



## **GRANT ADMINISTRATION MANUAL**

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**For FY18-19 Biomedical Research Grants, December 2018**

**Administered By:  
Public Health Research  
Division of Community Health Promotion**

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## 1. USING THIS MANUAL

Congratulations on receiving a Biomedical Research Grant from the Florida Department of Health! Funds for research in tobacco-related diseases, cancer and pediatric cancer, and Alzheimer's disease are provided through the James and Esther King Biomedical Research Program (Section 215.5602, Florida Statutes), the William G. "Bill" Bankhead, Jr., and David Coley Research Program (Bankhead-Coley) and the Live Like Bella Initiative (Section 381.922, Florida Statutes), and the Ed and Ethel Moore Alzheimer's Disease Research Program (Section 381.82, Florida Statutes).

This manual contains Department policies as well as the procedures necessary for compliance with those policies. It is organized around a typical grant lifecycle beginning with Section 4—"Administering the Grant." Definitions for key terms are compiled in "Appendix A—Definitions," along with acronyms and other conventions used throughout the document.

In instances where this manual conflicts with the grant's executed Terms and Conditions and incorporated documents, the Terms and Conditions will prevail.

## **2. GRANT ROLES AND CONTACT INFORMATION**

Grantee refers to both the eligible institution and its authorized agents. It is a generic reference to everyone associated with the grant at the institution receiving the grant. Specific references by grantee job title are used when appropriate. The “Department” refers to the Florida Department of Health and staff authorized to act on behalf of the Department.

### **2.1 GRANTEE ROLES**

Grants are awarded to the qualified Corresponding Principal Investigator’s eligible institution. The Corresponding Principal Investigator (CPI) has sole responsibility for the overall performance of the project. Key project roles are defined below.

#### **2.1.1 Corresponding Principal Investigator/Project Director**

The CPI, at a minimum, must complete the following duties:

- Understand the grant Terms and Conditions and remain in full compliance.
- Direct the project to achieve the specific aims in the approved protocol.
- Not make any changes in the project protocol(s) without prior Department approval.
- Hire and supervise qualified project personnel. No grant personnel can total more than 100% effort, inclusive of all active FDOH grants on which he/she may be included.
- Ensure the ethical conduct of the research, including compliance with laws governing research involving human subjects and vertebrate animals.
- Disclose required interests and comply with all requirements to manage conflicts of interest.
- Report problems and non-compliance, as defined below, promptly to the Department.
- Plan, review, and approve project expenditures.
- Ensure the Department’s deliverables are completed and submitted on time as defined in the Terms and Conditions, Attachment II, Schedule of Deliverables.
- Comply with the Department’s monitoring, reporting, and change notification requirements.
- Present and publish significant findings and report these outcomes to the Department in a timely fashion. (For more information about disseminating findings based on research

sponsored by the Department, see Section 6.4—“Publicizing Research Results.”)

- Disclose inventions and subsequent commercialization progress to the Department in a timely fashion. See Section 6.5—“Patents, Copyrights, and Royalties.”
- Maintain close working relationships with the institution’s administrative and fiscal personnel and the appropriate Department personnel.

### **2.1.2 Mentor**

A Mentor is highly recommended for postdoctoral fellowships and grants to new investigators. The role of the Mentor is to provide guidance, support, and experience to the CPI. The Mentor should provide scientific advice, grant experience, project management guidance, and lab management counsel related to the project. Furthermore, the Mentor is chosen by the CPI and should provide guidance in the development of the new investigator so that he/she can undertake independent research that is competitive for national research funding. The Mentor can be from the same or a different institution as the CPI.

### **2.1.3 Sponsored Research Official**

The Grantee’s Sponsored Research Official (SRO) is the one institutional official who has signatory authority for the eligible institution receiving a Department grant. The SRO may delegate his/her responsibilities with the understanding that he/she retains full responsibility. At a minimum, the SRO must:

- Accept the grant on behalf of the Grantee.
- Certify that the CPI is qualified to serve as an investigator at the institution, meet stated Department eligibility requirements, have access to the necessary facilities and equipment, and have approval to devote the time specified in the project plan.
- Sign and ensure compliance with the Terms and Conditions.
- Ensure that financial controls are in place within the Grantee institution to capture, monitor, and report labor and expenditures charged against the approved budget. The Department has authority to audit all financial records related to the research.
- Assist the Department during all site visits, reviews, and fact-gathering efforts related to the grant.

- Report problems and possible non-compliance within 48 hours to the Department, including internal investigations and/or suspensions for scientific misconduct or conflict of interest.

#### **2.1.4 Administrative Representative**

The Administrative Representative is the person at the eligible institution responsible for fiscal and administrative coordination of the grant, including creating invoices and quarterly financial reporting. This could be the same person as the SRO or may be an individual delegated by the SRO. The Administrative Representative must:

- Assist the CPI with financial management, budgeting, and re-budgeting.
- Sign/approve budgets, invoices, and maintain accurate financial records.
- Assist the CPI with timely close out at the end of the grant.

## **2.2 DEPARTMENT ROLES**

The Department administers the grant funds appropriated by the Legislature. An advisory council, called the Biomedical Research Advisory Council (BRAC), makes recommendations to the Department's agency head, the State Surgeon General, on the scope and direction of the grant funding for the Bankhead-Coley, Live Like Bella Initiative, and James and Esther King Biomedical Research Programs. The Alzheimer's Disease Research Grant Advisory Board makes recommendations to the Department's agency head, the State Surgeon General, in the scope and direction of the grant funding for the Ed and Ethel Moore Alzheimer's Disease Research Program.

### **2.2.1 Biomedical Research Advisory Council (BRAC)**

The BRAC is an eleven-member advisory council composed of appointees of the Governor, the Florida Senate President, and the Florida Speaker of the House of Representatives, and delegates from the American Heart Association, American Cancer Society, and American Lung Association. Each BRAC member holds a designated seat and provides specialized expertise and balance to this advisory body. All meetings of the BRAC are open to the public and Grantees are encouraged to attend. The responsibilities of the BRAC may include, but are not limited to:

- Providing advice on program research priorities and emphases.
- Providing advice on the overall program budget.
- Participating in periodic program evaluation.



- Assisting in the development of guidelines to ensure fairness, neutrality, and adherence to the principles of merit and quality in the conduct of the program.
- Assisting in the development of appropriate linkages to nonacademic entities, such as voluntary organizations, health care delivery institutions, industry, and government agencies.
- Developing criteria and standards for the award of research grants.
- Developing guidelines relating to solicitation, review, and award of research grants and fellowships to ensure an impartial, high-quality peer review system.
- Reviewing reports of peer-review panels and make recommendations for research grants and fellowships.

### **2.2.2 Alzheimer’s Disease Research Grant Advisory Board**

The Advisory Board, authorized in Section 381.82, Florida Statutes, advises the State Surgeon General as to the scope of the research program and submits its recommendations for proposals to be funded to the State Surgeon General by December 15<sup>th</sup> of each year. Other responsibilities of the board may include, but are not limited to:

- Providing advice on program priorities and emphases.
- Assisting in the development of appropriate linkages to nonacademic entities, such as voluntary organizations, health care delivery institutions, industry, government agencies, and public officials.
- Provide oversight regarding mechanisms for the dissemination of research results.

### **2.2.3 Administrative Services**

The Department’s Public Health Research provides administrative support and management for the biomedical research grants. The Biomedical Research Section is the first point of contact for grant-related matters.

Administrative support includes:

- Executing and managing all research grants.
- Responding to all Grantee inquiries.
- Receiving and processing all Grantee deliverables/reports (both project performance and financial).
- Evaluating project performance and progress, with assistance from technical subject matter experts as necessary.

- Evaluating project performance and progress by completing onsite monitoring visits to ensure compliance with grant Terms and Conditions.
- Reviewing financial reports and continually monitoring financial and business compliance.
- Providing support regarding invoices, changes in personnel, protocol, budgets, multi-year grant continuations, etc.
- Providing resolutions to change requests.
- Maintaining the official file of record for each grant.

### **2.2.3 Correspondence**

Grantees may contact the Department:

Administrator, Biomedical Research Section  
Public Health Research  
Division of Community Health Promotion  
Florida Department of Health

COURIER ADDRESS:  
2585 Merchants Row Blvd, Room 320N  
Tallahassee, FL 32399-1725

MAILING ADDRESS:  
4052 Bald Cypress Way Bin A-24  
Tallahassee, FL 32399-1749

PHONE: 850-245-4585

PROGRAM E-MAIL: [Research@flhealth.gov](mailto:Research@flhealth.gov)

WEBSITE: <http://www.floridahealth.gov/provider-and-partner-resources/research/index.html>

GRANT MANAGEMENT FORMS LIBRARY:  
<http://www.floridahealth.gov/provider-and-partner-resources/research/grant-programs-resources/forms-library.html>

### **3. FORMALIZING THE AWARD AND STARTING A GRANT**

#### **3.1 ACCEPTANCE OF AWARDS**

##### **3.1.1 Policy on Terms and Conditions**

After awards are finalized, each grantee must sign the Terms and Conditions. The Terms and Conditions are non-negotiable and acceptance is required as part of the grant award process. The Department reserves the right to change or modify the Terms and Conditions, as needed. By submitting a grant application pursuant to a Funding Opportunity Announcement (FOA), all applicants acknowledge this requirement. The Terms and Conditions also include the post-award schedule of deliverables.

Any necessary changes to the Terms and Conditions will require an official amendment to the original Terms and Conditions, legally modifying the original grant document. Terms and Conditions must be executed before the end of the State Fiscal Year as reflected in the FOA in order for the funds to be available.

##### **Terms and Conditions Execution Procedures**

- The Department will e-mail copies of the award letter, conflict of interest (COI) form, the Grant Administration Manual, and two budget attachments to the Grantee's SRO and the CPI. The CPI must complete and sign the conflict of interest. The budget attachments will be completed by the CPI and signed by the SRO. The COI and both budget attachments must then be submitted electronically to the Department. These three documents will be included in the Terms and Conditions.
- The Department uses the DocuSign software for routing the Terms and Conditions for execution.
- The SRO will receive an email from DocuSign with the Terms and Conditions. The SRO must review and electronically sign the document. Once the document is signed it will be electronically returned to the Department through the DocuSign system. If the Grantee's institution does not support electronic signatures, the option to print and sign the Terms and Conditions is available. In this case, the SRO would need to review the document, print, sign, and upload back into DocuSign for final execution.
- The Department will sign/execute the Terms and Conditions and will return an electronic executed copy to the SRO and

CPI. The grant is executed when signed by the Department-authorized signatory.

### **3.1.2 Policy on Award Contingency**

The Department's performance and obligation to pay under the Terms and Conditions are contingent upon annual appropriation by the Legislature and/or the availability of funds.

The Department reserves the right to offer a lesser award than is requested in a grant application. The Terms and Conditions will indicate the awarded amount.

#### **Procedures**

- If a lesser award amount than requested in the grant application is necessary, the Department will notify the SRO and CPI. The SRO and CPI will determine if the lesser amount is acceptable.
- The CPI may need to submit a revised budget and budget narrative (Attachments V.a. and V.b.) based on the award amount. In addition, he/she may submit revised aims in cases where there was a significant reduction to the requested grant application amount. However, these changes should not change the original intent of the research. See Section 5.4—"Protocol Changes."
- The SRO must review and sign the document. Once the document is signed, it will be electronically returned to the Department through the DocuSign system.
- The Department-authorized signatory will sign/execute the Amendment. The Department will return an electronic executed copy to the SRO and CPI.

### **3.1.3 Policy on Length of Awards**

The grant period, total award amount, and other specific information about the grant are shown in Attachment I of the Terms and Conditions. The grant period refers to the entire life of the grant as detailed in the Terms and Conditions, from the beginning date until the conclusion of the final continuation period and any no-cost extension period. The official start date of any grant is the date in which it is signed by both the Grantee and the Department (Date of Execution) or designated beginning date, whichever is later.

### **3.1.4 Policy on Withdrawal of an Award Offer Due to Ineligibility**

Regardless of grant execution, a project cannot begin if there are any unresolved eligibility or regulatory issues.

## **3.2 ADMINISTRATIVE REVIEW AND GRANT START**

### **3.2.1 Policy on Unresolved Issues**

Regardless of grant execution, research costs may not be charged against the grant, and funds may not be disbursed if there are any unresolved eligibility or regulatory issues, including, but not limited to, budget issues and Institutional Review Board (IRB) and Institutional Animal Care and Use Committee (IACUC) approvals.

#### **Procedures**

- Between the time of the award announcement and the start of the grant period, the Grant Manager reviews the grant for compliance with the requirements stated in the FOA and the Terms and Conditions. This review may include validation of appropriate human and animal use assurances (e.g., IRB and IACUC approvals) and verification of no financial and/or scientific overlap with other funded projects.
- If any issues arise, the Department will seek a resolution with the Grantee before the grant period starts.
- Work on the project cannot begin until all issues have been resolved, even if the grant period has officially started.

### **3.2.2 Policy on Reporting Delays**

CPI will notify the Department, in writing via e-mail using the information provided in Section 2.2.3 of this manual, of any delay in starting this project, reasons for the delay, actions being taken to resolve the delay, and expected start date. Delays in starting research may result in financial penalties. Failure to keep the Department informed will result in financial consequences of 10% per invoice or grant termination.

If research requires human subjects or vertebrate animals, the Grantee must submit application(s) for all institutional authorizations included, but not limited to the Institutional Animal Core and Use Committee (IACUC), Institutional Review Board (IRB), Institutional Biosafety Committee, and Radiation Safety Review. The Grantee may request in writing to the Grant Manager authority to begin a portion of the project that does not deal with human subjects or vertebrate animal pending institutional authorization(s).

The CPI is responsible for notifying the Department if work on the project will not begin on the grant start date. The Department may contact the CPI to confirm the project has begun by the expected start date. If the grant will not start on the start date specified in the Terms and Conditions, the Department will impose financial consequences.

## **Procedures**

To report a delay in project start, the CPI must:

- Contact the Department in writing to explain the reason for the delay.
- Outline the steps that will be taken to resolve the matter.
- Provide an anticipated date for the resolution of issues and project start date.

### **3.2.3 Policy on Grant Amendments and Policy Memoranda**

The Grantee shall comply with all subsequent Department of Health grant amendments and policy memoranda.

While most changes during the grant period can be handled without amending the Terms and Conditions, some changes may require an amendment and include, but are not limited to:

- Changes that affect the grant period (no-cost extensions), key personnel changes, deliverable due dates, payment schedules, or changes to the funding amount.
- Changes to relevant Florida Statutes.
- Changes in Department funding.

If an amendment to the Terms and Conditions is needed, the Department will e-mail it to the SRO for signature.

A policy memorandum is a formal change to the Terms and Conditions affecting an entire group of Grantees. If a policy memorandum is released, the Grant Manager will notify all affected SROs and CPIs.

**Note:** The CPI is responsible for understanding and complying with the Terms and Conditions and any subsequent amendments/memoranda, in order to avoid any disqualification of expenses due to non-compliance or non-continuation of the grant during the annual review process. See Section 7.1—“Continuing a Multi-Year Grant.”

## **3.3 SPECIAL REQUIREMENTS**

### **3.3.1 Policy on Research Involving Human Subjects**

Grantee must comply with applicable federal and state laws and regulations, including 45 CFR 46, 45 CFR 160 and 164, and 21 CFR 50, 56, 312, 812, and other applicable regulations.

Grantee is responsible for safeguarding the rights and welfare of human subjects in Department-supported projects. Grantees proposing to involve human subjects in nonexempt research must provide, upon request, a copy

of the organization's Assurance of Compliance with the Office of Human Research Protections (OHRP), and must establish and maintain appropriate policies and procedures for the protection of human subjects.

Grantees are required to obtain and maintain approval from an IRB accredited by the Association for Accreditation of Human Research Program Programs (AAHRPP), or an IRB acceptable to the Department, within 60 days of notice of award. Grantees are required to follow Department policies for reporting unanticipated problems and non-compliance involving the research to the Department. The Department has authority to review IRB records related to the research.

Grantees should contact the IRB Lead, which is in the Biomedical Research Section, to determine whether review by the Department's IRB is required. Send an email of inquiry to <https://flhealth.my.irbmanager.com/>. If review by the Department's IRB is required, approval must be obtained prior to work with human subjects beginning and charging of expenses that pertain to human subjects against the grant.

When appropriate, Grantee agrees to define the arrangements for medical care for research-related injury before the research starts and communicate it to prospective research subjects. Researchers must provide subjects, through the informed consent document/process, information about who will provide medical care and who will be responsible to pay for it, should a subject experience a research-related injury.

Grantee must comply with the "NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research."

### **Procedures**

Researchers must provide documentation of IRB approval prior to research on human subjects starting. No expenses can be charged against the grant for activities that would be covered by the IRB approval, until IRB approval is obtained.

If the project involves human subjects, the CPI must:

- Provide the Department with documentation of initial and renewal IRB approvals, as well as modifications, the protocol and any applicable consent form(s). The IRB approval must include the CPI name, project title, inclusive dates for which approval has been granted, and signature of the approving authority chairperson. The project title on the IRB approval must match the title of the awarded grant.

### **3.3.2 Policy on Research during Lapses in IRB Approval**

CPI agrees to report to the Department within 48 hours any expiration of IRB approval, serious or continuing non-compliance, unanticipated problems

involving risks to subjects or others, and any suspension or termination of IRB approval. The Grantee's IRB agrees to report to the Department when reporting to federal officials any serious or continuing non-compliance or unanticipated problem involving risks to subjects or others. During the time that one or more IRB approval(s) is expired, all activities covered by the expired IRB approval(s) must stop until approval is obtained, and expenses for those activities during the expired period will be disallowed.

### **Procedures**

If the required IRB approval expires, the CPI must:

- Notify the Department within 48 hours of the expiration.
- Document that all research activities have stopped until a renewal is obtained.
- Contact the Grant Manager, Public Health Research, to obtain a determination on whether any activities may continue if expiration of IRB approval occurs. The Department has final authority over which activities may continue.
- In general, no charges against the grant may occur during the period during which IRB approval lapses.
- Submit renewed IRB approvals to the Department.

**NOTE:** Research activities (covered by the expired IRB approval) that are conducted without necessary IRB approvals are considered scientific misconduct.

### **3.3.3 Policy on Research Involving Vertebrate Animals**

CPI is responsible for the humane care and use of animals in Department-supported research activities. Grantee must abide by the Animal Welfare Act as amended (7 USC 2131-2159) and other Federal statutes and regulations relating to animals.

CPI must obtain, maintain, and provide to the Department active verification or certification of Institutional Animal Care and Use Committee (IACUC) approval before project work involving vertebrate animals can begin. The verification must include CPI name, grant title, approval and expiration dates, and signature of the approving authority chairperson.

### **Procedures**

If the project involves the use of vertebrate animals, the CPI must:

- Ensure that IACUC approvals or exemptions are received before any project work begins and are maintained for the entire grant period. The authorized IACUC with jurisdiction



over the Grantee's research institution regulates the use of vertebrate animals in research.

- Provide the Department with documentation of IACUC approval, including CPI name, project title, inclusive dates for which approval has been granted, and signature of the approving authority chairperson. The project title on the approval must match the title of the awarded grant.
- Inform the Department of any investigation or administrative action taken by the institution or any other entity with jurisdiction on any research conducted with Department funds.

### **3.3.4 Policy on Research during Lapses in IACUC Approval**

CPI agrees to report within 48 hours to the Department any expiration of IACUC approval, serious or continuing non-compliance, and any suspension or termination of IACUC approval.

During the time that the IACUC approval is expired, all activities covered by the expired IACUC approval must be discontinued until a renewal is obtained, and expenses for those activities during the expired period will be disallowed. The only activities that may continue during an expired IACUC are those activities that are clearly severable and independent from activities that involve vertebrate animals covered by the expired IACUC approval.

#### **Procedures**

If the required IACUC approval expires, the CPI must:

- Immediately notify the Department of the expiration.
- Stop all activities covered by the expired IACUC approval until a renewal is obtained.
- Submit renewed IACUC approvals to the Grant Manager.

**NOTE:** Research activities (covered by the expired IACUC approval) that are conducted without necessary IACUC approvals is considered scientific misconduct. Related expenses incurred during a lapse may not be funded by the Program.

### **3.3.5 Policy on Inclusion of Women and Minorities in Research**

CPI must comply with the "NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research."

One of the Department's goals is to mitigate the disproportionate disease burden on disparate groups. For this reason, the Department strongly encourages the inclusion of disparate groups in human subject research.

### **3.3.6 Policy on Research Involving Recombinant DNA**

All research involving recombinant DNA techniques must meet the requirements of “NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines).”

#### **Procedures**

- Refer to the publication, “NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)” for directions regarding the manipulation of genetic material using recombinant DNA techniques. The Department respects these guidelines as a universal standard for safe scientific practice in this area of research. The guidelines outline appropriate biosafety practices and containment measures and reflect new technical developments and current scientific understanding.
- Review of the research by grantee’s Institutional Biosafety Committee should be requested. The CPI must provide documentation of compliance to the Department.

### **3.3.7 Policy on Stem Cell Research**

All research involving human stem cells must meet the requirements of the “National Institutes of Health Guidelines for Human Stem Cell Research.”

#### **Procedures**

- At the time of application, investigators proposing research involving the use of any kind of stem cells will be asked to clearly disclose that in their application.
- If the research involves stem cells, in order to ensure that Department funds are used to support only stem cell research that is scientifically sound, legal, and ethical, the CPI must indicate the type of stems cells, identify the source(s) of the stem cells, and include a brief description of the relevant research activities. The Department may request additional information.
- After a project is approved for funding, any changes involving stem cell usage must be pre-approved as a protocol change. (For more information, see Section 5.4—“Protocol Changes.”)

## **3.4 AVOIDING IMPROPRIETIES IN SCIENTIFIC RESEARCH**

All work sponsored by the Department must be conducted with the highest level of ethics and respect for fiscal accountability to the citizens of Florida. CPIs must understand Department policies relating to false claims, scientific misconduct, and conflicts of interest.

False claims submitted in connection with the grant are subject to civil penalties and damages under the “Florida False Claims Act,” 68.081 – 68.092, F. S. The purpose of the “Florida False Claims Act” is to ensure that requests for payment from the State are only for materials or services that have been provided. If claims prove to be false, remedies for obtaining damages and civil penalties must be provided to the state government.

### **Preventing False Claims**

Be sure factual data can be verified including:

- Qualifications of participating researchers.
- Reported scientific data.
- Labor effort and expenses charged to the project.
- Status of other funding that may present scientific or financial overlap.

#### **3.4.1 Policy on Scientific Misconduct**

Applicants for, and recipients of, grants must immediately, within 48 hours, inform the Department of any notices of scientific misconduct or suspensions. If an administrative action for scientific misconduct is imposed by the Department of Health and Human Services (HHS), by his/her own institution, or by any other regulatory agency, the CPI must notify the Department within 48 hours, whether or not a notice of final action has been provided. CPI must provide a copy of the final notice of the administrative action (i.e., after the disposition of any appeal) to the Department either at the time of application or within thirty (30) days of the imposition of the administrative action.

Each eligible institution that receives or applies for a grant must certify establishment of administrative policies consistent with 42 CFR 50, Subpart A, “Responsibility for PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science,” and 42 CFR 94, “Public Health Service Standards for the Protection of Research Misconduct Whistleblowers.”

The Department uses the same policies and procedures employed by the NIH regarding scientific misconduct. Any administrative action for scientific misconduct must be reported to the Department immediately.

If a determination of misconduct has been made, administrative actions may include the following, depending on the nature and seriousness of the misconduct:

- Correction of the scientific literature.
- Special plan of supervision to ensure the integrity of the scientific research.

- Certification of the accuracy of the scientific data.
- Certification of the accuracy of sources and contributions for scientific ideas and writings.
- Termination of the grant.
- Disqualification from receipt of future Department funds.

### **Procedures**

If a case of scientific misconduct arises, the CPI must:

- Provide a copy of any notice of administrative action imposed by any institution or regulatory agency to the Department immediately.
- Inform the Department within 48 hours of any notices, suspensions, or other actions against a CPI or any key personnel imposed by any institution or regulatory agency.
- Provide a copy of the final notice of administrative action imposed by any institution or regulatory agency to the Department within thirty (30) days of the final notice.
- Certify that administrative policies are consistent with the statutes listed in the above policy.
- Enforce standards of conduct and take appropriate action, if necessary.
- Upon notification or determination of scientific misconduct, the Department will determine what actions to take.

### **3.4.2 Policy on Confidentiality**

The CPI shall maintain confidentiality of all data, files, documents, papers, electronic storage media, and records, including client records, and shall protect the privacy of human subjects related to the grant and all services provided. The Grantee shall not use or disclose any information concerning a human subject under the grant for any purpose not in conformity with state and federal law or regulations (including 45 CFR 46.111, 21 CFR 56.111, and 38 CFR 16.111) and IRB policies, except upon written consent of the subject, or his or her responsible parent or guardian, when authorized by law. Where applicable, the Grantee will comply with the Health Insurance Portability Accountability Act (HIPAA) as well as all regulations promulgated thereunder (45 CFR 160, 162, and 164).

### **Procedures**

The Grantee must:

- Maintain confidentiality of all data, files, and records including subject records.

- When applicable, obtain consent of the subject or responsible parent/guardian before disclosing any information concerning a patient.
- Comply with all applicable state and federal confidentiality regulations, including HIPAA.

### **3.4.3 Policy on Financial Conflicts of Interest**

The Department manages the Florida Biomedical Research Programs in general accord with the policies and procedures employed by the National Institutes of Health, including policies regarding disclosure and resolution of conflict of interest. The Grantee shall have in place an administrative process to identify and resolve financial conflicts of interest that may affect the objectivity of the proposed research. Grantee shall inform the Department of all conflicts of interest that have been identified. Grantee must describe the method by which conflicts of interest have been resolved in order to protect the grant from bias.

The Grantee shall not offer to give or give any gift and/or payments to any Department employee/staff/representative during the grant period and for at least two years after the end of the grant period pursuant to section 112.3185, F.S.

#### **Procedures**

The Grantee Institution must have the following administrative procedures and policies in place:

- Establish safeguards to prevent employees, consultants, members of governing bodies, and others who may be involved in grant activities from using their positions for purposes that are, or give the appearance of being, motivated by a desire for private financial gain for themselves or others with whom they have family, business, or other ties.
- Prepare a written standard of conduct. Separate standards of conduct for grant activities are not necessary as long as the standards in place are consistent with federal, state, and local laws. Standards need to cover, at a minimum, expected conduct in regard to financial interests; gifts, gratuities, and favors; nepotism; and other areas such as political participation and bribery.

## **3.5 OTHER CONDITIONS OF THE GRANT**

### **3.5.1 Policy on Indemnification**

Unless the Grantee is an agency or subdivision of the State of Florida or a public college or university as identified in Chapter 1004, F.S., the Grantee shall be liable for and shall indemnify, defend, and hold harmless the State

of Florida, its officers, employees, and agents to the full extent allowed by law from all losses, expenses, claims, damages, actions, suits, and judgments, consequential or otherwise and including attorneys' fees and costs, arising out of any act, actions, neglect, or omissions by the Grantee, its agents, subcontractors, or employees during the performance or operation of the grant, whether direct or indirect, and whether to any person or tangible or intangible property. Only adjudication or judgment after highest appeal is exhausted specifically finding the Grantee not liable shall excuse performance of this provision. Nothing in the grant agreement is intended to serve as a waiver of sovereign immunity, nor shall anything in the grant agreement be construed as consent by a state agency or political subdivision of the State of Florida to be sued by third parties in any matter arising out of the grant agreement. If the Grantee is an agency or subdivision of the State of Florida, the Grantee agrees to be fully responsible for its acts of negligence, or its agents' acts of negligence when acting within the scope of their employment or agency, and agrees to be liable for any damages resulting from said negligence. Nothing herein is intended to serve as a waiver of sovereign immunity by any Grantee to whom sovereign immunity may be applicable.

### **3.5.2 Policy on Liability Insurance**

The Grantee shall provide adequate liability insurance coverage at all times during the grant period. Upon execution of the grant, unless it is a public college or university as identified in Chapter 1004, F.S., the Grantee accepts full responsibility for identifying and determining the type(s) and extent of liability insurance necessary to provide reasonable financial protections for the Grantee and the clients to be served under the grant, if any. Upon execution of the grant, the Grantee shall furnish the Department written verification supporting both the determination and existence of such insurance coverage. Such coverage may be provided by a self-insurance program established and operating under the laws of the State of Florida. The Department reserves the right to require additional insurance where appropriate. Insurance must be secured from a company licensed to do business in the State of Florida.

### **3.5.3 Policy on Disputes**

Failure of the agreement to cite all applicable state and federal laws and regulations does not waive compliance requirements.

Failure of the Department to declare any default immediately upon the occurrence thereof, or delay in taking any action in connection therewith, does not waive such default. The Department shall have the right to declare any default at any time and take such action as might be lawful or authorized hereunder, in law or in equity. No Department waiver of any term, provision, condition or covenant hereof shall be deemed to imply or constitute a further Department waiver of any other term, provision,

condition or covenant hereof, and no payment by the Department shall be deemed a waiver of any default hereunder.

#### **3.5.4 Policy on Grant Amendments**

Modifications of provisions of the agreement shall only be valid when they have been reduced to writing and duly signed by both parties.

#### **3.5.5 Policy on Grant Assignment**

The Department shall be entitled to assign or transfer, in whole or part, its rights, duties, or obligations under the agreement to another governmental agency in the State of Florida upon giving prior written notice to the Grantee.

### **4. ADMINISTERING THE GRANT**

#### **4.1 PAYMENT POLICIES**

##### **4.1.1 Policy on Payments**

Payments will be contingent on Grantee compliance with the Terms and Conditions and all other grant requirements. Payments are dependent on the grant being in good standing. Grants with outstanding issues may have payments held until issues are resolved.

All multi-year grants are subject to annual renewal after a review for compliance with the Terms and Conditions and satisfactory scientific progress against the project aims. More information about policies and procedures for making requests for award continuation is located in Section 7.1—“Continuing a Multi-Year Grant.” Information on No-Cost Extensions is found in Section 7.2.1—“Policy on No-Cost Extensions.”

##### **4.1.2 Policy on Payment of First Invoice**

If the project has not started 90 days after the date of execution of these Terms and Conditions, the Department will impose financial consequences of 10% per invoice or grant termination.

##### **4.1.3 Policy on Quarterly Fixed Payments**

The grant has a fixed payment schedule as shown in Attachment II of the Terms and Conditions. Payments will be contingent on Grantee’s compliance with the Terms and Conditions and all other grant requirements. The final payment will not be made until a reconciliation of all costs associated with the project is completed.

#### **Procedures**

The process for payment of grant expenses consists of these steps:

- The CPI or designee submits invoices along with all quarterly or final deliverables according to the due dates and

payment amounts outlined in Attachment II of the Terms and Conditions.

- Department staff or designee reviews these deliverables and notifies the CPI or designee if additional information or corrective actions are needed.
- Upon acceptance, Department staff or designee recommends invoice payment to the Department.
- The Department submits the invoice to the Florida Department of Financial Services (DFS) for payment. DFS may request additional information from the Department which will be requested from the Grantee.

#### **4.1.4 Policy on Total Payments**

Total payments to the Grantee cannot exceed the total award amount.

Grantees may spend the full award amount as long as the spending is in compliance with the grant's approved budget. See Section 5.1.1—“Policy on Budget Changes.”

Any project expenses exceeding the award amount will not be reimbursed.

#### **4.1.5 Policy on Final Fixed Payment**

Payment of the final invoice for the grant will take place after the end of the grant period, once all required documentation and deliverables have been received and approved. The final invoice and financial report should reflect the cumulative effect of all grant financial transactions. The final invoice amount is based on a reconciliation of all costs associated with the project. The final invoice may be adjusted and reduced for any disallowed expenditures, funds unaccounted for due to non-submission of required deliverables, or other unused grant funds at the end of the grant period. If the Grantee's expenditures indicate that they owe the Department a refund – the final payment will not be made and a refund check from the Grantee will be issued to the Department for the difference.

### **4.2 USE OF FUNDS**

The FOA may contain specific limitations on the level or type of expenses allowed for a particular type of grant. At the start of the grant, the Department works with the Grantee to ensure that the project budget is in compliance with these requirements. In addition, the following policies apply to all Department grants unless otherwise specified in the Terms and Conditions.

#### **4.2.1 Policy on Allowed Direct Costs**

Allowable costs are those which the Grantee may charge against the approved budget. All allowable costs must be tracked, monitored, and documented. There are two types of allowable costs: direct and indirect.



Allowable direct cost expenses must be directly related to the project and may include: salaries, fringe benefits, supplies, equipment, lab services, domestic travel, consultant costs, patient-care costs, animal-care costs, local or other IRB or IACUC fees (if required), or consortium or contractual costs.

Administrative costs may be included in direct cost categories, but only under the following condition: the services, functions, or activities are directly necessary for the grant, the administrative costs have not been included in the calculation of the indirect costs. The Department does not prohibit administrative costs as part of direct costs, but to be allowable, they must meet the above condition. All direct costs must be specifically and directly related to the project, necessary for the project's completion, and adequately justified.

#### **4.2.2 Policy on Travel Reimbursement**

Reimbursement for travel must be detailed in the Department-approved Budget and Budget Narrative (Attachment V.a. and V.b.) to be an allowable expense. Per Section 112.061, F.S., reimbursement for allowed travel must be at or below the current State of Florida travel rates. Only travel within the U.S. will be allowed.

All travel charged to the grant requires documentation to support travel expenses and the completion of the State of Florida or Division of Financial Services-approved travel voucher, per 112.061 (11) (b), F.S. Supporting documentation includes but is not limited to receipts for: flights, lodging, car rental, ground transportation, fuel, parking, and registration. Additionally, the meeting agenda/schedule, and a copy of any presentation made is required.

There are separate travel vouchers for in-state and out-of-state travel (these forms are available at the Department website: <http://www.floridahealth.gov/provider-and-partner-resources/research/grant-programs-resources/forms-library.html>). If a travel voucher is not completed in full and provided, the expenditures would not be considered allowable during audit and the grantee would not be reimbursed for expenses related to travel. Do not include the traveler's Social Security number on the form. The traveler and his/her supervisor must sign the travel voucher to be reimbursed.

#### **4.2.3 Policy on Human Subject Payment Reimbursement**

Reimbursement for human subject payments must be detailed in the Department-approved Budget and Budget Narrative (Attachment V.a. and V.b.) to be an allowable expense. The payment cannot exceed \$36 per day per subject and may only be provided by gift card not by cash or check. The IRB Approval(s), and referenced Protocol(s) and Consent Form(s) must be provided that includes the entire invoiced period, e.g., fiscal quarter. Also

provide a detailed participant incentive log including the subject's ID number (do not provide any personal information), amount of payment, date of payment, and form of payment.

#### **4.2.4 Policy on Tuition Waiver Reimbursement**

Reimbursement for tuition waiver(s) must be detailed in the Department-approved Budget and Budget Narrative (Attachment V.a. and V.b.) to be an allowable expense. Reimbursement for a tuition waiver must include a course description or class schedule illustrating connection to the research project.

#### **4.2.5 Policy on Subcontract Reimbursement**

Reimbursement for subcontract expenses must be detailed in the Department-approved Budget and Budget Narrative (Attachment V.a. and V.b.) to be an allowable expense. A copy of the Department-approved subcontract must be provided.

#### **4.2.6 Policy on Allowed Indirect Costs**

Indirect costs (also referred to as IDC, F&A, or administrative costs) are limited to 15% of the direct costs requested. Indirect costs are those costs that are incurred for the joint or common benefit of several separate organizational or financial components (cost centers) of an organization, which specifically or readily cannot be identified to a particular cost center, project, or program.

#### **4.2.7 Policy on Disallowed Costs**

All direct costs must be specifically and directly related to the project, necessary for the project's completion, adequately justified, and made during the grant period. Any other costs are disallowed. Additionally, grant funds shall NOT be used for: Florida Department of Health personnel, construction, renovation or remodeling, international travel (including Canada), vehicles, entertainment, employment subsidies, dues/membership fees, meals/food (other than as part of travel costs), or malpractice insurance premiums. Pursuant to Sections 11.062 and 216.347, F.S., no portion of grant funds shall be used for lobbying. No portion of grant funds may be used to reimburse travel or other expenses related to providing information to elected officials.

Use of grant funds for disallowed costs may result in financial consequences, the need for funds to be returned to the Department, or grant termination.

#### **4.2.8 Policy on Work Occurring in Florida**

It is the intent of the Department that activities funded through the Department, including data analysis, occur in Florida. One hundred percent of work (effort) must occur in Florida at the applicant's organization and any

collaborating entities. However, if pre-approved, the Department may make exceptions if the service is essential, only provided outside the state, and if the subcontract amount is less than 10% of the awarded grant amount.

In order to show the citizens of Florida that their money is being spent in Florida, the following limits apply to all grants:

- No more than 10% of all grant funds can be spent outside of Florida.
- The CPI must provide documentation that the product or service was not able to be obtained in Florida.
- The Grantee must neither assign the responsibility of this grant to another part nor subcontract for any of the work contemplated under this grant without prior written Department approval.
- The CPI shall give preference to Minority and Women-Owned Business Enterprise and Service-Disabled Veteran Business Enterprise, when applicable.

### **4.3 FISCAL ACCOUNTABILITY AND RECORDKEEPING**

Department grants are an investment by the citizens of Florida and are given for the purposes described in the FOA. The roles and responsibilities for fiscal accountability are:

- The Grantee accepts an obligation to maintain records and implement spending controls that provide clear evidence that grant funds are spent as approved.
- The Department staff is responsible for examining these records and controls to ensure the appropriate use of grant funds and for taking action when necessary to prevent or correct spending discrepancies.

Please read the policies listed below that describe specific cost-tracking and recordkeeping requirements. In certain cases, they contain prescribed consequences for unmet requirements.

#### **4.3.1 Policy on Tracking and Reporting Project Costs**

The Grantee shall establish a system to provide adequate accountability of grant funds.

#### **4.3.2 Policy on Commingling Grant Funds**

The Grantee shall not commingle grant funds with other personal or business accounts.

#### **4.3.3 Policy on Substituting Funds**

The Grantee shall not use grant funds to supplant or replace funds from other resources.

#### **4.3.4 Policy on Approved Expenses**

The Grantee shall maintain sufficient documentation of all grant expenditures as proof that such expenditures are allowable under this agreement, reasonable, and necessary for the work performed. The Grantee will not charge the Department for the value of donated goods, services, or facilities.

The Grantee shall develop a system for tracking all project costs incurred. All expenses paid with grant funds must be directly related to the project. Any grant funds utilized for purposes outside of the active, approved budget will be considered an overpayment and must be returned to the Department.

#### **4.3.5 Policy on Approved Expense Timing**

The Department will not be responsible for any project costs incurred before or after the grant period. Only project costs incurred during the grant period are eligible for payment. All project costs are subject to Department audit, and only those required for this project's use during the grant period will be allowed. The Department will notify the SRO and CPI of the grant period and start date.

A grant cannot start incurring costs related to human subjects or vertebrate animals, before all required regulatory approvals are obtained. See Section 3.3.1—"Policy on Research Involving Human Subjects", Section 3.3.2—"Policy on Research during Lapses in IRB Approval", Section 3.3.3—"Policy on Research Involving Vertebrate Animals", and Section 3.3.4—"Policy on Research during Lapses in IACUC Approval."

#### **Procedures**

Grantees should refer to this checklist to maintain fiscal accountability:

- The SRO and CPI should both have a clear understanding of the Grantee institution's internal systems, financial processes, and reporting requirements.
- Contact the Department with any questions regarding specific cost-tracking and recordkeeping requirements.
- Do not use Department funds to replace funds from existing resources or to fund activities beyond the aims of the grant.
- Keep financial information up-to-date and ready for an audit.
- Do not mix Department funds with other business/personal accounts.
- Do not use Department funds for purposes unrelated to the grant.
- Unused grant funds must be returned to the Department.
- Spend grant funds only during the grant period.

- Do not spend grant funds until the Department has approved the grant to start.
- Do not spend grant funds after the grant period has ended, even if there is still project work to do.

#### **4.3.6 Policy on Tracking Work Effort**

The Grantee shall establish a system to track work effort commitments of all key personnel. Effort certification documentation shall indicate the committed/actual work effort expended on the grant during the grant period as well as percent effort for all other duties/tasks/projects. All effort assigned to the grant must be for work directly related to the project.

The Grantee shall assure that effort certification records are available at all reasonable times for inspection, review, or audit by federal, state, or other personnel duly authorized by the Department.

#### **4.3.7 Policy on Compliance with Florida Single Audit Act**

The Grantee shall comply with the provisions of the Florida Single Audit Act, 215.97, F.S., as applicable. The following provisions apply:

The Grantee is required to maintain separate accounting of revenues and expenditures of funds and maintain sufficient documentation of all expenditures incurred (e.g., invoices, canceled checks, payroll detail, bank statements) under this grant that evidences that expenditures are:

- Allowable under the grant and applicable laws, rules, and regulations; reasonable; and necessary in order for the Grantee to fulfill the obligations under the Terms and Conditions.

#### **4.3.8 Policy on Retention of Records**

The Grantee shall retain all client records, financial records, supporting documents, statistical records, and any other documents (including electronic storage media) pertinent to the grant for a period of six (6) years after the end of the grant period. If an audit has been initiated and audit findings have not been resolved at the end of the six (6) years, the records shall be retained until resolution of the audit findings or litigation, which may be based on the terms of the grant.

#### **4.3.9 Policy on Access to Grant Records**

The Grantee shall assure that records shall be subject at all reasonable times to inspection, review, or audit by federal, state, or personnel duly authorized by the Department. Persons duly authorized by the Department shall have full access to and the right to examine any of the Grantee's grant and related records and documents, regardless of the form in which kept, at all reasonable times for as long as records are retained. Upon termination

of the grant, and at the request of the Department, the Grantee will cooperate with the Department to facilitate the duplication and transfer of any said records or documents during the required retention period. The Department unilaterally reserves the right to terminate the grant if the Grantee refuses to allow public access to all documents, papers, letters, or other materials subject to provision of Chapter 119, F.S., made or received by the Grantee or its contractor in conjunction with the grant.

## **4.4 EQUIPMENT**

### **4.4.1 Policy on Property/Equipment**

Property and equipment is defined as non-expendable, tangible property having a useful life of more than one year with a cost of \$1,000 or more. All property and equipment purchased with grant funds must be (1) necessary to carry out the proposed research, (2) justified to and pre-approved by the Department, (3) inventoried and tracked throughout the grant period, and (4) protected with sufficient insurance and security safeguards.

#### **Procedures**

When purchasing property and equipment, the Grantee must:

- Charge equipment purchases to the grant only if they are necessary for the approved project.
- Only purchase equipment that has been included in the active, approved budget or for which a budget change request has been approved. See Section 4.4.3—“Policy on Equipment Budget Changes.”
- Inventory and track equipment throughout the entire grant period.
- Protect equipment with appropriate security measures.
- Buy appropriate insurance to protect property/equipment.
- Maintain records for all property and equipment.

### **4.4.2 Policy on Timing of Property and Equipment Purchases**

All approved property and equipment must be purchased and received prior to the last 90 days of the grant period, unless prior written approval from the Department has been obtained. To request written approval for an equipment purchase during the last 90 days of the grant period, the CPI must send an e-mail request to the Department that contains:

- A brief description and purpose of the equipment.
- Equipment cost.
- Justification for purchase during the final 90 days of the grant period.

The Grant Manager will attempt to notify the CPI of a decision within ten business days of the request.

#### **4.4.3 Policy on Equipment Budget Changes**

Any over-spending in the equipment category must be justified to and pre-approved by the Department.

Any equipment purchase requires justification and Department approval before spending occurs if it is not already in the approved budget. Equipment listed in the original application budget received approval at the time of funding, unless specifically disallowed in the award notice or changed via a budget adjustment.

##### **Procedures**

When requesting a change in the budget for equipment purchase, the CPI must:

- Complete and submit the Budget Change Request form via e-mail to [Research@flhealth.gov](mailto:Research@flhealth.gov) and copy the Department's assigned Grant Manager.

The Department will attempt to approve adjustment requests within ten business days of receipt of the request. If the information submitted is incomplete or in error, the Department will decline the request and the CPI will receive a decline e-mail notification with instructions, otherwise, the CPI will receive an approval e-mail notification. The Department will provide an approved signed copy of the Budget Change Request form to the CPI and the institutional financial contact.

If the Department determines that expenditure changes are too numerous or significant, it may be necessary to submit a new budget form containing the signature of the Sponsored Research Official.

#### **4.4.4 Policy on Disposition of Property and Equipment**

All equipment purchased with grant funds is the property of the eligible institution, and is subject to Chapter 273, F.S., dealing with state-owned tangible personal property and the disposition thereof. For research institutions not covered under Title XLVIII, F.S., equipment no longer deemed to be useful shall remain state property and must be transferred or donated to a state agency or public university for redistribution or disposition.

One of the goals of the Department is to increase the infrastructure needed to conduct research in Florida. For this reason, all equipment purchased for research supported by a State of Florida Biomedical Research Grant Program, should continue to be used for research in the State after the end of the grant period.

## **Procedures**

To dispose of property or equipment purchased with Department funds the Grantee must:

- Coordinate equipment disposal with the institution property manager or custodian, if it is no longer useful to the institution.
- Seek to donate equipment to another location within the biomedical research community within the State of Florida.

**Note:** For research institutions not covered under Chapter 273, F.S.:  
Dispose of property purchased with Department funds by contacting the nearest public university in order to transfer the equipment into the State's pool of property.

## **5. MAKING CHANGES TO A GRANT**

### **5.1 BUDGET CHANGES**

#### **5.1.1 Policy on Budget Changes**

The approved budget is the annual budget approved by the Department at the beginning of the grant period and includes any approved budget adjustments. The Department will reimburse the Grantee for allowable, reasonable, and necessary costs as detailed in the line items of the approved budget.

The Department must review and approve any deviation from the approved budget. Any overspending in any category must be justified to and pre-approved by the Department. Any revisions to the previously approved budget must be submitted to the Grant Manager on the Budget Change Request form reflecting the changes and justification. Revisions will become effective upon approval and signature by the Department and signature by the CPI.

The Department reserves the right to: 1) require further justification, 2) reject any disallowed costs, and 3) request new/revised budgets as necessary.

- All equipment budget increases must be justified to and pre-approved by the Department. See Section 4.4.3—"Policy on Equipment Budget Changes."
- All personnel budget increases must be justified to and pre-approved by the Department with a Budget Change Request.

## **Procedures**

To initiate changes to the approved budget, the CPI must:

- Complete and sign the Budget Change Request Form.



- Submit it via e-mail to [Research@flhealth.gov](mailto:Research@flhealth.gov) and copy the Department's assigned Grant Manager.

The Department will attempt to approve adjustment requests within ten business days of receipt of the request. If the information submitted is incomplete or in error, the Department will decline the request and the CPI will receive a decline e-mail notification with instructions, otherwise, the CPI will receive an approval e-mail notification. The Department will provide an approved signed copy of the Budget Change Request form to the CPI and institution financial contact.

## **5.2 KEY PERSONNEL CHANGES**

### **5.2.1 Policy on Changing Key Personnel**

Project key personnel include the CPI, Project Director, Mentor, and other project personnel noted as such in the grant application. Prior Department approval is required to change (replace) the Project Director, CPI, and/or Mentor within the awarded institution.

A Project Director or CPI cannot be changed to another Project Director or CPI prior to the approved start of the grant or within the first year of the grant period.

The amount of effort of the Mentor must remain above the minimum percent required in the FOA. Prior Department approval is required for Mentor effort changes only if the change results in a percent effort below the required minimum percent.

### **Key Personnel Changes**

To replace or change the percent effort or salary of Key Personnel, the CPI must:

- Refer to the FOA before making changes in research personnel. There are special requirements such as restrictions on percent effort and salary.
- Complete the Key Personnel Change/Change in Effort form and submit to the Department via e-mail at [Research@flhealth.gov](mailto:Research@flhealth.gov).
- In the form, explain the need for the change and justify the replacement or change. Include a biographical sketch of the replacement.
- Complete a revised budget or Budget Change Request form, if the key personnel change affects more than one budget category.
- Obtain the required signatures.

- Submit it via e-mail to [Research@flhealth.gov](mailto:Research@flhealth.gov).
- Copy the Department's assigned Grant Manager.
- The Department will review the request and will attempt to approve or deny the request within ten business days. If the information submitted is incomplete, the Department will decline the request and the CPI will receive a decline e-mail notification with instructions, otherwise, the CPI will receive an approved copy of the Key Personnel Change/Change in Effort form by e-mail notification.

### **5.2.2 Policy on Changing a Corresponding Principal Investigator's Effort**

Reductions in Project Director or CPI effort are not allowed within the first year. Prior Department approval is required for a change in Project Director and/or CPI percent effort. Changes to either of these roles without the prior approval of the Department will result in a 10% financial consequence per invoice or grant termination. The amount of effort of the Project Director and/or CPI must remain consistent with the approved budget and any approved adjustments. To change a Project Director or CPI's percent effort, the CPI must:

- Refer to the FOA before requesting effort and salary changes. Specific grant mechanisms may have special requirements or restrictions on minimum effort commitment or maximum salary amounts.
- Complete the Key Personnel Change/Change in Effort form. Indicate the change and explain the need for the change.
- Prepare a revised Budget Change Request, if applicable.
- Obtain the required signatures.
- Submit it via e-mail to [Research@flhealth.gov](mailto:Research@flhealth.gov) and copy the Department's assigned Grant Manager.
- The Department will review the request and will attempt to approve or deny the request within ten business days. If the information submitted is incomplete, the Department will decline the request and the CPI will receive a decline e-mail notification with instructions, otherwise, the CPI will receive an approved copy of the Key Personnel Change/Change in Effort form by e-mail notification.

### **5.3 ASSIGNMENT AND SUBCONTRACTS**

One of the goals of the Department is to develop the research capacity of investigators in Florida and their Florida-based institutions. For this reason, collaboration among eligible institutions is encouraged.

### **5.3.1 Policy on Assignment and Subcontracts**

The Grantee shall neither assign the responsibility of the grant to another party nor subcontract for any of the work contemplated under the grant without prior written approval of the Department. Any sub-license, assignment, subcontract, or transfer otherwise occurring shall be null and void. No subcontracts or sub-grants will be authorized that involve researchers outside of the State of Florida. However, the Department may make exceptions if the service is essential and only provided outside the state, and if the subcontract or sub-grant amount is less than 10 % of the awarded grant amount. The Grantee shall be responsible for all work performed and all expenses incurred for the grant. If the Department permits the Grantee to subcontract part of the work contemplated under the grant, including entering into subcontracts with vendors for services and commodities, it is understood by the Grantee that the Department shall not be liable to the subcontractor for any expenses or liabilities incurred under the subcontract and the Grantee shall be solely liable to the subcontractor for all expenses and liabilities incurred under the subcontract. To the extent permitted by Florida law, the Grantee, at its expense, will defend the Department against such claims.

#### **Procedures**

If extraordinary circumstances arise that result in a need to assign or subcontract grant work that was not specified in the application, the CPI must:

- Contact the Department and obtain prior written approval. The Department will provide guidance for making any appropriate changes.
- Set up appropriate accounting and reimbursement procedures. The Grantee is responsible for all expenses made by the subcontractor.
- Provide the Department with a copy of the subcontract agreement.

## **5.4 PROTOCOL CHANGES**

### **5.4.1 Policy on Protocol/Project Changes**

The Grantee shall complete the work as described in the application. All project adjustments from those which were proposed in the application, including changes in the approach, designs, aims, or research plans, and any changes requiring IRB and/or IACUC approval, must be submitted in writing and is subject to Department approval prior to the change taking place. Failure to receive prior Department approval will result in financial consequences.

With the Department's approval, minor changes in planned work (including experiments) and methods from the original application would be allowed. However, major changes, such as removing or substantially changing a specific aim of a project, will undergo more careful analysis. This is because the modified project may deviate too far from the originally awarded, peer-reviewed work. The Department may seek a recommendation from scientific experts in evaluating the requested change(s).

**Note:** Any change in stem cell use is considered a protocol change that requires prior Department approval.

### **Procedures**

To request a protocol change in project activities, aims, designs, or research plans, the CPI must:

- Submit a Protocol Change Request form via e-mail to [Research@flhealth.gov](mailto:Research@flhealth.gov) and copy the Department's assigned Grant Manager.
- Obtain IRB or IACUC approval for the change, if appropriate.

The Department will review the request and will attempt to approve or deny the request within ten business days. If the information submitted is incomplete, the Department will decline the request and the CPI will receive a decline e-mail notification with instructions, otherwise, the CPI will receive an approval e-mail notification along with a copy of the signed approved Protocol Change Request form.

## **5.5 OTHER SUPPORT AND FINANCIAL OVERLAP**

### **5.5.1 Policy on Other Support**

Other Support is defined as all financial resources, whether federal, state, private, commercial, or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards (not included are training awards, prizes, or gifts). Financial overlap is defined as accepting financial compensation from one or more other support sources for the same or substantially similar scientific aims/projects that are funded by the Department. Financial overlap is not permitted. The Grantee is responsible for monitoring changes in other support for project key personnel to avoid financial overlap. The Grantee is responsible for notifying the Department of such changes and for resolving overlap or requesting an amendment to prevent overlap. If financial overlap is due to receipt of an award from another funding source during the grant period, the Grantee must immediately notify the Department and resolve the overlap by: a) modifying the start date or project aims of the new award to eliminate the overlap or b) relinquishing one of the awards. Updated information on other

support may be requested by the Department at any time during the grant period.

### **Procedures**

The CPI must keep the Department informed of any changes in support for or commitment of key personnel by following these guidelines:

- Notify the Department in writing regarding any changes in key personnel's time commitments, changes in other support, and/or overlap situations that may affect the grant.
- Complete updates on other support and key personnel at the time of award, at a change, in yearly reports, or if there is potential overlap.
- Include details of the change, such as source of alternate funding, award amount and term, and relationship to the Department grant.

The Department reviews this information and notifies the CPI if additional information is required to make a decision. Where overlap is substantial, the CPI must make a choice between the Department grant and the alternate award. For minor overlap, the CPI may resolve the overlap situation by proposing a solution to the Department that removes the affected scientific aims/projects from either grant and makes corresponding adjustments to the budget and potentially the grant award amount.

#### **5.5.2 Policy on Commitment Overlap**

An individual's effort cannot total more than 100%, including all research and other activities. It is the responsibility of the Grantee and CPI to monitor the percent effort of all project personnel and to resolve any conflicts.

## **6. REPORTING AND MONITORING THE STATUS OF A GRANT**

The Grantee will provide reports and agrees to make all reasonable efforts to assist the Department in gathering data required for reporting to the Legislature and Governor pursuant to Sections 215.5602(10) and 381.922(6), F.S., both during and after the grant period. Upon request, Grantee agrees to report to the Department a description of all research outcomes resulting from the grant, including but not limited to publications, presentations, published reports, databases, additional grants and monies received, patents, invention disclosures, copyrights, health impacts, community involvement, new partnerships, start-up companies, and progress towards commercialization. The Department must be able to show good stewardship of Florida's investment. The Department will present information provided by Grantees in Department annual reports, Department evaluations, and other reports to the Governor and Legislature.

Failure to comply with all deliverables required may have a negative effect on the Grantee's invoice payment, award continuation, or future funding opportunities.

## 6.1 REQUIRED FINANCIAL REPORTS AND INVOICES

The Grantee shall prepare and submit to the Department throughout the grant period: financial reports, narrative progress reports, and other deliverables as outlined in Attachment II of the Terms and Conditions. Reports must be prepared according to the format specified by the Department. Grantee must request payment using the Department's invoice form.

Reporting grant status includes two aspects: financial management and scientific progress. Reporting requirements are shown in Attachment II of the Terms and Conditions. This section describes the required financial reporting in more detail. The latest forms for all deliverables are available on the Department's Grant Management Forms Library website: <http://www.floridahealth.gov/provider-and-partner-resources/research/grant-programs-resources/forms-library.html>.

### 6.1.1 Policy on Approved Budget and Payment Requirements

Failure to submit the invoice and all required documentation and deliverables by the due date(s), or any other non-compliance with the Terms and Conditions, shall result in financial consequences of 10% per invoice or grant termination (check your grant's Terms and Conditions for specifics).

The Grant Budget (Attachment V.a.) must be approved before project work can begin. It must also be approved in the Budget Narrative (Attachment V.b.) and prior to any budget adjustments.

#### Procedures

Grantees must submit invoices and financial reports that track expenditures against the approved budget.

- To change the approved budget, see Section 5.1—"Budget Changes."
- The CPI and the appropriate financial support individual(s) should work together to create and review financial reports for the Department on a regular basis. While many people within the Grantee institution may provide support for the preparation of financial reports, the CPI is responsible for ensuring the accuracy and timely completion of financial information submitted including invoices, financial reports, expenditure tracking forms, and any other project information listed as deliverables in Attachment II.

### 6.1.2 Policy on Submitting Invoices and Financial Reports

The Grantee must request payment using the Department's invoice form. The project expenses will be reviewed for appropriateness against the approved budget. The Grantee will invoice the Department for the amount specified in Attachment II of the Terms and Conditions. Financial reports

track grant expenditures against the approved budget. Reports must be prepared according to the format specified by the Department.

### **Invoice and Financial Report Review**

After the invoice and financial report are submitted by the CPI, the following steps occur:

- The Department reviews invoices and financial reports against the approved budget. The Department will return the report if there are issues or concerns such as budget errors, incorrect invoice amount, incorrect form, or period covered.
- If requested, the CPI must supply additional information or clarification and if applicable, resubmit the modified report(s).
- After all issues, if any, are resolved, the Department will voucher the invoice, financial report, progress summary, and any other deliverable due and forward it to Finance and Accounting. After their review, the documents will be forwarded to the Florida Department of Financial Services for review and payment.

**Note:** If there is any overspending in any category, then the CPI will need to submit a Budget Change Request form to obtain proper spending authority within the overspent category. See Section 4.4.3—“Policy on Equipment Budget Changes” and Section 5.1.1—“Policy on Budget Changes” for policy and procedures on changing a budget. The Department reserves the right to declare expenditures under these conditions “disallowable”. CPIs must plan and track expenses within each category as carefully as possible to minimize the number of times the budget may need adjustment. If the overspending is due to error, the error should be corrected and a revised financial report and any applicable expenditure tracking forms should be submitted to the Department.

For procedures for submitting the final invoice and financial report, see Section 7.4.1—“Policy on Final Payment.”

## **6.2 REQUIRED SCIENTIFIC PROGRESS REPORTS**

### **6.2.1 Policy on Submitting Required Progress Reports**

The Grantee shall prepare and submit to the Department throughout the grant period financial reports, progress reports, and other deliverables as outlined in Attachment II of the Terms and Conditions. Reports must be prepared using the latest revision of the applicable Department form. The latest forms for all deliverables are available on the Department’s Grant Management Forms Library website: <http://www.floridahealth.gov/provider-and-partner-resources/research/grant-programs-resources/forms-library.html>.

There are four Progress Reports that could be due during the grant period. They are the Quarterly, Grant Continuation, Grant Legislative, and Final Cumulative Grant Progress Reports. Progress reports provide a means of accountability and a record of significant accomplishments. Progress reports also serve other important purposes including:

- To satisfy overall Department accountability and progress requirements. The Department may use independent peer reviewers to evaluate these reports. This review helps the Department accurately assess scientific progress for highly diverse scientific and technological projects, and provides the CPI with another source of helpful, authoritative, and meaningful feedback to ensure a successful outcome for the project.
- To allow the Department an opportunity to gather and share significant accomplishments toward Department goals.
- To provide information to characterize and promote the valuable findings gained by the State's sponsorship of this research with the State Surgeon General, the Governor, the Legislature, and other Florida constituents who may have an interest in the research.
- To provide questions to assess project status, for example:
  - How much of the planned work is complete?
  - What are the most significant findings to date?
  - What problems or unexpected outcomes, if any, are there, and how have they been addressed?
  - What are the project milestones for the next year (if applicable)?
  - How are findings publicized from this project?
  - Has this work led to other funding?
  - Has this work led to any patent applications?

### **Types of Required Progress Reports**

#### Quarterly Progress Report

The quarterly progress report is intended to provide a summary, by grant aims, of the progress that has occurred on this grant during the quarter. Submitted reports must be signed by the CPI and SRO or their designee. Demonstration of progress is reviewed and is a major factor in determining if the quarter's invoice will be paid in full.

#### Grant Continuation Progress Report

This report is due annually for multi-year awards with ending dates more than one year in the future. This report, along with the Quarter's Financial



and Expenditure Report will be submitted for independent assessment by scientific peer reviewers. These reviewers will only have access to these reports to determine if sufficient progress has been made to continue funding the research project for another state (*July to June*) fiscal year. After this review is complete, the Grantee will be notified of the outcome. Demonstration of significant progress is a major factor in the annual funding continuation. Submitted reports must be signed by the CPI and SRO.

#### Grant Legislative Progress Report

This progress report is intended to provide annual synopsis of the scientific progress of your grant to the Governor and the Florida Legislature. The Report will be submitted to the Florida Legislature and Governor pursuant to Section 381.82(4), F.S. for Alzheimer's grants. For Bankhead-Coley (BHC), James and Esther King (JEK), and Live Like Bella (LLB) grants, this report will be submitted pursuant to Section 381.922(4)(a) F.S. These sections of the Florida Statutes and other laws, as applicable, pertain both during and after the grant period. The Legislative Progress Report must be submitted by the date defined in the Attachment II of the Terms & Conditions. For BHC, JEK, and LLB grants, the submission date is July 31st of each year. For Alzheimer's grants, the submission date is October 31st of each year.

#### Final Cumulative Grant Progress Report

This report is intended to provide details of the grant's scientific progress achieved for the entire grant period. The report should include details of the progress by grant aims. Also, all peer-reviewed publications, follow-on funding, new investigator training, presentations, collaborations, and patents that were a result of the grant should be included. Submitted reports must be signed and dated by the CPI and SRO.

#### **Progress Report Review**

After a report is submitted, the following steps occur:

- The Department reviews the report for completeness and progress. If there are issues, the CPI will receive an e-mail notification that the report is deficient and may have an opportunity to provide additional information.
- For the Grant Continuation Progress Report, independent peer reviewers may review the report and ask questions or make suggestions regarding the research. Their comments form an evaluation report and determine funding continuation. The Department notifies the Grantee and CPI when the evaluation report is complete and whether funding is to be continued.

- The Department may require follow-up activities from the Grantee and CPI including but not limited to a response to the peer-reviewed evaluation report.

## **6.3 SITE VISITS**

### **6.3.1 Policy on Grant Monitoring**

The Grantee shall permit persons duly authorized by the Department to inspect any records, papers, documents, facilities, and/or goods and services of the Grantee that are relevant to the grant, and/or interview any clients, subcontractors, and employees of the Grantee to assure the Department of satisfactory performance of the terms and conditions of the grant. Monitoring may take place at any time during the grant period or records retention period, with reasonable advance notice, during normal business hours. Following such evaluation, the Department may deliver to the Grantee a written report of its findings and may include written recommendations with regard to the Grantee's performance of the Terms and Conditions of the grant. The Grantee will correct all noted deficiencies identified by the Department within the specified period of time set forth in the recommendations. The Grantee's failure to correct noted deficiencies may, at the sole and exclusive discretion of the Department, result in any one or a combination of the following: (a) the Grantee being deemed in breach or default of this agreement; (b) the withholding of payments to the Grantee by the Department; (c) the termination of the grant.

Department staff attempt to visit multi-year Grantees one time during the grant period in order to:

- Increase Department familiarity with the research project.
- Determine compliance with the Terms and Conditions.
- Examine financial records and controls.
- View work space and equipment purchased with grant funds.
- Review project progress and performance.
- Review applicable IRB, IACUC, or Institutional Biosafety Committee records.
- Make recommendations to resolve or prevent any problems.
- Obtain feedback from the Grantee regarding improvements to the Department.

#### **Procedures**

- The Department contacts the SRO to schedule a site visit for current active Grantees. If it is too early for some newly awarded grants, they may be rescheduled for a subsequent site visit.

- The Department provides detailed information regarding what to expect during the visit and the type of information that will be requested from the Grantee.
- An agenda for the onsite visit includes a brief presentation by the CPI, comments by the Mentor (if appropriate), followed by a question and answer period, a possible tour of the project laboratory/workspace, review of project records (financial, time keeping, etc.), review of select institutional policies and procedures, review of regulatory binders, and a closing meeting summarizing feedback from the visiting team.
- The Department will request financial information for offsite audit and will provide instructions for delivering the requested information.
- The site visit team will request feedback from the Grantee regarding Department improvements at the closing meeting.
- Within 60 days of the completion of the site visit and all offsite record auditing, the Department may provide a report documenting findings and providing recommendations for any problems encountered.
- The Department will give the Grantee a reasonable amount of time to correct problems and respond to the site visit report. Failure to respond to and comply with corrective actions is a violation of the Terms and Conditions and may be cause for grant termination.

## **6.4 PUBLICIZING RESEARCH RESULTS**

### **6.4.1 Policy on Publications, Presentations, and Printed Reports**

Any publications, presentations, printed reports, or resulting research findings related to the grant shall acknowledge the appropriate funding source: James & Esther King Biomedical Research Program, Florida Department of Health, William G. “Bill” Bankhead, Jr., and David Coley Research Program, Florida Department of Health, Live Like Bella Initiative, Florida Department of Health, or Ed and Ethel Moore Alzheimer’s Disease Research Program, Florida Department of Health. The Grantee must notify the Department in writing of all publications, presentations, printed reports, and resulting research findings created for this project both during and after the grant period for up to six years.

The Department tracks the numbers of presentations, published abstracts, journal articles, chapters in books, and papers. Publication in peer-reviewed journals is of particular value to the Department. The Department’s annual reports list all Grantee publications for that year. Sharing this information informs, inspires, and feeds the work of other qualified researchers.

#### **6.4.2 Policy on Open Access of Publications**

Publishing a scientific paper is a transaction whereby the author(s) receive credit and status in exchange for sharing their scientific findings. Authors have a responsibility to make available materials, databases, and software integral to their findings so that others may validate or refute the results and/or extend them in new directions. Grantees funded through this Department are encouraged to use materials transfer agreements to make materials, data and databases, and software, that result from this funding and which is integral to their research findings, freely and promptly available upon request for research use by other scientists.

One of the Department's goals is to increase collaboration in order to discover cures as quickly as possible. For this reason, and in accord with the NIH notice NOT-OD-08-033, Grantees shall submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscript upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication, in a manner consistent with copyright law. This applies to all publications resulting from Department-funded projects/research. For more information on the NIH Access Policy visit: <http://publicaccess.nih.gov/>.

#### **6.5 PATENTS, COPYRIGHTS, AND ROYALTIES**

One of the Department's goals is to bring new inventions from "the bench to the bedside" in order to maximize the return on the Department investment made possible by the citizens of the State of Florida and to improve the health and well-being of Floridians. The Department also strives to preserve the rights of the Grantee to any commercial value resulting from Department-sponsored research.

The following provisions apply to all intellectual property created under the grant:

- All intellectual property is the property of the Grantee.
- The Department shall have a fully paid up, royalty-free, non-exclusive, non-transferable, irrevocable license to practice or have practiced or to use or have used the invention on behalf of the State of Florida.
- It is expected that the Grantee shall make reasonable efforts to commercialize inventions that result from Department-funded research through patenting and licensing and shall make reasonable efforts to give preference to Florida-based companies.

### **6.5.1 Policy on the Disclosure of Inventions**

The Department manages the Florida Biomedical Research Programs in general accord with the policies and procedures employed by the NIH, including those that apply to intellectual property, patent rights, inventions, and commercialization, including the Bayh-Dole Act (37 CFR 401). The following provisions shall apply to all inventions, including intellectual property, created under a Department grant:

- All inventions shall be the property of the Grantee or business partner if a written agreement has been executed; and Grantee shall retain the entire right, title, and interest to such.
- The Department shall have a fully paid up, non-exclusive, non-transferable, irrevocable license to practice or have practiced or to use or have used the invention for or on behalf of the State of Florida.
- The Grantee shall disclose all inventions to the Department within two months of patent application and/or any licensing event, and will subsequently report on commercialization progress regarding patenting (filing dates and issue dates), licensing, and commercialization events.
- The Grantee shall make reasonable efforts to commercialize such invention through patenting and licensing and shall make reasonable efforts to give preference to Florida-based companies.
- If the Grantee seeks to apply for copyright, trademark, or patent when commercially reasonable for any property created, developed, or invented as a result of services provided under the grant, the Grantee shall furnish the Department with a description of said property and a copy of any licensing obtained.
- The Grantee shall report to the Department, upon request, any progress in securing or exploiting such inventions, trademarks, copyrights, or patents both during and up to six years after the grant ends.
- It is expressly agreed that neither Grantee nor Department transfers by operation of this Agreement to the other party any right in or license to any patents, copyrights, or other proprietary right owned as of the commencement date of the Agreement or arising outside of the research conducted under the Agreement.

#### **Procedures**

The Department strongly recommends the Grantee:

- Seek legal protection in the form of invention disclosures, patents, copyrights, and/or trademarks, as appropriate, for new intellectual property, inventions, methods and processes, literary works, names, and symbols.
- Once they are protected, commercialize these assets by licensing, selling, or donating rights to qualified companies, preferably those located in Florida.
- Notify the Department, in writing, within two months to report inventions and subsequent filing and granting of a patent or trademark including the date, type and subject of protection, name of the official owner, and patent or registration number. (Note: The Department does not need to see the actual invention disclosure, patent filing, or intellectual property.)
- Report progress toward commercialization on all inventions in the narrative progress reports.

## **7. CONTINUING OR ENDING A GRANT**

### **7.1 CONTINUING A MULTI-YEAR GRANT**

#### **7.1.1 Policy on Continuation of Multi-Year Grants**

In the case of multi-year grants, annual continuation is not automatic. A Grant Continuation Progress Report must be submitted according to the schedule in Attachment II of the Terms and Conditions (see 6.2.1, Policy on Submitting Required Progress Reports). Grant continuations shall be made contingent upon satisfactory project performance and compliance with the grant's Terms and Conditions.

Upon award, the Department reserves the full amount awarded for multi-year grants in order to continue payments for the entire grant period. However, authorization to continue work from one State fiscal year to the next is based on project performance and is contingent upon annual appropriation by the Legislature, and/or the availability of funds. At the end of each calendar year of the grant, a full or partial audit may be conducted, including: administrative and peer review of the annual Grant Continuation Progress Report, review of site visit results, and a financial audit. Only grants considered in good standing will be authorized to continue work.

#### **Procedures**

- See the Deliverable Schedule (Attachment II) in the grant's Terms and Conditions for actual due dates.

### **Continuation Request Review**

After the required forms are submitted, the Department evaluates the request on the basis of the following:

- Justification of the budget.
- Scientific progress is peer reviewed and measured against the specific aims, as shown in the progress report.
- Compliance with the Terms and Conditions.
- If there are issues, the CPI will receive an e-mail notification that the task is returned.
- The Department sends a continuation or denial letter to the SRO, with a copy to the CPI. Continuation may be granted in full or with conditions. If granted with conditions, the conditions will be explained in the letter. An example of a potential condition is a requirement for the CPI to provide an interim progress report.
- If continuation is approved by the Department, the CPI will formally respond to any questions, comments, or suggestions presented by the peer reviewer(s) of the Grant Continuation Progress Report in a reasonable timeframe. If the continuation is denied, the Department will terminate the grant. See Section 7.3.1—“Policy on Early Terminations without Cause.”

## **7.2 EXTENDING THE GRANT PERIOD**

### **7.2.1 Policy on No-Cost Extensions**

The Department may grant an extension of the grant period without additional funds (No-Cost Extension) upon request. A No-Cost Extension shall be made contingent upon satisfactory project performance and compliance with the grant’s Terms and Conditions. The grant period for all grants, including extensions, may not exceed 5.5 years. The Request for No-Cost Extension along with a Cumulative Grant Progress Report must be submitted by the due date shown in Attachment II of the grant’s Terms and Conditions.

The Department strongly prefers that CPIs complete projects according to the original schedule outlined in the Terms and Conditions. Under extraordinary circumstances, the Department may grant a No-Cost Extension. The availability of unspent funds or a late start is not sufficient reason to request a No-Cost Extension. The Department will not support additional research beyond the approved aims of the funded project. A No-Cost Extension requires an amendment to the Terms and Conditions to extend the grant period and change funding and reporting schedules.

## Procedures

### Requesting a No-Cost Extension

The CPI may submit a Request for No-Cost Extension form by following these steps:

- Prepare and submit the Request for No-Cost Extension on or before the due date shown in the grant Terms and Conditions. The request should be sent via e-mail to Research@flhealth.gov and a copy sent to the Department's assigned Grant Manager.
- A completed Cumulative Grant Progress Report must also be submitted at the same time as the Request for No-Cost Extension form for the request to be considered. See Section 6.2—"Required Scientific Progress Reports."

### No Cost Extension Request Review

After the required forms are submitted, the following steps occur:

- The Department evaluates the request on the basis of the following:
  - Justification of the budget.
  - Scientific progress, measured against the specific aims, as shown in the progress report.
  - Compliance with the Terms and Conditions.
- If denied, the Department will send a denial letter to the SRO, with a copy to the CPI, prior to the end of the grant.
- If approved, an amendment to the Terms and Conditions will be required. The grant will not be officially extended until the grant amendment is signed by both parties.

## 7.3 EARLY TERMINATION

### 7.3.1 Policy on Early Terminations Without Cause

Regardless of the cause of termination, the Grantee must comply with the Terms and Conditions of the grant at all times during and after the grant period. The Grantee may be reimbursed for allowable costs incurred during the grant period up to the total amount of the award.

The grant may be terminated by the Department or by the Grantee with no less than a 30-day notice in writing, without cause, at no additional cost, unless a different notice period is mutually agreed upon by the parties.



In the event funds to finance the grant become unavailable, the Department may terminate the grant with no less than a 24-hour notice in writing to the Grantee. The Department shall be the final authority as to the availability and adequacy of funds.

Either party may end a grant with a 30-day advance written notice.

- The Grantee may be reimbursed for allowable costs incurred and any irrevocable charges through the date of termination up to the total award amount.
- The CPI must reconcile all grant expenses, submit all deliverables scheduled at the end of the grant period as detailed in Attachment II within 60 days of the termination date, and return any unspent funds to the Department. (For more information about final financial and progress reports, see Section 6.1 —“Required Financial Reports” and Section 6.2 —“Required Scientific Progress Reports”).

## **7.4 CLOSING A GRANT**

At the end of the grant period, Grantees must prepare a Final Cumulative Grant Progress Report, reconcile all grant expenses, submit the Final Invoice, Final Expenditure Report, and Final Financial Report, and return any unspent funds to the Department.

### **7.4.1 Policy on Final Payment**

Payment of the final invoice for the grant will take place after the end of the grant period once all required documentation and deliverables have been received and approved.

The final invoice will be paid only after all deliverables have been submitted to and approved by the Department.

#### **Procedures:**

Grantees must complete these tasks to conclude the grant:

- The SRO and CPI should review the Terms and Conditions to ensure that all required deliverables have been submitted by the due dates.
- Review all costs charged to the grant for appropriateness.
- Post any late charges to reconcile the total expenses to the approved budget.
- Submit a Final Cumulative Grant Progress Report within 60 days of the end of the grant period unless otherwise specified otherwise in the Terms and Conditions. This final report must cover the entire grant period.

- Submit the final financial report within 60 days of the end of the grant period unless otherwise specified otherwise in the Terms and Conditions. This final report must cover the entire grant period and identify any unspent funds.
- Submit the final invoice within 60 days of the end of the grant period unless otherwise specified in the Terms and Conditions. The final invoice amount is based on a reconciliation of all costs associated with the project.
- Contact the Department with any concerns about final reports.

#### **7.4.2 Policy on Return of Funds**

The grant is a fixed payment grant. Therefore, the Grantee shall return to the Department any overpayment of grant funds related to disallowed expenditures, funds unaccounted for due to non-submission of required deliverables, or other unused grant funds at the end of the grant period. In the event that the Grantee or its independent auditor discovers that overpayment has been made, the Grantee shall repay said overpayment within 90 calendar days of grant end date without prior notification from the Department. In the event that the Department first discovers an overpayment has been made, the Department will notify the Grantee of such a finding. Should repayment not be made in a timely manner, the Department may withhold the amount of the overpayment from any future payments under this or any other agreement. Failure to return unspent funds to the Department may affect future funding opportunities through the Department. This provision shall not be a limitation on any remedies at law or equity available to the Department.

Returning unspent funds can happen at any time during the grant period. However, return of unspent funds is usually the last task a Grantee must complete before a grant is officially closed.

**Note:** If the final invoice has been adjusted and decreased accordingly, there should be no overpayment, and therefore no unspent funds to return to the Department.

#### **Procedures**

To remedy a grant overpayment, the Grantee must:

- Notify the Department as soon as an overpayment has been discovered.
- Return funds to the Florida Department of Health within 90 days of grant end date via a check mailed to the address identified in Section 2—“Grant Roles and Contact Information.”

### **7.4.3 Policy on Long-Term Reporting**

If the applicant's proposal is funded, the Grantee must respond to Department requests for information for a period of six (6) years after the end of the grant period, including any no cost extensions. The requested information may include but not limited to, long-term outcomes based on the funded project, including the value of additional grant awards for grant-related research, a list of grant-related presentations, a list of grant-related publications in peer-reviewed journals, commercialization results, and any invention disclosures, patent filings, and patents received.

- After the grant period, Grantees are required to continue sharing important developments, including presentations, publications, follow-on funding, further scientific breakthroughs, and clinical translation that result from Department grants. This information is used to track the impact of the Department and demonstrate Department value to the Florida Legislature and citizens, who provide this important funding. Grantees will be notified by a Department representative when this information is needed. It is usually collected annually around July 31st or October 31st in preparation for Department annual reports.
- In addition, some grant mechanisms have special reporting requirements after the end date of the grant period.

## APPENDIX A – DEFINITIONS

**Administrative Representative** is the person at the Grantee's institution who is responsible for the fiscal and administrative coordination of the grant, including creating invoices and quarterly financial reports. See also **Grantee** and **Sponsored Research Official**.

**Alzheimer's Disease Research Grant Advisory Board** is the governing body that advises the State Surgeon General as to the scope of the Alzheimer's disease Research Grant Program, submits its recommendations for proposals to be funded to the State Surgeon General. The board also provides advice on program priorities and emphases and assists in the development of appropriate linkages to nonacademic entities, such as voluntary organizations, health care delivery institutions, industry, government agencies, and public officials.

**Award** is the amount of money granted. It is used interchangeably with the term grant or grant amount.

**Biomedical Research Advisory Council (BRAC)** has eleven members that are appointed by the Governor, the Florida Senate President, or the Speaker of the Florida House of Representatives or representing one of three voluntary health organizations. BRAC responsibilities may include advice on program priorities, program evaluation, developing criteria and standards for grant awards, and reviewing peer-reviewed reports and making recommendations for grant awards to the State Surgeon General.

**Commencement** is when the Grantee is authorized by the Department to begin (commence) the funded research. All legal and administrative matters at the start of a grant first must be addressed and resolved to the satisfaction of the Department. (See definitions for grant period and effective date.)

**Continuation** refers to the annual authorization to continue work on a multi-year award.

**Corresponding Principal Investigator (CPI)** is the term used in this manual to refer to the one key Grantee contact who has sole responsibility for the overall performance of the project. In the case of investigator-initiated grants, awards are made to a CPI. In the case of an institutional or team research grant, this person may also be referred to as the Project Director.

**Department** refers to the Florida Department of Health. Unless otherwise stated, the "Department," the "Public Health Research – Biomedical Research Section," the "Program," "staff," and "The Department" are interchangeable and includes all personnel authorized to act on behalf of the Department.

**Effective date** is the date the Department's authorized signatory executes (signs) the Terms and Conditions for a grant.

**Eligible Institution** is any public university, non-public institution, or established research institute in Florida.

**Funding Opportunity Announcement (FOA)** refers to the document issued by the Department detailing the types of grant proposals being solicited for consideration. In most cases, it also refers to the specific document in response to which the Grantee submitted an application.

**Grant Manager** is the Program representative who is the first point of contact for the Grantee for all grant-related matters. If the Grantee has a question, the Grant Manager should be the first person contacted.

**Grant Period** refers to the entire life of the grant as detailed in the Terms and Conditions, from the beginning date until the conclusion of the final continuation period and any no-cost extension period. See Continuation and No-Cost Extension.

**Grantee** refers to both the eligible institution and its authorized agents. It is a generic reference to everyone associated with the grant at the institution receiving the grant.

**Key Personnel** are the individuals whose particular expertise is critical to the success of the project. The Corresponding Principal Investigator, Project Director, and Mentor are always included in Key Personnel. Key Personnel are identified as such in the approved budgets.

**Local IRB** is the Institutional Review Board with jurisdiction over human subject-related research performed at the Grantee's institution.

**Mentor** is a role on post-doctoral fellowships and grants to new investigators. The Mentor provides guidance, support, and experience to the Corresponding Principal Investigator.

**No-Cost Extension** is an extension of the grant period without additional Department funds. It is a period of time up to six months authorized by the Department after the normal end of the grant period as agreed upon in the amendment to the Terms and Conditions. Under extraordinary circumstances, and upon request and approval, a Grantee may continue a sponsored research project beyond its original date of completion with no additional Department funds. The submission and payment of the final invoice is postponed until the end of the No-Cost Extension, and the Grantee is authorized to accrue expenses against the approved budget during the no-cost extension.

**Other Support** is defined as all financial resources, whether Federal, State, private, commercial, or institutional, available in direct support of an individual's research endeavors. Other support may include, but is not limited to research grants, cooperative agreements, contracts, and/or institutional awards. (Not included as other support are training awards, prizes, or gifts.)

**Overlap, Commitment** occurs when any project staff has time commitments exceeding 100%. This is the case whether or not the grant includes salary support for the effort.

**Overlap, Financial** occurs when duplicate or equivalent budget items (e.g., equipment, salary) are funded by more than one source.

**Overlap, Scientific** occurs when: (1) the same research is approved for work by more than one funding source or (2) a specific research objective and the research design, for accomplishing it, are the same or closely related in more than one awarded project, regardless of the funding source.

**Performance date** is a specified date when a predefined action or condition occurs or exists.

**Policy memorandum** is a formal change to the grant's Terms and Conditions affecting an entire class of Grantees. If a policy memorandum is released, the Department will notify all affected Sponsored Research Officials and Corresponding Principal Investigators.

**Project Director** (see **Corresponding Principal Investigator**)

**Program** refers to the James and Esther King Biomedical Research Program, the William G. "Bill" Bankhead, Jr. and David Coley Cancer Research Program, the Live Like Bella Initiative, and the Ed and Ethel Moore Alzheimer's Disease Research Program.

**Project** is defined as the research plan and all of the attestations detailed in the original application, unless modified by mutual agreement by the Program and the Grantee at some later date.

**Property and equipment** is defined as non-expendable, tangible property or equipment having a useful life of more than one year and a cost of \$1,000 or more.

**Schedule of Deliverables** identifies the required reports and other tangible verifications that the Grantee must produce during and after the grant period as a condition of funding. The Schedule of Deliverables and corresponding due dates are part of Attachment II of the Terms and Conditions.

**Scientific Misconduct** is defined as fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretation or judgments of data.

**Sponsored Research Official (SRO)** is the one institutional official who has signatory authority for the eligible institution receiving a Department grant. The SRO may delegate his/her responsibilities to other agents of the institution, but with the

understanding that he/she retains full responsibility. See also Administrative Representative and Grantee.

**Terms and Conditions** is the legally binding contract/agreement between the Grantee and the Florida Department of Health. It identifies the legal terms and conditions of the grant and contains important information about financial and progress reporting requirements, grant monitoring, and method of payment. It also describes obligations of the Grantee regarding, but not limited to scientific conduct and the use of human and animal subjects.