



## ***Florida Biomedical Research Programs Grant Administration Manual***

**Florida Department of Health  
Florida Biomedical Research Programs**



**March 2012 Edition**

## TABLE OF CONTENTS

<b>1.</b>	<b>USING THIS MANUAL.....</b>	<b>1</b>
<b>2.</b>	<b>GRANT ROLES AND CONTACT INFORMATION.....</b>	<b>2</b>
2.1	GRANTEE ROLES.....	2
2.1.1	Principal Investigator/Project Director.....	2
2.1.2	Mentor.....	2
2.1.3	Sponsored Research Official.....	3
2.1.4	Administrative Representative.....	4
2.2	PROGRAM ROLES.....	4
2.2.1	Biomedical Research Advisory Council (Council).....	4
2.2.2	Solix, Inc. – Grant Managers.....	4
2.2.3	The Department’s Florida Biomedical Research Programs.....	5
<b>3.</b>	<b>ELECTRONIC RECORDS MANAGEMENT.....</b>	<b>7</b>
3.1	THE WEB-BASED SYSTEM.....	7
3.1.1	To Access GrantEase.....	7
3.1.2	To Obtain Help Using GrantEase.....	7
<b>4.</b>	<b>FORMALIZING THE AWARD AND STARTING A GRANT.....</b>	<b>8</b>
4.1	ACCEPTANCE OF AWARDS.....	8
4.1.1	Policy on Terms and Conditions.....	8
4.1.2	Policy on Award Contingency.....	8
4.1.3	Policy on the Length of Awards.....	9
4.1.4	Policy on the Withdrawal of an Award Offer Due to Ineligibility.....	10
4.2	ADMINISTRATIVE REVIEW AND GRANT START.....	10
4.2.1	Policy on Unresolved Issues.....	10
4.2.2	Policy on Reporting Delays.....	10
4.2.3	Policy on Contract Amendments and Policy Memoranda.....	11
4.3	SPECIAL REQUIREMENTS.....	12
4.3.1	Policy on Operating in General Accord with the NIH.....	12
4.3.2	Policy on Research Involving Human Subjects.....	12
4.3.3	Policy on Research During Lapses in IRB Approval.....	14
4.3.4	Policy on Research Involving Vertebrate Animals.....	15
4.3.5	Policy on Research During Lapses in IACUC Approval.....	15
4.3.6	Policy on Inclusion of Women and Minorities in Research.....	16
4.3.7	Policy on Research Involving Recombinant DNA.....	16
4.3.8	Policy on Stem Cell Research.....	16
4.4	AVOIDING IMPROPRIETIES IN SCIENTIFIC RESEARCH.....	17
4.4.1	Policy on Scientific Misconduct.....	17
4.4.2	Policy on Confidentiality.....	18
4.4.3	Policy on Financial Conflicts of Interest.....	19
4.5	OTHER CONDITIONS OF THE GRANT.....	20
4.5.1	Policy on Indemnification.....	20
4.5.2	Policy on Liability Insurance.....	20
4.5.3	Policy on Disputes.....	21
4.5.4	Policy on Contract Amendments.....	21
4.5.5	Policy on Contract Assignment.....	21
<b>5.</b>	<b>ADMINISTERING THE GRANT.....</b>	<b>22</b>
5.1	PAYMENT POLICIES.....	22
5.1.1	Policy on Payments.....	22
5.1.2	Policy on Payment of First Invoice.....	22

5.1.3	Policy on Quarterly Fixed Payments.....	22
5.1.4	Policy on Total Annual Payments.....	23
5.1.5	Policy on Final Fixed Payment.....	23
5.2	USE OF FUNDS .....	23
5.2.1	Policy on Allowed Direct Costs .....	23
5.2.2	Policy on Allowed Indirect Costs.....	24
5.2.3	Policy on Disallowed Costs.....	24
5.2.4	Policy on Work Occurring in Florida .....	24
5.2.5	Policy on Travel Reimbursement .....	25
5.3	FISCAL ACCOUNTABILITY AND RECORDKEEPING.....	25
5.3.1	Policy on Tracking and Reporting Project Costs.....	25
5.3.2	Policy on Commingling Grant Funds.....	25
5.3.3	Policy on Substituting Funds .....	25
5.3.4	Policy on Generally Accepted Accounting Principles.....	25
5.3.5	Policy on Approved Expenses.....	25
5.3.6	Policy on Approved Expense Timing.....	26
5.3.7	Policy on Tracking Work Effort.....	26
5.3.8	Policy on Matching Funds.....	27
5.3.9	Policy on Compliance with Florida Single Audit Act.....	27
5.3.10	Policy on Retention of Records .....	27
5.3.11	Policy on Access to Grant Records.....	27
5.4	EQUIPMENT .....	28
5.4.1	Policy on Property/Equipment.....	28
5.4.2	Policy on Timing of Property and Equipment Purchases.....	28
5.4.3	Policy on Equipment Budget Changes .....	29
5.4.4	Policy on Disposition of Property and Equipment.....	30
<b>6.</b>	<b>MAKING CHANGES TO A GRANT .....</b>	<b>31</b>
6.1	BUDGET CHANGES .....	31
6.1.1	Policy on Budget Changes.....	31
6.2	KEY PERSONNEL CHANGES .....	32
6.2.1	Policy on Changing Key Personnel.....	32
6.2.2	Policy on Changing a Principal Investigator Effort.....	33
6.2.3	Policy on a Principal Investigator Move to Another Eligible Institution.....	33
6.2.4	Policy on a Principal Investigator Move to an Ineligible Institution .....	35
6.3	ASSIGNMENT AND SUBCONTRACTS .....	36
6.3.1	Policy on Assignment and Subcontracts.....	36
6.4	PROTOCOL CHANGES.....	37
6.4.1	Policy on Protocol/Project Changes.....	37
6.5	OTHER SUPPORT AND FINANCIAL OVERLAP .....	38
6.5.1	Policy on Other Support.....	38
6.5.2	Policy on Commitment Overlap.....	39
<b>7.</b>	<b>REPORTING AND MONITORING THE STATUS OF A GRANT .....</b>	<b>40</b>
7.1	REQUIRED FINANCIAL REPORTS AND INVOICES .....	40
7.1.1	Policy on Approved Budget and Payment Requirements.....	40
7.1.2	Policy on Submitting Financial, Invoice Reports, and Quarterly Progress Summaries .....	41
7.2	REQUIRED SCIENTIFIC PROGRESS REPORTS.....	42
7.2.1	Policy on Submitting Required Progress Reports.....	42
7.3	REQUIRED REPORTS -- GRANT MECHANISM SPECIFIC.....	44
7.3.1	Policy on Mechanism-Specific Required Reports .....	44
7.4	SITE VISITS.....	46
7.4.1	Policy on Grant Monitoring .....	46
7.5	PUBLICIZING RESEARCH RESULTS.....	47
7.5.1	Policy on Publications, Presentations, and Printed Reports .....	47
7.5.2	Policy on Program Notification of Findings.....	48

---

7.5.3	<i>Policy on Open Access of Publications</i> .....	48
7.5.4	<i>Policy on Open Access of Research Materials</i> .....	49
7.6	<b>PATENTS, COPYRIGHTS, AND ROYALTIES</b> .....	49
7.6.1	<i>Policy on the Disclosure of Inventions</i> .....	49
<b>8.</b>	<b>CONTINUING OR ENDING A GRANT</b> .....	<b>51</b>
8.1	<b>CONTINUING A MULTI-YEAR GRANT</b> .....	51
8.1.1	<i>Policy on Continuation of Multi-Year Grants</i> .....	51
8.2	<b>EXTENDING THE GRANT PERIOD</b> .....	52
8.2.1	<i>Policy on No-Cost Extensions</i> .....	52
8.2.2	<i>Policy on Renewals</i> .....	53
8.3	<b>EARLY TERMINATION</b> .....	54
8.3.1	<i>Policy on Early Terminations Without Cause</i> .....	54
8.4	<b>CLOSING A GRANT</b> .....	54
8.4.1	<i>Policy on Final Payment</i> .....	54
8.4.2	<i>Policy on Return of Funds</i> .....	55
8.4.3	<i>Policy on Long-Term Reporting</i> .....	56
	<b>APPENDIX A – DEFINITIONS</b> .....	<b>57</b>
	<b>APPENDIX B – LINKS</b> .....	<b>60</b>

## 1. USING THIS MANUAL

Congratulations on receiving a grant through the Florida Biomedical Research Programs (FBRP)! The FBRP include both the James and Esther King Biomedical Research Program (section 215.5602, *Florida Statutes (F.S.)*) and the Bankhead-Coley Cancer Research Program (section 381.922, *F.S.*). The FBRP is located in the Florida Department of Health and represents a substantial commitment by the State to address diseases adversely affecting Floridians.

**In instances where this manual conflicts with the executed “Terms and Conditions” and incorporated documents, the “Terms and Conditions” will prevail.**

The manual contains Program policies as well as the procedures necessary for compliance with those policies. It is organized around a typical grant lifecycle beginning with [Section 4—“Formalizing the Award and Starting a Grant.”](#) Definitions for key terms are compiled in [“Appendix A—Definitions”](#) and are defined upon first use (shown in italics), along with acronyms and other conventions used throughout the document.

This manual is available at [www.floridabiomed.com](http://www.floridabiomed.com). Refer to [“Appendix B—Links”](#) for a list of useful web sites.

## 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. Unless otherwise stated, the “Department,” the “Florida Biomedical Research Programs,” the “FBRP,” the “Program,” “staff,” or “Program staff” are interchangeable and include all personnel authorized to act on behalf of the Department.

### 2.1 GRANTEE ROLES

Program grants are awarded in the name of a qualified investigator to an eligible institution. For each grant, there are key roles at the eligible institution, some of which are defined below.

#### 2.1.1 Principal Investigator/Project Director

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*. For the purposes of this manual, the term Principal Investigator will be used to refer to the one key grantee contact who has sole responsibility for the overall performance of the project. Minimally, this person must:

- Understand the grant “Terms and Conditions” and remain in full compliance.
- Direct the project to achieve the specific aims approved by the Program.
- Make appropriate changes in the project protocol(s) with prior Program approval.
- Hire and supervise qualified project personnel.
- Ensure the ethical conduct of the work, with highest regard to protecting the rights and welfare of human and animal subjects according to federal, state, institutional, and Program guidelines.
- Disclose and manage any real or apparent conflicts of interest.
- Report adverse incidents promptly to the applicable authorities and the Program.
- Plan, review, and approve project expenditures.
- Ensure Program deliverables are completed and submitted on time as defined in the “Terms and Conditions.”
- Comply with Program monitoring, reporting, and change notification requirements.
- Present and publish significant findings and report these outcomes to the Program in a timely fashion. (For more information about disseminating findings based on research sponsored by the Program, see [Section 7.5—“Publicizing Research Results.”](#))
- Maintain close working relationships with the institution’s administrative and fiscal personnel and the appropriate Program personnel.
- Disclose inventions and subsequent commercialization progress to the Program in a timely fashion. See [Section 7.6—“Patents, Copyrights, and Royalties.”](#)

#### 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 should provide guidance in the development of the new investigator so that s/he 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.

Program grants to a new investigator may require the active participation of a Mentor. The Mentor is a senior investigator with proven grant experience. She/He 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 Program 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 s/he can undertake independent research that is competitive for national funding.
- Provide periodic feedback to the Program when solicited.

### **2.1.3 Sponsored Research Official**

The *Sponsored Research Official* has signatory authority for the eligible institution. The Sponsored Research Official may delegate his/her responsibilities with the understanding that she/he retains full responsibility. Minimally, 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, meets stated Program eligibility requirements, has access to the necessary facilities and equipment, and has approval to devote the time specified in the project plan.
- Sign and assure 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.
- Ensure that any Grantee cost-sharing or matching funds are provided as originally committed and report this to the appropriate Program personnel.
- Assist the Program during all site visits, reviews, and fact-gathering efforts related to the grant.
- Report all irregularities in a timely fashion to the Program, 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 reports. 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 financial records.
- Assist the Principal Investigator with timely close out at the end of the grant.

## 2.2 PROGRAM ROLES

The Florida Department of Health Biomedical Research Programs operates the Program. While retaining ultimate programmatic, fiscal, and administrative, responsibility, the Department is advised by the Biomedical Research Advisory Council (Council). It also contracts with Solix, Inc., to provide specific Program support, including day-to-day grant management activities.

### 2.2.1 Biomedical Research Advisory Council (Council)

The Council is an eleven-member advisory council composed of appointees of the Governor, the Senate President, and the Speaker of the House of Representatives, and delegates from the American Heart Association, American Cancer Society, and American Lung Association. Each Council member holds a designated seat and provides specialized expertise and balance to this advisory body. Council members are public officials adhering to strict policies protecting against conflict of interest. As such, members do not represent their institutions of employment. All meetings of the Council are open to the public and grantees are encouraged to attend. The specific composition and current membership of the Council is available at the Program website at [www.floridabiomed.com](http://www.floridabiomed.com). Among other things, the Council is authorized to:

- Provide advice on Program priorities and emphases, including participation in strategic planning endeavors.
- Assist to develop guidelines to ensure fairness, neutrality, and adherence to the principles of merit and quality.
- Develop criteria and standards for the award of grants.
- Make funding recommendations to the State Surgeon General.
- Participate in periodic Program evaluations.

### 2.2.2 Solix, Inc. – Grant Managers

As previously mentioned, the Department contracts with the Grant Management Solutions Division of Solix, Inc., to manage the day-to-day grant management activities for the Program; therefore, **the Program Grant Manager is an employee of Solix. The Grant Manager should always be the first point of contact on all grant-related matters.** The term Grant Manager in this manual always refers to the Program Grant Manager at Solix.

Minimally, the Grant Manager will:

- Respond to all Grantee inquiries.
- Receive and process all Grantee deliverables/reports (both project performance and financial).
- Evaluate project performance and progress, with assistance from technical subject matter experts as necessary.
- Review financial reports and continually monitor financial and business compliance.
- Conduct Grantee site visits to review records and scientific progress and to gather feedback from the Grantee on how to improve the Program.
- Provide recommendations for the Department regarding invoices, changes in personnel, protocol, budgets, multi-year grant continuations, etc.
- Provide resolutions to change requests.
- Maintain the official file of record for each grant.

**Grant Manager for the James & Esther King Biomedical Research Program:**

**Ms. Sarah Mesa**

**Solix, Inc.**

**Grant Management Solutions**

**Phone: 816-347-9449**

**Fax: 816-347-0325**

**E-mail: [programsupport@floridabiomed.com](mailto:programsupport@floridabiomed.com)**

**Grant Manager for the Bankhead-Coley Cancer Research Program:**

**Ms. Glenda Sapp**

**Solix, Inc.**

**Grant Management Solutions**

**Phone: 816-347-9449**

**Fax: 816-347-0325**

**E-mail: [bcprogramsupport@floridabiomed.com](mailto:bcprogramsupport@floridabiomed.com)**

### **2.2.3 The Department's Florida Biomedical Research Programs**

The Florida Biomedical Research Programs are ultimately responsible for the entire operation of the Program. Specific responsibilities include issuance of the "Terms and Conditions", invoice approvals for payment, and active engagement of the Council. To avoid confusion, Grantees should limit contact with the Department except when specifically instructed to do so (for instance, contracts and contract amendments requiring original signatures are sent directly to the Department), or at any time the Grantee has a concern regarding performance of Solix, Inc.

Direct all correspondence to the Department to:

Programs Manager  
Florida Department of Health  
Florida Biomedical Research Programs

COURIER ADDRESS:  
4030 Esplanade Way, Suite 280  
Tallahassee, FL 32399

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

PHONE: 850-245-4585  
FAX: 850-245-4371

PROGRAM EMAIL: [FBRP@doh.state.fl.us](mailto:FBRP@doh.state.fl.us)

WEBSITE: [www.floridabiomed.com](http://www.floridabiomed.com)

*We encourage feedback on this manual and Program policies and procedures.*

### **3. ELECTRONIC RECORDS MANAGEMENT**

#### **3.1 THE WEB-BASED SYSTEM**

Grant applicants and grantees are required to use the *GrantEase System*. The Program uses a web-based information management system as a resource for Grantees and Program staff. Authorized users of GrantEase perform all key administrative tasks throughout the *grant period*. GrantEase allows the Principal Investigator to monitor the status of individual grants, access the “Terms and Conditions”, and perform administrative activities such as submitting financial and scientific progress reports and initiating project change requests. These tasks and others are accomplished using convenient, downloadable forms. Due dates for deliverables, along with links for completing the associated tasks, appear in a “ToDo List.” An archive of previously filed reports and grant documents is also available in “History.”

##### **3.1.1 To Access GrantEase**

- Visit [www.floridabiomed.com](http://www.floridabiomed.com) and log in on the home page.
- Use the same username and password obtained during the application process. Only the Principal Investigator has a username and password.
- Regenerate lost passwords by going to the login screen. Click on the “Forgot Password” link. An e-mail message containing the password will be sent to the Principal Investigator.
- Protect login information (password) to preserve the security of grant information.

##### **3.1.2 To Obtain Help Using GrantEase**

**To obtain help using GrantEase, choose one of the following options:**

- Open an online chat session with an operator by first logging in and then clicking the “Live Help” icon during normal business hours. There is an immediate response.
- Select the “Contact Us” option on the left menu while in GrantEase to send an e-mail message; a response will be sent within one business day.
- E-mail [techsupport@floridabiomed.com](mailto:techsupport@floridabiomed.com).
- Call Solix at 816-347-9449.

## 4. FORMALIZING THE AWARD AND STARTING A GRANT

Receiving an award offer from the Program is the exciting part, and then the work begins! Before a grant can start, certain legal and administrative matters must be addressed. The following policies relate to starting a Program grant.

### 4.1 ACCEPTANCE OF AWARDS

#### 4.1.1 Policy on Terms and Conditions

***After awards are offered, each grantee must sign a contract, called the “Terms and Conditions,” agreeing to certain legal requirements of the award. An example of the “Terms and Conditions” is located on the Program website. The “Terms and Conditions” are non-negotiable and acceptance is required as part of the grant award process. The Program reserves the right to change or modify the “Terms and Conditions” as needed. By submitting a grant application pursuant to this “Call for Applications”, 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 contract. “Terms and Conditions” must be executed before the end of the Fiscal Year of the award offer in order for the funds to be available.

##### 4.1.1.1 Procedures

1. 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 Department prefers to use generic Sponsored Research e-mail addresses, such as “SponsoredResearch@university.edu.”
2. The Solix Grant Manager e-mails the Principal Investigator information about starting the grant.
3. The Sponsored Research Official must review, sign, and return a hardcopy of the “Terms and Conditions” to the Department as directed in the text of the e-mail.
4. The Department will sign the “Terms and Conditions” and will return a copy to the Sponsored Research Official. The contract is “executed” when signed by the Department-authorized signatory.
5. The Grant Manager will upload the “Terms and Conditions” to GrantEase.

#### 4.1.2 Policy on Award Contingency

***The Department’s performance and obligation to pay under this grant agreement are contingent upon annual appropriation by the Legislature, and/or the availability of funds.***

The Florida Legislature has the responsibility of passing a state fiscal year (FY) budget for the period of July 1 to June 30. The state budget is based upon on estimated revenue projections. All grant offers are contingent upon the availability of funds.

The Program reserves the right to offer a lesser award than is requested in a grant application. In such cases, input is sought from the Advisory Council to apply the reductions appropriately. The “Terms and Conditions” will show the reduced award amount.

If actual revenue is less than the estimates used by the Legislature when creating the State’s budget, a fiscal correction (reduction) to a grant could become necessary. If this were to happen, it would be in the first year of the grant. If it becomes necessary to apply a reduction after the grant has started, every effort will be made to preserve the first year’s award amount and budget, applying the reduction to the remaining year(s). For more information see [Section 8.1.1—“Policy on Continuation of Multi-Year Grants.”](#)

#### 4.1.2.1 Procedures

If an award reduction is necessary, the Department notifies the Principal Investigator and Sponsored Research Official and issues an amendment to the “Terms and Conditions”.

1. The Department e-mails the “Terms and Conditions” amendment to the Sponsored Research Official.
2. The Sponsored Research Official must review, sign, and return a hardcopy of the amendment to the Department upon receipt as directed in the instructions contained in the e-mail.
3. The Department-authorized signatory will sign the amendment and return a copy to the Sponsored Research Official.
4. The Grant Manager e-mails a copy of the executed amendment to the Principal Investigator and uploads the executed amendment to GrantEase.
5. 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 6.4—“Protocol Changes.”](#)

#### 4.1.3 Policy on the Length of Awards

***The grant period, total award amount, and other specific information about this grant are shown in Attachment 1 of the “Terms and Conditions.” The grant period shall include the original term of the grant and all approved extensions. The grant period for all grants excepting Research Project Grants (RPGs), including extensions, may not exceed 5.5 years. After the first 3-year term, RPG grants may be eligible for one non-competitive renewal of the grant period for up to 2 years, with a total grant period not to exceed 8.5 years.***

Generally, grants are awarded in twelve-month increments, following the State’s fiscal year of July 1 to June 30 up to a maximum of three years. The grant period is clearly stated in Attachment 1 of the “Terms and Conditions.” Funds appropriated in any given fiscal year may be held in a trust fund and paid out over a maximum period of six years from the start of that fiscal year; however, all grant payments must be disbursed before the end of that sixth year. Therefore, to allow for completion of all fiscal and administrative tasks, the grant period, including any extensions must end no later than 5.5 years from July 1 of the year of award.

RPGs awarded in July 2010 are for a term of 3 years, with an option to request an additional 2-year *non-competitive renewal*. A non-competitive renewal means the Program has committed to use available funds from one or more future year's appropriations to fund a grant exceeding the previous three-year maximum length. Funds for renewals will come from the FY2013-2014 budget. Including no cost extensions, the total grant period for FY2010-11 RPGs cannot be more than 8.5 years from July 1, 2010.

#### 4.1.4 Policy on the 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 documentation of a full-time faculty position is not provided by this date, the Department may withdraw the grant offer and offer an award with those funds to another eligible applicant.

## 4.2 ADMINISTRATIVE REVIEW AND GRANT START

### 4.2.1 Policy on Unresolved Issues

***Regardless of contract execution, this project cannot begin 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.***

#### 4.2.1.1 Procedures

1. 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 Call for Applications 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.
2. If any issues arise, the Grant Manager seeks a resolution with the Grantee before the grant period starts.
3. Work on the grant cannot begin until all issues have been resolved, even if the grant period has officially started.

### 4.2.2 Policy on Reporting Delays

***Grantee shall notify the Department of any delays in starting this project, reasons for the delay, actions being taken to resolve the delays, and expected start date.***

***Grantee shall update the Department, in writing, every 30 days after the original start date of the grant period as shown in Attachment 1 of the "Terms and Conditions". Failure to keep the Department informed may result in grant termination.***

**If the project has not started 6 months (180 days) after the original start date of the grant period, the Department may elect to terminate the grant.**

**Projects for which work must be performed before IRB approval can be requested may seek an exemption from the IRB requirement in this section.**

The Principal Investigator is responsible for notifying the Grant Manager if work on the grant will not begin on the grant start date. The Grant Manager will contact the Principal Investigator if it is not clear that the project has begun by the expected start date. If the grant will start more than 180 days late, the Department will either amend the “Terms and Conditions”, or terminate the grant.

#### **4.2.2.1 Procedures**

**To report a delay in project start, the Principal Investigator must:**

1. Contact the Grant Manager in writing to explain the reason for the delay. If IRB approval cannot be requested until after certain grant work is completed (for example, preliminary animal studies), the Grant Manager may allow work to begin without IRB approval.
2. Outline the steps that will be taken to resolve the matter.
3. Provide an anticipated date for the resolution of issues and project start date.
4. Update the Grant Manager at least every thirty days regarding the delay and its resolution.

#### **4.2.3 Policy on Contract Amendments and Policy Memoranda**

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

While most changes during the grant period can be handled without amending the “Terms and Conditions”, some types of changes may require an amendment and include:

- Changes that affect report due dates, payment schedules, or the funding amount
- Changes to relevant Florida Statutes
- Changes in Program funding
- A significantly delayed start date
- A no-cost extension

If an amendment is needed, the Department will e-mail it to the Sponsored Research Official for execution, with a copy to the Principal Investigator.

A *policy memoranda* is a formal change to the “Terms and Conditions” affecting an entire group of grantees. If a policy memoranda is released, the Grant Manager will notify all affected Sponsored Research Officials and Principal Investigators.

**Note:** The Principal Investigator should be very familiar 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 8.1—“Continuing a Multi-Year Grant.”](#)

## 4.3 SPECIAL REQUIREMENTS

### 4.3.1 Policy on Operating in General Accord with the NIH

***The Program has historically operated in general accord with the policies and procedures for extramural funding employed by the National Institutes of Health (NIH) and looks to the NIH as a source of standard practices. To protect the credibility of the Program and to ensure public trust, this general accord includes but is not limited to similar expectations of adequate institutional control and oversight to guard against financial conflict of interest, scientific misconduct, scientific and financial overlap and the mismanagement of funds, the protection of human and vertebrate animals, and compliance with applicable state and federal laws or regulations.***

The Program acknowledges the National Institutes of Health (NIH) as a source of practices with which most institutions are familiar. In cases where the Program will follow NIH policy, it will be clearly stated.

### 4.3.2 Policy on Research Involving Human Subjects

***The Department manages the Florida Biomedical Research Programs in general accord with the policies and procedures employed by the NIH and the HHS, including those that apply to human subjects. If this project involves human subjects, the following terms apply.***

***Grantee must abide by all 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 file a written Assurance of Compliance with the Office of Human Research Protections (OHRP), must establish and maintain appropriate policies and procedures for the protection of human subjects.***

***Grantee must obtain, maintain, and provide to the Department active verification or certification of IRB 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.***

***Grantee may also be required to obtain and maintain approval from the Florida Department of Health Institutional Review Board (DOH IRB) within 60 days of notice of award. When the sole activity of the Department is funding research with non-Federal funds, and the research does not involve Department clients, personnel, non-public data, or facilities, then review by the DOH IRB is NOT required. Information is available at the DOH IRB website at <http://flpublichealthethics.net/>.***

**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. This DOES NOT require any particular party to be responsible for such care; it requires that it be made clear to participants through the informed consent document/process who will provide medical care and who will be responsible to pay for it should a participant experience a research-related injury.**

If the project will involve the use of human subjects at any time, the project must demonstrate how the protocol will:

- Minimize risks to subjects by using procedures that are consistent with sound research design and, whenever appropriate, use procedures already being performed on the subjects for diagnostic or treatment purposes.
- Assess risks to subjects and determine if risks are reasonable in relation to expected benefits to subjects and the importance of the knowledge that may be gained from their involvement.
- Select subjects without bias in terms of the setting and purposes of the research.
- Obtain informed consent from each prospective subject. Keep a copy of the consent and be sure it includes all appropriate information.
- Include steps for monitoring data in the protocol that safeguards the health and well-being of subjects.
- Take necessary measures and document them to protect the privacy of subjects and maintain the confidentiality of data.
- Include safeguards in the study to protect the rights and welfare of subjects who are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, children, or persons who are economically or educationally disadvantaged.

#### **4.3.2.1 Procedures**

If the project is exempt from IRB approval, the Principal Investigator must provide documentation.

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

1. Ensure that local IRB approvals or exemptions and if required, Department of Health (DOH) IRB approvals, are received before any project work begins and are maintained for the entire grant period.

**NOTE:** The local IRB is the institutional review board with jurisdiction over research performed at the Grantee's institution. The Department of Health IRB has jurisdiction when Department of Health clients, personnel, non-public data, or facilities are being used.

**NOTE:** The DOH IRB has agreements with the University of Central Florida, University of Miami, and University of South Florida in order to simplify the process when dual IRB approvals are required. These agreements allow the DOH IRB to be the sole IRB approval required if the grantee needs approval from both the local and DOH IRBs. The Principal Investigator must still file an

application with their local IRB. Check the DOH IRB website at [www.flpublichealthethics.net](http://www.flpublichealthethics.net) for additional information.

2. Provide the Grant Manager 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. Inform the Grant Manager of any investigation or administrative action taken by the institution or any other entity with jurisdiction involving the use of human subjects on any project conducted with Program funds.

As a courtesy, the Grant Manager sends a reminder to the Principal Investigator at least 30 days prior to the expiration of the local and/or DOH IRB approval(s).

#### 4.3.3 Policy on Research During Lapses in IRB Approval

***Grantee agrees to report within 48 hours to the Department 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 discontinue until a renewal is obtained, and expenses for those activities during the expired period will be disallowed. The only activities that may continue in the event of expired IRB approval(s) are those activities that are clearly severable and independent from activities that involve human subjects covered by the expired IRB approval(s). Project expenses for these clearly severable and independent activities will be allowed and it is incumbent upon the Grantee to maintain accurate and clear records in case of an audit.***

##### 4.3.3.1 Procedures

If the required IRB approval expires, the Principal Investigator must:

1. Immediately notify the Grant Manager of the expiration.
2. Stop all activities covered by the expired IRB approval until a renewal is obtained.
3. Continue only those activities that are clearly separate and independent from activities that involve human subjects covered by the expired IRB approval.
4. Keep exact financial records to clearly show that expenses during the lapse period are unrelated to activities covered by the expired IRB approval.
5. Submit renewed IRB approvals to the Grant Manager.

**NOTE:** Research activities (covered by the expired IRB approval) that are conducted without necessary IRB approvals are considered scientific misconduct and related expenses incurred during a lapse will not be funded by the Program.

#### 4.3.4 Policy on Research Involving Vertebrate Animals

***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 vertebrate animals. If this project involves the use of vertebrate animals, the following terms apply.***

***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.***

##### 4.3.4.1 Procedures

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

1. 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 Program research.
2. Provide the Grant Manager 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.
3. Inform the Grant Manager of any investigation or administrative action taken by the institution or any other entity with jurisdiction on any research conducted with Program funds.

As a courtesy, the Grant Manager sends a reminder to the Principal Investigator at least 30 days prior to the expiration of the IACUC approval.

#### 4.3.5 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. Project expenses for these clearly severable and independent activities will be allowed and it is incumbent upon the Grantee to maintain accurate and clear records in case of an audit.***

#### 4.3.5.1 Procedures

If the required IACUC approval expires, the Principal Investigator must:

1. Immediately notify the Grant Manager of the expiration.
2. Stop all activities covered by the expired IACUC approval until a renewal is obtained.
3. Continue only those activities that are clearly separate and independent from activities covered by the expired IACUC approval.
4. Keep exact financial records to show clearly that expenses during the lapse period are unrelated to activities covered by the expired IACUC approval.
5. 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, and related expenses incurred during a lapse will not be funded by the Program.

#### 4.3.6 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 Program’s goals is to mitigate the disproportionate disease burden on disparate groups. For this reason, the Program strongly encourages the inclusion of disparate groups in human subjects research.

#### 4.3.7 Policy on Research Involving Recombinant DNA

***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 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.”***

##### 4.3.7.1 Procedures

1. 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 Program 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.
2. For more information about these NIH Guidelines and how to submit the necessary paperwork, refer to the following web site:  
[http://oba.od.nih.gov/rdna/nih\\_guidelines\\_oba.html](http://oba.od.nih.gov/rdna/nih_guidelines_oba.html).

#### 4.3.8 Policy on Stem Cell Research

***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 use of human stem cells. All research involving human stem cells***

**must meet the requirements of the “National Institutes of Health Guidelines for Human Stem Cell Research.”**

**4.3.8.1 Procedures**

1. 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.
2. If the research involves stem cells, in order to ensure that Program 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 Program Manager may request additional information.
3. 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 6.4—“Protocol Changes.”](#))

**4.4 AVOIDING IMPROPRIETIES IN SCIENTIFIC RESEARCH**

All work sponsored by the Program must be conducted with the highest level of ethics and respect for fiscal accountability to the citizens of Florida. Grantees must understand Program policies relating to false claims, scientific misconduct, and conflicts of interest. Grantees must avoid any perception of wrongdoing that might bring dishonor to the Program.

False claims submitted in connection with this 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 assure 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

**4.4.1 Policy on Scientific Misconduct**

***The Department manages the Florida Biomedical Research Programs in general accord with the policies and procedures employed by the National Institutes of Health (NIH), including those that apply to scientific misconduct.***

***Applicants for, and recipients of, grants must promptly 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. 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 Program uses the same policies and procedures employed by the NIH regarding scientific misconduct. Any administrative action for scientific misconduct must be reported to the Program 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 Program funds

#### **4.4.1.1 Procedures**

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

1. Provide a copy of the any notice of administrative action imposed by any institution or regulatory agency to the Program immediately.
2. Inform the Grant Manager within 48 hours of any notices, suspensions, or other actions against a Principal Investigator or any key personnel imposed by the any institution or regulatory agency.
3. Provide a copy of the final notice of administrative action imposed by the institution or any regulatory agency to the Program within 30 days of the final notice.
4. Certify that administrative policies are consistent with the statutes listed in the above policy.
5. Enforce standards of conduct and take appropriate action if necessary.

Upon notification or determination of scientific misconduct, the Program will determine what actions to take.

#### **4.4.2 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 this grant and all services provided. The**

**Grantee shall not use or disclose any information concerning a human subjects under this 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 Institutional Review Board policies, except upon written consent of the recipient, 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 this grant for any purpose not in conformity with state regulations and federal law or regulations, except upon written consent of the recipient, or his/her responsible parent or guardian when authorized by law.

#### **4.4.2.1 Procedures**

The Grantee must:

- Maintain confidentiality of all data, files, and records including client records.
- Obtain written consent of the patient or responsible parent/guardian before disclosing any information concerning a patient.
- Comply with all applicable state and federal confidentiality regulations, including HIPAA (Health Insurance Portability and Accountability Act).

#### **4.4.3 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 (NIH), 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 conflicting financial interests that have been identified. Excepting Technology Transfer/Commercialization (TTCP) and Technology Transfer Feasibility (TTF) Grants, Grantee must describe the method by which conflicting financial interests have been resolved in order to protect this 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.**

#### **4.4.3.1 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.

- In general accord with the policies and procedures employed by the NIH for Small Business Innovation Research (SBIR) awards, Technology Transfer/Commercialization Partnership (TTCP) and Technology Transfer Feasibility (TTF) Grantees must disclose financial conflicts of interest, but are not required to resolve those conflicts.

## 4.5 OTHER CONDITIONS OF THE GRANT

### 4.5.1 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 this 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 this grant agreement is intended to serve as a waiver of sovereign immunity, nor shall anything in this 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 this 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.***

### 4.5.2 Policy on Liability Insurance

***The Grantee shall provide adequate liability insurance coverage on a comprehensive basis at all times during the grant period. Upon execution of this 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 this grant, if any. Upon execution of this grant, upon request 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.***

Grantees must provide adequate liability insurance coverage unless the Grantee institution is a public college or university as identified in Chapter 1004, F.S. All other grantees should:

- Determine type(s) and extent of coverage to provide adequate protection.
- Procure coverage from a company licensed to do business in Florida and operating under Florida laws.
- Upon request, provide the Program with written verification supporting both the determination and existence of insurance coverage. The Grant Manager usually requests this of the Sponsored Research Official during a site visit.

#### **4.5.3 Policy on Disputes**

***Failure of this 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.***

#### **4.5.4 Policy on Contract Amendments**

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

#### **4.5.5 Policy on Contract Assignment**

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

## 5. ADMINISTERING THE GRANT

### 5.1 PAYMENT POLICIES

#### 5.1.1 Policy on Payments

***Payments will be contingent on Grantee compliance with these 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 8.1—“Continuing a Multi-Year Grant.”](#) Information on no-cost extensions is found in [Section 8.2.1—“Policy on No-Cost Extensions.”](#)

#### 5.1.2 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 started work. Disbursement of funds occur in arrears, meaning certain deliverables as defined in the “Terms and Conditions”, Attachment 2 “Schedule of Deliverables” must be completed before a payment can take place.

#### 5.1.3 Policy on Quarterly Fixed Payments

***This grant has a fixed payment schedule as shown in Attachment 2 of the “Terms and Conditions.” This grant is a fixed payment grant, not a fixed price grant.***

Do not confuse the fixed payment schedule established within this Program with the mechanism in state of Florida purchasing known as a “fixed price contract.” Disbursed Program funds are subject to payback if the Grantee does not spend the total award amount as authorized. Refer to [Section 8.4.2—“Policy on Return of Funds”](#) for more information.

Grantees receive two different reminders regarding due dates:

- The Grant Manager sends courtesy reminders of upcoming report due dates and approval expirations to the Principal Investigator.
- The “ToDo” list in GrantEase contains a list of tasks and due dates.

**The Principal Investigator is responsible for meeting all deadlines and reporting requirements.** Contact the Grant Manager with questions and notify the Grant Manager in advance regarding any expected delays.

##### 5.1.3.1 Procedures

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

1. The Grant Manager provides a reminder approximately 30 days in advance of upcoming due dates for invoices and financial reports and instructions.
2. The Principal Investigator submits invoices and financial reports according to the due dates and payment amounts outlined in the “Terms and Conditions.” Refer to [Section 7.1—“Required Financial Reports”](#) for specific instructions of how to submit the reports.
3. The Grant Manager reviews these deliverables and notifies the Principal Investigator if additional information or corrective actions are needed.
4. Upon acceptance, the Grant Manager recommends invoice payment to the Department.
5. The Department pays the invoice.

#### 5.1.4 Policy on Total Annual Payments

***Total per annum payments to the Grantee shall not exceed the total per annum allocation as shown in Attachment 1 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 6.1.1—“Policy on Budget Changes”](#).

Grantees may spend the full award amount. Any project expenses exceeding the award amount will not be reimbursed.

#### 5.1.5 Policy on Final Fixed Payment

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

Grantees must submit the final invoice after the final deliverables, including the final financial report and final progress report. The final invoice and financial report should reflect the cumulative effect of all grant financial transactions. Once all deliverables have been received and approved, the final invoice will be paid.

## 5.2 USE OF FUNDS

The Call for Grant Applications 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 Grant Manager works with the Grantee to ensure that the project budget is in compliance with these requirements. In addition, the following policies apply to all Program grants **unless otherwise specified in the “Terms and Conditions.”**

#### 5.2.1 Policy on Allowed Direct Costs

***Allowed 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 of Health IRB fees (if required), Consortium or contractual costs. Administrative costs may be included in direct***

**cost categories, but only under two conditions: the services, functions, or activities are directly necessary for this grant, AND these administrative costs have not been included in the calculation of the indirect costs. The Program does not prohibit administrative costs as part of direct costs, but to be allowable, they must meet both of the above conditions. All direct costs must be specifically and directly related to the project, necessary for the project's completion, and adequately justified.**

Allowable costs are those which the Grantee may charge against the approved budget. All allowed costs must be tracked, monitored, and documented. There are two types of allowable costs: direct and indirect. In some cases, administrative costs may be included in direct costs; in most cases, administrative costs should be included as indirect costs.

### 5.2.2 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.**

Starting in FY2010-2011, indirect costs must be no more than 15% of the direct costs of the grant. Prior year grants have an indirect cost cap of 10%.

### 5.2.3 Policy on Disallowed Costs

**All direct costs must be specifically and directly related to the project, necessary for the project's completion, and adequately justified. 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), Malpractice insurance premiums. Pursuant to sections 11.062 and 216.347, F.S., no portion of grant funds shall be used for lobbying.**

Use of grant funds for disallowed costs may result in future payments being decreased, the need for funds to be returned to the Department, or grant termination.

### 5.2.4 Policy on Work Occurring in Florida

**It is the intent of the Program that activities funded through the Program, including data analysis, occur in Florida. Ninety percent of work (effort) must occur and 90% of funds must be spent in Florida at the applicant organization and any collaborating entities. Funding for any out-of-state personnel or consulting expenses cannot exceed 10% of the total requested direct costs. This out-of-state limitation does not include lab services, supplies, or equipment.**

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 work (measured as effort) can be conducted outside of Florida.
- No more than 10% of all grant funds can be spent outside of Florida.

### 5.2.5 Policy on Travel Reimbursement

***Per s. 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 6.1.1— “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>.

## 5.3 FISCAL ACCOUNTABILITY AND RECORDKEEPING

Program grants are an investment by the citizens of Florida and are given for the purposes described in the Call for Grant Applications. 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.
- Program staff are 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.

### 5.3.1 Policy on Tracking and Reporting Project Costs

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

### 5.3.2 Policy on Commingling Grant Funds

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

### 5.3.3 Policy on Substituting Funds

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

### 5.3.4 Policy on Generally Accepted Accounting Principles

***All grant funds must be properly accounted for using Generally Accepted Accounting Principles (GAAP) and all financial records are subject to review.***

### 5.3.5 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; however, donations may be used to meet any required match.***

***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.***

### **5.3.6 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 of human and animal subjects, if applicable. See [Section 4.3.2—"Policy on Research Involving Human Subjects"](#) and [Section 4.3.4—"Policy on Research Involving Vertebrate Animals."](#) Also see [Section 4.3.3—"Policy on Research During Lapses in IRB Approval"](#) and [Section 4.3.5—"Policy on Research During Lapses in IACUC Approval."](#)

#### **5.3.6.1 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 Grant Manager with any questions regarding specific cost-tracking and recordkeeping requirements.
- Plan to account for Program funds using Generally Accepted Accounting Principles. [See Appendix B for more information.](#)
- Do not use Program 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 Program funds with other business/personal accounts.
- Do not use Program 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 Grant Manager 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.

### **5.3.7 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 this 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 Program.

### 5.3.8 Policy on Matching Funds

***If matching funds are a condition of this grant per the Call, the Grantee agrees it will specifically provide at a minimum the funds or other consideration as outlined in the application. Grantees may match more than the minimum required amount. Donations may be used to meet any required match. If the Grantee does not contribute the agreed-to match amount, the total award amount may, at the discretion of the Department, be reduced proportionately to maintain the required matching ratio.***

Matching funds are a requirement for Team Science Program (TSP) Grants and may be required for other grant mechanisms as identified in the Calls for Grant Applications. Discounted services, the cost of services/effort provided in-kind, or donations can be used to meet the matching requirement as “resources” if the contribution supports the allowable direct cost of the project. These contributions must have monetary values that can be substantiated by evidence. For example, if the Grantee institution normally charges fees for the use of core facilities, it may be willing to waive or reduce these fees as part of the required match. Match spending must be reported in the grant quarterly financial reports and is subject to audit.

### 5.3.9 Policy on Compliance with Florida Single Audit Act

***The Grantee shall comply with the provisions of the Florida Single Audit Act, section 215.97, F.S.***

### 5.3.10 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 this 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 this grant.***

#### 5.3.10.1 Procedures

Previous “Terms and Conditions” allowed for records retention of five years, excepting records covered by the Health Insurance Portability Accountability Act (HIPAA), which must be retained for six years.

### 5.3.11 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 this 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 this grant.***

#### **5.3.11.1 Procedures**

The Grantee shall assure that records are available at all reasonable times for inspection, review, or audit by federal, state, or other personnel duly authorized by the Program. Upon termination of the grant, and at the request of the Program, the Grantee will cooperate with the Program to facilitate the duplication and transfer of any records or documents during the required retention period. The Program reserves the right to terminate this 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 this grant.

## **5.4 EQUIPMENT**

### **5.4.1 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.***

#### **5.4.1.1 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 5.4.3—“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.

### **5.4.2 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.***

#### 5.4.2.1 Procedures

Grantees need to purchase equipment **before** the last 90 days of the grant period in order to use it for the grant research for a reasonable period of time before the grant ends.

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 Grant Manager 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.

#### 5.4.3 Policy on Equipment Budget Changes

***Any over-spending in the personnel, equipment, or travel budget categories must be justified to and pre-approved by the Department.***

Any equipment purchase or travel requires justification and Program approval before spending occurs if it is not already in the approved budget. Equipment and travel 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.

##### 5.4.3.1 Procedures

When requesting a change in the budget for personnel, equipment purchase or travel, the Principal Investigator must:

1. Submit budget change requests online by logging on to GrantEase. Go to the "ToDo List."
2. Select "Budget Changing" on the right side menu; the "Budget Changing" page appears with information about change guidelines.
3. Click the "Start" button; the "Fill Form" screen appears.
4. Select and download the appropriate expenditure change form.
5. Complete the form, obtain required signatures, and upload a scanned, signed copy of the completed form.
6. Click "Submit Form;" the status of "Budget Changing" on the "ToDo List" page now appears as "In Routing."

The Grant Manager will attempt to approve adjustment requests within 15 business days of receipt of the request. If the information submitted is incomplete or in error, the Grant Manager will decline the request and the Principal Investigator receives a decline e-mail notification with instructions on how to view the feedback; otherwise, the Principal Investigator will receive an approval e-mail notification. The Grant Manager will provide an approved signed copy of the expenditure change or budget form to the Principal Investigator and the institutional financial contact.

If the Grant Manager 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.

#### **5.4.4 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, Florida Statutes, 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 Program is to increase the infrastructure needed to conduct research in Florida. For this reason, all equipment purchased for Program research should continue to be used for research in the State after the end of the grant period.

##### **5.4.4.1 Procedures**

To dispose of property or equipment purchased with Program 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 Program funds by contacting the nearest public university in order to transfer the equipment into the State's pool of property.

## 6. MAKING CHANGES TO A GRANT

### 6.1 BUDGET CHANGES

#### 6.1.1 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.***

***Any overspending in the personnel, equipment, or travel budget categories must be justified to and pre-approved by the Department.***

***Excepting the personnel, equipment, and travel budget categories, spending is allowed to deviate from the approved budget, whether within a single budget category or in aggregate, by less than 20% of the total approved budget without requiring justification to or approval by the Department. Overspending of 20% or more must be justified to and pre-approved by the Department.***

***The Department reserves the right to: 1) require further justification, 2) reject any disallowed costs, 3) reject overspending of more than 20% of the annual approved budget that has not been pre-approved, and 4) request new/revised budgets as necessary.***

Overspending of 20% or more must be justified to and pre-approved by the Department with a budget change request. This includes both single line items over 20% as well as any combination of line items that add up to 20% or more of the approved budget.

All equipment budget increases must be justified to and pre-approved by the Department. See [Section 5.4.3—“Policy on Equipment Budget Changes.”](#)

All personnel budget increases must be justified to and pre-approved by the Department with a budget change request.

Travel budget limits are specific to each grant mechanism and are identified in the Calls for Applications. All travel budget increases must be justified to and pre-approved by the Department with a budget change request.

##### 6.1.1.1 Procedures

To initiate changes to the approved budget, the Principal Investigator must:

1. Submit budget changes online by logging on to GrantEase. Go to the “ToDo” list.
2. Select “Budget Changing” on the right side menu; the “Budget Changing” page appears with information about change guidelines such as pre-approvals.
3. Click the “Start” button; the “Fill Form” screen appears.
4. Select and download the appropriate form based on the instructions on the screen.
5. Complete the form, obtain the required signatures, and upload a scanned, signed copy of the budget file or expenditure change file.

6. Click "Submit Form;" the status of "Budget Changing" on the "ToDo List" page now appears as "In Routing."

The Grant Manager will attempt to approve adjustment requests within 15 business days of receipt of the request. If the information submitted is incomplete or in error, the Grant Manager will decline the request and the Principal Investigator receives a decline e-mail notification with instructions of how to view the feedback; otherwise, the Principal Investigator will receive an approval e-mail notification. The Grant Manager will provide an approved signed copy of the expenditure change or budget form to the Principal Investigator and institution financial contact.

If the Grant Manager determines that budget changes are too numerous or significant, it may be necessary to submit a new budget form containing the appropriate institutional signature.

## 6.2 KEY PERSONNEL CHANGES

### 6.2.1 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 for Project Director, Principal Investigator, and Mentor changes.***

#### 6.2.1.1 Procedures

##### Principal Investigator Change

If the Principal Investigator is moving within Florida and the grant will be moving with the Principal Investigator, see [Section 6.2.3—"Policy on a Principal Investigator Move to Another Eligible Institution."](#) If the Principal Investigator is moving to an ineligible institution (out of Florida) and the Grantee institution will replace the Principal Investigator, see [Section 6.2.4—"Policy on a Principal Investigator Move to an Ineligible Institution."](#) If the Principal Investigator is moving to an ineligible institution and the Grantee institution cannot find a suitable replacement, the Program will terminate the grant in good standing; see [Section 8.4—"Closing A Grant."](#)

##### Mentor Changes

To replace or change the percent effort or salary of the Mentor, the Principal Investigator must:

1. Refer to the Call for Grant Applications before making changes in research personnel. There are special requirements such as restrictions on percent effort and salary.
2. Log in to GrantEase, go to the "ToDo" list and select "Change Key Personnel" on the right side menu to submit a change report to the Grant Manager.
3. Click the "Start" button; the "Fill Form" screen appears.
4. Explain the need for the change and justify the replacement or change.

5. Include a biographical sketch of the individual for any key personnel replacement.
6. Upload a revised budget or request an expenditure change if the key personnel change affects more than one budget category.
7. Click "Submit Form;" the status of "Change Key Personnel" on the "ToDo List" page now appears as "In Routing."

The Grant Manager will review the request and will attempt to approve or deny the request within 15 business days. If the information submitted is incomplete, the Grant Manager will decline the request and the Principal Investigator receives a decline e-mail notification with instructions of how to view the feedback; otherwise, the Principal Investigator will receive an approval e-mail notification.

### 6.2.2 Policy on Changing a Principal Investigator Effort

***Reductions in Project Director or Principal Investigator effort are not allowed within the first six months and may not exceed 10% within any one year of the grant period. The amount of effort of the Project Director and/or Principal Investigator must remain above the minimum percent required in the Call for Applications. Prior Department approval is required for Project Director, Principal Investigator, and Mentor changes.***

#### 6.2.2.1 Procedures

To change a Principal Investigator's percent effort, the Principal Investigator must:

1. Refer to the Call for Grant Applications before requesting effort and salary changes. Specific grant mechanisms may have special requirements or restrictions on minimum effort commitment or maximum salary amounts.
2. Log in to GrantEase and select "Change Key Personnel" to submit a change request to the Grant Manager.
3. Indicate the change and explain the need for the change.
4. Upload a revised budget or expenditure change request if the change affects more than one budget category.
5. Click "Submit Form." The status of "Change Key Personnel" on the "ToDo List" page now appears as "In Routing."

The Grant Manager will review the request and will attempt to approve or deny the request within 15 business days. If the information submitted is incomplete, the Grant Manager will decline the request and the Principal Investigator receives a decline e-mail notification with instructions of how to view the feedback; otherwise, the Principal Investigator will receive an approval e-mail notification.

### 6.2.3 Policy on a Principal Investigator Move to Another Eligible Institution

***The applicant must be an eligible institution. According to s. 215.5602(5)(a) and s. 381.922(3)(a), F.S., applications for biomedical research funding may be submitted from any university or established research institute in Florida. For the purposes of this program, eligible institutions are: state universities, nonpublic institutions, and established research institutes. To be eligible as a Principal Investigator at an eligible institution, the individual must be a full-time faculty member. Prior***

**Department approval is required to transfer a grant if a Principal Investigator accepts a position with another eligible institution.**

If the Principal Investigator wishes to move the grant to another eligible institution, follow these procedures:

**6.2.3.1 Procedures**

A request to transfer a grant to another eligible institution requires the following actions:

**Principal Investigator:**

1. Write a request letter to the Grant Manager that includes the following:
  - Reason(s) for the transfer
  - How the move alters the research plans, if at all
  - An estimate of the unspent balance of the award
  - An assessment of the impact on budget, time, and personnel
  - Signatures of both the Principal Investigator and the Sponsored Research Official at the original institution
2. Request other key personnel changes
3. Complete all new IRB/IACUC approvals at the new institution after the approval of the move. See [Section 4.3—“Special Requirements”](#) for more information.
4. Revise the Research Milestone Chart
5. Provide any grant mechanism specific documentation, such as the Mentorship Form for any grants requiring a mentor
6. Provide any other information requested by the Grant Manager

**Original Grantee institution’s Sponsored Research Official:**

7. Provide final financial report and final quarterly invoice no more than 60 days after the last day of work at the original institution. See [Section 8.4—“Closing A Grant”](#) for information on ending the grant.
8. If necessary, return any unspent funds to the Department

**Prospective Grantee institution’s Sponsored Research Official:**

9. Write a letter of intent to accept the award within 30 days (of Principal Investigator request of move) and supply any additional information requested by the Grant Manager including:
  - Confirmation of full-time faculty status of the Principal Investigator
  - Detailed budget for the remaining funds
  - Statements concerning available facilities and resources
  - Statement concerning matching funds, if required
  - Key personnel information

- Assurance that key personnel and others required to complete the work are available
  - Letter of support from the Department Chair
10. Sign a new or amended “Terms and Conditions” if the transfer request is approved.

**Department and Grant Manager:**

11. If the transfer is approved, the Grant Manager will notify the Principal Investigator.
12. The Department will terminate the award (in good standing unless there are outstanding issues) at the original Grantee institution by mailing a termination letter to the original institution’s Sponsored Research Official.
13. The Department will send a revised “Terms and Conditions” to the new Grantee institution as described in [Section 4.1.1—“Policy on Terms and Conditions.”](#) All required IRB and IACUC approvals must be obtained and provided to the Grant Manager before work on the project may start. The Grant Manager will notify the Principal Investigator when work may begin.

**6.2.4 Policy on a Principal Investigator Move to an Ineligible Institution**

***The applicant must be an eligible institution. According to s. 215.5602(5)(a) and s. 381.922(3)(a), F.S., applications for biomedical research funding may be submitted from any university or established research institute in Florida. For the purposes of this program, eligible institutions are: state universities, nonpublic institutions, and established research institutes. To be eligible as a Principal Investigator at an eligible institution, the individual must be a full-time faculty member.***

The Grantee is encouraged to replace a Principal Investigator who is moving to an ineligible institution with someone of equal or similar qualifications. If a suitable replacement cannot be found at the Grantee institution, the Program will terminate the grant in good standing. See [Section 8.4 – “Closing A Grant.”](#)

NOTE: Postdoctoral Research Fellowship (PRF) Principal Investigators can NOT be replaced because a significant portion of the peer review scores for the original application were based on the qualifications of the Principal Investigator.

**6.2.4.1 Procedures**

A request to replace a Principal Investigator at the Grantee Institution requires the following actions:

**Principal Investigator and Sponsored Research Official:**

1. Submit a signed request letter or e-mail to the Grant Manager that outlines:
  - Reason for the change and the plans for how the project and Program goals are going to be met.
  - Evidence that the project is going to continue to produce high-quality research after the change.

- Evidence that the new Principal Investigator meets all eligibility requirements as stated in the Call for Grant Applications. The Grant Manager can assist the Sponsored Research Official in determining these special requirements.
  - Qualifications of the prospective Principal Investigator, including a biographical sketch.
  - Statement of the new Principal Investigator's percent effort, percent salary, and base salary.
  - Confirmation of available resources, lab space, equipment and facilities to support the grant.
2. Supply any additional information requested by the Grant Manager, which may include a revised budget, revised research milestone chart, etc.

**Department and Grant Manager:**

The Program may approve the change if there is evidence that the requirements and goals of the approved grant can still be met.

3. The Grant Manager will review the request, make a recommendation to the Department, and attempt to notify the Sponsored Research Official of the decision within 30 days.
4. If the change is approved, the Department will send an amendment to the "Terms and Conditions," naming the new Principal Investigator, to the Sponsored Research Official as described in [Section 4.1.1—"Policy on Terms and Conditions."](#)

## 6.3 ASSIGNMENT AND SUBCONTRACTS

One of the goals of the Program is to develop the research capacity of investigators in Florida and their Florida-based institutions. For this reason, collaboration among eligible institutions is encouraged, but subcontracting to ineligible institutions (outside of Florida) is not viewed favorably by the Program.

### 6.3.1 Policy on Assignment and Subcontracts

***The Grantee shall neither assign the responsibility of this grant to another party nor subcontract for any of the work contemplated under this 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 this grant. If the Department permits the Grantee to subcontract part of the work contemplated under this 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 this grant. The Program is not responsible to the subcontractor for any expenses or liabilities and the Grantee shall defend the Program if such claims are made.

#### **6.3.1.1 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 Grant Manager and obtain written approval. The Grant Manager provides guidance for making any appropriate changes.
- Set up appropriate accounting and reimbursement procedures; the Grantee is responsible for all expenses made by the subcontractor.

## **6.4 PROTOCOL CHANGES**

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

***The Grantee shall complete the work as described in the application. Any type of project adjustment from that which was proposed in the application, including changes in the 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 Program allows minor changes in planned work 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 Program 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 Program approval.

#### **6.4.1.1 Procedures**

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

1. Submit a protocol change online by logging in to GrantEase. Go to the "ToDo" list.
2. Select "Protocol Change" on the right side menu; the screen appears with information about change guidelines.
3. Click the "Start" button; the "Fill Form" screen appears.
4. Download, complete the form, and obtain the required signatures.
5. Scan and upload the signed request.
6. Click "Submit Form;" the status of "Protocol Change" on the "ToDo List" page now appears as "In Routing."
7. Obtain IRB or IACUC approval for the change if appropriate.

The Grant Manager will review the request and will attempt to approve or deny the request within 15 business days. If the information submitted is incomplete, the Grant Manager will decline the request and the Principal Investigator receives a decline e-mail notification with instructions of how to view the feedback and correct the problem; otherwise, the Principal Investigator will receive an approval e-mail notification. If approved, the Grant Manager will e-mail a signed approved copy of the Protocol Change Form to the Principal Investigator.

## 6.5 OTHER SUPPORT and FINANCIAL OVERLAP

### 6.5.1 Policy on Other Support

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

The same science cannot be funded by more than one source. The Principal Investigator is responsible for monitoring other support of all project personnel, including key personnel, and resolving all cases of financial overlap.

#### 6.5.1.1 Procedures

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

- Notify the Grant Manager 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 Program grant.

The Grant Manager 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 Program grant and the alternate award. For minor overlap, the Principal Investigator may resolve the overlap situation by proposing a solution to the Grant Manager that removes the affected scientific

aims/projects from either grant and makes corresponding adjustments to the budget and potentially the grant award amount.

#### **6.5.2 Policy on Commitment Overlap**

***Commitment of any individual's effort greater than 100% is not permitted.***

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.

## 7. REPORTING AND MONITORING THE STATUS OF A GRANT

***The Grantee will provide reports to the Department for the purposes of accountability and compilation of information for the Governor, Legislature, and other stakeholders. Failure to comply with all deliverables required may have a negative effect on the Grantee's invoice payment, award continuation, or future funding opportunities.***

***The Grantee 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), Florida Statutes (F.S.), both during and after the grant period. Upon request, Grantee agrees to report to the Department a description of all outcomes resulting from this grant, including but not limited to publications, presentations, published reports, databases, additional grants and monies received, patents, invention disclosures, and copyrights.***

Grantees must assist the Program in gathering data both during and after the grant period. Research outcomes, including publications, presentations, follow-on funding received, invention disclosures, new partnerships, start-up companies, and progress towards commercialization are of particular interest to the Program. The Program must be able to show good stewardship of Florida's investment. The Program will present information provided by Grantees in Program annual reports, Program evaluations, and other reports to the Governor and Legislature.

### 7.1 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 2 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. Grantees must assist the Program in gathering data both during and after the grant period. Reporting requirements are shown in Attachment 2 of the "Terms and Conditions." This section describes the required financial reporting in more detail.

#### 7.1.1 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 these terms and conditions, may result in a reduction of the award, late or non-payment of the invoice, and/or grant termination. Failure to submit the invoice and all required documentation within 60 days of the due date, may result in a reduction of the amount eventually paid by two percent (2%).***

A grant budget must be approved before project work can begin. It will be approved at the beginning of every year of the grant and whenever there are significant budget adjustments.

### 7.1.1.1 Procedures

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

1. Note any specific reporting requirements in the “Terms and Conditions.” The nature and content of the report may vary depending on the type of grant.
2. During the grant initiation, the Grant Manager reviews any special reporting requirements with the Grantee.
3. The Grant Manager reminds the Principal Investigator approximately 30 days in advance of each report due date and may provide other instructions or information.
4. To change the approved budget, see [Section 6.1—“Budget Changes.”](#)
5. The Principal Investigator and the appropriate financial support individual(s) should work together to create and review financial reports for the Program 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.

### 7.1.2 Policy on Submitting Financial, Invoice Reports, and Quarterly Progress Summaries

***Grantee must request payment using the Department’s invoice form. Expenses will be reviewed for appropriateness against the approved budget.***

Grantees must submit invoices, financial reports, and Quarterly Progress Summaries through GrantEase. Invoices bill the Department for the amount specified in Attachment 2 of the “Terms and Conditions”. Financial reports track expenditures against the approved budget. Starting with FY11-12 grants, every invoice will need to be accompanied by a Quarterly Progress Summary, which should provide a lay person overview of the scientific progress achieved for the invoice period (usually one quarter).

#### 7.1.2.1 Procedures

##### Submitting Invoices and Financial Reports

Principal Investigators should check the “ToDo” list frequently; the financial report task appears here as a reminder. The Grant Manager reminds the Principal Investigator approximately 30 days before each report due date and may provide other instructions.

To submit invoices and financial reports, the Principal Investigator must:

1. Log in to GrantEase and download the appropriate form(s) by starting the Financial Reporting and the Invoice Task from the “ToDo” list.
2. Complete or arrange for the completion of forms and obtain necessary signatures.
3. Review the financial report for accuracy.
4. Log in to GrantEase and upload a scanned copy of the completed and signed reports through the “ToDo” list “Financial Reporting” and “Invoicing” tasks. Click “Submit Form” to send. The status of these tasks on the “ToDo List”

page now appears as “In Routing.” Electronic copies of submitted reports are retained in GrantEase “History” for reference.

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

After the report is submitted by the Principal Investigator, the following steps occur:

5. The Grant Manager reviews invoices and financial reports against the approved budget. The Grant Manager declines the report in GrantEase if there are issues or concerns such as budget errors or an incorrect invoice amount.
6. If there are issues, the Principal Investigator will receive an e-mail notification that the report is declined. Log in to GrantEase to review specific report feedback.
7. If requested, the Principal Investigator must supply additional information or clarification and resubmit a modified report(s).
8. If there are no issues, the Grant Manager will accept the financial report in GrantEase, and the Principal Investigator receives an e-mail notification that the report is approved.
9. The Department will pay the invoice only after the invoice, financial report, and any other reports have been approved by the Grant Manager.

**Note: If over-expenditures are discovered within the personnel, travel 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 5.4.3—“Policy on Equipment Budget Changes”](#) and [Section 6.1.1—“Policy on Budget Changes”](#) for policy and procedures on changing a budget.** The Program 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 Grant Manager.

For procedures for submitting the final invoice and financial report, see [Section 8.4.1—“Policy on Final Payment.”](#)

## **7.2 REQUIRED SCIENTIFIC PROGRESS REPORTS**

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

***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 2 of the “Terms and Conditions.” Reports must be prepared according to the format specified by the Department.***

Narrative progress reports are one of several significant factors the Program 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. Narrative progress reports also serve other important purposes:

- To satisfy overall Program accountability requirements. The Program may use independent peer reviewers to evaluate these reports. This review helps Program 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.
- To allow the Program an opportunity to gather and share significant accomplishments toward Program goals.
- To provide information to characterize and promote the valuable findings gained by the State's sponsorship of this research with the State Surgeon General, the Governor, the Legislature, and other Florida constituents who may have an interest in the research.

Grantees must use the Progress Report Form and Milestone Chart Form provided by the Department. 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?

See the Deliverable Schedule for the grant in the "Terms and Conditions" for actual due dates.

The Grant Manager reminds Principal Investigators approximately 30 days in advance of each report due date and may provide other instructions. Principal Investigators should check GrantEase frequently. The Progress Reporting task appears on the "ToDo" list as a reminder.

#### **7.2.1.1 Procedures**

##### **Submitting Progress Reports**

The Principal Investigator must:

1. Login to GrantEase and start the "Progress Reporting" task from the "ToDo" list.
2. Select and download the form(s).
3. Complete the appropriate form and obtain any required signatures.
4. Log in to GrantEase and upload a scanned copy of the forms through the "ToDo" list "Progress Reporting" task. Click "Submit Form" to send. The status of this task on the "ToDo List" page now appears as "In Routing." Electronic copies of submitted reports are retained in GrantEase "History" for reference.

### **Progress Report Review**

After the report is uploaded, the following steps occur:

5. The Grant Manager reviews the report for completeness.
6. The Grant Manager declines the report in GrantEase if there are issues or missing information.
7. If there are issues, the Principal Investigator will receive an e-mail notification that the report is declined.
8. The Principal Investigator must log in to GrantEase to review specific report feedback. If requested, the Principal Investigator must supply additional information or clarification by going to the "Progress Reporting" task on the "ToDo" list and submit a modified report.
9. Independent peer reviewers may review the report and ask questions or make suggestions regarding the research. Their comments form an evaluation report. The Grant Manager notifies the Principal Investigator when the evaluation report is complete.
10. The Grant Manager notifies the Principal Investigator when the Progress Report is approved/accepted.
11. The Grant Manager may require follow-up activities from the Grantee including but not limited to a response to the peer-reviewed evaluation report.
12. The Principal Investigator may access the evaluation report by selecting "History" in the "ToDo" list in GrantEase.

For procedures for submitting the Final Progress Report, see [Section 8.4.1—"Policy on Final Payment."](#)

## **7.3 REQUIRED REPORTS -- GRANT MECHANISM SPECIFIC**

### **7.3.1 Policy on Mechanism-Specific Required Reports**

***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 2 of the "Terms and Conditions." Reports must be prepared according to the format specified by the Department.***

Certain grant mechanisms have specific reporting requirements based on the goals, purpose, and intent of the mechanism. Below is a table of examples of deliverables by grant mechanism. Actual due dates for deliverables such as these are included in the "Terms and Conditions" schedule of deliverables (Attachment 2). Deliverables provide a means of accountability and a record of status and accomplishment as required by ss. 215.97 and/or 215.971, F.S. Links to these statutes can be found in the appendix.

<b>Mechanism</b>	<b>Example of Special Deliverables</b>	<b>Approximate Timeframe</b>
Bridge Grant	Copy of Federal Proposal Submission Status (or other proof of follow-on funding application)	Before the last day of the grant period
Florida RC1 Grant	Copy of Federal Proposal Submission Status (or other proof of follow-on funding application)	Before the last day of the grant period
Shared Instrument Grant (SIG)	Management Plan	End of the first quarter
	Interim Narrative Progress Report	End of the first six months
	Annual Project Impact Report describing the impact of the shared instrument for five years annually after the end of a SIG	Annually for 5 years, normally at the end of August
Research Project Grant (RPG)	Copy of Federal Proposal Submission Status (or other proof of follow-on funding application)	Before the last day of the grant period
Specialized Program of Research Excellence Planning Grant (Pre-SPORE)	Evidence of Pre-Application Consultation with NCI Program Staff.	Last half of the final year
	Copy of the NCI SPORE Letter of Intent	Last half of the final year
	Copy of Submitted NCI SPORE Proposal	End of the final year
Team Science Program (TSP) Grant	Copy of Federal Proposal Submission Status (or other proof of follow-on funding application)	Before the last day of the grant period
Technology Transfer/Commercialization Partnership (TTCP) Grant	Intellectual Property Agreement Between the Institution and Small Business	End of the First Quarter

### 7.3.1.1 Procedures

#### Reporting Schedule

1. See the Deliverables Schedule in the “Terms and Conditions” for actual due dates.
2. The Grant Manager reminds the Principal Investigator approximately 30 days before the due date and may provide other instructions.
3. Check GrantEase frequently. The specific reporting task appears on the “ToDo List” as a reminder.

#### Submitting the Reports

The Principal Investigator must:

4. Login to GrantEase and start the specific reporting task from the “ToDo List.”
5. Follow the instructions on the website. If indicated, download any required forms, complete the forms, and obtain any required signatures.

6. Upload any required forms, reports, or information. Click “Submit Form” to send. The status of this task on the “ToDo List” page now appears as “In Routing.” Electronic copies of submitted deliverable are retained in GrantEase “History” for reference.

### **Report Review**

After the deliverable is submitted, the following steps occur:

7. The Grant Manager reviews the deliverable for completeness.
8. The Grant Manager declines the deliverable in GrantEase if there are issues or missing information.
9. If there are issues, the Principal Investigator will receive an e-mail notification that the deliverable is declined. Log in to GrantEase to review specific deliverable feedback. If requested, supply additional information or clarifications by going to the specific reporting task on the “ToDo List” and submit a modified deliverable.
10. The Grant Manager notifies the Principal Investigator when the deliverable is approved/accepted.

## **7.4 SITE VISITS**

### **7.4.1 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 this 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 this 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 this 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: (1) the Grantee being deemed in breach or default of this agreement; (2) the withholding of payments to the Grantee by the Department; (3) the termination of this grant.***

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

- Increase Program 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 Program

Following a site visit, the Program will provide to the Grantee a written report of findings, which will include recommendations with regard to the Grantee's performance, if necessary. The Grantee must correct all noted deficiencies identified by the Program within the specified period.

#### **7.4.1.1 Procedures**

1. The Grant Manager 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 scheduled for a subsequent site visit.
2. The Grant Manager provides detailed information regarding what to expect during the visit and the type of information that will be requested from the Grantee.
3. A typical 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.
4. The Grant Manager will request financial information for offsite audit and will provide instructions for delivering the requested information.
5. The site visit team will request feedback from the Grantee regarding Program improvements at the closing meeting.
6. Within 30 days of the completion of the site visit and all offsite record auditing, the Program will provide a report documenting findings and providing recommendations for any problems encountered.
7. The Program 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.

## **7.5 PUBLICIZING RESEARCH RESULTS**

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

***Any publications, presentations, printed reports, or resulting research findings related to this 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.***

Principal Investigators and key personnel must acknowledge the Program in any presentation and published work.

The purposes of citing the Program are to:

- Give proper credit to the citizens of Florida for their investment in the sponsored research.

- Build awareness of the Program as a funding source for high-quality research in cancer and/or tobacco-related diseases.

### 7.5.2 Policy on Program Notification of Findings

***Grantee shall notify the Department of all publications, presentations, printed reports, and resulting research findings created for this project both during and after the grant period.***

The Program 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 Program. The Program's annual reports list all Grantee publications for that year. Sharing this information informs, inspires, and feeds the work of other qualified researchers.

#### 7.5.2.1 Procedures

The Principal Investigator must:

- Notify the Program of all presentations and publications created under this grant both during and after the grant period.
- Log in to GrantEase and go to the "ToDo" list and click on "Publications & Presentations." Upload a PDF copy of the published work. The system will acknowledge receipt via e-mail.
- Include publication information in annual/interim narrative progress reports. Submit information about a publication in AMA citation style. See <http://www2.liu.edu/cwis/cwp/library/workshop/citation.htm> for more information about AMA style.

### 7.5.3 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 Program 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.***

***In accord with the National Institutes of Health 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 Program funded projects/research. For more information on the NIH Open Access Policy visit <http://publicaccess.nih.gov/>.***

**AND**

***In concert with the National Institutes of Health (NIH) notice NOT-OD-08-033, the Grantee 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.***

One of the Program's goals is to increase collaboration in order to discover cures as quickly as possible. For this reason, Grantees are required to make their published manuscripts available on PubMed Central within 12 months of the official date of publication.

#### **7.5.4 Policy on Open Access of Research Materials**

***Upon publication of their work, grantees funded through this Program are encouraged to make materials, data and databases, and software that result from this funding and which is integral to their publication, freely and expeditiously available upon request for research use by other scientists, utilizing materials transfer agreements.***

The Program strongly encourages Grantees to share materials, data, databases, and software with other scientists for research purposes.

## **7.6 PATENTS, COPYRIGHTS, AND ROYALTIES**

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

The following provisions apply to all intellectual property created under this 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 Program-funded research through patenting and licensing and shall make reasonable efforts to give preference to Florida-based companies.

#### **7.6.1 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 National Institutes of Health (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 this 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.**

**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.**

**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 this grant, the Grantee shall furnish the Department with a description of said property and a copy of any licensing obtained.**

**Grantee shall report to the Department, upon request, any progress in securing or exploiting such inventions, trademarks, copyrights, or patents both during and after the grant period.**

**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 this Agreement.**

#### **7.6.1.1 Procedures**

The Program 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 Program 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 Program 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.

## 8. CONTINUING OR ENDING A GRANT

### 8.1 CONTINUING A MULTI-YEAR GRANT

#### 8.1.1 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 2 of the “Terms and Conditions.” Awards, continuations, extensions, renewals, and payments shall be made contingent upon satisfactory project performance and compliance with the grant terms and conditions.***

Upon award, the Program 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. 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.

##### 8.1.1.1 Procedures

###### Continuation Schedule

1. See the Deliverable Schedule for the grant in the “Terms and Conditions” for actual due dates.
2. The Grant Manager reminds the Principal Investigator approximately 30 days in advance of due dates and may provide other instructions.
3. Check GrantEase frequently. The Continuation Request task appears on the “ToDo” list as a reminder.

###### Submitting the Continuation Request

The Principal Investigator must:

4. Log in to GrantEase and go to the “ToDo” list; select the “Continuation Request” task.
5. Download and complete the budget form and the other support form. Obtain all required institution signatures.
6. Scan and upload the completed forms. Click “Submit Form” to send. The status of these tasks on the “ToDo List” page now appears as “In Routing.”

###### Continuation Request Review

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

7. The Program evaluates the request on the basis of the following:
  - Justification of the budget
  - Scientific progress, measured against the specific aims, as shown in the narrative progress report and research milestone chart
  - Other support information
  - Compliance with the “Terms and Conditions”

8. If there are issues, the Principal Investigator will receive an e-mail notification that the task is declined. Log in to GrantEase to review specific feedback. If requested, supply additional information or clarification by going to the “Continuation Request” task on the “ToDo” list and submitting modified forms.
9. The Department sends a continuation or denial letter to the Sponsored Research Official, with a copy to the Principal Investigator. This normally occurs within 15 days of the anniversary of the grant. If necessary, an amendment to the “Terms and Conditions” will also be sent. 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.
10. If the continuation is approved, the Grant Manager 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 8.3.1—“Policy on Early Terminations Without Cause.”](#)

## 8.2 EXTENDING THE GRANT PERIOD

### 8.2.1 Policy on No-Cost Extensions

***The Department may grant an extension of the grant period without additional funds (no-cost extension) upon request. 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 excepting RPGs, including extensions, may not exceed 3.5 years.***

The Program strongly prefers that Principal Investigators complete projects according to the original schedule outlined in the “Terms and Conditions.” Under special circumstances, the Program may grant a no-cost extension. The availability of unspent funds is not sufficient reason to request a no-cost extension. A no-cost extension requires an amendment to the “Terms and Conditions” to extend the grant period and change funding and reporting schedules.

Due to state purchasing requirements, the total grant period cannot exceed 3.5 years. The grant period must end no later than 3.5 years after the first day of the fiscal year in which the grant was awarded.

#### 8.2.1.1 Procedures

##### Requesting a No-Cost Extension

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

1. Prepare to submit a request to the Grant Manager at least 60 days before the end of the grant period.
2. Log in to GrantEase and go to the “ToDo” list.
3. Select the “No-Cost Extension” task on the right side menu. Supply the following information:

- The length of extension time requested
  - Why an extension is needed
  - An estimate of the amount of unspent money remaining for the no cost extension period
  - Any additional information requested
4. Download, complete the form, and obtain all required signatures.
  5. Scan and upload a signed copy of the request form.
  6. Click “Submit Form” to send. The status of the “No-Cost Extension” task on the “ToDo List” page now appears as “In Routing.”

#### **No Cost Extension Request Review**

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

7. The Program evaluates the request on the basis of the following:
  - Justification of the budget
  - Scientific progress, measured against the specific aims, as shown in the narrative progress report and research milestone chart
  - Other support information
  - Compliance with the “Terms and Conditions”
8. If there are issues, the Principal Investigator will receive an e-mail notification that the task is declined. Log in to GrantEase to review specific feedback. If requested, supply additional information or clarification by going to the “No-Cost Extension” task on the “ToDo” list and submitting modified forms.
9. The Department sends a no cost extension or denial letter to the Sponsored Research Official, with a copy to the Principal Investigator, prior to the anniversary of the grant. An amendment to the “Terms and Conditions” will also be sent. This normally occurs within 15 days of the end of the grant period.

#### **8.2.2 Policy on Renewals**

***After the first 3-year term, RPG grants may be eligible for one non-competitive renewal of the grant period for up to 2 years, with a total grant period not to exceed 8.5 years.***

Only Research Project Grants (RPGs) are eligible to receive non-competitive renewals. The process for renewals is similar to the continuation process. However, an amendment to the “Terms and Conditions” to extend the grant period and allocate funds from the first fiscal year of the renewal is necessary. For continuation procedures, see [Section 8.1—“Continuing a Multi-year Grant.”](#)

## 8.3 EARLY TERMINATION

### 8.3.1 Policy on Early Terminations Without Cause

***Regardless of the cause of termination, the Grantee shall comply with the terms and conditions of this grant at all times during and after the grant period. The Grantee may be reimbursed for allowable costs incurred and any irrevocable charges through the date of termination up to the total award amount.***

***This grant may be terminated by the Grantee upon no less than 30-calendar days notice in writing, without cause, at no additional cost, unless a different notice period is mutually agreed upon by both parties.***

***This grant may be terminated by the Department upon no less than 30-days notice, without cause, at no additional cost, unless a different notice period is mutually agreed upon by the parties or outlined elsewhere herein. The provisions herein do not limit the Department's right to any legal remedies.***

***In the event funds to finance this grant become unavailable, the Department may terminate this grant upon no less than 24 hours notice in writing to the provider. Said notice shall be delivered by certified mail, return receipt requested, or in person with proof of delivery. 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 Program 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 narrative progress report within 60 days of the end date. (For more information about final financial and narrative progress reports, see [Section 7.1—"Required Financial Reports"](#) and [Section 7.2—"Required Scientific Progress Reports"](#))

## 8.4 CLOSING A GRANT

At the end of the grant period, Grantees must prepare a final narrative progress report, reconcile all grant expenses, submit the final invoice and financial report, and return any unspent funds to the Program.

### 8.4.1 Policy on Final Payment

***Payment of the final invoice for this 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.

#### 8.4.1.1 Procedures:

Grantees must complete these tasks to conclude the grant:

1. 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.)
2. Review all costs charged to the grant for appropriateness.
3. Post any late charges to reconcile the total expenses to the approved budget.
4. Submit a final narrative 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. Use the task and form provided in GrantEase. See the “Terms and Conditions” for the due date. See [Section 7.2.—“Required Scientific Reports”](#) for more information and procedures.
5. 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. Use the task and form in GrantEase. Refer to [Section 7.1—“Required Financial Reports”](#) for more information and procedures.
6. 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 will be the amount owed to the Grantee by the Department up to the total award amount. Use the task and form in GrantEase. Refer to [Section 7.1—“Required Financial Reports”](#) for more information and procedures.
7. Contact the Grant Manager with any concerns about final reports.

#### 8.4.2 Policy on Return of Funds

***This grant is a fixed payment grant, not a fixed price 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, with the exception of PRF stipend 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 Grantee discovers that overpayment by the Program has been made, the Grantee shall repay the overpayment within 40-calendar days.

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 Program. Failure to return unspent funds to the Program may affect future funding opportunities through the Program.

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

#### **8.4.2.1 Procedures**

To remedy a grant overpayment, the Grantee must:

1. Notify the Grant Manager as soon as an overpayment has been discovered.
2. 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.”](#)

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

***If the applicant’s proposal is funded, the Grantee must respond to Program requests for information for a period of five (5) years after the end of the grant period, including any no cost 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, et cetera.***

After the grant period, Grantees are required to continue sharing important developments, including presentations, publications, follow-on funding, further scientific breakthroughs, and clinical translation that result from Program grants. This information is used to track the impact of the Program and demonstrate Program value to the Florida legislators and citizens who provide this important funding. Grantees will be notified by a Program representative when this information is needed. It is usually collected annually around August or September in preparation for Program 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.” The Grant Manager will send a reminder e-mail with instructions to the Principal Investigator at least 30 days in advance of deliverable due dates. Deliverable due dates will also appear in the GrantEase “ToDo” list. Submission instructions are similar to “Progress Reporting” shown in [Section 7.2.1—“Policy on Required Progress Reports.”](#)

**THANK YOU**

## 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.

**Call for Applications** 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 Call for Applications in response to which the Grantee submitted an application.

**Commencement** is when the grantee is authorized by the Program Grant Manager 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 Program. (See definitions for grant period, and effective date.)

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

**Council** 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** means the Florida Department of Health. Unless otherwise stated, the “Department,” the “Florida Biomedical Research Programs,” the “FBRP,” the “Program,” “staff,” and “Program staff” are interchangeable and includes all personnel authorized to act on behalf of the Department.

**Effective date** is the date the Department 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.

**FBRP** is short for the Florida Biomedical Research Programs, which include the James and Esther King Biomedical Research Program and the Bankhead-Coley Cancer Research Program. Unless otherwise stated, the “Department,” the “Florida Biomedical Research Programs,” the “FBRP,” the “Program,” “staff,” and “Program staff” are interchangeable and includes all personnel authorized to act on behalf of the Department.

**GrantEase™** is a web-based information management system applicants and grantees are required to use.

**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. The Department contracts with Solix, Inc. to manage the day-to-day operations of the Program.

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

**GrantEase™** is the web-based information management system accessed by logging in at [www.floridabiomed.com](http://www.floridabiomed.com). It is used by grantees to submit grant deliverables and grant documents. It is used by Program staff to monitor and approve grantee deliverables. It is also the online system used to submit grant applications, process peer reviews, and view application evaluation reports.

**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 Extension** is an extension of the grant period without additional Program funds. It is a period of time up to 12 months authorized by the Program 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 Program funds. The submission and payment of the final invoice is postponed until the end of the no-cost extension, and the Grantee is authorized to accrue expenses against the approved budget during the no-cost extension.

**Non-Competitive Renewal** means the Program has committed to use available funds from one or more future year’s appropriations to a grant exceeding the normal three-year maximum length. Non-competitive renewals are subject to the availability of funds.

**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 value 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 memoranda** is a formal change to the grant “Terms and Conditions” affecting an entire class of grantees. If a policy memoranda is released, the Program 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 “Florida Biomedical Research Programs,” the “FBRP,” the “Program,” “staff,” and “Program staff” 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** is the one institutional official who has signatory authority for the eligible institution receiving a Program grant. The Sponsored Research Official may delegate his/her responsibilities to other agents of the institution, but with the understanding that she/he 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 – LINKS

### Accounting Guidelines

Generally Accepted Accounting Principles (GAAP)—available at <http://www.fasab.gov/accepted.html>

### Florida Websites

Florida Biomedical Research Programs and GrantEase—[www.floridabiomed.com](http://www.floridabiomed.com)

Florida Department of Health—[www.doh.state.fl.us](http://www.doh.state.fl.us)

Florida Single Audit Act: Section 215.97, *Florida Statutes*—available at <http://www.leg.state.fl.us/statutes/index.cfm>

Agreements Funded With Federal and State Assistance: Section 215.971—available at <http://www.leg.state.fl.us/statutes/index.cfm>

James & Esther King Biomedical Research Program Statute: Section 215.5602, *Florida Statutes*—available at <http://www.leg.state.fl.us/statutes/index.cfm>

William G. “Bill” Bankhead, Jr. and David Coley Cancer Research Program Statute: Section 381.922, *Florida Statutes*—available at <http://www.leg.state.fl.us/statutes/index.cfm>

Florida Department of Health IRB—[www.flpublichealthethics.net](http://www.flpublichealthethics.net)

### NIH Websites

Stem Cell Registry: NIH Human Embryonic Stem Cell Registry—<http://stemcells.nih.gov/research/registry/>

Recombinant DNA Molecules, NIH Guidelines for Research—[http://oba.od.nih.gov/rdna/nih\\_guidelines\\_oba.html](http://oba.od.nih.gov/rdna/nih_guidelines_oba.html)

Stem Cell Federal policy—<http://stemcells.nih.gov/policy/defaultpage.asp>