GRANT ADMINISTRATION MANUAL

February 2016 Edition

Administered By:
Public Health Research Unit
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 (Department). Funds for research in tobacco-related diseases and cancer are provided through the James and Esther King Biomedical Research Program (Section 215.5602, Florida Statutes) and the Bankhead-Coley Cancer Research Program (Section 381.922, Florida Statutes), respectively.

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 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 Principal Investigator's eligible institution. The Principal Investigator has sole responsibility for the overall performance of the project. Key project roles are defined below.

2.1.1 Principal Investigator/Project Director

The Principal Investigator, 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.
- Ensure the ethical conduct of the research, including compliance with laws governing research involving human participants and 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 required for post-doctoral fellowships and grants to new investigators. The role of the Mentor is to provide guidance, support, and experience to the Principal Investigator. 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 Principal Investigator 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.

For Postdoctoral Research Fellowships (PRFs), the Mentor is referred to as the Sponsor. The Mentor can be from the same or a different institution as the Principal Investigator..

Department grants to a new investigator may require the active participation of a Mentor. The Mentor is a senior investigator with proven grant experience, and is important for ensuring a successful project outcome and developing the capacity of the new investigator to direct highly productive research. Minimally, Mentors are expected to:

- Maintain a formal plan for meeting with the Principal Investigator on a regular basis to review results, discuss challenges, and offer assistance in planning future work.
- Review and approve Progress Reports.
- Assist with interpreting Department feedback.
- Provide guidance regarding presenting and publishing research results and seeking additional funding.
- Provide counsel on lab management.
- Foster development of the new investigator so that he/she can undertake independent research that is competitive for national funding.
- Provide periodic feedback to the Department when solicited.

2.1.3 Sponsored Research Official

The Sponsored Research Official is the one institutional official who has signatory authority for the eligible institution receiving a Department grant.

The Sponsored Research Official may delegate his/her responsibilities with the understanding that he/she retains full responsibility. At a minimum, the Sponsored Research Official must:

- Accept the grant on behalf of the Grantee.
- Certify that the Principal Investigator 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.
- Ensure that any Grantee cost-sharing or matching funds are provided as originally committed and report this to the appropriate Department personnel.
- Assist the Department during all site visits, reviews, and fact-gathering efforts related to the grant.
- Report problems and possible non-compliance in a timely fashion 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 Sponsored Research Official or may be an individual delegated by the Sponsored Research Official. The Administrative Representative must:

- Assist the Principal Investigator with financial management, budgeting, and re-budgeting.
- Sign/approve budgets, invoices, and maintain accurate financial records.
- Assist the Principal Investigator 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 programs.

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, government agencies, and public officials.
- 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 Administrative Services

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

Administrative support includes:

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

- Reviewing financial reports and continually monitor 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 Unit
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

WEBSITE: http://www.floridahealth.gov/provider-and-partner-resources/research/index.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 granted, 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 e-mails PDF copies of the award letter from the State Surgeon General and the Terms and Conditions to the Sponsored Research Official and the Principal Investigator.
- The Sponsored Research Official must review, sign, and return two original hardcopies of the Terms and Conditions to the Department as directed in the text of the e-mail.
- The Department will sign/execute the Terms and Conditions and will return an original executed copy to the Sponsored Research Official. 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 an award reduction is necessary, the Department notifies the Sponsored Research Official and Principal Investigator and issues an amendment to the Terms and Conditions.
- The Department e-mails the Amendment to the Sponsored Research Official.
- The Sponsored Research Official must review, sign, and return two original hardcopies of the Amendment to the Department as directed in the text of the e-mail.
- The Department-authorized signatory will sign/execute the Amendment and return an original executed copy to the Sponsored Research Official.
- The Principal Investigator may need to submit a revised budget based on the new award amount. In addition, he/she may submit revised aims in cases where a reduction to the original award amount compromises the original proposal. See Section 5.4—"Protocol Changes."

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 1 of the Terms and Conditions. The grant period shall include the beginning and end date of the grant.

3.1.4 Policy on Withdrawal of an Award Offer Due to Ineligibility

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

The Department may offer an award based on the anticipation of future proof of meeting key eligibility requirements. For instance, an applicant may not be a full-time faculty member at the time of application, but reasonably expects to be by the grant start date. If the Department makes an award based on conditions, and the conditions are not met, then the Department's offer is no longer valid.

3.2 ADMINISTRATIVE REVIEW AND GRANT START

3.2.1 Policy on Unresolved Issues

Regardless of contract 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

Grantee shall notify the Department, in writing via e-mail using the information provided on page 6 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 shall result in financial consequences of ten percent per invoice or grant termination.

If research requires human or animal participants 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), and Radiation Safety Review. The Grantee may request in writing to the Grant Manager authority to begin a portion of the project pending IRB approval.

The Principal Investigator is responsible for notifying the Department if work on the project will not begin on the grant start date. The Department may contact the Principal Investigator 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 shall impose financial penalties.

Procedures

To report a delay in project start, the Principal Investigator 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 Contract Amendments and Policy Memoranda

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

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 time extensions), key personnel changes, changes in protocol, report 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 Sponsored Research Official for signature, with a copy to the Principal Investigator.

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 Sponsored Research Officials and Principal Investigators.

Note: The Principal Investigator 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 Manager, Public Health Research Unit to determine whether review by the Department's IRB is required. If review by the Department's IRB is required, approval must be obtained prior to project implementation and charging of funds 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 participants. Researchers must provide participants through the informed consent document/process information about who will provide medical care and who will be responsible to pay for it should a participant 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 starting. If the study involves human participants, no charges against the grant are allowed until IRB approval is obtained.

If the project involves human subjects, the Principal Investigator must:

- Contact the Manager, Public Health Research Unit to determine whether review by the Department's IRB is required.
- The Department IRB has agreements with the University of Central Florida and University of Miami in order to simplify the process when dual IRB approvals are required. These agreements allow the Department IRB to be the sole IRB approval required if the grantee needs approval from both the local and Department IRBs. The Principal Investigator must still file an application with their local IRB.
- Provide the Department with documentation of IRB approvals, including Principal Investigator 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

Grantee agrees to report to the Department within 48 hours any expiration of IRB approval, serious or continuing non-compliance, unanticipated problems involving risks to participants or others, and any suspension or termination of IRB approval. The Grantee IRB agrees to report to the Department when

reporting to federal officials any serious or continuing non-compliance or unanticipated problem involving risks to participants 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 Principal Investigator must:

- Notify the Department within 48 hours of the expiration.
- Document that all research activities have stopped until a renewal is obtained.
- Contact the Manager, Public Health Research Unit, 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. The Department may impose a financial penalty if 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. The Department may impose financial penalties for research conducted without IRB approval.

3.3.3 Policy on Research Involving Vertebrate Animals

Grantee 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.

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

Procedures

If the project involves the use of vertebrate animals, the Principal Investigator 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 Principal Investigator 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

Grantee 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 discontinue 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. The Department may impose financial penalties for a lapse in IACUC approval.

Procedures

If the required IACUC approval expires, the Principal Investigator 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, and the Department may impose financial penalties for the lapse in approval.

3.3.5 Policy on Inclusion of Women and Minorities in Research

Grantee 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 Notice NOT-OD-02-052, "NIH Guidelines for Research Involving Recombinant DNA Molecules."

Procedures

- Refer to the publication, "NIH Guidelines for Research Involving Recombinant DNA Molecules" for guidelines 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.
- The Principal Investigator 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 Principal Investigator 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. Grantees

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," s. 68.082, 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 Grantee must notify the Department within 48 hours, whether or not a notice of final action has been provided. Grantee 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, "Responsibilities 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 Grantee 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 Principal Investigator 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 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 Grantee 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 and 21 CFR 56.111) and IRB policies, except upon written consent of the participants, 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).

Grantees must not use or disclose any information concerning a recipient of services under the grant for any purpose not in conformity with state

regulations and federal law or regulations, except upon written consent of the participants, or his/her responsible parent or guardian, when authorized by law.

Procedures

The Grantee must:

- Maintain confidentiality of all data, files, and records including participant records.
- When applicable, obtain consent of the participant 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 Contract 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 Contract 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 time extensions is found in Section 7.2.1—"Policy on No-Cost Time Extensions."

4.1.2 Policy on Payment of First Invoice

In the case of a delayed start, payment of invoices will only be approved after project work has started. Payments can only begin after the Grantee has received approval to start, and has begun work on the project.

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 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 Principal Investigator submits invoices along with all quarterly 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 Principal Investigator if additional information or corrective actions are needed.
- Upon acceptance, Department staff or designee recommends invoice payment to the Department.
- The Department pays the invoice.

4.1.4 Policy on Total Annual Payments

Total per annum payments to the Grantee shall not exceed the total per annum allocation as shown in Attachment I of the Terms and Conditions, and cannot exceed the total award amount.

Grantees may spend the full amount of the annual award in each year of funding 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), Department IRB 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 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.

4.2.3 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.

4.2.4 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 organization and any collaborating entities.

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 Principal Investigator must provide documentation that the product or service was not able to be obtained in Florida, or demonstrate that obtaining the product or service outside of the state reduced costs.
- The Principal Investigator shall give preference to Minority and Women-Owned Business Enterprise and Service-Disabled Veteran Business Enterprise when applicable.

4.2.5 Policy on Travel Reimbursement

Per Section 112.061, F.S., reimbursement for allowed travel must be at or below the current State of Florida travel rates.

All approved travel (see Section 5.1.1— "Policy on Budget Changes") must be reimbursed at no more than the State of Florida travel reimbursement rates. Additional travel reimbursements may NOT use grant funds. Current State of Florida reimbursement rates can be found in s. 112.061, F.S. at http://www.leg.state.fl.us/Statutes/ and in chapter 69I-42, F.A.C. at https://www.flrules.org/gateway/ChapterHome.asp?Chapter=69I-42.

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.

A grant cannot start, and therefore cannot incur costs, before all required regulatory approvals are obtained, such as those for use with human and animal subjects, if applicable. The Department will notify the Principal Investigator and Sponsored Research Official of the grant period and start date. See Section 3.3.1—"Policy on Research Involving Human Subjects" and Section 3.3.3—"Policy on Research Involving Vertebrate Animals." Also

see Section 3.3.2—"Policy on Research during Lapses in IRB Approval" 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 Principal Investigator and the Sponsored Research Official 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, s. 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 contract that evidences that expenditures are:

- Allowable under the contract 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. 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 an expenditure 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 Principal Investigator 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 Principal Investigator 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 Principal Investigator must:

- Complete and submit the budget change form via e-mail to Research@flhealth.gov.

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

Principal Investigator will receive a decline e-mail notification with instructions, otherwise, the Principal Investigator will receive an approval e-mail notification. The Department will provide an approved signed copy of the expenditure change or budget form to the Principal Investigator 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 Department research 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:
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 annually thereafter and includes any approved budget adjustments. The Department will reimburse the Grantee

for allowable, reasonable, and necessary costs as detailed in the line items budget.

The Department must review and approve any deviation from the approved budget. Any overspending in the personnel, equipment, or travel budget categories must be justified to and pre-approved by the Department. Any revisions to the Budget Form in excess of ten percent of the total amount of any one budget category being revised must be submitted to the Grant Manager on the Budget Revision Form reflecting the changes and justification. Revisions will become effective upon approval and signature by the Department and signature by the Grantee.

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 Principal Investigator must:

- Complete the Budget Change Request Form.
- Obtain the required signatures.
- Submit it via e-mail to Research@flhealth.gov.
- 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 Principal Investigator will receive a decline e-mail notification with instructions, otherwise, the Principal Investigator will receive an approval e-mail notification. The Department will provide an approved signed copy of the expenditure change or budget form to the Principal Investigator and institution financial contact.

5.2 KEY PERSONNEL CHANGES

5.2.1 Policy on Changing Key Personnel

Project key personnel include the Principal Investigator, 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, Principal Investigator, and/or Mentor within the awarded institution.

A Project Director or Principal Investigator cannot be changed to another Project Director or Principal Investigator prior to the approved start of the grant or within the first six months of the grant.

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.

Mentor Changes

To replace or change the percent effort or salary of the Mentor, the Principal Investigator 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 Change Key Personnel form and submit to the Department via e-mail at 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 request an expenditure change if the key personnel change affects more than one budget category.
- Obtain the required signatures.
- Submit it via e-mail to 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 Principal Investigator will receive a decline e-mail notification with instructions, otherwise, the Principal Investigator will receive an approval e-mail notification.

5.2.2 Policy on Changing a Principal Investigator's Effort

Reductions in Project Director or Principal Investigator effort are not allowed within the first six months. The amount of effort of the Project Director and/or Principal Investigator must remain above the minimum percent required in the FOA. Prior Department approval is required for Project Director and/or Principal Investigator if the change in the percent effort devoted to the project results in a 25% or more decrease from what was approved in the first year budget. For example, effort changing from 40% to 30% is a 25% change (10%/40%=25%) which would require prior approval. To change (reduce only) a Principal Investigator's percent effort, the Principal Investigator 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 Change Key Personnel form. Indicate the change and explain the need for the change.
- Prepare a revised budget or expenditure change request if the change effects more than one budget category.
- Obtain the required signatures.
- Submit it via e-mail to 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 Principal Investigator will receive a decline e-mail notification with instructions, otherwise, the Principal Investigator will receive an approval 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. 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.

The Grantee shall be responsible for all work performed and all expenses incurred for the grant project. The Grantee may not subcontract all of the work for the grant. The Department is not responsible to the subcontractor for any expenses or liabilities and the Grantee shall defend the Department if such claims are made.

Procedures

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

- Contact the Department and obtain 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. Project adjustment from that which was 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.

The Department allows minor changes in planned work (including experiments) and methods from the original application. However, major changes, such as removing or substantially changing a specific aim of a project, will undergo more careful scrutiny. This is because the modified project may stray 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, designs, or research plans, the Principal Investigator must:

- Submit a Protocol Change Form via e-mail to Research@flhealth.gov
- 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 Principal Investigator will receive a decline e-mail notification with instructions, otherwise, the Principal Investigator will receive an approval e-mail notification along with a copy of the signed approved Protocol Change 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: 1) modifying at least one of the awards to eliminate the overlap or 2) 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 Principal Investigator 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 Principal Investigator if additional information is required to make a decision. Where overlap is substantial, the Principal Investigator must make a choice between the Department grant and the alternate award. For minor overlap, the Principal Investigator 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 Principal Investigator's responsibility 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(4), 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.

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 ten percent per invoice or grant termination.

A grant budget must be approved before project work can begin. It must also be approved at the beginning of each year of the grant and whenever there are significant 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 Principal Investigator 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 Principal Investigator is responsible for ensuring the accuracy and timely completion of financial information submitted including invoices, budgets, expenditure changes, and any other project information.

6.1.2 Policy on Submitting Financial, Invoice Reports, and Quarterly Progress Summaries

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.

Invoice and Financial Report Review
After the report is submitted by the Principal Investigator, 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, or period covered.

- If requested, the Principal Investigator must supply additional information or clarification and resubmit a modified report(s).
- If there are no issues, the Department will pay the invoice only after the invoice, financial report, progress summary, and any other reports have been approved by the Department.

Note: If over-expenditures are discovered within the personnel or equipment categories and are not due to error, submit an Expenditure Change Request via the Budget Changing task 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 "disallowed" and to seek reimbursement from the Grantee, even though money has already been spent. Principal Investigators 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 over-expenditure is due to error, the error should be corrected and a revised financial report 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 according to the format specified by the Department.

Progress reports are one of several significant factors the Department considers to determine eligibility for continued funding of multi-year awards. These reports provide a means of accountability and a record of significant accomplishments. They are required annually during and after the grant period. Progress reports also serve other important purposes:

- Satisfies overall Department accountability requirements. The Department may use independent peer reviewers to evaluate these reports. This review helps Department staff accurately assess scientific progress for highly diverse scientific and technological projects, and provides the Principal Investigator with another source of helpful, authoritative, and meaningful feedback to ensure a successful outcome for the project.

- Allows the Department an opportunity to gather and share significant accomplishments toward Department goals.
- Provides 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.
- The Progress Report Form provided by the Department must be used by the Grantee. The Progress Report Form provides 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?

Progress Report Review
After the report is submitted, the following steps occur:

- The Department reviews the report for completeness. If there are issues, the Principal Investigator will receive an e-mail notification that the report is declined.
- Independent peer reviewers may review the report and ask questions or make suggestions regarding the research. Their comments form an evaluation report. The Department notifies the Principal Investigator when the evaluation report is complete.
- The Department may require follow-up activities from the Grantee 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 will deliver to the Grantee a written report of its findings and will 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: the Grantee being deemed in breach or default of this agreement; the withholding of payments to the Grantee by the Department; 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.
- Make recommendations to resolve or prevent any problems.
- Obtain feedback from the Grantee regarding improvements to the Department.

Procedures

- The Department contacts the Sponsored Research Official to schedule a site visit for current active Grantees. If it is too early for some newly awarded grants, they will 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 Principal Investigator, comments by the Mentor (if appropriate), a tour of the project laboratory/workspace, review of project records (financial, time keeping, etc.), review of select institution policies and procedures, 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 will 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 OR Bankhead-Coley Cancer 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.

The purposes of citing the Department are to:

- Give proper credit to the citizens of Florida for their investment in the sponsored research.
- Build awareness of the Department as a funding source for high-quality research in cancer and or tobacco-related diseases.

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 manuscripts 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 Open 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 after the grant period for a period of six years.
- 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 30 days 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 and continuation requests must be submitted according to the schedule in Attachment II of the Terms and Conditions. Awards, continuations, no-cost time extensions, renewals, and payments shall be made contingent upon satisfactory project performance and compliance with the grant 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 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 year of the grant, a full or partial audit may be conducted, including: administrative and peer review of the annual 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 for the grant in the 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 Principal Investigator will receive an e-mail notification that the task is returned.
- The Department sends a continuation or denial letter to the Sponsored Research Official, with a copy to the Principal Investigator. 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 Principal Investigator to provide an interim progress report.

- If the continuation is approved, the Department provides an approved budget to the Principal Investigator and the appropriate institution financial contact. 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 Time Extensions

The Department may grant an extension of the grant period without additional funds (no-cost time extension) upon request. Awards, continuations, extensions, renewals, and payments shall be made contingent upon satisfactory project performance and compliance with the grant terms and conditions. The grant period for all grants, including extensions, may not exceed 5.5 years. The No-Cost Time Extension request along with a Cumulative Progress Report must be submitted by the due date shown in Attachment II of the grant Terms and Conditions.

The Department strongly prefers that Principal Investigators complete projects according to the original schedule outlined in the Terms and Conditions. Under extreme extraordinary circumstances, the Department may grant a no-cost time extension. The availability of unspent funds or a late start is not sufficient reason to request a no-cost time extension. The Department will not support additional research beyond the approved aims of the funded project. A no-cost time 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 Time Extension

The Principal Investigator may submit a No-Cost Time Extension request by following these steps:

- Prepare and submit the request for No-Cost Time 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 Progress Report must also be submitted at the same time as the No-Cost Time Extension request 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 and research milestone chart.
  - Compliance with the Terms and Conditions.
- If denied, the Department will send a denial letter to the Sponsored Research Official, with a copy to the Principal Investigator, 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 30-days 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 24 hours 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 30 days advance written notice.

- The Department may pay for all legitimate costs actually incurred through the termination date, plus obligations that cannot be cancelled.
- The Principal Investigator must submit a final accounting of all funds and a Final Progress Report within 60 days of the termination date. (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 Progress Report, reconcile all grant expenses, submit the final invoice and 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:

- Review the Terms and Conditions to ensure that all required deliverables have been submitted by the due dates. (Both Sponsored Research Official and the Principal Investigator.)
- 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 Progress Report within 60 days of the end of the grant period unless 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 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 specified otherwise 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 45 calendar days 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. 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.

If the Department discovers an overpayment has been made, the Department will notify the Sponsored Research Official by letter. The Sponsored Research Official will have 40 calendar days to reimburse the Department. Failure to return unspent funds to the Department may affect future funding opportunities through the Department.

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 40 days 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 five (5) years after the end of the grant period, including any no cost time extensions. The requested information may include 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, patents received, etc.

- After the grant period, Grantees are required to continue sharing important developments, including presentations, publications, follow-on funding, further scientific break throughs, 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 legislators 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 August or September in preparation for Department annual reports.

- In addition, some grant mechanisms have special reporting requirements after the end date of the grant period, such as Shared Instrument Grants, which require “Annual Project Impact Reports.”

APPENDIX A – DEFINITIONS

Administrative Representative is the person at the Grantee 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**.

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

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.

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.

BRAC is short for Biomedical Research Advisory Council. Eleven members 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.

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.

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 time extension periods. See Continuation and No-Cost Time 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 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 institution.

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

No-Cost Time 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 time extension, and the Grantee is authorized to accrue expenses against the approved budget during the no-cost time 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.

Per annum award refers to the dollar amount of a single year of a multi-year grant.

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

Policy memorandum is a formal change to the grant 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 Principal Investigators.

Principal Investigator 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 Principal Investigator. In the case of an institutional or team research grant, this person may also be referred to as the Project Director.

Project Director (see **Principal Investigator**)

Program refers to both the James and Esther King Biomedical Research Program and the Bankhead-Coley Cancer Research Program. 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.

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.

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 is part 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 Sponsored Research Official 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.

Appendix B – Invoice

Florida Public Health Research Programs

James and Esther King Biomedical Research Program
Bankhead-Coley Cancer Research Program

INVOICE FORM

Invoice #: _____

Grant #: _____

Institution Official Name and Address (listed on W-9):

_____

_____

_____

_____

Remit to Name and Address ("same as above" if same as Official Address):

_____

_____

_____

_____

Federal ID#: _____
Contact Name: _____
Contact Phone: _____

DELIVERABLE(S)	Period Covered	Invoice Amount
Research data with the goal of better prevention, diagnosis, treatments, and cures of cancer related diseases to expand the foundation of biomedical knowledge and improve the health of Floridians.		

_____ _____
Authorized Signature **Date**

_____ _____
Printed Name of Authorized Signature **Date**

PLEASE SUBMIT ALL INVOICES, FINANCIAL STATUS REPORTS, AND PROGRESS REPORTS VIA EMAIL TO:
Research@flhealth.gov
Be sure to copy Jennifer Drake and Gavin Grigg at Jennifer.Drake2@flhealth.gov and Gavin.Grigg@flhealth.gov
PLEASE NOTE: INVOICES WILL NOT BE PROCESSED FOR PAYMENT UNTIL ALL DELIVERABLES ARE RECEIVED.

Appendix C – Financial Status Report

James and Esther King Biomedical Research Program
and
Bankhead-Coley Cancer Research Program
Quarterly Financial Report

Grant Number: _____ **Financial Report #:** _____

Principal Investigator Name: _____ **Fiscal Contact Person:** _____

Grantee Institution: _____ **Telephone:** _____

Award Amount: $0.00 **E-Mail Address:** _____

Reporting Period:	**1**	July 1 through September 30	*Due:* October 31
(Check One)	**2**	October 1 through December 31	*Due* : January 31
	3	January 1 through March 31	*Due:* April 30
	4	April 1 through June 30	*Due:* July 31
	Final	Entire Grant Period	*Due:* *<60 days after end of grant period*

Budget Category (do not modify these categories)	Budget (Through current fiscal year)	Expenditures This Quarter	Expenditures To Date (include current quarter)	Balance To Date ()
Personnel				$0.00
Consultant Cost				$0.00
Consortium/Contractual Costs				$0.00
Equipment				$0.00
Supplies				$0.00
Travel				$0.00
Patient Care Costs				$0.00
Other Expenses				$0.00
Indirect Costs				$0.00
Total	**$0.00**	**$0.00**	**$0.00**	**$0.00**
			Total Balance (Award Amount minus Expenditures To Date)	$0.00

I certify that this report is a true, accurate, and correct reflection of the actual expenditures for this grant and that funds were used soley for the grant as approved by the Program. I further certify that no occurrence of budgetary, scientific, or commitment overlap has occurred during this quarter.

Printed Name of Fiscal Agent _____ Signature, Authorized Fiscal Agent _____ Date _____

Appendix D - Quarterly Expenditure Status Report

Personnel Expenditure Tracking					
Grant Number:					
Grantee Institution:					
Reporting Period:					
Budget Category Allotment:	$0.00		Amount		
Date	Name of Personnel	Description (period covered)	Salaries	Fringe Benefits	Balance
			$ -	$ -	
			$ -	$ -	
			$ -	$ -	
			$ -	$ -	
			$ -	$ -	
			$ -	$ -	
			$ -	$ -	
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			$ -	$ -	
			$ -	$ -	
			$ -	$ -	
		Total Spent:	$ -	$ -	

Personnel Expenses: $ - **This figure should match the quarterly Personnel expenditures reported on the Quarterly FSR*

Personnel Balance: $ - **This figure should match the reported balance figure on the Quarterly FSR*

Appendix E - Quarterly Progress Report

Bankhead-Coley Cancer Research Program
and
James and Esther King Biomedical Research Program

Quarterly Progress Summary

DOH GRANT ID	DATE	CURRENT REPORTING QUARTER From: Through:
1. TITLE OF PROJECT		
2. PRINCIPAL INVESTIGATOR NAME		3. INSTITUTION

Instructions: This report is required for invoice payment. Provide a brief summary by grant aims of the progress that has occurred on this grant during the quarter. Diagrams and detailed data are not necessary.

4. GRANT PROGRESS SUMMARY

5. PRINCIPAL INVESTIGATOR ASSURANCE:	SIGNATURE OF PI *(In ink. "Per"* signature *not acceptable.)*	DATE
I certify that the statements herein are true, complete, and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports as requested.		

Appendix F - Cumulative Progress Report

CUMULATIVE Grant Progress Report ☐ **James and Esther King** ☐ **Bankhead-Coley Cancer Research**	Grant Type ☐ NIR ☐ Bridge ☐ TTCP/SBTT ☐ RC1 ☐ TTF ☐ RPG ☐ HBCU	DOH Grant ID
	Total Project Period From: Through:	
	Current Reporting Period From: Through:	

1. TITLE OF PROJECT	
2. PRINCIPAL INVESTIGATOR NAME	3. INSTITUTION

General Instructions: This progress report is intended to illustrate cumulative progress over the life of your grant and is designed to allow you to make successive entries and/or modify previously reported information (when appropriate) for each reporting period. Demonstration of progress is a major factor in the annual funding continuation and no-cost extension determinations. Progress reports may be submitted for independent progress assessment by scientific peer reviewers who will only have access to this report, your milestone chart, and your original proposal. Please expand fields as necessary and ensure that when form is printed that all input data is displayed.

SECTION A - PROJECT LEVEL DETAILS

4. PROJECT PROGRESS OVERVIEW

<Provide a brief summary highlighting the most significant scientific accomplishments on this project to date by reporting period. (More detailed progress reporting will be requested below). Broadly discuss any important changes in key personnel, scientific programs, shared resources and/or institutional commitments that have favorably or unfavorably impacted your research.>

Period one: From Date: To Date:

Period two: From Date: To Date:

Period three: From Date: To Date:

5. PLANS FOR NEXT REPORTING PERIOD (***typically 12 months or your remaining grant term***)
<Provide a brief description of the research planned for the next 12 months (or remaining term) of the grant including plans for developing any new scientific directions and/or taking advantage of new research opportunities. If this is the last year of your grant and you are requesting an extension, please include detailed plans for all of the activities remaining to complete your grant along with the corresponding timeframe.>

Year 2 Plans:

Year 3 Plans:

Extension Plans:

6. PEER REVIEWED JOURNAL PUBLICATIONS
<List ALL citations for publications that have resulted from this research grant. If publications previously reported as "submitted, "in review," or "in press" have been published during this period, please include or update as necessary. >

7. PRESENTATIONS
< List ALL citations for presentations that have resulted from this research grant.>

8. INVENTIONS AND PATENTS
< List ALL inventions based on your research on this project and note any related patent filings.>

9. STATUS OF GRANT PROPOSAL SUBMISSION

< List all additional grants received for work related to research completed on this project, including project title, source, amount, and term of award. >

PROPOSAL/GRANT TITLE:

Federal Agency/Institute: Grant Mechanism (RO1, PO1, etc.):

Principal Investigator: Proposal Submission Date:

Grant Start – End Date: Submission Status (Funded/Not funded/Pending):

Total Funds Requested: Total Funds Awarded:

Briefly describe the how the data/results from this grant are related to this proposal submission and any other comments you would like to communicate regarding the submission:

PROPOSAL/GRANT TITLE:

Federal Agency/Institute: Grant Mechanism (RO1, PO1, etc.):

Principal Investigator: Proposal Submission Date:

Grant Start – End Date: Submission Status (Funded/Not funded/Pending):

Total Funds Requested: Total Funds Awarded:

Briefly describe the how the data/results from this grant are related to this proposal submission and any other comments you would like to communicate regarding the submission:

SECTION B – PROGRESS AGAINST RESEARCH AIMS *Please address <u>all aims included</u> in the sponsored research even if previously completed. For more than two aims you may copy and insert additional pages into this section.*

AIM DETAILS	GRANT ID	AIM NUMBER

ORIGINAL PROPOSAL INFORMATION

1. HYPOTHESIS
<List hypothesis being tested by the aim, if appropriate>

2. AIM DESCRIPTION
<. Describe the specific aim as defined in your original proposal.>

3. EXPERIMENT DESCRIPTION
<List and briefly describe the specific experiments as defined in your original proposal.>

a. Exp. 1 -

b. Exp. 2 -

c. Exp. 3 -

PROJECT CHANGES

4. PROJECT CHANGES
< If this aim or experiments has been altered from that stated in the original competing application for any reason (including amendments, discoveries, reviewer feedback , etc.) describe the change to the aim or experiments and give the reason for the modification.>

a. Experiment Changed - Date of Change:

Description of change and reason for modification:

b. Experiment Changed - Date of Change:

Description of change and reason for modification:

5. HUMAN SUBJECT DATA

< If your project involves enrolling subjects, describe any challenges in recruiting, screening, enrolling, or retaining patients and specific actions taken to overcome challenges. Also, describe any serious risks to participants or suspension or termination of IRB approvals. (Subject and Enrollment information is reported in the milestone chart)>

Have there been any serious or continuing non-compliance, unanticipated problems involving risks to participants or others, and any suspension or termination of IRB approval. ☐ Yes ☐ No If yes, describe in appropriate period below.

Period one: From Date: To Date:

Challenges:

Strategies/Action plans:

Period two: From Date: To Date:

Challenges:

Strategies/Action plans:

6. PROGRESS / RESULTS

<Describe work performed, progress, challenges, delays, issues, results, and conclusions on each experiment by reporting period. Be sure to include specific relevant data to demonstrate overall progress. Include discussion on deviations, negative results, and future plans as necessary. Results below should be comprehensive for the life of the grant to date by reporting period.>

Period one: From Date: To Date:

a. Exp. 1 -
b. Exp. 2 -
c. Exp. 3 -

Period two: From Date: To Date:

a. Exp. 1 -
b. Exp. 2 -
c. Exp. 3 -

PROGRESS / RESULTS

1. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR NAME TITLE TEL	2. ADMINISTRATIVE OFFICIAL SIGNING FOR APPLICANT ORGANIZATION NAME TITLE TEL	
3. PRINCIPAL INVESTIGATOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports as requested.	SIGNATURE OF PI *(In ink. "Per"* signature *not acceptable.)*	DATE
4. FOR NEW INVESTIGATOR GRANTS ONLY MENTOR ASSURANCE: I have reviewed this progress report and I certify that the statements herein are true, complete and accurate to the best of my knowledge.	MENTOR NAME: SIGNATURE OF MENTOR *(In ink. "Per"* signature *not acceptable.)*	DATE
5. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with terms and conditions associated with this grant. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.	SIGNATURE OF ADMINISTRATIVE OFFICIAL *(In ink. "Per" signature not acceptable.)*	DATE