any other means.

Department of Health and Human Services (DHHS): The United States government agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves. As indicated in section 381.86, F.S., the Department applies the same requirements and policies used to comply with DHHS requirements to all research.

Directed Audit: These audits may be conducted by the IRB staff, Department Inspector General, or an outside third party to assess the researcher's compliance with federal regulations, state and local laws, and IRB policies and procedures. These audits of IRB-approved research studies are in response to identified concern(s). Concerns may be identified by an IRB, an external source (e.g., Office for Human Research Protections [OHRP], FDA, or sponsor), or an internal source (e.g., participant, family member, or Department personnel, including IRB staff).

Dissent: An individual's negative expressions, verbal and/or non-verbal, that they object to participation in the research or research activities.

Document: A physical or electronic record submitted to the IRB.

Emergency Research: The use of an unapproved test article (drug, agent, biologic, or device) on a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval.

Emergency Treatment Investigational Device Exemption (IDE): A mechanism through the FDA for providing eligible participants with investigational devices for the treatment of an immediate serious or life-threatening illness for which there are no satisfactory alternatives.

Emergency Treatment Investigational New Drug (IND): A mechanism through the FDA for providing eligible participants with investigational drugs, agents, or biologics for the treatment of an immediate serious or life-threatening illness for which there are no satisfactory alternatives.

Exempt Review: Studies determined by the IRB to meet the exempt criteria as defined by the federal regulations. Exempt studies do not require periodic review by the IRB unless a change in the project is planned.

Expedited Review: Studies determined by the IRB to meet the expedited criteria as defined by the federal regulations.

Expired Study: When continuing review of the research does not occur prior to the end of the approval period specified by the IRB, IRB approval expires automatically and requires no decision, determination, or action by the IRB. The study expires at midnight on the last approval date specified on the approval letter and the informed consent document. No activities can occur after the expiration date. Such expirations of approval are not suspensions of IRB approval, terminations of IRB approval, or administrative holds. Allowing a protocol to expire is considered non-compliance.

Family Member: Any one of the following legally competent persons: spouse; children (including adopted children); brothers, sisters, and spouses of brothers and sisters; and any individual related by blood or affinity whose close association with the participant is the equivalent of a family relationship.

Federal-Wide Assurance of Compliance (Assurance): A contract or agreement that establishes standards for human subjects research as approved by OHRP.

Fetus: The product of conception from implantation until delivery.

Financial Interest Related to the Research: Financial interest in the sponsor, product or service being tested, or competitor of the sponsor.

Finder's Fee: Compensation of any type (cash, office or medical supplies, educational stipends, gift certificates, priority in authorship listings, travel reimbursement, or anything else of value) to an individual made in exchange for referral or recruitment of a participant to a research study. Such payments, generally, are made to residents, physicians, nurses, or others in a position to identify potential participants that might qualify for enrollment into a study. The fee is paid only for participants who are actually enrolled into the study. Any financial interest related to research must be reported.

Food and Drug Administration (FDA): The United States government office under DHHS responsible for implementing regulations governing drugs, devices, and biologics.

Grant-letting: The process of distributing funds to various organizations or projects through grants.

Guardian: Defined by DHHS as an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care.

Guidelines for Good Clinical Practice (GCP): An international, ethical, scientific, and quality standard for conduct of trials that involve human participants developed by the International Council for Harmonisation (ICH).

Human Fetal Tissue: Tissue or cells obtained from a dead human embryo or dead fetus after a spontaneous or induced abortion, or after a stillbirth.

Human Participant: As defined by DHHS regulations, a living individual about whom a researcher conducting research obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens.

Human Subject: As defined by FDA regulations, an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. For research involving medical devices a human subject is also an individual on whose specimen an investigational device is used.

Human Subject Research: Any activity that either meets the DHHS definition of “research” and involves “human subjects” as defined by DHHS regulations or meets the FDA definition of “research” and involves “human subjects” as defined by FDA regulations.

Humanitarian Use Device (HUD): A device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 8,000 individuals in the United States per year.

Humanitarian Use Device Exemption (HDE): A Federal Drug Administration (FDA) approval for a physician to use a HUD in clinical treatment or as the subject of a clinical investigation.

Immediate Family Member: Spouse, domestic partner, children, and dependents.

Individual Conflict of Interest: A circumstance such that any action or decision in which an individual is substantially involved with the research may have direct or predictable effect on a financial interest of the individual, spouse, minor child, or organization in which the individual serves as an officer, trustee, partner or employee.

Informed Consent: An individual’s voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure.

Institutional Review Board (IRB): A specifically constituted review body established or designated by an entity to protect the rights and welfare of human subjects recruited to participate in research.

Interaction: Includes communication or interpersonal contact between a researcher or his/her research staff and the research participant or their private identifiable information.

International Council for Harmonisation of Technical Requirements for

Pharmaceuticals for Human Use (ICH): Created in 1990 and its mission is to achieve greater harmonisation worldwide to ensure safe, effective, and high-quality medicines are developed, and registered and maintained in the most resource-efficient manner whilst meeting high standards.

Intervention: Includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subjects' environment that are performed for research purposes.

Investigational Agents: A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial. This includes products with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, products used for an unapproved indication, or products used to gain further information about an approved use.

Investigational Product or Device: Any health care product that does not achieve its primary intended purposes by chemical action or by being metabolized. Investigational product is synonymous for test article. A medical device that is the subject of a clinical study designed to evaluate the effectiveness and/or safety of the device. Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices.

Investigational Device Exemption (IDE): An FDA-approved IDE permits a device that otherwise would be required to comply with a performance standard or to have pre-market approval to be shipped lawfully for the purpose of conducting investigations of that device.

Investigational Drugs/Investigational Biologics (Test Articles): A new drug/agent or biologic used in a clinical investigation. The term investigational biologic also includes a biological product that is used in vitro for diagnostic purposes. Investigational drugs or biologics may include: 1. Products that are not generally recognized as being safe and effective for any use under the conditions prescribed, recommended, or suggested by the FDA; or 2. Products already approved by the FDA as safe and effective for specific indications that are being studied for new indications (or doses, strengths, or frequency).

Investigational New Drug (IND): FDA granting of permission that a new drug, agent, or biologic may be used in humans prior to FDA review of clinical data that has determined a particular product is safe and effective for a specific use. The FDA permission is evidenced by the assignment of an IND number by the FDA or the granting of an IND exemption.

IRB Manager: An online, web-based IRB management service. This service houses all documents related to the IRB and those related to any research studies that have come

under the purview of the IRB.

IRB Member: Individual appointed by the institutional official to serve as a voting member on a designated IRB that meets requirements of expertise or experience, or community representation; membership counts toward a quorum.

IRB of Record: An IRB is considered the IRB of record when it assumes IRB responsibilities for another institution and is designated to do so through an approved Assurance with OHRP. A memorandum of understanding is required, designating the relationship, for the Department to serve as the IRB of record.

Joint Commission: A national accrediting body for hospitals and other health care delivery organizations.

Key Research Personnel: The principal investigator and all individuals responsible for the design or conduct of the study

Legally Acceptable Representative: An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. Legally acceptable representatives may not give permission for research involving children unless they are guardians.

Major Amendment: A proposed change in research related activities that is more substantial than, influential than, or affective of a study change than a minor amendment.

Memorandum of Understanding (MOU): A formal agreement between the Department and another institution that identifies the Department IRB as the IRB of record for that institution.

Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For research involving prisoners, minimal risk means the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examinations of healthy persons.

Minor Amendment: A proposed change in research-related activities that does not materially affect an assessment of the risks and benefits of the study, does not substantially change the specific aims or design of the study, and all added procedures that qualify for review under expedited review per 21 CFR § 50.110 and 45 CFR § 46.110.

Neonate: A newborn.

Non-compliance: Failure to comply with federal and state regulations, IRB policy, or the determinations or requirements of the IRB. Examples include conducting research

without prior IRB approval, protocol deviations, and making changes to the research protocol or study design without prior approval, except when necessary to eliminate immediate hazard to participants, releasing confidential Department data for research without prior IRB approval, complaints, and the results of audits.

Non-human Subject Research: Any activity determined by the institution to not represent “human subject research.” The following activities are not considered research:

- A.** Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- B.** Public health surveillance activities conducted by a public health authority, limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance.
 - 1. Including the collection and testing of information or biospecimens conducted, supported, requested, ordered, required, or authorized by a public health authority.
 - 2. Including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products.
 - 3. Including those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or manmade disasters).
 - 4. Including a description of who may be designated a public health authority. For example, whether this is limited to Department employees or agents, or whether it may extend to external researchers.
- C.** Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- D.** Authorized operational activities (as determined by the relevant federal agency) in support of intelligence, homeland security, defense, or other national security missions.

Non-significant Risk (NSR) Device Study: A study of a device that does not meet the definition for a significant risk device and does not present a potential for serious risk to the health, safety, or welfare of participants.

Nonviable Neonate: A neonate after delivery that, although living, is not viable.

Not-Identifiable Information: The identity of the participant is not or may not readily be ascertained by the researcher or associated with the information.

Office for Human Research Protections (OHRP): The United States government office under DHHS responsible for implementing DHHS regulations (45 CFR 46) governing biomedical and behavioral/social science research involving human subjects.

Parent: A child's biological or adoptive parent.

Pass-Through Funding: Where the Department receives support directly from federal agencies for non-exempt research, and all activities are conducted by community-based organizations or partners of the Department. For example, if the Centers for Disease Control and Prevention provide research funding through the Department to a community-based organization or private partner of the Department, this activity requires IRB review, even if the activity is conducted solely by agents or contractors of the Department.

Periodic Compliance Review: Random assessments of IRB-approved human research studies, including site visits, and the internal IRB program may be conducted by internal or external compliance teams. Internal compliance reviews monitor the adherence to federal regulations, state and local law, and IRB policies and procedures. Local compliance reviews monitor the adherence to federal regulations, state and local law, IRB policies and procedures, adherence to the study protocol, accurate documentation and reporting of study related activities, and evaluation/observation of the informed consent process.

Permission: The agreement of parents or legal guardians to the participation of their child or ward in research.

Policy: A statement defining a plan, guiding principle, or course of action intended to determine decisions, actions, and procedures as set forth by the Department, Public Health Research, and the IRB as it pertains to the HRPP.

Pregnancy: Encompasses the period from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the presumptive signs of pregnancy, such as a missed menses, until the results of a pregnancy test are negative or until delivery.

Principal Investigator (PI): The lead researcher responsible for the design, conduct, and oversight of a research project.

Prisoner: Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. Probation and parole are treated the same and are usually **not** considered as incarceration. Ankle bracelets/in home restrictions are considered incarceration. Mental and substance abuse facilities are considered incarceration if someone is

mandated to attend in lieu of jail or prison; however, an individual in such a facility is **not** considered incarcerated if they voluntarily commit themselves.

Privacy: Freedom from unauthorized intrusion or the state of being left alone and able to keep certain personal information to oneself and control other's access to that information.

Private Information: Includes information about behavior that occurs in a setting in which an individual can reasonably expect no observation or recording is taking place. It includes information, which has been provided for specific purposes by an individual, and the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable to be considered information to constitute research involving human participants. This may include identifiable private information obtained from a primary participant about a third party.

Prospective: Research utilizing human participants' specimens/data that will be collected after the research is approved by the IRB.

Public Health Research: The unit within the Division of Public Health Statistics and Performance Management responsible for research and human research protections at the Department.

Radiation Exposure: The quantity used to indicate the amount of ionization in air produced by x- or gamma-ray radiation while conducting radiological procedures.

Radiation Safety Committee: A committee composed of individuals with expertise in various disciplines pertinent to the field of radiology, radiological sciences, nuclear medicine, and radiation oncology. Such a committee must also include an individual with special competence in radiation safety and radiation dosimetry, and must comply with all applicable law and regulation, including FDA regulations at 21 CFR Part 361 and state regulations at Chapter 64E-5, Florida Administrative Code.

Radioactive Drug: Any substance defined as a drug under the Federal Food, Drug, and Cosmetic Act that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons. Included are any non-radioactive reagent kit or nuclide generator that is intended to be used in the preparation of a radioactive drug and "radioactive biological products." Drugs such as carbon-containing compounds or potassium-containing salts containing trace quantities of naturally occurring radionuclides are not considered radioactive drugs.

Radiological Procedure: Any procedure involving radiation (e.g., X-ray) or a radioactive agent (e.g., a radionuclide).

Recruitment: Seeking individuals to enroll or participate in a research project.

Related: An adverse event is "related to the research procedures" if in the opinion of the principal investigator, it was more likely than not to be caused by the research procedures or if it is more likely than not the event affects the rights and welfare of

current participants.

Repository: A storage site or mechanism by which identifiable human tissue, blood, genetic material, or data are stored or archived for research by multiple researchers or multiple research projects.

Research: As defined by FDA regulations, any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA under section 505(i) or 520(g) of the Food, Drug, and Cosmetics Act, or need not meet the requirements for prior submission to the FDA under these sections of the Food, Drug, and Cosmetics Act, but the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. For research involving drugs, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous.

- A.** "Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act" means any use of a drug other than the use of an approved drug in the course of medical practice. [21 CFR § 312.3(b)]
- B.** "Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act" means any activity that evaluates the safety or effectiveness of a medical device. [21 CFR § 812.2(a)]
- C.** "Any activity in which results are being submitted to or held for inspection by FDA as part of an application for a research or marketing permit is considered to be FDA-regulated research." [21 CFR § 50.3(c), 21 CFR § 56.102(c)]

Research: As defined by DHHS regulations, any systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

- A.** Investigation: An inquiry, examination, or search for facts, usually involving the formulation or testing of a hypothesis.
- B.** Systematic: Conducted according to a plan, organized method, or procedure for testing or formulating a question or hypothesis and interpreting results.
- C.** Designed: Planned or conducted to apply to phenomena outside the observed data, or to contribute to such understanding.
- D.** Generalizable Knowledge: Observations, findings, information, or results that have been demonstrated with enough confidence and significance to confirm or alter the consensus within the professional norms of a community or discipline.

Researcher: An individual who conducts systematic and investigative studies, investigations, or experiments in order to gather and analyze information, data, or evidence to advance knowledge in a particular field of study or to address a specific research question or problem.

Research Misconduct: Any fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results or any attempt to unduly influence an IRB member or IRB staff.

Research Payments: Cash and non-cash payments for reimbursement of time and expenses associated with participation in research activities.

Retrospective: Research utilizing human participants' specimens/data that were previously collected (e.g., on the shelf) before the research was approved by the IRB.

Roster: Current listing of members appointed to serve on a designated IRB.

Sensitive Information: Includes, but is not limited to, information relating to sexual attitudes, preferences, or practices; information relating to the use of alcohol, drugs, or other addictive products; information pertaining to illegal conduct; information that, if released, might be damaging to an individual's financial standing, employability, or reputation within the community or might lead to social stigmatization or discrimination; information pertaining to an individual's psychological well-being or mental health; and genetic information.

Serious Non-compliance: An action or omission taken by a researcher that any other reasonable researcher would have foreseen as compromising the rights and welfare of, or harming, a participant.

Short Form Consent: A written informed consent document that summarizes the required elements of informed consent to be presented orally to the participant or his or her legally acceptable representative.

Significant Risk (SR) Device Study: A study of a device that presents a potential for serious risk to the health, safety, or welfare of a participant and 1) is intended as an implant; 2) is used in supporting or sustaining human life; or otherwise prevents impairment of human health; 3) is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or 4) otherwise presents a potential for serious risk to the health, safety, or welfare of a participant.

Sponsor-imposed Suspension: A determination from the sponsor of the study to place specific research activities on hold. This determination may be made for interim data analysis; inadequate drug availability; response to a DSMB report/recommendation; or a pre-planned stopping point.

Standard Review: Studies reviewed by the full, convened IRB with a recorded vote and corresponding minutes to document the discussion.

Suspension of the Research: All interventions or interactions with living individuals cease until the IRB determines research may commence, except when the suspension of study drugs or other interventions would place participants at risk.

Termination of the Research: All interventions or interactions with living individuals cease. When terminating research would place participants at risks of harm, the IRB will work with the researcher to transition patients to a new study or other appropriate action.

Test Article: Any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to FDA regulation.

Third-party: Any person or vendor (external to the Department) who receives payment for providing research-related services and/or products.

Treatment IDE: A mechanism through the FDA for providing eligible participants with investigational devices for the treatment of a serious or life-threatening illness for which there are no satisfactory alternatives.

Unanticipated Adverse Device Effect: Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem to participants or others associated with a device that relates to the rights, safety, or welfare of participants.

Unanticipated Problem Involving Risks to Participants or Others: Any problem, event, or information, as determined by the Department, that (1) was unforeseen, (2) indicates participants or others are at increased risk of harm, and (3) is related to the research.

Unexpected: An adverse event is "unexpected" when its specificity and severity are not accurately reflected in the informed consent document.

Viable: As it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

III. Authority

Section 381.86, F.S., Institutional Review Board

IV. History Notes

Created: 2007

Previously Amended: 06/28/2010, 08/23/2013, 01/31/2020

Formerly: DOHP 400-11.1

V. Signature and Effective Date



Shay Gonzalez, BSN, MBA
Interim Chief of Staff

10/29/26

Effective Date