



Refractory and Intractable Epilepsy Treatment and Research

Funding Opportunity Announcement

FY 2014-2015

TABLE OF CONTENTS

**Refractory and Intractable Epilepsy Treatment and Research
Funding Opportunity: FY 2014-2015**

I. OVERVIEW 4

1. INTRODUCTION 4

2. RESEARCH PRIORITIES..... 4

3. HIGHLIGHTS 5

4. SCHEDULE OF IMPORTANT DATES 6

Table 1. Schedule of Important Dates6

II. APPLICATION REQUIREMENTS 8

1. INTRACTABLE CHILDHOOD EPILEPSY-RELATEDNESS..... 8

2. ELIGIBILITY REQUIREMENTS 8

A. Eligible Applicants8

B. Letter of Intent8

C. Guidelines for Florida Biomedical Research Advisory Council Member Participation9

3. REQUIRED APPLICATION COMPONENTS..... 9

4. ALLOWED AND DISALLOWED COSTS12

A. Allowed Direct Costs12

B. Allowed Indirect Costs.....13

C. Disallowed Costs.....13

5. INQUIRIES AND CONTACTS14

A. Questions About This Funding Opportunity.....14

B. Technical Questions About the Online Application.....14

6. REQUIREMENTS FOR PROTECTING INTELLECTUAL PROPERTY.....14

7. DEFINITIONS.....15

III. INSTRUCTIONS FOR APPLICATION PREPARATION AND SUBMISSION.....18

1. GENERAL INSTRUCTIONS FOR APPLICATION SUBMISSION18

A. Online Registration and Application Submission.....18

B. General Application Guidelines19

IV. AFTER APPLICATION SUBMISSION20

1. CHANGES TO A SUBMITTED APPLICATION20

2. EVALUATION OF APPLICATIONS.....	20
A. <i>Administrative Review</i>	20
B. <i>Peer Review</i>	21
C. <i>Department Review</i>	22
D. <i>Evaluation Reports</i>	22
3. NOTIFICATION OF FUNDING DECISION	22
4. REQUESTS FOR RE-CONSIDERATION.....	22
5. GRANTEE REQUIREMENTS.....	23
A. <i>Terms and Conditions</i>	23
B. <i>Grantee Reporting Requirements</i>	23
C. <i>Open Innovation and Sharing of Publication-Related Materials, Data, and Software</i>	23
V. APPENDIX	24
1. REPORTABLE FINANCIAL INTERESTS	24
2. BUDGET TEMPLATE FORM**.....	25
3. BUDGET NARRATIVE FORM.....	26
4. TERMS AND CONDITIONS TEMPLATE.....	27
I HAVE READ THE ABOVE TERMS AND CONDITIONS AND UNDERSTAND EACH SECTION.....	37

NOTE: ONLY APPLICATIONS RECEIVED THROUGH THE ONLINE APPLICATION SYSTEM WILL BE ACCEPTED.

Applicants must register online at the Department’s website:
<http://www.floridahealth.gov/provider-and-partner-resources/research/funding-opportunity.html>
to be able to submit an application. See section III for application preparation and submission instructions.

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

Pursuant to Section 7, Chapter 2014-157, Laws of Florida, the Biomedical Research Advisory Council is authorized to support research initiatives on cannabidiol and its effects on intractable childhood epilepsy.

2. Research Priorities

The Florida Biomedical Research Advisory Council has recommended research priorities to support clinical research. Clinical research means a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical research is used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective.

The following research priorities are recommended for the inclusion in any research initiative:

- Enhanced access to existing clinical trials of investigational new drugs for Florida residents, to cover costs of enrolling additional patients.
- Corollary studies to existing clinical trials of investigational new drugs that address other outcomes such as quality of life, cognitive development, educational attainment, psychological delays, or other significant health concerns.
- Methodically sound small *n* studies or pilot studies of investigational new drugs designed to improve the design of future clinical trials, with a translational focus.

The Department will make awards to one or more research projects in an amount not exceeding a total of \$1 million for up to three years.

Additional Information:

All materials submitted to the Department are subject to the provisions of Art. 1, Sec. 24, Florida Constitution and Chapter 119, Florida Statutes. These laws grant a right to inspect any public record to anyone upon request. All Department materials, including applications, are public record. Refer to II.6 for instructions on how to properly identify confidential/proprietary information.

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.

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.

3. Highlights

- Applications will only be accepted through the online application system. Instructions for use of the online system will be published on the website listed in Table 1.
- All applications must be submitted by the date indicated in I.4, Table 1 to be considered for funding during this competition.
- There is a defined question and answer timeframe as indicated in I.4, 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 I.4, Table 1. Questions that are received after the timeframe as indicated in I.4, 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) 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 should be prepared to start the IRB review process 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.
- Applicants are encouraged to check the Department website (<http://www.floridahealth.gov/provider-and-partner-resources/research/funding-opportunity.html>) regularly throughout the application, peer review, and award processes for Department announcements, amendments, and answers to questions.

4. Schedule of Important Dates

Table 1. Schedule of Important Dates		
ACTIVITY	DATES	IMPORTANT INFORMATION
Funding opportunity announced	Anticipated Date: February 5, 2015	Located on the Department website at: http://www.floridahealth.gov/provider-and-partner-resources/research/funding-opportunity.html
Letter of Intent due (required)	Letter of Intent must be submitted by February 20, 2015 5:00 p.m. EST	Letter of Intent must be submitted to research@flhealth.gov Applications without a letter of intent are not eligible and will not be considered.
Application system opens	Anticipated Date: February 20, 2015	Located on the Department website at: http://www.floridahealth.gov/provider-and-partner-resources/research/funding-opportunity.html
Written questions accepted	Questions may be submitted any time until 5:00 p.m. EST February 27, 2015	E-mail questions to: research@flhealth.gov
Answers posted to written questions	Anticipated Date for responses to questions: March 6, 2015	Questions and answers will be published on the Department website in groups as they come in.
Applications due	Applications must be <u>submitted</u> before 5:00 p.m. EST March 27, 2015	Applications must be submitted using the online system available on the Department website at: http://www.floridahealth.gov/provider-and-partner-resources/research/funding-opportunity.html Applications must be <u>submitted before the deadline</u> . Applications being edited will not be accepted after the deadline.

Awards announced	Anticipated date: May 22, 2015	Award letters and Terms & Conditions will be E-mailed to the Administrative Official and the Principal Investigator. Terms and Conditions must be executed and returned no later than June 5, 2015
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 Review Board (IRB). 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.	Visit the Department website for guidance on regulatory review procedures. Grantees should be prepared to start the regulatory review process at their institutions immediately upon being notified of award.
Grants begin	Anticipated date: June 30, 2015	Contingent on verification of all eligibility requirements and regulatory approvals.
Proposal evaluation summaries available to applicants online	On or before August 1, 2015	Individual evaluation reports will be provided to applicants. Applicants will be notified when the evaluation report is available.

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

II. APPLICATION REQUIREMENTS

1. Intractable Childhood Epilepsy-Relatedness

All applicants must clearly demonstrate how the proposed project is relevant to the effect of cannabidiol on intractable childhood epilepsy. Proposals that do not or cannot demonstrate the relatedness between intractable childhood epilepsy and the proposed project will not be funded.

2. Eligibility Requirements

A. Eligible Applicants

The applicant must be a research university located in Florida that has approval from the US Food and Drug Administration for an Investigational New Drug (IND) application authorizing research involving cannabidiol and its effects on intractable childhood epilepsy.

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

Each application must identify a Principal Investigator. The Principal Investigator is the individual designated by the applicant organization legally responsible to direct the grant project. The 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 principal investigator. There may be multiple collaborators on a project, but there must be only one principal investigator.

When applications involving collaborations with different universities or research institution the lead institution should complete the budget form and include collaborating institutions as a contractual expense.

If the principal investigator moves to another eligible institution during the award period, the Department may approve a request to move the award to another eligible institution.

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 LOI is not received by the deadline listed in Table 1. Letters of intent are required; applications will not be accepted if the researcher has not submitted a letter of intent. However, applicants who submit letters of intent are not bound to submit applications, and a decision to submit a letter of intent and not submit an application will not impact eligibility for future funding opportunity announcements or be considered by peer reviewers in future funding applications.

Prospective applicants must submit a letter of intent that includes *all* of the following information to Research@flhealth.gov:

- Name, address, email address, and telephone number of the principal investigator at the lead site
- Research Priority
- Names of other research personnel
- Lead institution
- Collaborating organizations, if any
- Descriptive title of proposed research
- Keywords

Researchers may not submit a project under a different research priority than specified in the Letter of Intent.

C. Guidelines for Florida Biomedical Research Advisory Council Member Participation

The Florida Biomedical Research Advisory Council (Council) has a statutory obligation to avoid conflicts of interest regarding the participation of its members in funded research.

Council members shall not:

- Receive any form of financial compensation from a grant award.
- Participate in any named role on a proposed grant project.
- Advise applicants regarding the preparation of a specific application.
- Answer any questions (eligibility, content of the Funding Opportunity, competition procedures, etc.).
- Violate any provision of Chapter 112, Part III, F.S.

3. Required Application Components

A complete application package must contain all required items listed in Table 2.

Proposals exceeding the page limits where specified are subject to truncation to the page limit or may be disqualified without review. All required application forms are available for download within the online application system.

Table 2. Application Components

The online application will prompt applicants of required fields.

Category	Comment
General Project Information	Required. Identifies general project information, the applicant organization, and the principal investigator.
Project Summary	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.
Health Impact	Applications must describe how the proposed project impacts the health of Floridians. Health impact means the ability of the research to reduce morbidity and mortality from intractable childhood epilepsy. 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 through improvements in health literacy and changes in behavior within a certain amount of time. Do not 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 as a health impact that may result from the research. Applicants will complete this in the General Project Information section of the application.
Intractable childhood epilepsy-relatedness	Required. Provides a clear explanation of how the project is related to intractable childhood epilepsy. Applicants will complete this in the General Project Information section of the application.
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.
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.
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.

Table 2. Application Components

The online application will prompt applicants of required fields.	
Category	Comment
Recombinant DNA Molecules	Required (if applicable). Describe use of recombinant DNA molecules involved in the research.
Survey Instruments	Required (if applicable). Survey Instruments must be uploaded as a single document.
Investigational New Drug Application and Approval	Required. IND application and approval must be uploaded in a single pdf file.
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	Required. The budget must explain the planned spending. See appendix for template. The completed budget template form must be uploaded as a single document.
Letters of Support	Optional. Letters must be uploaded as a single document.
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.
Reportable Financial Interests	Required. The 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 3% increase per year.
- Tuition
- Fringe benefits
- Supplies
- Equipment, including CT, 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% of the total budget
- Patient-care costs
- Animal-care costs
- IRB or IACUC fees (if the project involves human participants or animals)
- Consortium or contractual costs
- Fees to obtain data or samples from any tissue bank.

Administrative costs *may* be included in direct cost categories, but only under two conditions:

- the services, functions, or activities are directly necessary for this grant,
and
- these administrative costs have not been included in the calculation of the indirect costs.

The Department 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.

When the project involves multiple collaborating institutions indirect costs are calculated based on the total cost of the grant. Additional indirect costs by subcontractors are not allowed in excess of the allowable amount based on the total cost of the grant.

Maximum Annual Base Salary Calculations:

The Department 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:

All activities funded through this competition must occur in Florida. Work (effort) must occur and funds must be spent in Florida at the applicant organization and any collaborating entities. However, the Department may allow exceptions if the researcher can demonstrate the service is essential and only provided outside the state (such as a laboratory service) and the amount is less than 10% of the requested amount.

B. Allowed Indirect Costs

Indirect costs (also referred to as IDC, F&A, or administrative costs) are limited to 15% of the total direct costs requested, regardless of whether subcontractors are used. 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
- 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. 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, accepting applications, and is responsible for answering all applicant questions during the specified timeframe in Table 1. Applicants and persons acting on their behalf may contact the Department in writing via E-mail as indicated below regarding questions. 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 questions must be submitted in writing via E-mail to research@flhealth.gov.

Answers to questions will be available on Department website. Answers to submitted questions will be posted according to the schedule in I.4, Table 1. Questions sent after the deadline in Table 1 will not be answered.

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 research@flhealth.gov.

If you experience technical difficulties during the final hours of the competition, please contact technical support at research@flhealth.gov immediately for assistance. 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, *F.S.*, 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 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 section. The applicant must clearly identify the confidential information with [brackets].

7. Definitions

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

Clinical investigation: Per 21 CFR 312, means any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505 (i) or 520 (g) of the Federal Food, Drug, and Cosmetic Act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the Federal Food, Drug and Cosmetic Act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations. (21 CFR 50.3(c), 21 CFR 56.102(c))

Collaborator: An individual involved with the 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.

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 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.

Cooperative Agreement: A support mechanism that will have substantial scientific and/or programmatic involvement. Substantial programmatic involvement means that after award, scientific or project staff will assist, guide, coordinate, or participate in programmatic activities beyond the normal stewardship responsibility in the administration of grants. Proposed cooperative agreements will be published as policy announcements, program announcements, or requests for applications.

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.

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.

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.

Investigational new drug: A new drug or biological drug that is used in a clinical investigation. The term also includes a biological product that is used in vitro for diagnostic purposes. The terms "investigational drug" and "investigational new drug" are deemed to be synonymous for purposes of this part.

Investigator: An individual who actually conducts a clinical investigation (i.e., under whose immediate direction the drug is administered or dispensed to a subject). In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. "Sub-investigator" or "Co-investigator" includes any other individual member of that team.

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.

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

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.

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

Public University: A public (state) university is defined in s. 1000.21, *F.S.*, 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 Department, 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.

Sponsor: A company that takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator.

Sponsor-Investigator: An individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. The term does not include any person other than an individual. The requirements applicable to a sponsor-investigator under this part include both those applicable to an investigator and a sponsor.

III. INSTRUCTIONS FOR APPLICATION PREPARATION AND SUBMISSION

1. General Instructions for Application Submission

Applicants must register online at the Department's website:

<http://www.floridahealth.gov/provider-and-partner-resources/research/funding-opportunity.html> to be able to submit an application.

All applications must be prepared and submitted online through the Research Management System, accessible from the Department's website. Application materials not submitted in the specified manner and in the specified format will be disqualified from competition.

Required signature materials 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 materials will be disqualified.

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, such as links to external websites.

A. Online Registration and Application Submission

The Research Management System (<http://www.floridahealth.gov/provider-and-partner-resources/research/funding-opportunity.html>) 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 at <http://www.floridahealth.gov/provider-and-partner-resources/research/funding-opportunity.html> and complete the brief project profile. Information entered into the Registration fields will carry forward to the application and can be modified within the application if needed. Registration will be acknowledged with an E-mail message containing login instructions and a username and password.
2. Complete the online application form. Deviations may be grounds for the Department to reject the entire application.
3. If an application is accidentally submitted, contact Department staff for assistance.

4. An application cannot be changed after the submission due date. Errata sheets or replacement files will not be accepted after the application deadline. If an application has been submitted and the applicant wishes to change the submitted application before the deadline, contact Department staff, and the application can be returned using the electronic system so that the applicant can edit, change, and resubmit the application using the electronic system. The change and resubmission must occur before the submission deadline.

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 documents must be self-contained within specified limits. Unless otherwise specified in this document, Internet Web site addresses (URL's) 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. Appended material may not be used to circumvent the limits for individual sections of the application.
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 Florida State Surgeon General.

A. Administrative Review

Application materials not received according to the date, time, and location specified in Table 1 of I.4 will be disqualified.

Each application submitted by the deadline indicated in Table 1 of I.4 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 the State. At its option, the Department 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 will be comprised of reviewers with expertise in the substance and methodology of the proposed project. Individual reviewers will review and rate applications, including assessing intractable childhood epilepsy-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 may 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 National Institutes of Health, 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 children with intractable epilepsy.

Other Review Considerations:

Reviewer concerns regarding protection of human and/or animal subjects will be considered.

Separately, peer reviewers will rate the relationship of the project to the advancement toward prevention, diagnosis, treatment, and/or cure of intractable childhood epilepsy. Peer reviewers will be asked the question “Has the applicant made a compelling case for a strong relationship to intractable childhood epilepsy?” Intractable childhood epilepsy-relatedness will be rated using a five-point scale: (1) Definitely, (2) Yes, minor reservations, (3) Somewhat, (4) Minimally, and (5) Not at all. The intractable childhood epilepsy-relatedness ratings of all reviewers will be averaged to determine the overall score for intractable childhood epilepsy-relatedness.

Peer reviewers will also identify any concerns regarding the proposed budget or apparent scientific or budgetary overlap with active or pending support.

C. Department Review

The Department and the Florida Biomedical Research Advisory Council will consider the peer review scores/rankings and scores regarding intractable childhood epilepsy-relatedness in a manner that eliminates or appropriately manages any conflicts of interest. Other interests, such as the availability of funds, and Department 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 researchers on the date specified in Table 1.

3. Notification of Funding Decision

The applicant organization and Principal Investigator will receive written notification of the funding decisions as indicated in in Table 1 in I.4. 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 intractable childhood epilepsy-related research, a list of intractable childhood epilepsy-related presentations, a list of intractable childhood epilepsy-related 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.

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

1. Reportable Financial Interests

**Sample. Subject to revisions.

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:	
"Immediate Family" means spouse, domestic partner, children, and dependents.	
"Financial Interest Related to the Research" means financial interest in the sponsor, product or service being tested, or competitor of the sponsor.	
<div style="border: 1px dashed black; padding: 5px;"><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. <input type="checkbox"/> Compensation of any value related to the research. <input type="checkbox"/> Proprietary interest related to the research of any value including, but not limited to, a patent, trademark, copyright or licensing agreement. <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. <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. <input type="checkbox"/> Any other interest that could be affected by the outcome of the research</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 _____
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:	
<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.	

2. Budget Template Form**



Intractable Childhood Epilepsy Research

BUDGET BREAKDOWN BY CATEGORY

INSTITUTION: _____ FDOH GRANT # _____

PRINCIPAL INVESTIGATOR (NAME): _____

GRANT PERIOD FROM: _____ TO: _____

	BUDGET YEAR 1 PERIOD	BUDGET YEAR 2 PERIOD	BUDGET YEAR 3 PERIOD			TOTAL BUDGET FOR GRANT PERIOD
CATEGORY						0.00
a. Personnel						0.00
b. Fringe Benefits						0.00
c. Travel						0.00
d. Equipment						0.00
e. Supplies						0.00
f. Contractual						0.00
g. Patient Care Costs						0.00
h. Other						0.00
i. SUB-TOTAL						0.00
j. Indirect						0.00
k. TOTAL						

Signature:

Name:

Title:

Date:

**Sample. Subject to revisions.

3. Budget Narrative Form

Justify each entry by describing how it is related 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	Base Salary	Fringe	Project Salary (% effort x base salary)	Project Fringe (% effort x fringe)	Total
TOTAL PERSONNEL:								

Personnel:

Consultants:

Consortium /Contractual:

Equipment:

Supplies:

Travel:

Patient Care:

Other Expenses:

**Sample. Subject to revisions.

4. Terms and Conditions Template

Sample. Subject to revisions

Intractable Childhood Epilepsy Research



Terms and Conditions

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

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

- Intractable and refractory childhood epilepsy funding opportunity announcement: Grant for Intractable and refractory disease research, Fiscal Year (To Be Determined), Fiscal Year (TBD) and Fiscal Year (TBD) (TBD), effective on or before (TBD) – (TBD).
- 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 period, total award amount, and other specific information about this grant are shown in Attachment I. The grant period shall include the original term of the grant and all approved extensions. In the case of multi-year grants, annual continuation is not automatic and continuation requests must be submitted according to the schedule in Attachment II. The Department may grant an extension of the grant period without additional funds (no-cost extension) at the sole discretion of the Department. Awards, continuations, extensions, renewals, and payments shall be made contingent upon satisfactory project performance and compliance with the grant terms and conditions. The grant period, including extensions, may not exceed 5.5 years. The Department’s performance and obligation to pay under this grant agreement are contingent upon annual appropriation by the Florida Legislature, and/or the availability of funds.
 - 2. Starting the Grant Project:** This project may begin only with an approved budget, an approved conflict of interest, management plan, when appropriate, Institutional Review Board (IRB) approvals, and Institutional Animal Care and Use Committee (IACUC) approvals.
 - a. 30 Day Updates:** Grantee will update the Department, in writing, every 30 days after the start date of the grant period. Failure to keep the Department informed will result in financial consequences of ten percent per invoice or grant termination.
 - 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 Core and Use Committee (IACUC) and Institutional Review Board (IRB) and Radiation Safety Review. The Grantee may seek authority to begin a portion of the project pending IRB approval.
3. **Required Deliverables:** The 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, patents; and any subsequent additional grant funding related to this research. Failure to comply with all deliverables required shall result in financial consequences of ten percent per invoice or grant termination.
 - a. Grantee must prepare and submit to the Department within 30 days of the end of each quarter; 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. Reports must be prepared in the format specified by the Department.
 - b. The Grantee agrees to make all reasonable efforts to assist the Department in gathering data required for reporting to the Florida Legislature and Governor pursuant to sections 215.5602(10), 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.
4. **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.
 - a. Total per annum payments to the Grantee shall not exceed the total per annum allocation as shown in Attachment I, and cannot exceed the total award amount.
 - b. Grantee must request payment using the Department's invoice form. Expenses will be reviewed for allow-ability.
 - c. The grantee will only be paid for satisfactory and timely deliverables. Payment of the final invoice for this grant will take place after the end of the grant period once all required documentation and deliverables have been received and approved.
5. **Scope of Work and Project Adjustments:**
 - a. The Grantee shall complete the work as described in the application.
 - b. Any changes or adjustments in the designs, aims, or research plans as proposed in the application; and any changes requiring IRB and/or IACUC approval, and any change that may result in a conflict of interest must be submitted in writing and is subject to Department approval prior to the change taking place. Failure to obtain prior approval shall result in financial consequences of ten percent per invoice.
6. **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% is not permitted.

- b. The Grantee shall establish a system to track work effort commitments of all key personnel. Effort certification documentation shall indicate the committed/actual work effort expended on the grant during the grant period as well as percent effort for all other duties/tasks/projects. All effort assigned to this grant must be for work directly related to the project.
 - 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 Call.
7. **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 the Grantee for allowable, reasonable, and necessary costs as detailed in the line item budget.
 - b. The Department must review and approve any deviation from the approved budget. Any overspending in the personnel, equipment, or travel budget categories must be justified to and pre-approved by the Department. Any revisions to the Budget Form in excess of ten percent of the total amount of any one budget category being revised must be submitted to the grant manager on the Budget Revision Form reflecting the changes and justification. Revisions will become effective upon approval by the Department and signature by the Grantee and Department.
 - c. The Department reserves the right to: 1) require further justification, 2) reject any disallowed costs, and 3) request new/revised budgets as it deems necessary.
8. **Property/Equipment:** Property and equipment is defined as non-expendable, tangible property having a useful life of more than one year. All property and equipment purchased with grant funds must be (1) necessary to carry out the proposed research; (2) justified to and pre-approved by the Department; (3) inventoried and tracked throughout the grant period; and (4) protected with sufficient insurance and security safeguards.
- 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 shall remain state property and must be transferred or donated to a state agency or public university for redistribution or disposition.
9. **Fiscal Accountability:** The Grantee shall 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. The Grantee shall not commingle grant funds with other personal or business accounts. The Grantee shall not use grant funds to supplant or replace funds from other resources.

- b. The Grantee shall maintain sufficient documentation of all grant expenditures as proof that such expenditures are allowable under this agreement, reasonable, and necessary for the work performed. The Grantee will not charge the Department for the value of donated goods, services, or facilities; however, donations may be used to meet any required match.
 - c. The Grantee shall 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.
- 10. Matching Funds:** If matching funds are a condition of this grant per the Call, the Grantee agrees it will specifically provide at a minimum the funds or other consideration as outlined in the application. Grantees may match more than the minimum required amount. If the Grantee does not contribute the agreed-to match amount, the total award amount may, at the discretion of the Department, be reduced proportionately to maintain the required matching ratio.
- 11. Return of Funds:** This grant is a fixed payment grant, not a fixed price grant. The Grantee shall return to the Department any overpayment of grant funds related to disallowed expenditures, funds unaccounted for due to non-submission of required deliverables, or other unused grant funds at the end of the grant period. In the event that the Grantee or its independent auditor discovers that overpayment has been made, the Grantee shall repay said overpayment within 40 calendar days of discovery without prior notification from the Department. In the event that the Department first discovers an overpayment has been made, the Department will notify the Grantee of such a finding. Should repayment not be made in a timely manner, the Department may withhold the amount of the overpayment from any future payments under this agreement. This provision shall not be a limitation on any remedies at law or equity available to the Department.
- 12. Monitoring:** The Grantee shall permit persons duly authorized by the Department to inspect any records, papers, documents, facilities, and/or goods and services of the Grantee that are relevant to this grant, and/or interview any clients, subcontractors, and employees of the Grantee to assure the Department of satisfactory performance of the terms and conditions of this grant. Monitoring may take place at any time during the grant period or records retention period with reasonable advance notice during normal business hours. Following such evaluation, the Department may deliver to the Grantee a written report of its findings and may include written recommendations with regard to the Grantee's performance of the terms and conditions of this grant. The Grantee will correct all noted deficiencies identified by the Department within the specified period of time set forth in the recommendations. The Grantee's failure to correct noted deficiencies may, at the sole and exclusive discretion of the Department, result in any one or a combination of the following: (1) the Grantee being deemed in breach or default of this agreement; (2) the withholding of payments to the Grantee by the Department under this agreement; (3) the termination of this grant.
- 13. Access to Records:** The Grantee shall assure that records shall be subject at all reasonable times to inspection, review, or audit by federal, state, or personnel duly authorized by the Department. Persons duly authorized by the Department shall have full access to and the right to examine any of

the Grantee's grant and related records and documents, regardless of the form in which kept, at all reasonable times for as long as records are retained. Upon termination of the grant, and at the request of the Department, the Grantee will cooperate with the Department to facilitate the duplication and transfer of any said records or documents during the required retention period. The Department unilaterally reserves the right to terminate this grant if the Grantee refuses to allow public access to all documents, papers, letters, or other materials subject to provision of Chapter 119, Florida Statutes, made or received by the Grantee or its contractor in conjunction with this grant.

- 14. Retention of Records:** The Grantee shall retain all client records, financial records, supporting documents, statistical records, and any other documents (including electronic storage media) pertinent to this grant for a period of six (6) years after the end of the grant period. If an audit has been initiated and audit findings have not been resolved at the end of the six (6) years, the records shall be retained until resolution of the audit findings or litigation, which may be based on the terms of this grant. Upon completion or 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 as specified.
- 15. 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/or institutional awards (not included are training awards, prizes, or gifts). Financial overlap is defined as accepting financial compensation from one or more other support sources for the same or substantially similar scientific aims/projects that are funded by the Department. Financial overlap is not permitted. The Grantee is responsible for monitoring changes in other support for project key personnel to avoid financial overlap. The Grantee is responsible for notifying the Department of such changes and for resolving overlap or requesting an amendment to prevent overlap. If financial overlap is due to receipt of an award from another funding source during the grant period, the Grantee must immediately notify the Department and resolve the overlap by: a) modifying at least one of the awards to eliminate the overlap or b) relinquishing one of the awards. Updated information on other support may be requested by and shall be provided to the Department at any time during the grant period.
- 16. Financial Conflict of Interest:** Grantee shall report to the Department any reportable interests, regardless of any conflict of interest procedures at the Grantee's institution, at the time of the application and before the grant starts. The Grantee shall have in place an administrative process to identify and resolve financial conflicts of interest that may affect the objectivity of the proposed research. The Grantee shall inform the Department of any conflict of interest management plan required by the Grantee's institution prior to starting research. The Department may require an additional management plan if the plan developed by the Grantee institution is not acceptable to the Department. If a reportable interest as defined by the Department arises after the grant starts, the Grantee must immediately notify the Department within 48 hours.
- 17. Assignment and Sub grants:** The Grantee shall neither assign the responsibility of this grant to another party nor subcontract for any of the work contemplated under this grant without prior written approval of the Department. Any sub-license, assignment, subcontract, or transfer otherwise occurring shall be null and void. No sub grants will be authorized that involve researchers outside the Florida. The Grantee shall 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 the Grantee to subcontract part of the work contemplated under this grant, including entering into subcontracts with vendors for services and commodities, it is understood by the Grantee that the

Department shall not be liable to the subcontractor for any expenses or liabilities incurred under the subcontract and the Grantee shall be solely liable to the subcontractor for all expenses and liabilities incurred under the subcontract. To the extent permitted by Florida law, the Grantee, at its expense, will defend the Department against such claims.

18. Confidentiality: The Grantee shall maintain confidentiality of all data, files, documents, papers, electronic storage media, and records, including client records, and shall protect the privacy of human subjects related to this grant and all services provided. The Grantee shall not use or disclose any information concerning 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, 160, 162, and 164, and 21 CFR 56.111 and 45) 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 shall report any breach of confidentiality to the Department within 48 hours of an allegation being made.

19. Publications, Presentations or Printing of Reports: Any publications, presentations, printed reports, or resulting research findings related to this grant shall acknowledge the appropriate funding source: Florida Department of Health, Intractable and Refractory Childhood Epilepsy Research Department. Grantee shall notify the Department of all publications, presentations, printed reports, and resulting research findings created for this project both during the grant period and for a period of six years after the grant period.

20. Public Access:

- a. Upon publication of their work, grantees funded through this Department 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, the Grantee shall submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication, in a manner consistent with copyright law.

21. Patents, Copyrights, and Royalties: Notwithstanding the provision at Section I.T of the Standard Contract, the following provisions shall apply to all inventions, including intellectual property, created under this grant:

- a. All inventions shall be the property of the Grantee or business partner if a written agreement has been executed; and Grantee shall retain the entire right, title and interest to such.
- b. The Department shall have a fully paid up, non-exclusive, non-transferable, irrevocable license to practice or have practiced or to use or have used the invention for or on behalf of the State of Florida.
- c. Grantee shall disclose all inventions to the Department within two months of patent application and/or any licensing event, and will subsequently report on commercialization progress regarding patenting (filing dates and issue dates), licensing, and commercialization events.
- d. Grantee shall make reasonable efforts to commercialize such invention through patenting and licensing and shall make reasonable efforts to give preference to Florida-based companies.

- e. If the Grantee seeks to apply for copyright, trademark or patent when commercially reasonable for any property created, developed or invented as a result of services provided under this grant, the Grantee shall furnish the Department with a description of said property and a copy of any licensing obtained.
- f. Grantee shall report to the Department, upon request, any progress in securing or exploiting such inventions, trademarks, copyrights, or patents both during and after the grant period.
- 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.

22. Policy Regarding Scientific Misconduct: The following provisions shall 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, the Grantee must notify the Department within 48 hours. Grantee must provide a copy of the final notice of the administrative action (i.e., after the disposition of any appeal) to the Department either at the time of application or within thirty (30) days of the imposition of the administrative action.
- 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.*"

23. Human Subjects: The following provisions shall 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. The Grantee IRB agrees to report to the Department when reporting to federal officials any serious or continuing non-compliance or unanticipated problem involving risks to participants or others.
- 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.*”

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

25. Recombinant DNA: All research involving recombinant DNA techniques must meet the requirements of NIH Notice NOT-OD-02-052, “*NIH Guidelines for Research Involving Recombinant DNA Molecules.*”

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

27. Lobbying: Pursuant to sections 11.062 and 216.347, Florida Statutes, no portion of grant funds shall be used for lobbying.

28. Insurance: The Grantee shall provide adequate liability insurance coverage on a comprehensive basis at all times during the grant period. Upon execution of this grant, unless it is a public college or university as identified in Chapter 1004, F.S., the Grantee accepts full responsibility for identifying and determining the type(s) and extent of liability insurance necessary to provide reasonable financial protections for the Grantee and the clients to be served under this grant, if any. Upon execution of this grant, upon request the Grantee shall furnish the Department written verification supporting both the determination and existence of such insurance coverage. Such coverage may be provided by a self-insurance program established and operating under the laws of the State of Florida. The

Department reserves the right to require additional insurance where appropriate. Insurance must be secured from a company licensed to do business in the State of Florida.

29. Florida Single Audit Act Financial Audit: The Grantee shall comply with the provisions of the Florida Single Audit Act, section 215.97, Florida Statutes, as applicable. The following provisions apply:

- a. The Grantee is required to maintain separate accounting of revenues and expenditures of funds and maintain sufficient documentation of all expenditures incurred (e.g., invoices, canceled checks, payroll detail, bank statements, 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 the Grantee to fulfill the obligations under these Terms and Conditions.
- b. The aforementioned documentation is subject to review by the Department and/or the State Chief Financial Officer and the Grantee will comply timely with any requests for documentation.

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

- a. This grant may be terminated by the 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 the Grantee. Said notice shall be delivered by certified mail, return receipt requested, or in person with proof of delivery. The Department shall be the final authority as to the availability and adequacy of funds.
- 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 the Grantee.

31. Indemnification: Unless the Grantee is an agency or subdivision of the State of Florida or a public college or university as identified in Chapter 1004, Florida Statutes, the Grantee shall be liable for and shall indemnify, defend, and hold harmless the State of Florida, its officers, employees and agents to the full extent allowed by law from all losses, expenses, claims, damages, actions, suits and judgments, consequential or otherwise and including attorneys' fees and costs, arising out of any act, actions, neglect, or omissions by the Grantee, its agents, subcontractors, or employees during the performance or operation of this grant, whether direct or indirect, and whether to any person or

tangible or intangible property. Only adjudication or judgment after highest appeal is exhausted specifically finding the Grantee not liable shall excuse performance of this provision.

Nothing in this grant agreement is intended to serve as a waiver of sovereign immunity, nor shall anything in this grant agreement be construed as consent by a state agency or political subdivision of the State of Florida to be sued by third parties in any matter arising out of this grant agreement. If the Grantee is an agency or subdivision of the State of Florida, the Grantee agrees to be fully responsible for its acts of negligence, or its agents' acts of negligence when acting within the scope of their employment or agency, and agrees to be liable for any damages resulting from said negligence. Nothing herein is intended to serve as a waiver of sovereign immunity by any Grantee to whom sovereign immunity may be applicable.

32. 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 shall have the right to declare any default at any time and take such action as might be lawful or authorized hereunder, in law or in equity. No Department waiver of any term, provision, condition or covenant hereof shall be deemed to imply or constitute a further Department waiver of any other term, provision, condition or covenant hereof, and no payment by the Department shall be deemed a waiver of any default hereunder.
- c. Modifications of provisions of this agreement shall only be valid when they have been reduced to writing and duly signed by both parties.
- d. The Department shall be entitled to assign or transfer, in whole or part, its rights, duties, or obligations under this agreement to another governmental agency in the State of Florida upon giving prior written notice to the Grantee.

33. 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, 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 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


Florida Department of Health



Terms and Conditions

*** Sample subject to change

Department:	
Department CSFA #:	
Grant ID:	
Type of Grant:	
Institution:	
Principal Investigator:	
Project Title:	
Grant Period:	
Total Grant Award:	
Year One Amount:	
Year Two Amount:	
Year Three Amount:	

Florida Department of Health		
Terms and Conditions		
		
Schedule of Deliverables and Payments		
Deliverable	Period Covered	Due Dates
<ul style="list-style-type: none"> • Completed Financial Information Form • 1st Quarter Progress Summary • 1st Quarter Financial Report • Invoice for \$ 		
<ul style="list-style-type: none"> • Continuation Request • New Budget Review 		
<ul style="list-style-type: none"> • 2nd Quarter Progress Summary • 2nd Quarter Financial Report • Invoice for \$ 		
<ul style="list-style-type: none"> • 3rd Quarter Progress Summary • 3rd Quarter Financial Report • Invoice for \$ 		
<ul style="list-style-type: none"> • 4th Quarter Progress Summary • 4th Quarter Financial Report • Invoice for \$ 		
<ul style="list-style-type: none"> • Annual Narrative Progress Report • Research Milestone Chart 		
YEAR TWO		
<ul style="list-style-type: none"> • 1st Quarter Progress Summary 		

<ul style="list-style-type: none"> • 1st Quarter Financial Report • Invoice for \$ 		
<ul style="list-style-type: none"> • Continuation Request • New Budget Review 		
<ul style="list-style-type: none"> • 2nd Quarter Progress Summary • 2nd Quarter Financial Report • Invoice for \$ 		
<ul style="list-style-type: none"> • 3rd Quarter Progress Summary • 3rd Quarter Financial Report • Invoice for \$ 		
<ul style="list-style-type: none"> • 4th Quarter Progress Summary • 4th Quarter Financial Report • Invoice for \$ 		
YEAR THREE		
<ul style="list-style-type: none"> • 1st Quarter Progress Summary • 1st Quarter Financial Report • Invoice for \$ 		
<ul style="list-style-type: none"> • 2nd Quarter Progress Summary • 2nd Quarter Financial Report • Invoice for \$ 		
<ul style="list-style-type: none"> • 3rd Quarter Progress Summary • 3rd Quarter Financial Report • Invoice for \$ 		
<ul style="list-style-type: none"> • Final Narrative Progress Summary 	Life of the Grant	≤ 60 days after the end of grant period

<ul style="list-style-type: none"> Final Financial Report 		
<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

Sample. Subject to revisions