

Sample Human Subject Research Determination Worksheet

Step 1: Is your project research?

Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

- Investigation: an inquiry, examination, or search for facts, usually involving the formulation or testing of a hypothesis
- Systematic: conducted according to a plan, organized method, or procedure for testing or formulating a question or hypothesis and interpreting results
- Designed: Planned, purposed, or conducted
- Generalizable knowledge: Observations, findings, information, or results that apply to phenomena outside the observed data and may confirm or alter the consensus within a professional community or scientific discipline

If no, then your project does not require IRB review; stop here. If yes, go to Step 2.

Step 2: Does your project involve human subjects?

Human subject as defined by DHHS (45 CFR 46.102(f): the project involves one or more living individuals about whom an investigator obtains data (results, findings) through

- intervention or interaction OR
- private and identifiable data or biological specimens

If no, then your project does not require IRB review; stop here. If yes, go to Step 3.

Step 3: Is the Florida Department of Health involved in your project?

- The research is sponsored (funded) in whole or in part from federal research appropriations to DOH, even where all activities involving human subjects research are carried out by agents or employees of another institution ("pass-through funding");
- The research is conducted by or under the direction of any employee or agent of DOH in connection with his or her official responsibilities;
- The research is conducted using any property or facility of the DOH;
- The research involves DOH clients, including Healthy Start or Children's Medical Services;
- The research involves the use of non-public information maintained by the DOH when released outside DOH, except as otherwise required by law, including Florida Cancer Registry, Vital Statistics, Florida Trauma Registry, and others.
- The research is affiliated with an institution that can use the FL DOH IRB in place of its own through an Assurance or MOU.

If none of the above are true, your project may require IRB review by another institution; stop here. If any of the above are true, got to Step 4.

Step 4: Is your project Public Health Practice?

The project is *designed* to improve the health of a population; it is not *designed* in whole or in part, *to contribute to generalizable knowledge*.

The project involves specific legal authorization for conducting the activity under state public health law; The *Department* is required in the project to:

- Identify, assess, and control the presence and spread of communicable diseases (381.001(2) F.S.)
- Detect and investigate food-borne disease, waterborne disease, and other diseases of environmental causation where the Department under statutory authority conducts epidemiological investigations and ongoing surveillance (381.006(2) and (10))
- Investigate the sanitary condition of any city, town, or place in the state (386.02)

- Collect data and conduct analyses and studies related to health care needs of the community for purposes of advising county health departments and the state health department regarding local and state health planning (408.033 F.S.)
- Conduct epidemiological investigations, surveillance, programmatic evaluations, and clinical care for the population.(381.0031) Includes a corresponding governmental duty to perform the activity to protect the public's health;

The project involves direct performance or oversight by a governmental public health authority (or its authorized partner) and accountability to the public for its performance.

For more information, see *Public Health Practice vs. Research: A Report for Public Health Practitioners Including Cases and Guidance for Making Distinctions*. Hodge and Gostin, et al. 2004.

<http://www.cste.org/pdffiles/newpdffiles/CSTEPHResRptHodgeFinal.5.24.04.pdf>

If all of the above are true, then your project does not require IRB review; stop here. If not true, go to Step 5.

Step 5: Is your project program evaluation or quality improvement?

Quality improvement: data-guided activities designed to bring about immediate, positive changes in the delivery of health care or organizational effectiveness *in particular settings*.

The project is *designed* for the purpose of continuously improving ongoing care and management of the system for delivering clinical care, including but not limited to activities that

- implement and monitor a practice to improve the quality of patient care
- collect patient or provider data regarding the implementation of the practice for clinical, practical, or administrative purposes
- measures or report provider performance data for clinical, practical, or administrative uses

Any of the following might also describe your project:

- It is an integral, ongoing, possibly funded, part of standard program operations (organization may require participation and the use of a specific quality framework, such as Kaizen, Six Sigma , PDCA, TQM, etc.)
- It helps the organization track activities in terms of existing quality improvement frameworks or national best practices or benchmarks.
- It is the responsibility of institutional leadership who supervise quality initiatives; may involve a quality improvement committee or other ongoing organizational structure.
- It supports organization efforts to provide high quality care.

If these generally describe your project, then your project does not require IRB review; stop here. If this is not true, go to Step 6.

Step 6: Your project requires IRB review

Congratulations! You are doing scientific research involving human subjects that falls under the regulatory authority of the Department of Health and Human Services and/or the Food and Drug Administration. Your study require IRB review. Fill out a determination form and deliver it to the Public Health Research Program:

Rotanya.Bryan@flhealth.gov or Karen.Card@flhealth.gov.

Disclaimer

This document is provided for informational purposes only; it cannot be substituted for a non-research or an exempt research determination letter. The Florida Department of Health Institutional Review Board provides letters of non-research determination for applicable studies or projects. If you need documentation, please contact Karen Card (Karen.Card@flhealth.gov) or Rotanya Bryan (Rotanya.Bryan@flhealth.gov) to request a Determination Form. If you have any questions about whether your research project should get IRB review, please contact Karen Card (Karen.Card@flhealth.gov) or Rotanya Bryan (Rotanya.Bryan@flhealth.gov).