



Zika Research Grant Initiative

Funding Opportunity Announcement

FY 2016-2017

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Funding Opportunity: FY 2016-2017**

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NOTE: All awards in response to this Funding Opportunity are subject to the availability of funds and spending authority provided by the Florida Legislature. By submitting a grant application pursuant to this Funding Opportunity, all applicants acknowledge and consent to this condition.

Direct all questions about the online application process and related issues to:

Florida Department of Health
 Public Health Research Unit
 Division of Community Health Promotion
 4052 Bald Cypress Way Bin A24
 Tallahassee, Florida 32399-1725
 Office: 850-245-4585
 Email: research@flhealth.gov

I. OVERVIEW

1. Introduction

On September 22, 2016, Governor Rick Scott authorized \$25 million in state funds to support Zika research. The Zika Research Grant Initiative (hereafter referred to as the Initiative) shall provide grants for Zika research to pursue the following goals:

1. Support the development, testing, or delivery of a vaccine or other methods to prevent Zika infection;
2. Develop innovative, cost-effective Zika testing methods or therapeutics; and
3. Investigate health impacts of Zika virus on children and adults.

Grants will be awarded for up to three years. Applicants should focus on research designed to yield tangible results within the time allotted. Emphasis is placed on short-term deliverables and funded research should make advances within the award period.

The intent of these research funds is to initiate new research and discoveries. To accomplish this, researchers who intend to respond to this Funding Opportunity Announcement (FOA) should review the following links to increase their understanding of the current research.

National Institutes of Health Grants Database: <https://report.nih.gov/research.aspx>

Biomedical Advanced Research and Development Authority:
<http://www.phe.gov/about/barda/Pages/default.aspx>

2. Research Priorities

The Biomedical Research Advisory Council (BRAC) advises the State Surgeon General as to the direction and scope of the Initiative. The responsibilities of the council may include, but are not limited to:

- Providing advice on priorities and emphases of the Initiative.
- Developing criteria and standards for the award of research grants.

The priorities listed in this Funding Opportunity were developed by BRAC based on the initial priorities outlined by Governor Scott in his September 22 press release, available at: <http://www.flgov.com/2016/09/22/gov-scott-authorizes-25-million-in-state-funds-for-zika-virus-vaccine-research-and-development/>.

All applications submitted in response to this Funding Opportunity must be responsive to one of the following three research priorities. Efforts to foster collaborations among institutions, researchers, and community practitioners is encouraged, when possible.

1. Support Development of Vaccine or Other Methods – Participate in Zika vaccine **Phase II** clinical trial studies for advancing the overall progress of promising vaccines (or other prevention technologies) being developed. By partnering with Investigators already in the process of developing a vaccine, Florida research centers can establish additional clinical trial sites and increase the volume of participants. This provides additional support and information about the relative safety and effectiveness of the new vaccine, including among vulnerable populations. In addition, researchers can propose the development of other methods for the prevention of Zika virus transmission.
2. Innovative Diagnostic Testing or Therapeutics – Research in this area will develop methods that will determine the presence of disease in an individual suspected of having Zika. New diagnostic testing methods can include but are not limited to:
 - Predictive
 - Serologic
 - Point of service testing
 - Genetic screening
 - Screening and treatment, including barriers and opportunities (e.g., longitudinal studies with children who do not have overt signs of microcephaly but may have other long-term disabilities).
 - Multiplexed assays
 - Subtractive or reductive diagnostics for flavivirus pre-exposed populations
 - Therapeutic approaches for viral clearance and treatment post-infection

Applications can also be submitted for advancing screening methods, such as improved screening accuracy, detection of high risk subgroups, and/or improved implementation of a screening program that results in an increase in early detection of Zika virus.

In addition, applications may also be submitted that address the development of innovative therapeutics.

3. Health Effects of Zika Virus – Expand upon research that improves scientific understanding of causes and subsequent impact of Zika-related morbidities in other systems (e.g., cardiovascular, pulmonary, endocrine, lymphatic, central nervous system, reproductive, developmental). This can be accomplished through longitudinal, observational studies and discovery science. This could include natural history studies of infection in pregnant women (asymptomatic and symptomatic) and evolution of the virus. Researchers are encouraged to identify promising new treatments from laboratory-based to cellular discoveries. This can include drug discovery and/or drug pilot trials. The Zika virus research can draw from other research on viruses, such as HIV or dengue, to make advancements in Zika. Treatment should focus on diminishing the long-term effect of Zika on various organs, senses, and systems and may include:
 - hearing and vision;
 - neurodevelopment, neurocognition in children, effects on central nervous system, neuromuscular diseases, peripheral nervous system;
 - cognitive effects in adults; and,
 - organ damage.

Treatment options and effects can be for children and adults. Studying courses of treatment for long-term effects of exposure, even in the absence of a positive Zika test, is encouraged.

3. Mechanisms of Support

Collaboration with other Florida institutions (e.g., universities, teaching hospitals, colleges, Florida-based Veteran’s Administration), research centers, biotech companies, and private industry is encouraged and will be considered during the review process.

The following types of grants are available to pursue the above three research priorities.

Grant Mechanism	Maximum Amount per Year, including direct and indirect costs	Maximum Duration
Rapid Pilot	\$ 200,000	Up to 1 year
Dynamic Change Team Science	\$ 700,000	Up to 3 years
Investigator Initiated/Discovery Science	\$ 400,000	Up to 3 years
Clinical Research	\$ 400,000	Up to 3 years

1. **Rapid Pilot** – The intent of a Rapid Pilot grant mechanism is for exploratory, novel studies that break new ground or extend previous discoveries toward new directions or applications. No preliminary data are required, but may be included if available. Within a Rapid Pilot, the following are included as examples: development of novel mosquito abatement and repellent, screening, and diagnostic methods and the implementation of serum and epidemiologic studies of Zika-infected patients.
2. **Dynamic Change Team Science** – The purpose of this grant mechanism is to stimulate a consortium of clinical, basic, or translational research centers to conduct high quality grant-supported research. The consortium should involve partnerships among investigators across Florida, with the award made to a single lead organization. The lead organization of the consortium must perform a substantive role in conducting the planned research including providing oversight of all scientific, programmatic, financial, and administrative matters related to the grant. The collaborating organizations must have well-defined roles that contribute to the common scientifically rigorous research goals, and include sound background information, hypotheses, protocols, and promising practices that clearly address one or more areas of research interest. A letter of commitment from all collaborating organizations is required. Grants may range from discovery science to more mature projects that are attempting to advance a therapeutic approach or concept.

Dynamic funding changes could be distributed based on progress. This would be accomplished through multiple aims and then, based on progress, the team could change its

focus to concentrate on the most promising aim of those initially proposed. A management team needs to be part of this proposal.

This could include a Florida-based network of clinical trial sites.

3. **Investigator Initiated/Discovery Science** – In line with RO1 grants, this Investigator Initiated grant mechanism supports discrete, specified, circumscribed projects to be performed by the named investigator(s) in an area representing the investigator's specific interest and competencies which address one or more of the Research Priority Areas listed in this FOA.

Discovery Science is fundamental, theoretical, or experimental investigative research to advance knowledge without a specifically envisaged or immediately practical application. For this mechanism, Discovery Science should focus on understanding the events related to the development or prevention of Zika and related complications at the molecular, cellular, and organismic levels, as well as the discovery and development of new drugs or therapies.

4. **Clinical Research** – Clinical research refers to research that gathers evidence of the benefits and harms of various treatment options for Zika infection, directly involves a particular person or group of people, or uses materials from humans, such as their behavior or samples of their tissue. Clinical research can involve observational trials, trials of new medications, trials of novel medication combinations, behavioral health interventions, or health care delivery comparisons. Projects to collect and/or store tissue or fluid samples would be consistent with this research focus.

4. Highlights

- **All awards in response to this Funding Opportunity are subject to the availability of funds and spending authority provided by the Florida Legislature. By submitting a grant application pursuant to this Funding Opportunity, all applicants acknowledge and consent to this condition.**
- Applications will only be accepted through the online application system.
- Applicants conducting research with the Department of Health Florida Birth Defects Registry data registry should follow the instructions in the link below.
Florida Birth Defects Registry Data Inquiries and Requests:
http://fbdr.org/Data_Research/data_inquiry.html. For all other research involving Department of Health data, applicants must include a letter of support from the program office which houses the data.
- There is a defined question and answer timeframe as indicated in Table 1. To ensure equal access by all applicants to questions and answers, all questions must be submitted in writing. Answers to questions will be published according to the schedule indicated in Table 1. Questions that are received after the timeframe as indicated in Table 1 will not be answered.

- When research involves human participants, grantees are required to obtain and maintain approval from an Institutional Review Board (IRB) within 60 days of notice of award. Grantees should be prepared to start the regulatory review process at their institution immediately upon being notified of award. Grantees are required to follow Department policies for reporting unanticipated problems and non-compliance involving the research to the Department.
- The Initiative will pay a proportional percentage of the base salary (based on effort) of any personnel named on the application for this grant. The **maximum annual base salary** used in calculating these payments must not exceed the Executive Level 2 annual salary rate of the Federal Executive Pay Scale that is in effect as of the application submission date. See [II.7](#), Definitions, for more information about the Federal Executive Pay Scale.
- Applicants are encouraged to check the Initiative website (<http://www.floridahealth.gov/provider-and-partner-resources/research/zika-research.html>) regularly throughout the application, peer review, and award processes for announcements, addendums, and answers to programmatic questions.
- All materials submitted to the Department are subject to the provisions of Article 1, Section 24, Florida Constitution and Chapter 119, Florida Statutes, Florida’s public records law. These laws grant a right to inspect any public record to anyone upon request. All materials related to this Initiative, including applications, are public record. Refer to [II.6](#) for instructions on how to properly identify confidential/proprietary information.
- After awards are made, each grantee must sign a contract, called the “Terms and Conditions,” agreeing to certain legal requirements of the award. The “Terms and Conditions” are non-negotiable and acceptance is required as part of the grant award process. The Department reserves the right to change or modify the “Terms and Conditions” as needed. By submitting a grant application pursuant to this Funding Opportunity, all applicants acknowledge this requirement. The “Terms and Conditions” also include the post-award schedule of deliverables.

5. Schedule of Important Dates

Table 1. Schedule of Important Dates		
ACTIVITY	DATES	IMPORTANT INFORMATION
Funding Opportunity Announcement published to the Initiative website	October 21, 2016	Located on the Initiative website at: http://www.floridahealth.gov/provider-and-partner-resources/research/zika-research.html

Table 1. Schedule of Important Dates

ACTIVITY	DATES	IMPORTANT INFORMATION
Letter of Intent Opens	Anticipated date: October 24, 2016	Applicants must register, prepare, and submit a letter of intent and application through the online system found on the Initiative’s website: http://www.floridahealth.gov/provider-and-partner-resources/research/zika-research.html .
Written questions accepted	Questions may be submitted any time until 5:00 p.m. EST November 1, 2016	Email questions to: research@flhealth.gov
Answers posted to written questions	Anticipated Date for responses to questions: October 28 and November 4, 2016	Questions and answers will be published on the Initiative’s website in two groups as they come in.
Letter of Intent due (required)	Letter of Intent must be submitted by 5:00 p.m. EST November 10, 2016	Applicants must register, prepare, and submit a letter of intent and application through the online system found on the Initiative’s website: http://www.floridahealth.gov/provider-and-partner-resources/research/zika-research.html . Applications without a Letter of Intent by the deadline are not eligible and will not be considered.
Main application opens	Anticipated date: November 14, 2016	Applications must be submitted in the online system located on the Initiative’s website.
Applications due	Applications must be <u>submitted</u> before 5:00 p.m. EST December 5, 2016	Applications must be submitted using the online system available on the Initiative’s website. Applications must be <u>submitted before the deadline</u> . Applications being edited will not be accepted after the deadline.

Table 1. Schedule of Important Dates		
ACTIVITY	DATES	IMPORTANT INFORMATION
Awards announced	Anticipated date: January 16, 2017	Award letters and Terms & Conditions will be emailed to the Sponsored Research Official and the Corresponding Principal Investigator.
Institutional reviews due (if applicable)	Immediately after award notification, grantees should submit application(s) for all institutional authorizations including, but not limited to the Institutional Animal Core Use Committee (IACUC), Institutional Review Board (IRB) and Radiation Safety Review. Project work may not begin until documentation of all approvals is provided. The documentation of institutional approval(s) must have the same project title as the application project title and must be signed by the Review Board chairperson or organizational representative.	Grantees should be prepared to start the regulatory review process at their institutions immediately upon being notified of award.
Grants begin	Anticipated date: January 23, 2017	Contingent on verification of all eligibility requirements, regulatory approvals and executed Terms and Conditions. Executed Terms and Conditions requires signatures by both the awardee and Department.
Proposal evaluation summaries available to applicants	On or before February 8, 2017	Individual evaluation reports will be provided to applicants. Applicants will be notified via e-mail when their evaluation report is available.

Changes will be posted to the Initiative website. Applicants should monitor the website for changes and announcements.

II. ELIGIBILITY AND APPLICATION REQUIREMENTS

1. Zika-Relatedness

All applicants must clearly demonstrate how the proposed project is relevant to Zika. Proposals must demonstrate a close relationship with innovative approaches to prevention, testing, or investigation of Zika virus health impact.

2. Eligibility Requirements

A. Eligible Applicants

Funding considerations will be given to investigators who show collaboration with other Florida institutions (universities, teaching hospitals, colleges, Veteran's Administration Florida Research Sites). Collaboration with private industry, biotech companies, and research centers is allowed, however the lead institution must be an established research institution in the state of Florida.

Each application must identify a Corresponding Principal Investigator. The Corresponding Principal Investigator is the individual designated by the applicant organization legally responsible to direct the grant project. The Corresponding Principal Investigator is responsible and accountable to the applicant organization officials for the project's scientific and technical direction as well as the proper conduct of the project. There must be one designated Corresponding Principal Investigator. There may be multiple collaborators on a project, but there must be only one Corresponding Principal Investigator.

To be eligible as a Corresponding Principal Investigator at an eligible institution, the individual must be a full-time faculty member by the time the application is submitted. Temporary faculty members, even though full-time, are not eligible to apply. The Corresponding Principal Investigator must be a U.S. citizen or permanent resident; unauthorized aliens shall not be employed pursuant to §274A(e) of the Immigration and Naturalization Act (8 U.S.C. 1324a), section 101 of the Immigration Reform and Control Act of 1986, and Florida Executive Order 11-02.

Grant applications failing to meet the eligibility requirements will be rejected.

B. Letter of Intent

Submission of a Letter of Intent (LOI) is required prior to submission of an application. For collaborative applications, the lead organization is required to submit the LOI. The information it contains allows Department of Health staff to estimate the potential review workload and plan for the review. Applications will not be accepted if the researcher has not submitted a LOI by the deadline listed in Table 1. However, applicants who submit a LOI are not bound to submit an application, and a decision to submit a LOI and not submit an application will not impact eligibility for future funding opportunity announcements or be considered by peer reviewers in future funding applications. Researchers must submit an application under the same title that was specified in the LOI. Corresponding Principal Investigators are allowed to submit one LOI.

Applicants must register, prepare, and submit a LOI through the online system found on the Initiative's website: <http://www.floridahealth.gov/provider-and-partner-resources/research/zika-research.html>.

The LOI must include all of the following information:

- Name of funding opportunity (Zika Research Grant Initiative)
- Name, address, telephone number, email address of the project director or Corresponding Principal Investigator
- Names of other research personnel
- Lead organization
- Collaborating institutions and collaborating research personnel, if any
- Descriptive title of proposed research
- Type of research priority
- Grant mechanism
- General Audience Abstract (no more than 500 words)
- Key Words

C. Guidelines for Florida Biomedical Research Advisory Council Member Participation

The BRAC has statutory conflict of interest obligations regarding the participation of its members in Bankhead-Coley Cancer Research Program (BC) and James and Esther King Biomedical Research Program (JK) grants and grant applications. These obligations continue with the Zika Research Grant Initiative.

BRAC members shall not:

- Receive any form of financial compensation from a Zika grant award.
- Participate in any named role on a proposed Zika grant project in this Funding Opportunity.
- Advise applicants regarding the preparation of a specific Zika grant application.
- Answer any programmatic questions (e.g., eligibility, content of the Funding Opportunity, competition procedures, etc.).

- Violate any provision of Chapter 112, Part III, Florida Statutes

BRAC members may:

- Provide and sign letters of assurance, support or cover pages submitted as part of the application in cases where doing so is part of their official duties at the applicant organization.

Violations of these restrictions may result in the disqualification of an applicant for this competition. For a list of BRAC members, refer to the program website.

D. Duplicate Applications and Overlap Limits

Eligible Corresponding Principal Investigators can submit **one** application to the Zika Research Grant Initiative. There is no limit on the number of applications that may be submitted from an eligible institution.

The Corresponding Principal Investigator may serve as co-PI or as collaborator on other applications, provided they are not over-committed.

The Corresponding Principal Investigator shall not submit the same project/research to the Zika Research Grant Initiative that is also being submitted by another investigator regardless of the grant mechanism.

Applicants must ensure that their proposed project does not duplicate or significantly overlap, scientifically or financially, with other projects in which they or any key personnel are involved. Overlap, whether scientific or financial, or commitment of a project member's effort greater than 100 percent is prohibited.

3. Required Grant Application Components

Table 2. Application Components	
The online application will prompt applicants of required fields and word limits for each section.	
Category	Comment
General Project Information	Required. Identifies general project information, the applicant organization, and the Corresponding Principal Investigator
General Audience Abstract	Required. Explains the proposed project in lay terms, including its relationship to the goals of the Department. Applicants will complete this in the General Project Information section of the application.
Scientific Abstract	Required. This is the scientific description of the project. Applicants will complete this in the General Project Information section of the application.

Table 2. Application Components

The online application will prompt applicants of required fields and word limits for each section.

Category	Comment
Health Impact	<p>Required. Applications must describe how the proposed project impacts the health of Floridians. Health impact means the ability of the research to reduce the incidence, prevalence, and health effects of Zika. Applications must describe how the results of the research can provide information and evidence for changes in policy, or improve health service delivery and quality of care, or improve disease prevention.</p> <p>Consider possible long-range effects of applying knowledge gained in the research or the ability of the research to support future research grant applications or publications or patents.</p> <p>Applicants will complete this in the General Project Information section of the application.</p>
Zika-Relatedness	<p>Required. Provides a clear explanation of how the project is related to Zika.</p> <p>Applicants will complete this in the General Project Information section of the application.</p>
Collaborator Information	Required. Identifies all key personnel.
Biographical Sketch	Required. Bio-sketches of key personnel must be uploaded as a single document in the format specified in the online system.
Consultants	Required (if there are consultants). Letters from all consultants confirming their roles in the project, including the rate/charge for consulting services must be uploaded as a single document.
Research/Project Plan	Required. Describe the specific aims including the significance, innovation, and approach. Provide a bibliography of any references cited and list facilities and other resources.
Human Subjects	Required (if applicable). Describe protections for human subjects involved in the research.
Vertebrate Animals	Required (if applicable). Describe protections for animals involved in the research.
Recombinant Nucleic Acid Molecules	Required (if applicable). Describe use of Recombinant Nucleic Acid Molecules involved in the research.
Survey Instruments	Required (if applicable). Survey Instruments must be uploaded as a single document.
Stem Cells	Required (if applicable). Describe use of stem cells involved in the research.

Table 2. Application Components

The online application will prompt applicants of required fields and word limits for each section.

Category	Comment
Table, Image, or Graph	Optional. Upload a single document containing images, graphs, and figures. (There is no page limit on the number of images, graphs, and figures). Images, graphs, and figures cannot appear in the text of the application, but must be uploaded separately in this section. Figure legends need to be included in the document.
Budget Template and Narrative	Required. The budget must explain the planned spending. See appendix for budget template and budget narrative forms. The budget template and narrative form can be downloaded within the online application system. The completed budget template and narrative forms must be uploaded as a single document. When applications involving collaborations with different universities or research institutions, the lead institution should complete the budget form and include collaborating institutions as a contractual expense.
Letters of Support	Required (if applicable). If applying for a grant involving Department of Health data, a signed letter of support from the program office which houses the data must be uploaded. Letters of support are not required for other types of research. Upload as a single document. There is no page limit on the number of letters of support.
Letters of Commitment	Required (if applicable). If applying for the Dynamic Change Team Science mechanism of support, a letter of commitment from all collaborating organizations is required.
Federal Agency Peer Review Summary Statement	Required (if applicable). If the grant has previously been submitted to a federal funding agency, applicants must upload their Federal Agency Peer Review Summary Statement. For this FOA, "high scientific merit" is a percentile ranking of 16th or better.
Reportable Financial Interests	Required. The Corresponding Principal Investigator must disclose any financial interests that the researcher, the researcher's immediate family, or any other personnel on the project (sub-investigators and research staff) and their immediate families, have related to the research.
<p>Applicants are discouraged from submitting information considered proprietary unless it is deemed by the applicant to be essential for proper evaluation of the application.</p> <p>If the application contains information that the applicant believes constitutes trade secrets or proprietary information or is protected by a specific statutory exemption; it should be limited to the Research Project Plan section. The applicant must CLEARLY identify the information with [brackets] and a footnote that specifies the law that makes the document or information exempt from the public records laws. If a public records request is made involving documents with declarations of confidentiality, the Department will notify the applicant so that he/she may defend the claim in circuit court. The Department of Health will not provide legal representation to assert a confidentiality claim when a public record request is made.</p>	

4. Allowed and Disallowed Costs

The following information explains direct and indirect costs allowed by the Department, as well as disallowed costs.

A. Allowed Direct Costs

Allowed direct cost expenses must be directly related to the project and may include:

- Salaries, including up to a three percent increase per year.
- Tuition
- Fringe benefits
- Supplies
- Equipment, including computed tomography (CT), magnetic resonance imaging (MRI), or other imaging systems, and improvements to existing systems
- Lab Services
- Domestic travel (Travel will be reimbursed at no more than the state of Florida travel reimbursement rates. Current state of Florida reimbursement rates can be found in section 112.061, Florida Statutes)
- Consultant costs, provided they do not exceed 10 percent of the total budget
- Patient-care costs
- Animal-care costs
- IRB or IACUC fees
- Consortium or contractual costs
- Fees to obtain data from the Florida Office of Vital Statistics

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
- these administrative costs have not been included in the calculation of the indirect costs

The Initiative 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. Pay particular attention to these criteria with costs such as copying charges, telephone and Internet charges, maintenance contracts, etc.

Maximum Annual Base Salary Calculations:

The Initiative will pay a proportional percentage of the base salary (based on effort) of any personnel named on the application for this grant. The maximum annual base salary used in calculating these payments must not exceed the Executive Level 2 annual salary rate of the Federal Executive Pay Scale that is in effect as of the application submission date. See [II.7](#), Definitions, for more information about the Federal Executive Pay Scale. This salary cap excludes fringe benefits, facilities, and administrative (F&A) expenses, and also excludes any income that an individual may be permitted to earn outside of the duties to the applicant organization. This provision is consistent with the NIH salary limitations on grants, cooperative agreements, and contracts.

Work Must Occur in Florida:

Activities funded through this competition must occur in Florida. All work (effort) must occur and funds must be spent in Florida at the applicant organization and any collaborating entities. However, the Department may make exceptions if the service is essential and only provided outside Florida, and if the amount is less than 10 percent of the requested amount.

B. Allowed Indirect Costs

Indirect costs (also referred to as IDC, F&A, or administrative costs) are limited to 15 percent 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.

C. Disallowed Costs

All direct costs must be specifically and directly related to the project, necessary for the project's completion, adequately justified, and made during the active grant period. Any other costs are disallowed. Additionally, the following items shall NOT be paid for with grant funds:

- Florida Department of Health personnel salary
- Construction, renovation, or remodeling
- International travel (including Canada)
- Vehicles
- Entertainment
- Employment subsidies
- Dues/Membership fees
- Lobbying
- Meals/Food (other than as part of travel costs)
- Malpractice insurance premiums

5. Inquiries and Contacts

A. Programmatic Questions about This Funding Opportunity

This Funding Opportunity is issued by the Florida Department of Health. The Public Health Research Unit manages the Funding Opportunity and is responsible for answering all applicant questions. Applicants and persons acting on their behalf may contact the Department in writing via email as indicated below regarding programmatic issues. Applicants who attempt to contact Biomedical Research Advisory Council members regarding this Funding Opportunity Announcement may have their applications disqualified.

To ensure equal access by all applicants to questions and answers, all programmatic questions must be submitted in writing via email to research@flhealth.gov. Answers to questions will be available on the Initiative website. Answers to submitted questions will be posted in groups as they are received and published on the website, according to the schedule in **Table 1**.

B. Technical Questions about the Online Application

Direct all questions about the online application process and related issues (e.g., username and password problems) to Help.fldoh_zika@orau.org.

The Department recommends that applications be submitted early. **Applications submitted past the deadline will not be considered, regardless of the reason.**

6. Requirements for Protecting Intellectual Property

Submitted materials are subject to the provisions of Art. I, Sec. 24, Florida Constitution and Chapter 119, Florida Statutes, Florida's public records law. These laws grant the right to any person to inspect any public record. There are some documents and information that are exempt from the public records laws. All application materials are public record unless the applicant can show how they are exempt.

Applicants are strongly discouraged from submitting information considered proprietary unless it is deemed by the applicant to be essential for proper evaluation of the application. If the application contains information that the applicant believes constitutes trade secrets, intellectual property, proprietary information, or information protected by a specific statutory exemption, it should be limited to the research/project plan. The applicant must clearly identify the confidential information with [brackets].

If a public records request is made involving documents with declarations of confidentiality, the Department will notify the applicant so that he/she may substantiate and defend the claim. The Department will not provide legal representation to assert a confidentiality claim.

7. Definitions

Business entity: Per section 606.03(1), Florida Statutes, this means any form of corporation, partnership, association, cooperative, joint venture, business trust, or sole proprietorship that conducts business in Florida.

Collaborator: An individual involved with the Corresponding Principal Investigator in the scientific development or execution of the project. These individuals typically devote a specific percent of effort to the project and are identified as key personnel. The collaborator may be employed by, or affiliated with, either the Grantee institution or an institution participating in the project under a consortium or contractual agreement.

Commercialization: The process of developing markets and producing and delivering products or services for sale (whether by the originating party or by others). As used by the Initiative, commercialization includes both government and non-government markets.

Consortium or Contractual Agreement: An agreement whereby a project is carried out by the Grantee and one or more other organizations that are separate legal entities. In this arrangement, the Grantee contracts for the performance of a substantial and/or a significant portion of the activities to be conducted under the grant. These agreements typically involve a specific percent of effort from the consortium's Corresponding Principal Investigator and a breakdown of costs by category, such as personnel, supplies, and other allowable expenses, including indirect costs.

Consultant: An individual hired to give professional advice or services for a fee, normally not as an employee of the hiring entity. Consultants may also include firms that provide paid professional advice or services.

Community-Based Participatory Research (CBPR): A collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR begins with a research topic of importance to the community (which can be self-defined, regional, or by interest) and has the aim of combining knowledge with action to improve health outcomes

Department: Florida Department of Health.

Development: The systematic application of knowledge toward the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements.

Eligible Institution: Any university, research hospital, Florida-based Veteran's Administration, or established research institute in Florida.

Feasibility: The practical extent to which a project is capable of being successfully performed within the requested time and for the awarded money.

Federal Executive Pay Scale, Executive Level 2: The U.S. Office of Personnel Management establishes executive pay schedules each year normally around the first month of the calendar year. To view the current Executive Level 2 pay scale, visit the website of the U.S. Office of Personnel Management at <http://www.opm.gov/oca/> and search for executive schedule.

Full-time Equivalent (FTE): The definition of a Full-time Equivalent must be in accordance with the institution's policy, used consistently by the institution regardless of the source of support, and may be different in terms of actual months per year or days per week at the applicant institution.

Full-time Faculty: Full-time Faculty positions are defined as teaching, clinical, and research appointments carrying classroom teaching, laboratory teaching, clinical teaching or service, or research assignments equal to at least nine months per fiscal year or 0.75 FTE. This includes tenured, tenure-track, and non-tenure track appointments.

Institutional Base Salary: The annual compensation that the applicant institution pays for an employee's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of duties to the applicant institution. Base salary may not be increased as a result of replacing institutional salary funds with grant funds.

Institutional Review Board (IRB): A committee that reviews research involving human subjects to determine if research complies with law, including but not limited to 45 CFR 46, and 21 CFR 50, 56, 312 and 812 as applicable.

Key Personnel: Key personnel are defined as, and should be limited to, individuals who contribute to the scientific development or execution of the project in a substantive way, whether or not salaries are requested.

Nonpublic Institutions: Nonpublic institutions in Florida operating under Chapter 1005, Florida Statutes are eligible. For the purposes of the Initiative, any branch campuses, centers, or other affiliates of a nonpublic institution are considered one and the same with that institution. Where the number of applications is limited, the institution and its branch campuses, centers, or other affiliates must coordinate submission(s) in order to comply with the limitation.

Overlap, Commitment: Commitment overlap occurs when any project staff has time commitments exceeding 100 percent. This is the case whether or not the grant includes salary support for the effort. While information on other support is only requested for the Corresponding Principal Investigator, no individual on the project may have combined commitments in excess of 100 percent.

Overlap, Financial: Financial overlap occurs when duplicate or equivalent budget items (e.g., equipment, salary) are requested in an application but are already funded or provided for by another source.

Overlap, Scientific: Scientific overlap occurs when: (1) substantially the same research is funded by two or more different funding sources, or (2) a specific research objective and the research design for accomplishing that objective are the same or closely related in two or more awards, regardless of the funding source.

Corresponding Principal Investigator: The one individual designated by the applicant organization to direct the project to be supported by the grant. The Corresponding Principal Investigator is responsible and accountable to applicant organization officials for the proper conduct of the project.

Public University: A public (state) university is defined in section 1000.21, Florida Statutes, except as otherwise specifically provided in that statute; are the 12 named public, postsecondary institutions and any branch campuses, centers, or other affiliates of the institution. For purposes of the Initiative, any branch campuses, centers, or other affiliates of a public university are considered one and the same with that university. Where the number of applications is limited, the university and any branch campuses, centers, or other affiliates must coordinate submission(s) in order to comply with the limitation.

III. INSTRUCTIONS FOR APPLICATION PREPARATION AND SUBMISSION

1. General Instructions for Application Submission

Applicants must register, prepare, and submit a letter of intent and application through the online system found on the Initiative's website: <http://www.floridahealth.gov/provider-and-partner-resources/research/zika-research.html>.

Application materials not submitted in the specified manner and in the specified format will be disqualified from competition.

Required signature pages such as budgets and letters of support, must be included in the appropriate section of the application as indicated in the online instructions. Online applications without scanned copies of these pages will be disqualified.

Other documentation and materials such as biographical sketches and other support must be converted to electronic format and placed in the appropriate section of the online application.

Peer reviewers evaluate only the materials in the application, and do not consider other sources of information.

A. Online Registration and Application Submission

The online system will be available to accept applications for this Funding Opportunity on the date published in Table 1.

To complete the online application process:

1. Applicants must register to access the online application and forms. Register for an online application on the Initiative's website (<http://www.floridahealth.gov/provider-and-partner-resources/research/zika-research.html>) and complete the brief project profile. Information entered into the Registration fields will carry forward to the application. Registration will be acknowledged with an email message containing login instructions and a username and password.
2. Complete the online application form. Deviations may be grounds for the Initiative to reject the entire application. Special formatting, scientific notation, pictures, and objects may be included in these documents. However, within the online application form fields such as the Project Title, General Audience Abstract and the Scientific Abstract, use only conventional alphanumeric letters and numbers (i.e. ASCII text) with no drawings, special characters, or symbols.
3. An application cannot be changed after the submission due date. Errata sheets or replacement files will not be accepted after the application deadline.
4. Once the application is submitted, the Corresponding Principal Investigator cannot make any further changes.

B. General Application Guidelines

1. Applications must be in English.

2. The entire text of all documents uploaded into the online application must be single spaced in an easily readable font. Use standard 11-point type for the text, and no less than 10-point type for table figures and legends. Margins on all applicant created documents should be at least one inch (excluding required headers and footers). Do not use photo reduction for scanned items. Use black type for all text. The application must contain only materials that, when scanned or converted to PDF format, are clear, sharp, and easy to read.
3. All applications must be self-contained within specified page limits. Unless otherwise specified in this document, Internet website addresses (URLs) may not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites.
4. Before it can be submitted, the application must contain all of the required sections identified in [Table 2](#). Uploaded files should be titled by the categories listed in the table.
5. Applications must comply with space limitations specified in the online application. Appendices are not allowed.

IV. AFTER APPLICATION SUBMISSION

1. Changes to a Submitted Application

It is the responsibility of the applicant to ensure that a complete application is submitted before the date and time specified in [Table 1](#). The Department does not allow submitted application files or data to be replaced or changed after the submission deadline. This decision will help ensure no applicants receive an unfair advantage. Before submitting your application, please check it for completeness, accuracy, quality, and readability. This should include verifying that all graphic elements, including tables, charts, and images, converted properly when saving the original documents in PDF format as required.

2. Evaluation of Applications

The Department will use a multi-step evaluation process before making award determinations for all applications submitted in response to this Funding Opportunity. The Department will consider the outcome of each of these evaluation steps in making final funding recommendations to the State Surgeon General.

A. Administrative Review

Application materials not received according to the date, time, and location specified in [Table 1](#) will be disqualified.

Each application submitted by the deadline indicated in [Table 1](#) will receive an administrative review verifying mandatory eligibility requirements and the completeness of the application. The administrative review does not include review of the overall scientific impact.

Any application failing to meet all administrative requirements may be ruled ineligible for funding in response to this Funding Opportunity and not entitled to further consideration, and will not undergo peer review.

The Department reserves the right to disqualify any and all applications or to waive minor irregularities when doing so would be in the best interest of the State of Florida. A minor irregularity is defined as a variation from the specifications of this Funding Opportunity that does not give any applicant an advantage or benefit not enjoyed by other applicants, does not affect the cost of the application, nor adversely affects the interests of Florida. At its option, the Initiative may correct minor irregularities, but is under no obligation to do so.

B. Peer Review

Department peer reviewers will assess the overall impact of all qualified/eligible applications. Peer review panels comprise reviewers with expertise in the substance and methodology of the proposed project. Individual reviewers will review and rate applications, including assessing Zika-relatedness, health impact, examining budget requests, and recommending the level of support necessary to complete the work. Reviewers will be nationally prominent individuals drawn from various sectors in the life sciences including universities, government agencies, and industry. Reviewers will be located outside of Florida and will not be associated with any Florida-based public or private entity working in the life sciences. Before being granted access to proposals, every reviewer will be required to accept the terms of a Confidential Nondisclosure Agreement. Reviewers are required to disclose financial interests to the Department, and the Department determines if any disclosed financial interests are conflicts of interests. Reviewers with financial conflicts of interest are not allowed to review applications. Reviewers will receive honoraria for their participation and are expected to set a high standard for scientific excellence. The number and composition of peer review panels will be determined by the number and scientific range of applications received.

Overall Impact Score:

Similar to the NIH, peer reviewers will use a standard rating format:

- (1) Exceptional – Exceptionally strong with essentially no weaknesses
- (2) Outstanding – Extremely strong with negligible weaknesses
- (3) Excellent – Very strong with only some minor weaknesses
- (4) Very Good – Strong but with numerous minor weaknesses
- (5) Good – Strong but also at least one moderate weakness
- (6) Satisfactory – Some strengths and some moderate weaknesses
- (7) Fair – Some strengths but with at least one major weakness
- (8) Marginal – A few strengths and a few major weaknesses

(9) Poor – Very few strengths and numerous major weaknesses

Peer reviewers will rate all proposals for overall impact on the following criteria:

- Significance: the importance of the topic being addressed.
- Investigators: the qualifications of the key personnel contributing to the project.
- Innovation: the potential for the project to shift current paradigms.
- Approach: the appropriateness of the planned strategy, methodology, and analyses.
- Environment: the suitability of institutional support, equipment, and physical resources.
- Health impact on the people of Florida.

Other Review Considerations:

Separately, peer reviewers will rate the relationship of the project to the advancement toward prevention, diagnosis, and/or treatment of Zika. Peer reviewers will be asked the question “Has the applicant made a compelling case for a strong Zika relationship?”

Peer reviewers will also identify any concerns regarding the proposed budget or apparent scientific or budgetary overlap with active or pending support. Reviewer concerns regarding protection of human and/or animal subjects will be considered.

C. Programmatic Review

The Department and the BRAC will consider the peer review scores in a manner that eliminates or appropriately manages any conflicts of interest. Other programmatic interests, such as the availability of funds, and Initiative goals and preferences, will be used to form a funding recommendation to the State Surgeon General.

D. Evaluation Reports

For all eligible and qualified applications, an evaluation report will be sent to the researcher on the date specified in Table 1.

3. Notification of Funding Decision

The applicant organization and Corresponding Principal Investigator will receive written notification of the funding decisions as indicated in Table 1. All awards in response to this Funding Opportunity are subject to the availability of funds and spending authority provided by the Florida Legislature. By submitting a grant application pursuant to this Funding Opportunity, all applicants acknowledge and consent to this condition.

4. Requests for Re-Consideration

All funding decisions of the State Surgeon General are final.

5. Grantee Requirements

A. Terms and Conditions

After awards are made, each grantee must sign a contract, called the “Terms and Conditions,” agreeing to certain legal requirements of the award. The “Terms and Conditions” are non-negotiable and acceptance is required as part of the grant award process. The Department reserves the right to change or modify the “Terms and Conditions” as needed. The “Terms and Conditions” include the post-award schedule of deliverables.

B. Grantee Reporting Requirements

If the applicant’s proposal is funded, the Grantee must respond to Department requests for information for a period of five (5) years after the end of the grant period, including any no cost extensions. The requested information may include, but is not limited to long-term outcomes based on the funded project, including the value of additional grant awards for Zika research, a list of Zika presentations, a list of Zika publications in peer-reviewed journals, commercialization results and any invention disclosures, patent filings, and patents received.

C. Open Innovation and Sharing of Publication-Related Materials, Data, and Software

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 the Department are encouraged to use material 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. Also, grantees should provide a copy of any article published from research supported by this Initiative to the Department within three months of the date the article is published.

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 the Department funded projects/research. For more information on the NIH Open Access Policy visit <http://publicaccess.nih.gov/>.

V. APPENDIX

Terms and Conditions Template

Florida Department of Health Zika Research Grant Initiative



Terms and Conditions

The Florida Department of Health (“Department”) requires that a Grant recipient (“Grantee”) for the Zika Research Grant Initiative agree to certain legally enforceable terms and conditions. “Grantee” refers to both the eligible institution and its authorized agents.

The following Funding Opportunity Announcement (“FOA”), including any FOA amendments, and the application submitted by the Grantee in response thereto (“application”), are hereby incorporated by reference as part of this binding agreement:

- a. Zika Research Grant Initiative Funding Opportunity Announcement: Fiscal Year 2016-2017.

Grant Mechanisms:

1. Rapid Pilot Grants will be effective: Date of Execution and will have a maximum duration of 1 year.
 2. Dynamic Change Team Science Grants will be effective: Date of Execution and will have a maximum duration of 3 years.
 3. Investigator Initiated/Discovery Science Grants: Date of Execution and will have a maximum duration of 3 years.
 4. Clinical Research Grants will be effective: Date of execution and will have a maximum duration of 3 years.
- b. Grantee must comply with the provisions outlined in those documents, all applicable federal and state of Florida laws, rules, and regulations, and with the following terms and conditions to receive and maintain grant awards.
-

1. **Grant Period and Award:** The grant titled, **(ADD TITLE)**, total award amount, a description of the project funded by this grant, and other specific information about this grant are shown in Attachment I. The grant period will include the original term of the grant and all approved extensions. Awards, extensions, renewals, and payments will be made contingent upon satisfactory project performance and compliance with the grant terms and conditions. **The Department’s performance and obligation to pay under this grant agreement are contingent upon annual appropriation by the Florida Legislature, and the availability of funds.**

2. **Starting the Grant Project:** This project may begin only with: an approved budget; a conflict of interest form signed by Grantee; an approved management plan; Institutional Review Board (IRB) approvals

(when applicable); and Institutional Animal Care and Use Committee (IACUC) approvals (when applicable).

- a. **30 Day Updates:** Grantee must update the Department, in writing, via email every 30 days after the start date of the grant period regarding the status of all applicable regulatory applications. Failure to update the Department on time will result in either a financial consequence of a reduction of ten percent per invoice or grant termination. Once all applicable regulatory approvals are received, and the Department has been sent a final update stating that all applications have been approved, the Grantee will no longer need to provide the Department with updates.
- b. **Starting the Project:** If the project has not started 90 days after the start date of the grant period, the Department will impose financial consequences of ten percent per invoice or grant termination.
- c. **IRB Approval:** If the research requires human or animal participants the Grantee must submit application(s) for all institutional authorizations included, but not limited to the Institutional Animal Care and Use Committee (IACUC), Institutional Review Board (IRB), and Radiation Safety Review. The Grantee may request in writing to the Grant Manager authority to begin a portion of the project pending IRB approval.

3. Scope of Work and Project Adjustments:

- a. Grantee must complete all work as described in the approved application.
- b. Any changes or adjustments in the designs, aims, or research plans as proposed in the application; any changes requiring IRB or IACUC approval; and any change that may result in a conflict of interest, must be submitted in writing and are subject to Department approval prior to the change taking place. Failure to obtain prior written approval will result in financial consequences of ten percent per invoice.

4. Required Documentation: Grantee will provide reports to the Department describing the impact of the research on health outcomes; scientific impact such as publications in peer review journals, presentations, or patents; and any subsequent additional grant funding related to the research subject. Failure to comply with all deliverables required will either result in a financial consequence of a ten percent reduction per invoice or grant termination.

- a. Grantee must prepare financial status reports, narrative progress reports that include a description of the impact of the research on health outcomes, and the deliverables as outlined in Attachment II and submit it to the Department within 30 day of the end of each quarter. Reports must be prepared in the format specified by the Department.
- b. Grantee will make all reasonable efforts to assist the Department in gathering data required for reporting to the Florida Legislature and Governor pursuant to section 381.82(4), Florida Statutes, and other laws, as applicable, 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 a description of the impact of the research on health outcomes, publications, presentations, published reports, databases, additional grants and monies received, patents, invention disclosures, and copyrights.

5. **Financial Consequences:** Failure to provide the deliverables as specified in Attachment II will result in financial consequences of ten percent per invoice or grant termination.

6. **Quarter:** There are four quarters in a fiscal year, consisting of three months each. The quarters are as follows: Quarter 1 is July 1 through September 30; Quarter 2 is October 1 through December 31; Quarter 3 is January 1 through March 31; Quarter 4 is April 1 through June 30.

7. **Payment:** This grant has a fixed payment schedule as shown in Attachment II. Payments will be contingent on Grantee compliance with these Terms and Conditions and all other grant requirements. Total payment cannot exceed the total award amount.
 - a. Grantee must request payment using the Department's invoice form. Expenses will be reviewed for and only allowable expenses will be reimbursed.
 - b. Grantee will only be paid for satisfactory and timely completion of the deliverables. Payment of the final invoice for this grant will take place after the end of the grant period once all required deliverables have been received and approved.

8. **Key Personnel Requirements and Adjustments:** Project key personnel include the Principal Investigator, Project Director, Mentor, and other project personnel noted as such in the grant application.
 - a. Commitment of any individual's effort greater than 100 percent is not permitted.
 - b. Grantee must establish a system to track work effort commitments of all key personnel. Effort certification documentation must indicate the committed or actual work effort expended on the grant during the grant period as well as the percentage of effort performed for all deliverables. All effort assigned to this grant must be for work directly related to the project.
 - c. Prior Department approval is required for Project Director, Principal Investigator, and Mentor changes.
 - d. Reductions in Project Director or Principal Investigator effort are not allowed within the first year and may not be decreased more than ten percent 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 FOA.

9. **Budget Adjustments:** The approved Budget Form is the annual budget approved by the Department at the beginning of the grant period and annually thereafter and includes any approved budget adjustments.
 - a. The Department will reimburse Grantee for allowable, reasonable, and necessary costs as detailed in the line item budget.
 - b. Any overspending in the personnel budget category must be justified and pre-approved by the Department. Any overspending to any other budget categories in excess of ten percent must be submitted to the grant manager using the Budget Change Form reflecting the changes and

justification. Revisions will become effective upon approval by the Department and signature by Grantee and Department.

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

10. No-Cost Extensions: Extension of a grant period without additional funds.

- a. All no-cost extension requests must be received in writing in the form provided by the Department no less than three months prior to the ending date of the grant or date defined in Attachment II.
- b. No-cost extension requests are subject to review and approval or disapproval from the Department.
- c. The Grant will not be eligible for more than one six month no-cost extension.

11. Property and 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.

- a. 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.
- b. All equipment purchased with grant funds is the property of the eligible institution, and is subject to Chapter 273, Florida Statutes, 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 will remain state property and must be transferred or donated to a state agency or public university for redistribution or disposition.

12. Fiscal Accountability: Grantee must establish and maintain books, records, and documents (including electronic storage media) in accordance with generally accepted accounting procedures and practices, which sufficiently and properly reflect all revenues and expenditures of funds provided by the Department.

- a. Grantee must not co-mingle grant funds with other personal or business accounts. Grantee must not use grant funds to supplant or replace funds from other resources.
- b. Grantee must maintain sufficient documentation of all grant expenditures as proof that such expenditures are allowable under this agreement, reasonable, and necessary for the work performed. Grantee may not charge the Department for the value of donated goods, services, or facilities; however, donations may be used to meet any required match.
- c. Grantee must develop and use 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 budget will be considered an overpayment and must be returned to the Department.

- d. 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 during the grant period will be allowed.
- e. Per section 112.061, Florida Statutes, reimbursement for allowed travel must be at or below the current State of Florida travel rates.

13. Matching Funds: If matching funds are a condition of this grant per the FOA, Grantee agrees it will specifically provide at a minimum the funds or other consideration as outlined in the application. Grantee may match more than the minimum required amount. If 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.

14. Return of Funds: This grant is a fixed payment grant, which provides a specific level of quarterly support without regard to actual costs incurred. The final invoice is based on a reconciliation of all costs associated with the project not to exceed the fixed amount indicated in Attachment II. The Grantee must return to the Department any overpayment of grant funds related to disallowed expenditures, funds unaccounted for due to non-submission of required deliverables, or other unused grant funds at the end of the grant period. If the Grantee or its independent auditor identifies that overpayment has been made; the Grantee must repay the overpayment within 90 calendar days of grant end date. 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 will not be a limitation on any remedies at law or equity available to the Department.

15. Monitoring: The Grantee must permit persons duly authorized by the Department to inspect any records, papers, documents, facilities, or goods and services of Grantee that are relevant to this grant, and interview any clients, subcontractors, and employees of 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 may deliver to Grantee a written report of its findings and may include written recommendations with regard to Grantee's performance of the terms and conditions of this grant. Grantee will correct all noted deficiencies identified by the Department within the specified period of time set forth in the recommendations. 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) Grantee being deemed in breach or default of this agreement; (2) the withholding of payments to Grantee by the Department under this or any other agreement; (3) the termination of this grant.

16. Access to Records: All records related to this Grant or Grant Project will 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 will 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, Florida Statutes, made or received by the Grantee or its contractor in conjunction with this grant.

- 17. Retention of Records:** The Grantee must 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 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 years, the records must be retained until resolution of the audit findings or litigation, which may be based on the terms of this grant. Upon completion or termination of the grant and at the request of the Department, Grantee will cooperate with the Department to facilitate the duplication and transfer of any said records or documents during the required retention period as specified.
- 18. Financial Overlap:** 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 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. Grantee is responsible for monitoring changes in other support for project key personnel to avoid financial overlap. 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, 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 and must be provided to the Department at any time during the grant period.
- 19. Financial Conflict of Interest:** The Grantee must report to the Department any reportable interests, regardless of any conflict of interest procedures at Grantee's institution, at the time of the application and before the grant starts. Grantee must have in place an administrative process to identify and resolve financial conflicts of interest that may affect the objectivity of the proposed research. Grantee must inform the Department of any conflict of interest management plan required by Grantee's institution prior to starting research. The Department may require an additional management plan if the plan developed by Grantee's institution is not acceptable to the Department. If a reportable interest as defined by the Department arises after the grant starts, Grantee must immediately notify the Department within 48 hours.

20. Assignment and Sub grants: The Grantee must 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 must be null and void. No sub grants will be authorized that involve researchers outside of Florida. Grantee will be responsible for all work performed and all expenses incurred for this grant and for ensuring compliance with these terms and conditions. If the Department permits 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 Grantee that the Department will not be liable to the subcontractor for any expenses or liabilities incurred under the subcontract and Grantee will be solely liable to the subcontractor for all expenses and liabilities incurred under the subcontract. To the extent permitted by Florida law, Grantee, at its expense, will defend the Department against such claims.

21. Confidentiality: The Grantee must maintain confidentiality of all data, files, documents, papers, electronic storage media, and records, including client records, and must protect the privacy of human subjects related to this grant and all services provided. Grantee must not use or disclose any information concerning human subjects under this grant for any purpose not in conformity with applicable state and federal law or regulations (including but not limited to 45 CFR 46, 45 CFR 160, 162, and 164, and 21 CFR 45 and 21 CFR 56.111) and Department Institutional Review Board policies, except upon written consent of the recipient, or his or her responsible parent or guardian, when authorized by law. Grantee must report any breach of confidentiality to the Department within 48 hours of an allegation being made.

22. Publications, Presentations, or Printing of Reports: Any publications, presentations, printed reports, materials designed for use by the lay public (e.g., educational pamphlets), or resulting research findings related to this grant must acknowledge the appropriate funding source: Florida Department of Health, Biomedical Research Program. Grantee must notify the Department of all publications, presentations, printed reports, materials designed for use by the lay public, and research findings as a result of this grant both during the grant period and for a period of six years after the grant ends. The Grantees are to provide the Department a copy of each peer-reviewed journal article that is published. Further, if research is presented at a conference, the presentation, poster, and abstract should be submitted to the Department. If the presentation was scientific, a summary should be developed and submitted that can be understood by and provided to the general public.

23. Public Access:

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

24. Patents, Copyrights, and Royalties:

- a. All inventions will be the property of Grantee or business partner if a written agreement has been executed; and Grantee will retain the entire right, title, and interest to such.
- b. Grantee will grant the state of Florida 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.
- c. Grantee must disclose all inventions to the Department within two months of patent application or any licensing event, and will subsequently report on commercialization progress regarding patenting (filing dates and issue dates), licensing, and commercialization events.
- d. Grantee will make reasonable efforts to commercialize such invention through patenting and licensing and will make reasonable efforts to give preference to Florida-based companies.
- e. If 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, Grantee must furnish the Department with a description of said property and a copy of any licensing obtained.
- f. Grantee must 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 for up to six years after the grant ends.
- g. 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.

25. Policy Regarding Scientific Misconduct: The following provisions must apply to ensure research integrity and manage scientific misconduct.

- a. 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, 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 (30) days of the imposition of the administrative action.
- b. 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*."

26. Human Subjects: The following provisions must apply if the project involves human subjects:

- a. Grantee must comply with 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 when research is covered by regulations or the organization has committed to applying federal regulations or equivalent protections to all research.
- b. Grantee is responsible for safeguarding the rights and welfare of human subjects in Department-supported projects. Grantees proposing to involve human subjects in nonexempt research must provide, upon request, a copy of the organization's Assurance of Compliance with the Office of Human Research Protections (OHRP), and must establish and maintain appropriate policies and procedures for the protection of human subjects.
- c. Grantees are required to obtain and maintain approval from an IRB accredited by the Association for Accreditation of Human Research Program Programs (AAHRPP), or an IRB acceptable to the Department, within 60 days of notice of award. Grantees are required to follow Department policies for reporting unanticipated problems and non-compliance involving the research to the Department.
- d. 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.
- e. Grantee agrees to report to the Department within 48 hours any expiration of IRB approval, serious or continuing non-compliance, unanticipated problems involving risks to participants or others, and any suspension or termination of IRB approval. Grantee IRB must report to the Department when reporting to federal officials any serious or continuing non-compliance or unanticipated problem involving risks to participants or others.
- f. During the time that one or more IRB approval(s) is expired, all activities covered by the expired IRB approval(s) must stop until approval is obtained, and expenses for those activities during the expired period will be disallowed.
- g. Grantee must comply with the "*NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research.*"

27. Vertebrate Animals: If this project involves the use of vertebrate animals, the following terms apply.

- a. 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.
- b. 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.

- c. Grantee must 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.
 - d. 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.
- 28. Recombinant Nucleic Acid:** All research involving recombinant Nucleic Acid techniques must meet the requirements of the “*NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.*”
- 29. Stem Cells:** All research involving human stem cells must meet the requirements of the “National Institutes of Health Guidelines for Human Stem Cell Research.”
- 30. Lobbying:** Pursuant to sections 11.062 and 216.347, Florida Statutes, no portion of grant funds will be used for lobbying.
- 31. Insurance:** Grantee must 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, Florida Statutes, Grantee accepts full responsibility for identifying and determining the type(s) and extent of liability insurance necessary to provide reasonable financial protections for Grantee and the clients to be served under this grant, if any. Upon execution of this grant, upon request Grantee must 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.
- 32. Florida Single Audit Act Financial Audit:** Grantee must comply with the provisions of the Florida Single Audit Act, Section 215.97, Florida Statutes, as applicable. The following provisions apply:
- a. Grantee is required to maintain separate accounting of revenues and expenditures of funds and maintain sufficient documentation of all expenditures incurred (e.g., invoices, canceled checks, payroll detail, bank statements, etc.) under this contract that evidences that expenditures are:
 - i. Allowable under the contract and applicable laws, rules, and regulations;
 - ii. Reasonable; and
 - iii. Necessary in order for Grantee to fulfill the obligations under these Terms and Conditions.
 - b. The aforementioned documentation is subject to review by the Department and the State Chief Financial Officer and Grantee will comply timely with any requests for documentation.
- 33. Termination:** Regardless of the cause of termination, Grantee must comply with the terms and conditions of this grant at all times during and after the grant period. Grantee may be reimbursed for allowable costs incurred and any irrevocable charges through the date of termination up to the total award amount.
- a. This grant may be terminated by Grantee upon no less than 30 calendar days’ notice in writing, without cause, at no additional cost.

- b. 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.
- c. 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 Grantee. The notice must be delivered by certified mail, return receipt requested, or in person with proof of delivery. The Department will be the final authority as to the availability and adequacy of funds.
- d. In the event of research non-compliance or violation of the terms of this agreement, the Department may terminate this research grant upon no less than 24 hours' notice in writing to Grantee.

34. Indemnification: Unless Grantee is an agency or subdivision of the State of Florida or a public college or university as identified in Chapter 1004, Florida Statutes, Grantee will be liable for and must 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 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 Grantee not liable will excuse performance of this provision.

Nothing in this grant agreement is intended to serve as a waiver of sovereign immunity, nor must 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.

35. Dispute, Dispute Resolution, and Renegotiation:

- a. Failure of this agreement to cite all applicable state and federal laws and regulations does not waive compliance requirements.
- b. 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 must 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 must 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 must be deemed a waiver of any default hereunder.
- c. Modifications of provisions of this agreement must only be valid when they have been reduced to writing and duly signed by both parties.
- d. The Department must 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 Grantee.

36. Contact:

- a. All correspondence relating to contractual matters should be directed to Research@flhealth.gov or via mail to Florida Department of Health, Office of Public Health Research, Biomedical Research Programs, 4052 Bald Cypress Way, Bin A-24, Tallahassee, FL 32399-1749. The Department requires original signatures for all grant contract matters (invoices, budgets, and reports). These documents should be mailed to the above address.
- b. A Vendor Ombudsman has been established within the Department of Financial Services, whose duties include acting as an advocate for Grantees who may be experiencing problems in obtaining timely payment from a state agency. The Vendor Ombudsman may be contacted at (850) 413-5516 or (800) 342-2762, the State of Florida Chief Financial Officer's Hotline.

I have read the above Terms and Conditions and understand and agree to each section.

The parties hereto have caused these Terms and Conditions to be executed by their undersigned officials as duly authorized.


GRANTEE:

Signature of Authorized Official	Date
Typed or Printed Name of Authorized Official	Eligible Institution Name


FLORIDA DEPARTMENT OF HEALTH:

Signature of Authorized Official	Date
Typed or Printed Name of Authorized Official	Florida Department of Health

**Attachment I
Grant Information**

Florida Biomedical Research Programs Terms and Conditions		
Program:	<i>Zika Research Grant Initiative</i>	
Program CSFA #:	<i>(insert CSFA)</i>	
Grant Number:	<i>(insert grant number)</i>	
Type of Grant:	<i>(insert grant type)</i>	
Institution:	<i>(insert institution)</i>	
Principal Investigator:	<i>(insert PI)</i>	
Project Title:	<i>(insert project title)</i>	
Project Abstract:	<i>(insert project abstract)</i>	
Grant Period:	<i>Date of Execution through (insert grant end date)</i>	
Total Grant Award:	<i>(insert grant total)</i>	
Year One Amount:	<i>(insert year 1 amount)</i>	
Year Two Amount:	<i>(insert year 2 amount)</i>	
Year Three Amount:	<i>(insert year 3 amount)</i>	

**Attachment II
Schedule of Deliverables and Payments**

Florida Biomedical Research Programs		
Terms and Conditions		
Zika Research Grant Initiative		
Grant Title: (insert grant title)		
Deliverable	Period Covered	Due Dates
FISCAL YEAR 2016-2017		
<ul style="list-style-type: none"> • 3rd Quarter Progress Report • 3rd Quarter Financial Report • 3rd Quarter Expenditure Report • Proof of Liability Insurance • Invoice for \$ 	Date of Execution - (insert date)	(insert date)
<ul style="list-style-type: none"> • 4th Quarter Progress Report • 4th Quarter Financial Report • 4th Quarter Expenditure Report • Invoice for \$ 	(insert date)	(insert date)
FISCAL YEAR 2017-2018		
<ul style="list-style-type: none"> • 1st Quarter Progress Report • 1st Quarter Financial Report • 1st Quarter Expenditure Report • Invoice for \$ 	(insert date)	(insert date)
<ul style="list-style-type: none"> • 2nd Quarter Progress Report • 2nd Quarter Financial Report • 2nd Quarter Expenditure Report • Invoice for \$ 	(insert date)	(insert date)
<p>Cumulative Grant Continuation Progress Report *Please note this report will be peer reviewed along with the quarterly Financial and Expenditure Reports. Additionally, the Quarterly Invoice will not be processed for payment until this report is received by the Department.</p>	Date of Execution – (insert date)	(insert date)
<ul style="list-style-type: none"> • 3rd Quarter Progress Report • 3rd Quarter Financial Report • 3rd Quarter Expenditure Report • Proof of Liability Insurance • Invoice for \$ 	(insert date)	(insert date)

<ul style="list-style-type: none"> • 4th Quarter Progress Report • 4th Quarter Financial Report • 4th Quarter Expenditure Report • Invoice for \$ 	(insert date)	(insert date)
FISCAL YEAR 2018-2019		
<ul style="list-style-type: none"> • 1st Quarter Progress Report • 1st Quarter Financial Report • 1st Quarter Expenditure Report • Invoice for \$ 	(insert date)	(insert date)
<ul style="list-style-type: none"> • 2nd Quarter Progress Report • 2nd Quarter Financial Report • 2nd Quarter Expenditure Report • Invoice for \$ 	(insert date)	(insert date)
<p>Cumulative Grant Continuation Progress Report *Please note this report will be peer reviewed along with the quarterly Financial and Expenditure Summary Reports. Additionally, the Quarterly Invoice will not be processed for payment until this report is received by the Department.</p>		
<ul style="list-style-type: none"> • 3rd Quarter Progress Report • 3rd Quarter Financial Report • 3rd Quarter Expenditure Report • Proof of Liability Insurance • Invoice for \$ 	(insert date)	(insert date)
<ul style="list-style-type: none"> • 4th Quarter Progress Report • 4th Quarter Financial Report • 4th Quarter Expenditure Report • Invoice for \$ 	(insert date)	(insert date)
FISCAL YEAR 2019-2020		
<p>IF REQUESTING A 6 MONTH NO-COST EXTENSION SUBMIT THE FOLLOWING:</p>		
<ul style="list-style-type: none"> • No-Cost Extension Request Form • Cumulative Grant Progress Report 	Life of the Grant	(insert date)
<ul style="list-style-type: none"> • 1st Quarter Progress Report • 1st Quarter Financial Report • 1st Quarter Expenditure Report 	(insert date)	(insert date)

<ul style="list-style-type: none"> • Invoice for \$ 		
<ul style="list-style-type: none"> • Final Cumulative Grant Progress Report • Final Financial Report • Final Expenditure Report 	Life of the Grant	≤ 60 days after the end of grant period
<ul style="list-style-type: none"> • Final Invoice is based on a reconciliation of all cost associating with project not to exceed 		≤ 60 days after the end of grant period

**Attachment III
Reportable Financial Interests**

Florida Department of Health Financial Conflict of Interest in Research	
Principal Investigator:	
Title of project:	
Grant number:	
Step 1: Use the following tests to determine if the researcher and the researcher's immediate family, or any other personnel on the grant (sub-investigators and research staff) and their immediate families, have any of the following financial interests related to the research:	
<p>"Immediate Family" means spouse, domestic partner, children, and dependents.</p> <p>"Financial Interest Related to the Research" means financial interest in the sponsor, product or service being tested, or competitor of the sponsor.</p> <div style="border: 1px dashed black; padding: 5px;"> <p><input type="checkbox"/> Ownership interest, stock options, or other financial interest of any value related to the research. Does not include mutual funds or companies publicly traded on a stock exchange.</p> <p><input type="checkbox"/> Compensation of any value related to the research.</p> <p><input type="checkbox"/> Proprietary interest related to the research of any value including, but not limited to, a patent, trademark, copyright or licensing agreement.</p> <p><input type="checkbox"/> Board or executive relationship in a company (such as a startup company but including publicly traded companies) related to the research, regardless of compensation.</p> <p><input type="checkbox"/> Any arrangement where the value of the ownership interests will be affected by the outcome of the research. For example, an arrangement has been made where the value of stock options given to the researcher by a startup company will vary depending on the outcome of the research.</p> <p><input type="checkbox"/> Any other interest that could be affected by the outcome of the research</p> </div>	
If any of the following above conditions are met, provide a description of financial interests related to the research:	
<input type="checkbox"/> The grantee has no financial interests requiring disclosure	
Signed _____	Dated _____
<p>Failure to disclose financial interests related to the research, and failure to provide an updated disclosure at least at the time of the continuation request or if the financial interests of the researcher and personnel on the grant change, may result in:</p> <ul style="list-style-type: none"> - Immediate termination of the grant. - Financial consequences, including repayment of all grant funds. - Any other action required by state law. 	

**Attachment IV:
Reportable events for research involving human participants**

Researchers must report to the Department within 48 hours any of the following reportable events, regardless of whether IRB has oversight of the research:

- Adverse events and adverse outcomes which in the opinion of the principal investigator are both unexpected and related and suggest that the research places subjects or others at a greater risk of harm than was previously known or recognized.
- Any interim analysis or safety monitoring report indicating the frequency or magnitude of harms or benefits may be different than initially presented to the IRB.
- Any breach of confidentiality.
- Any change in FDA labeling or withdrawal from marketing of a drug, device, or biologic used in a research protocol.
- Any change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research participant.
- Any incarceration of a participant in a protocol not approved to enroll prisoners.
- Any event that requires prompt reporting to the sponsor.
- Any sponsor imposed suspension for risk.
- Any protocol violation (meaning an accidental or unintentional change to the IRB approved protocol) that harmed participants or others or that indicates participants or others may be at increased risk of harm or has the potential to recur.
- Any unanticipated adverse device effect.
- Any non-compliance identified by Department of Health audit or monitoring.
- Any investigation by FDA or OHRP or other federal agency of research (not just including this study) by any researcher on the study.
- Any loss of license or hospital privileges by any researcher on the study.

**Attachment V.a.:
Grant Budget**



The budget must include the entire proposed project cost broken down by category and fiscal year. The total budget may not exceed the award amount. Please note the table below is an embedded Excel worksheet. Double click to activate spreadsheet.

	FISCAL YEAR 2016-2017 BUDGET	FISCAL YEAR 2017-2018 BUDGET	FISCAL YEAR 2018-2019 BUDGET	FISCAL YEAR 2019-2020 BUDGET	TOTAL BUDGET
BUDGET CATEGORY					
Personnel / Fringe Benefits	\$ -	\$ -	\$ -	\$ -	\$ -
Consultant Cost	\$ -	\$ -	\$ -	\$ -	\$ -
Consortium / Contractual Cost	\$ -	\$ -	\$ -	\$ -	\$ -
Equipment	\$ -	\$ -	\$ -	\$ -	\$ -
Supplies	\$ -	\$ -	\$ -	\$ -	\$ -
Travel	\$ -	\$ -	\$ -	\$ -	\$ -
Patient Care Costs	\$ -	\$ -	\$ -	\$ -	\$ -
Other	\$ -	\$ -	\$ -	\$ -	\$ -
DIRECT COST SUB-TOTAL:	\$ -	\$ -	\$ -	\$ -	\$ -
Indirect	\$ -	\$ -	\$ -	\$ -	\$ -
TOTAL:	\$ -	\$ -	\$ -	\$ -	\$ -

GRANTEE
Signature of Authorized Official:

DEPARTMENT OF HEALTH
Signature of Authorized Official:

Name:

Name: Bonnie Gaughan-Bailey, ASQ-CQIA

Title:

Title: Administrator, Biomedical Research Section

Date:

Date:

**Attachment V.b.:
BUDGET NARRATIVE BY YEAR**

The budget narrative must provide a cost breakdown for each budget category by fiscal year for the entire grant period. The numbers in the budget narrative should coincide with the total budget by year and category as shown in Attachment Va. Please justify expenditures in each category as it relates to the project. Where appropriate, include details that show how the estimated cost was calculated. Use additional sheets as necessary.

Name	Role on Project	Type of Appt. (months)	% Effort on Project	Annual Base Salary	Fringe	Project Salary (% effort x base salary)	Project Fringe (% effort x fringe)	Total
			0.00%	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
			0.00%	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
			0.00%	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
			0.00%	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
			0.00%	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
			0.00%	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
TOTAL PERSONNEL COST:								\$0.00
<i>*Insert rows as needed*</i>								

Personnel/Fringe:

Consultant Cost:

Consortium /Contractual:

Equipment:

Supplies:

Travel:

Patient Care Cost:

Other Expenses: