Public Health Research Program
Rare Pediatric Diseases
Research Grant Program

Fiscal Year 2024-2025
Funding Opportunity Announcement

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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
Division of Public Health Statistics and Performance Management
4052 Bald Cypress Way Bin A-15
Tallahassee, Florida 32399-1720
Office: 850-245-4585
Email: research@flhealth.gov

I. OVERVIEW

1. Introduction

This grant program provides a funding opportunity to the state of Florida for innovative approaches to research and treatment for rare pediatric diseases. Funding is available exclusively to Florida-based institutions.

Major Goals of Funding:

These funds will be used to solicit innovative grant funding applications and distribute funds to successful grantees. A total of $500,000 in funding is available for the purpose of awarding research grants to support innovative research projects. This funding opportunity represents a recurring opportunity for research specific to rare pediatric diseases, depending on fund availability. For the purposes of the grant, new ideas for improving the health and well-being of all children with a rare disease are not defined, but open based on need. The Florida Department of Health (Department) is responsible for the procurement process and contractual management.

Grant proposals should further the search for rare disease cures and treatment, by pursuing goals to:

- Significantly expand rare disease research capacity in Florida.
- Investigate novel approaches in rare disease research and therapeutics.
- Reduce the impact of rare diseases on underserved populations.
- Reduce rare disease research silos through diverse partnerships with nontraditional partners.

2. Research Priorities

The Department will prioritize applications that address the following:

- Reducing mortality and morbidity in relation to disproportionately impacted individuals.
- Improving screening accuracy and detection in high-risk groups.
- Establishing consortia to collaboratively work on rare pediatric diseases.

All applications submitted in response to this Funding Opportunity Announcement (FOA) must be responsive to fostering collaborations among institutions, researchers, and community practitioners should be included, when possible.

- Prevention and Treatment: Research with a focus on prevention and improved treatment or care delivery that contributes to a reduction in deaths.
- Disproportionately Impacted Communities: Research that contributes to reductions in deaths due to rare pediatric diseases resulting from disproportionately impacted individuals due to race, ethnicity, or income.

- Screening: Improve screening accuracy, detection of high-risk subgroups, and/or improved implementation of a screening program that results in an increase in early detection or prevention.

3. Mechanisms of Support

Funding for the following four types of grants is available to pursue the research priorities described in this FOA.

Rare Pediatric Diseases Research Programs		
Grant Mechanism	**Maximum Award Amount** (Including direct and indirect costs)	**Maximum Duration**
Consortium	$500,000	Up to 36 Months
Discovery Science	$500,000	Up to 36 Months
High-Risk, High-Reward Discovery Science	$300,000	Up to 36 Months
Equipment	$100,000	Up to 12 Months

Consortium Grant

Stimulate a consortium of clinical, basic, translational, and underrepresented research institutions/centers to conduct high quality grant-supported research. The consortium should involve partnerships to be developed among investigators across the state of Florida, with the award made to the 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 address clearly one or more areas of research interest.

Discovery Science

Discovery science means fundamental theoretical or experimental investigative research to advance knowledge without a specifically envisaged or immediately practical application. Directed to understanding the events related to rare diseases at the molecular, cellular, and organismic levels, as well as the discovery and development of new drugs or therapies.

Applications under this mechanism can include observational or cross-sectional studies not involving a clinical trial. Outcome measures can be self-reported, observational, behavioral, biologic, or genetic.

- **Bioinformatics:** The solicitation seeks applications to expand existing infrastructure/

resources for analysis of biomedical data, including genomic and proteomic information and the study of biological systems. Projects may include improving algorithms, databases, and modeling of biological phenomena; purchase of equipment, and software; and support for the expansion of cross-disciplinary research teams. The expectation is that projects will include sustainable ongoing mechanisms to improve sharing of infrastructure/resources with external researchers and research institutes in Florida.

Projects should describe measurable targets and time frames for expanding access as well as describe a process to evaluate improved outcomes related to this infrastructure.

Projects may include, but are not limited to, expanding the ability to analyze very large data sets; the identification of tissue-specific biomarkers; or improvements in ways of automating clinical imaging.

- **Medical imaging:** The solicitation seeks to expand existing infrastructure that improves the quality, speed, and accuracy of medical imaging or develops processes that measure the effectiveness of imaging technologies. Projects may include, but are not limited to, improvements in screening or research examining the correlation between the expanded use of imaging technologies and health outcomes. Projects may include improvements to software and equipment. The expectation is that projects will include sustainable ongoing mechanisms to improve sharing of infrastructure/resources with external researchers and research institutes in Florida. Projects should describe measurable targets and time frames for expanding access as well as describe a process to evaluate improved outcomes related to this infrastructure.

- **Genomics:** The solicitation seeks to expand existing infrastructure in the areas of functional genomics, genomic biomarkers, epigenetics, next-generation sequencing, miRNA and non- coding RNA, qPCR, proteomics, and proteome analysis including chromatography or mass spectroscopy. Funds are intended to be used to upgrade software and equipment that will make organizations competitive for additional funding and serve as a national resource. The expectation is that projects will include sustainable ongoing mechanisms to improve sharing of infrastructure/resources with external researchers and research institutes in Florida. Projects should describe measurable targets and time frames for expanding access as well as describe a process to evaluate improved outcomes related to this infrastructure.

- **Disproportionately impacted individuals:** In Florida there are significant differences in the morbidity and mortality of rare disease depending on location, and other social factors influencing health. Projects may include, but are not limited to, expanding access to core resources for researchers, development of clinical guidelines and education programs to improve the quality and consistency of screening and clinical care, or the development of coordinating centers for research on diseases with significant disproportionately impacted individuals. The expectation is that projects will include sustainable ongoing mechanisms to improve sharing of infrastructure/resources with external researchers and research institutes in Florida. Projects should describe measurable targets and time frames for expanding access as well as describe a process to evaluate

improved outcomes related to this infrastructure.

High-Risk, High Reward Discovery Science

Research that can be considered high-risk, high-reward that: meets fundamental technological or scientific challenges, involves multidisciplinary work, and involves a high degree of novelty.

Equipment

The solicitation is for infrastructure/resources to augment research equipment that advances the current and future research capability. The expectation is that new equipment will be shared with other researchers as beneficial. Reporting on the role of equipment in research studies will be required.

4. Highlights

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

Applications will only be accepted through the online application system.

Applications that propose research relying on or using Department data must include a letter of support from the office which houses the data. For example, if conducting research using data from the Florida Cancer Data System, you must include a letter of support. Contact Heather Lake-Burger for a letter of support, at Heather.Lake-Burger@flhealth.gov to request a letter of support and more information regarding the Florida Cancer Data System. If you are interested in data from the Bureau of Vital Statistics, contact Gary Sammet at Gary.Sammet@flhealth.gov. Additionally, you must indicate an overview of the data that will be requested from each data registry.

Research studies that include research participant incentives in their budgets must receive approval from an accredited Institutional Review Board (IRB). If the research proposal is selected for Department funding, the original IRB approval protocol and consent form must be submitted to the Department before any incentives are distributed. These documents will be kept in the grant management folder at the Department. Participant incentives in the form of cash, check, or gift cards, are permissible.

There is a defined question and answer time frame 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 time frame as indicated in Table 1 will not be answered.

When research involves human participants, grantees are required to obtain and maintain approval from an 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 and to report unanticipated problems and non-compliance involving the research to the Department.

Grant funds may be used to pay a proportional percentage of the base salary (based on effort) of any personnel named on this grant application. The maximum annual base salary used to calculate these payments must not exceed the Executive Level II annual salary rate of the Federal Executive Pay Scale that is in effect as of the application submission date. See II. Eligibility and Application Requirements, Definitions, for more information about the Federal Executive Pay Scale.

The Grant Manual is an important reference document for grant awardees. It contains Department policies as well as the procedures necessary for compliance with those policies and is organized around a typical grant lifecycle. The Grant Manual can be found at GrantAdministrationManualforFY18-191.pdf (floridahealth.gov). Applicants are encouraged to check the Biomedical Research Program website (https://www.floridahealth.gov/provider-and- partner-resources/research/funding-opportunity.html) regularly throughout the application, peer review, and award processes for program 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 program materials, 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, referred to as 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 Announcement, 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 Announced	On or around November 19, 2024	Located on the Biomedical Research Program's website at: Biomedical Research Funding Opportunities
Letter of Intent Opens (REQUIRED)	By 8 a.m., ET, December 04, 2024	Letter of Intent must be submitted in the online system located on the Biomedical Research Program's website. Applications without a Letter of Intent by the deadline are not eligible and will not be considered.
Informational Webinar	9 a.m., ET, December 10, 2024	Program staff will conduct an informational webinar about the current FOA and answer participant questions in real time.
Written Questions Accepted	Questions may be submitted any time until 5 p.m., ET, December 17, 2024	Email questions to: Research@flhealth.gov
Answers Posted to Written Questions	By December 23, 2024	Questions and answers will be published on the Biomedical Research Program's website in two groups as they are received.
Letter of Intent Due (REQUIRED)	Letter of Intent must be submitted by 5 p.m., ET, January 07, 2025	Letter of Intent must be submitted in the online system located on the Biomedical Research Program's website. Applications without a Letter of Intent by the deadline are not eligible and will not be considered.

Main Application Opens	Anticipated date: January 21, 2025	Applications must be submitted in the online system located on the Biomedical Research Program's website.
Applications Due	Applications must be submitted before 5 p.m., ET, February 20, 2025	Applications must be submitted using the online system available on the Biomedical Research Program's website. Applications must be submitted before the deadline. Applications being edited will not be accepted after the deadline.
Awards Announced	Anticipated date: May 20, 2025	Award letters and Terms and Conditions will be emailed to the Sponsored Research Official and the Corresponding Principal Investigator.
New Awardee Orientation Webinar	May 27, 2025	Discussion on Budget revisions and orientation, open to all Principal Investigators and Administrative staff
Institutional Reviews due (if applicable)	Immediately following award notification, grantees should submit application(s) for all institutional authorizations including, but not limited to the Institutional Animal Care and 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 and must be signed by the Review Board chairperson or organizational representative. Research proposals that include research participant incentives must receive approval from an accredited Institutional Review Board (IRB). If the research proposal is selected for Department funding, the original IRB approval protocol and consent form must be submitted to the Department before any incentives are distributed. These documents will be kept in the grant management folder at the Department.	Grantees should be prepared to start the regulatory review process at their institutions immediately upon being notified of award.
Grants Begin	Anticipated date: July 01, 2025	Contingent on verification of all eligibility requirements and regulatory approvals.

Proposal Evaluation Summaries Available to Applicants	Anticipated date: On or about June 01, 2025	Individual evaluation reports will be provided to applicants. Applicants will be notified via e-mail when their evaluation report is available.

Any changes to the schedule will be posted to the Biomedical Research Program website. Applicants should monitor the website for changes and announcements.

II. ELIGIBILITY AND APPLICATION REQUIREMENTS

1. Eligibility Requirements

A. Eligibility Requirements

According to subsections 215.5602(5)(a) and 381.922(3)(a), Florida Statutes, applications for biomedical research funding may be submitted from any Florida university or established Florida research institute.

Each application must identify a Corresponding Principal Investigator. The Corresponding Principal Investigator is the individual designated by the applicant organization as legally responsible to direct the grant project. The Corresponding Principal Investigator is responsible and accountable to 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 Principal Investigators on a project, but there must be only one Corresponding Principal Investigator.

The Corresponding Principal Investigator must work at an eligible Florida-based institution and meet that institution's criteria for serving as a principal investigator, in addition to the eligibility requirements listed in this FOA. 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. Non-U.S. citizens can serve as Collaborators or members of a research team.

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

B. Letter of Intent (REQUIRED)

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.

Applications will not be accepted if the researcher has not submitted an LOI by the deadline listed in Table 1. Researchers must apply under the same title that was specified in the LOI.

Prospective applicants must submit a LOI through the online system that includes the following information:

- Name, address, telephone number, email address of the Project Director or Corresponding Principal Investigator.
- Names of other research personnel.
- Lead institution.
- Collaborating institutions and collaborating research personnel, if any.
- Descriptive title of proposed research.
- Research priority.
- Mechanism of support.

- General audience abstract (no more than 3,500 characters).
- Key words.

C. Duplication Applications and Overlap Limits

Eligible applicants can submit **one** application. Applicants may not submit the same applications, or substantially similar applications, as determined by the Department to the Live Like Bella Initiative and the Rare Pediatric Diseases Initiative.

Applicants who submitted but were not funded in the previous fiscal year funding competition, may submit a revised application **only one time**. Applicants may submit **either** a new application or revised application from the previous fiscal year funding competition but cannot submit both.

The Corresponding Principal Investigator may serve as Co-Principal Investigator or other role on other applications, provided they are not over-committed. The Corresponding Principal Investigator shall not:

- Submit an application for the same research project for which he or she was a previously funded grant recipient. The aims and experiments in the new proposal must be significantly different from any previously funded grants.

- Submit the same project/research that is also being submitted by another investigator regardless of the grant mechanism.

- Submit duplicate projects or projects with significant scientific or financial overlap during the same competition year.

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% is prohibited.

2. Required Grant Application Components

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

Table 2.a. Application Components The online application will prompt applicants of required fields and character limits for each section.	
Category	**Comment**
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.
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.
Health Impact	Required. 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 rare diseases. 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. 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. Applicants will complete this in the General Project Information section of the application.
Pediatric-Relatedness	Required. Provides a clear explanation of how the project is related to children. 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 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. If human subjects will be involved **at any time** in the research, even if the project protocol has already received Institutional Review Board approval or is deemed exempt, the applicant must address all human subject questions in the online application. If all questions are not answered, the application will be disqualified.

Table 2.b. Application Components The online application will prompt applicants of required fields and character limits for each section.	
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.
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 budget template can be downloaded within the online application system. The completed budget template form 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.
Budget Narrative	Required. The Budget Narrative must explain in detail how funds from each budget category will be spent for each year of project funding.
Letters of Support	Required (if applicable). If applying for a grant involving Department of Health data, a signed letter of support must be uploaded. Letters of support are not required for other types of research. Upload a single document in the appropriate upload field. There is no limit to the number of letters of support that may be submitted.
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.
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 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.	

3. 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
- Background Screening: Level II (if required) should be included under other expense category.
- Tuition: To ensure that the tuition waiver or reimbursement is related to the research project, a course description or class schedule must be submitted with the quarterly invoice that includes the tuition waiver or expenditure. Tuition waivers or support should be included in the approved Public Health Research Program Budget Template and the purpose of the tuition support must be included in the final Budget Narrative. Submitting class schedule or attestation of verification by the Principal Investigator with quarterly invoices is required for payment.
- Fringe benefits
- Supplies
- Equipment, including computed tomography (CT), magnetic resonance imaging (MRI), or other imaging systems, and improvements to existing systems. For the purposes of this FOA, “equipment” refers to items with a purchase price of over $5,000.00 and with a useful life of over one year.
- Lab Services
- Consultant costs, provided they do not exceed 10% of the total budget
- Patient-care costs
- Animal-care costs
- Committee fees for IRB or Institutional Animal Care and Use
- Consortium or contractual costs
- 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. In order to implement appropriations in the General Appropriations Act for state travel and notwithstanding section 112.061, Florida Statutes, costs for lodging associated with a meeting, conference, or convention organized or sponsored in whole or in part by a state agency or the judicial branch may not exceed $225 per day.) If awarded, grantees must submit a travel voucher form in every quarter in which they will charge travel to their grant budgets. Travel is only approved within the United States (US). The State of Florida Voucher for Reimbursement of Travel Expenses should be used for all travel-related expenses unless the research institution’s travel voucher/expenditure form has received prior approval from the Department of Financial Services (DFS). Support documentation for all travel-related expenses is needed, e.g., receipts for flight, hotel (up to $225/night), parking, rental car, gas, ground transportation, as well as registration, meeting agenda/schedule, and copy of any presentation(s) made. The State of Florida Voucher for Reimbursement of Travel Expenses may be found here.

Grant Management Forms Library and Other Resources | Florida Department of Health (floridahealth.gov).

- Research Participant Incentives in the form of cash, check, or gift card. Gift cards should not be purchased in bulk as tracking and inventory control can be difficult. Gift cards should be purchased as needed. If awarded, the original approved IRB protocol and consent form must be submitted to the Department before any participant incentive charges may be made to the grant. Each grant agreement executed will reference the approved IRB protocol in the method of payment section of each grant agreement.
- Indirect costs up to 15% may be included in direct cost categories for services, functions, or activities that are directly necessary for this grant.

Maximum Annual Base Salary Calculations:

Grant funds may be used to 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 II 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 (Finance and Accounting) expenses, and 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 and cooperative agreements.

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% of the requested amount.

Subcontracts must be pre-approved in the Public Health Research Program Budget Template (Attachment V). The Budget Narrative must justify the purpose of the subcontract, whether this is the only vendor that can perform the services, regardless of if they are in-state or out-of-state.

B. Allowed Indirect Costs

Indirect costs (also referred to as IDC, Finance and Accounting, or administrative costs) may not exceed a total of 15% of the direct costs requested.

C. Disallowed Costs

All direct costs must be specifically and directly related and allocated 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

4. 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 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 the 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 Biomedical Research Program website: Grant Management Forms Library and Other Resources | Florida Department of Health (floridahealth.gov). Answers to submitted questions will be posted in groups as they are received and published on the website, according to the schedule in I.5, 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@orau.org.

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

5. 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.

6. Definitions

Application materials: Any documents or information to be included in the LOI, the main application, or both.

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).

Consortium: A consortium should involve partnerships to be developed among investigators across the state of Florida, with the award made to the 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 address clearly one or more areas of research interest. A letter of commitment from all collaborating organizations is required.

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.

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.

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.

Department: Florida Department of Health.

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

Established Research Institute: An established research institute eligible for program funding is an organization that is any Florida nonprofit covered under Chapter 617, Florida Statutes, with a physical location in Florida, whose stated purpose and powers are scientific, biomedical or biotechnological research and/or development and is legally registered with the Florida Department of State, Division of Corporations.

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 II: 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 II pay scale, visit the website of the U.S. Office of Personnel Management 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.

Health Systems Research: Research that addresses health system and policy questions that concern system problems and have repercussions on the performance of the health system as a whole. It addresses a wide range of questions, from health financing, governance, and policy to problems with structuring, planning, management, human resources, service delivery, referral, and quality of care in the public and private sector.

Indirect Costs: Indirect costs up to 15% *may* be included in direct cost categories for services, functions, or activities that are directly necessary for this grant.

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: Project key personnel include the Corresponding Principal Investigator and all other Principal Investigators and Co-Principal Investigators, Project Director, and Mentor (in the case of directed research projects involving post-doctoral researcher). These personnel contribute to the scientific development or execution of the project in a substantive way, whether salaries are requested or not.

Nonpublic Institutions: Nonpublic institutions in Florida operating under Chapter 1005, Florida Statutes, are eligible. For the purposes of the Biomedical Research Program, 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) to comply with the limitation.

Overlap, Commitment: Commitment overlap occurs when any project staff has time commitments exceeding 10%. This is the case whether 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 more than 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.

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 Biomedical Research Program, 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) to comply with the limitation.

III. INSTRUCTIONS – 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 Biomedical Research Program's website: http://www.floridahealth.gov/provider-and- partner-resources/research/funding-opportunity- announcements/coleyfoa.html.

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

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 FOA 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 Biomedical Research program website (http://www.floridahealth.gov/provider-and- partner-resources/research/funding-opportunity-announcements/coleyfoa.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 Biomedical Research Program 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. If an application is accidentally submitted, contact program staff for assistance.

4. An application cannot be changed after the submission due date. Some sections of the LOI—such as the Corresponding Principal Investigator, Lead Institution, Research Project Title, Research Priority, Mechanism of Support, and Keywords—will not be editable after the LOI deadline and will become part of the main application. 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 program staff, and the application can be unsubmitted so that the applicant can change and resubmit the application. 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 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.

C. Budget Guidelines

1. General Instructions: Budget documents are in Excel format and available in the PeerNet application. When calculating the budget summary and narrative be sure to use whole dollars. The budget summary contains totals for each fiscal year and calculations for determining total grant costs. The budget summary must correspond to the calculations in the budget narrative. The budget contains two parts, Attachment V Budget Summary and Budget Narrative:

    a. The Budget Summary provides an overview of the estimated budget for the life of the grant by category and by state Fiscal Year (FY) (July 1– June 30). Do not use calendar months to calculate the budget. The grant start date is *Anticipated* to begin April 1, 2025 (Fiscal Year 2024-25) the first three months of the grant) The first fiscal year grant budget should be calculated for three

months. Each remaining year will be for 12 months (July–June) The final budget year should be calculated for nine months.

b. The Budget Narrative provides information regarding how expenses will be used to support the grant. Each budget category requested should include enough detail to justify the expense and should include all calculations for arriving at the totals.

    i. Personnel/Fringe: The name, staff member's role on the project, percent of effort and any other specific rates or cost details to justify the total personnel and fringe expense. Be sure to account for any cost-of-living increases and include a statement in the narrative. Cost of living increases are limited to three percent per year. Detailed calculations are required to justify the cost for each staff.

    ii. Subcontracting: Preapproval of subcontracting is required prior to grant execution. A copy of the proposed or sample subcontract must be provided to the assigned contract manager.

    iii. Indirect Costs: Indirect cost rates may not exceed 15 percent of the total direct costs requested. Direct costs are all expense categories directly associated with the research project.

IV. POST APPLICATION SUBMISSION

1. Changes to a Submitted Application

It is the responsibility of the applicant to ensure that a complete application is submitted prior to 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. Prior to 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 are 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 in 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 includes a check for potential scientific or budgetary overlap with active or pending projects supported by the Department. 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 Biomedical Research Program 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.

- 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.
- Reviewers will individually review and rate applications, including assessing rare pediatric disease-relatedness, health impact, examining budget requests, and recommending the level of support necessary to complete the work.
- Prior to 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 National Institute of Health process, 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

Peer reviewers will also identify any concerns regarding the proposed budget. Reviewer concerns regarding protection of human and/or animal subjects will also be considered.

Applications that score within the top 30% during the individual review stage will progress to the peer review panel stage. Panelists will discuss a set of proposals and provide written comments and numeric scores.

C. Programmatic Review

The Department and the Biomedical Research Advisory Council members 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 program goals and preferences, will be used to form a funding recommendation to the State Surgeon General.

D. Evaluation Reports

For all eligible and qualitied 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 via email of the funding decisions as indicated in Table 1. All awards in response to this FOA are subject to the availability of funds and spending authority provided by the Florida Legislature. By submitting a grant application pursuant to this FOA, all applicants acknowledge and consent to this condition.

4. Requests for Re-Consideration

All funding decisions of the State Surgeon General or designee 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 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 cancer research, a list of cancer presentations, a list of cancer 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 scientific findings. Authors have a responsibility to make available materials, databases, and software integral to grant 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 the 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 program 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. I APPENDIX

1. Reportable Financial Interests Sample

Florida Department of Health Financial Conflict of Interest in Research	
Principal Investigator:	
Grant Title:	
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.

- ☐ 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.
- ☐ Compensation of any value related to the research.
- ☐ Proprietary interest related to the research of any value including, but not limited to, a patent, trademark, copyright or licensing agreement.
- ☐ Board or executive relationship in a company (such as a startup company but including publicly traded companies) related to the research, regardless of compensation.
- ☐ 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.
- ☐ Any other interest that could be affected by the outcome of the research

If any of the following above conditions are met, provide a description of financial interests related to the research:

☐ 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:

- Immediate termination of the grant.
- Financial consequences, including repayment of all grant funds.
- Any other action required by state law.

2. Budget Summary and Narrative Sample (PENDING UPDATE)

Attachment V

Grant Budget Summary

Institution:		**Principal Investigator:**	
Grant Number:		**Financial Contact:**	

BUDGET CATEGORY	FISCAL YEAR ONE 2023-2024 BUDGET (4/1/24-6/30/24)	FISCAL YEAR TWO 2024-2025 BUDGET (7/1/24-6/30/25)	FISCAL YEAR THREE 2025-2026 BUDGET (7/1/25-6/30/26)	FISCAL YEAR FOUR 2026-2027 BUDGET (7/1/26-6/30/27)	FISCAL YEAR FIVE 2027-2028 BUDGET (7/1/27-6/30/28)	TOTAL BUDGET
Personnel / Fringe Benefits	$0	$0	$0	$0	$0	$0
Subcontracting	$0	$0	$0	$0	$0	$0
Equipment	$0	$0	$0	$0	$0	$0
Supplies	$0	$0	$0	$0	$0	$0
Travel	$0	$0	$0	$0	$0	$0
Patient Care	$0	$0	$0	$0	$0	$0
Other Expenses	$0	$0	$0	$0	$0	$0
DIRECT COST SUB-TOTAL:	$ -	$ -	$ -	$ -	$ -	$ -
Indirect Amount:	$0	$0	$0	$0	$0	$0
TOTAL:	$ -	$ -	$ -	$ -	$ -	$ -

GRANTEE		**FLORIDA DEPARTMENT OF HEALTH**	
Signature of Authorized Official		**Signature of Authorized Official**	
Name:		**Name:**	
Title:		**Title:**	Deputy Director, Public Health Research
			Biomedical Research Section
Date:		**Date:**	

INSTRUCTIONS:

1. The budget must include the entire proposed project cost broken down by category and state fiscal year (July 1 – June 30).
2. Complete the appropriate number of columns below as appropriate for the term of your grant award.
3. The total budget may not exceed the award amount and should be rounded to the nearest whole dollar amount.
4. Cost of Living Adjustments are allowable on Fiscal Year Two and forward, not to exceed 3%. Please note, a standard statement has been included on the Budget Narrative.
5. Contractual Costs requires additional forms and prior approval, including a copy of the draft/proposed subcontract.
6. Budget categories may not be altered, combine or revised.
7. Modified Total Direct Cost (MTDC): Hard enter the total for each fiscal year. Formulas will calculate the indirect cost rate x the MTDC amount, not to exceed 15%. Excluded costs should be clearly identified on the Budget Narrative.
8. Indirect costs are limited to no more than 15% of the modified total direct costs requested.
9. Where appropriate, include details that show how the estimated cost was calculated.
10. If changes are needed to adjust direct costs throughout the life of the grant, a budget change request must be submitted and approved.
11. Insert additional rows in the Personnel chart as necessary. The remaining budget category text boxes will expand as you type. Select ALT + Enter to go to the next line.
12. Please contact your assigned Grant Manager for assistance.

FDOH Rev. 5/1/2023

Rare Disease Research Grant Budget Narrative

FISCAL YEAR ONE 2023-2024 (4 Month Budget March - June)

Personnel/Fringe

Name/Role on Project	Annual Base Salary	% Effort on Project	Project Salary Total (Salary/12 months x 4 months x % Effort)	Fringe %	Fringe Amount (Column D x E)	Fringe Fixed/Flat Rate (if applicable)	Total Personnel & Fringe (Column D + F + G)
	$ -	0.00%	$ -	0.00%	$ -	$ -	$ -
	$ -	0.00%	$ -	0.00%	$ -	$ -	$ -
	$ -	0.00%	$ -	0.00%	$ -	$ -	$ -
	$ -	0.00%	$ -	0.00%	$ -	$ -	$ -
	$ -	0.00%	$ -	0.00%	$ -	$ -	$ -
						TOTAL PERSONNEL COST:	**$ -**

Consultant	$ -
Consortium	$ -
Contractual Services (*require pre-approval by DOH*)	$ -
Equipment *(Itemize all equipment costs and describe how the equipment will be used toward the research project. Show total cost of category)*	$ -
Supplies *(This line item may be adjusted to bring the budget to the exact award amount)*	$ -
Travel *(Domestic travel will be reimbursed in accordance with s.112.061, Florida Statutes. Lodging costs may not exceed $175 per night)*	$ -
Patient Care Costs *(Itemize estimated patient care costs)*	$ -
Other Expenses *(Itemize all Other expense costs)*	$ -
Indirect *(Show Total Direct Costs x Rate % = $Total Indirect Costs)*	$ -

Rare Disease Research Grant Budget Narrative

FISCAL YEAR TWO 2024-2025 (12 Month Budget)

Personnel/Fringe

Name/Role on Project	Annual Base Salary	% Effort on Project	Project Salary Total (Salary x % Effort)	Fringe %	Fringe Amount (Column D x E)	Fringe Fixed/Flat Rate (if applicable)	Total Personnel & Fringe (Column D + F + G)
	$ -	0.00%	$ -	0.00%	$ -	$ -	$ -
	$ -	0.00%	$ -	0.00%	$ -	$ -	$ -
	$ -	0.00%	$ -	0.00%	$ -	$ -	$ -
	$ -	0.00%	$ -	0.00%	$ -	$ -	$ -
	$ -	0.00%	$ -	0.00%	$ -	$ -	$ -
						TOTAL PERSONNEL COST:	**$ -**

Note: A Cost of Living Adjustment up to 3% is allowed during this budget period.

Consultant	$ -
Consortium	$ -
Contractual Services (*require pre-approval by DOH)*	$ -
Equipment *(Itemize all equipment costs and describe how the equipment will be used toward the research project. Show total cost of category)*	$ -
Supplies *(This line item may be adjusted to bring the budget to the exact award amount)*	$ -
Travel *(Domestic travel will be reimbursed in accordance with s.112.061, Florida Statutes. Lodging costs may not exceed $175 per night)*	$ -
Patient Care Costs *(Itemize estimated patient care costs)*	$ -
Other Expenses *(Itemize all Other expense costs)*	$ -
Indirect *(Show Total Direct Costs x Rate % = $Total Indirect Costs)*	$ -

Rare Disease Research Grant Budget Narrative

FISCAL YEAR THREE 2025-2026 (12 Month Budget)

Personnel/Fringe

Name/Role on Project	Annual Base Salary	% Effort on Project	Project Salary Total (Salary x % Effort)	Fringe %	Fringe Amount (Column D x E)	Fringe Fixed/Flat Rate (if applicable)	Total Personnel & Fringe (Column D + F + G)
	$ -	0.00%	$ -	0.00%	$ -	$ -	$ -
	$ -	0.00%	$ -	0.00%	$ -		$ -
	$ -	0.00%	$ -	0.00%	$ -		$ -
	$ -	0.00%	$ -	0.00%	$ -		$ -
	$ -	0.00%	$ -	0.00%	$ -		$ -
						TOTAL PERSONNEL COST:	**$ -**

Note: A Cost of Living Adjustment up to 3% is allowed during this budget period.

Consultant	$ -
Consortium	$ -
Contractual Services (*require pre-approval by DOH)*	$ -
Equipment *(Itemize all equipment costs and describe how the equipment will be used toward the research project. Show total cost of category)*	$ -
Supplies *(This line item may be adjusted to bring the budget to the exact award amount)*	$ -
Travel *(Domestic travel will be reimbursed in accordance with s.112.061, Florida Statutes. Lodging costs may not exceed $175 per night)*	$ -
Patient Care Costs *(Itemize estimated patient care costs)*	$ -
Other Expenses *(Itemize all Other expense costs)*	$ -
Indirect *(Show Total Direct Costs x Rate % = $Total Indirect Costs)*	$ -

Rare Disease Research Grant Budget Narrative

FISCAL YEAR FOUR 2026-2027 (8 Month Budget)

Personnel/Fringe

Name/Role on Project	Annual Base Salary	% Effort on Project	Project Salary Total (Salary/12 months x 8 months x % Effort)	Fringe %	Fringe Amount (Column D x E)	Fringe Fixed/Flat Rate (if applicable)	Total Personnel & Fringe (Column D + F + G)
	$ -	0.00%	$ -	0.00%	$ -	$ -	$ -
	$ -	0.00%	$ -	0.00%	$ -	$ -	$ -
	$ -	0.00%	$ -	0.00%	$ -	$ -	$ -
	$ -	0.00%	$ -	0.00%	$ -	$ -	$ -
	$ -	0.00%	$ -	0.00%	$ -	$ -	$ -
						TOTAL PERSONNEL COST:	**$ -**

Note: A Cost of Living Adjustment up to 3% is allowed during this budget period.

Consultant	$ -
Consortium	$ -
Contractual Services (*require pre-approval by DOH)*	$ -
Equipment *(Itemize all equipment costs and describe how the equipment will be used toward the research project. Show total cost of category)*	$ -
Supplies *(This line item may be adjusted to bring the budget to the exact award amount)*	$ -
Travel *(Domestic travel will be reimbursed in accordance with s.112.061, Florida Statutes. Lodging costs may not exceed $175 per night)*	$ -
Patient Care Costs *(Itemize estimated patient care costs)*	$ -
Other Expenses *(Itemize all Other expense costs)*	$ -
Indirect *(Show Total Direct Costs x Rate % = $Total Indirect Costs)*	$ -

MEMORANDUM OF AGREEMENT
BETWEEN
"Institution Name"
and the
FLORIDA DEPARTMENT OF HEALTH

This Memorandum of Agreement "Agreement" is entered into between the Florida Department of Health "Department", and "Institution Name", "Grantee", each a "Party" and jointly referred to as the "Parties." In consideration of the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

SECTION I: DEFINITIONS

A. **Definition of Term**:

1) **Rare Pediatric Diseases Research Grant Program**: The purpose of the program is to advance the progress of research and cures for pediatric rare diseases by awarding grants through a competitive, peer-reviewed process.

2) **Quarter**: A three-month period of the executed agreement. The quarters for this Agreement are July through September (Quarter One); October through December (Quarter Two); January through March (Quarter Three); and April through June (Quarter Four).

3) **Grantee**: A person or institution that receives Rare Pediatric Diseases Research Grant Funds to conduct rare pediatric disease research.

SECTION II: GENERAL TERMS AND CONDITIONS

A. **General Statement**: This Agreement is to support innovative approaches to research and treatment for rare pediatric diseases.

B. **Legal Authority**: This Agreement is made pursuant to the Specific Appropriation Line item 546A of the 2023-2024 Appropriations Act.

C. **Entire Agreement**: This Agreement embodies the entire Agreement and understanding between the Parties, on the subject hereof.

D. **Term**: The term of this Agreement is for 12 months from the date of execution. This Agreement may be renewed on a yearly basis in writing upon mutual agreement and subject to the same terms and conditions as set forth in this Agreement.

SECTION III: PROPERTY AND EQUIPMENT

A. Property and equipment are defined as non-expendable, tangible property having a useful life of more than one year with a cost of $5,000 or more. All property and equipment purchased with Rare Pediatric Diseases Research Grant Program 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. Grantee must ensure the following:

1) All approved property and equipment must be purchased and received prior to the last three months of the grant period unless prior written approval from the Department has been obtained.

2) 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 Chapter 1000, 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.

SECTION IV: SERVICES TO BE PROVIDED

A. **Task List**: Grantee will perform the following tasks:

1) Ensure the following tasks are performed as needed each quarter:

a. Conduct research related to rare pediatric diseases. Document quarterly in supportive records or affidavit the peer-reviewed funding.

b. Prepare quarterly progress reports on the rare pediatric disease project. Progress reports should be written for the general audience and provide an overview of the quarter's activities. Additionally, the report should list and add a narrative of any innovative therapies and best practices that were developed using these funds and how these will be shared with the public. Supporting technical documentation and protocols developed with these funds should also be provided as supplements to the report. The reports should be submitted to the Grant Manager within 30 days from the end of each quarter.

c. As needed, submit ad hoc reports to share with the Department.

SECTION V: DELIVERABLES AND METHOD OF PAYMENT

A. **Deliverables**: Grantee must complete and submit the following deliverable in the time and manner specified:

1) Quarterly: Provision of rare pediatric diseases research and associated activities specified in Task 1.

B. **Performance Measures and Financial Consequences**: Grantee must perform the deliverable as specified in this Agreement. If Grantee fails to perform the deliverable as specified in this Agreement, the Department reserves the right to assess a financial consequence in the Amount of $5,000.00 to that quarter's invoice.

C. **Method of Payment**:

1) Payment: The Department will pay Grantee for completion of the deliverable specified in section V.A., in accordance with the terms and conditions of this Agreement. The Department will pay one quarterly payment of $00,000.00 and three quarterly payments of $00,000.00.

2) Invoice Requirements: Grantee must submit a properly completed invoice to the Grant Manager within 30 days of the end of the quarter.

3) Advance Payment:

a. Provider may request an advance of up to one-fourth of the total annual contract amount. Advance payments are subject to approval. Requests must be made in writing, to the Department's Grant Manager, no later than 30 days after the start of the contract year. The advance payment amount will be recouped by the Department over the three months preceding the last month of the contract year in which the advance is made.

b. Interest on Advance Payment: Provider may temporarily invest advanced funds in an insured interest-bearing account. Interest earned on advanced funds must be returned to the Department monthly.

D. **Financial Assistance Requirements**:

1) As a recipient or subrecipient as specified in Attachment I, Grantee will perform the required Financial and Compliance Audits in accordance with the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, 2 C.F.R. Part 200 as revised, subpart F and section 215.97, Florida Statutes, as applicable and conform to the following requirements:

a. Documentation: Maintain separate accounting of revenues and expenditures of funds under this Agreement and each Catalog of State Financial Assistance (CSFA) or Catalog of Federal Domestic Assistance (CFDA) number identified on the attached Exhibit 1, in accordance with generally accepted accounting practices and procedures. Expenditures that support Grantee 's activities not solely authorized under this Agreement must be allocated in accordance with applicable laws, rules, and regulations and the allocation methodology must be documented and supported by competent evidence.

b. Maintain sufficient documentation of all expenditures incurred (e.g., invoices, canceled checks, payroll detail, bank statements, etc.) under this Agreement. Expenditures should be:

i. Allowable under the Agreement and applicable laws, rules, and regulations;
ii. Reasonable; and
iii. Necessary for Grantee to fulfill its obligations under this Agreement.
iv. All documentation required by this section is subject to review by the Department and the State's Chief Financial Officer. Grantee must timely comply with any requests for documentation.

c. Annual Financial Report: Submit to the Department an annual financial report stating, by line item, all expenditures made as a direct result of services provided through this Agreement within 45 days from the end of each Agreement year, but no later than submission of the final invoice for that year. Each report must include a statement signed by an individual with legal authority to bind Grantee, certifying that these expenditures are true, accurate, and directly related to this Agreement.

d. Ensure that funding received under this Agreement in excess of expenditures is remitted to the Department within 45 days of the end of each Agreement year and the Agreement end date.

e. Annual Compensation Report: This section is not applicable to agreements executed with State agencies or subdivisions, as defined in section 768.28, Florida Statutes. If applicable, Grantee must submit Attachment II, Annual Compensation Report, including the most recent Internal Revenue Services (IRS) Form 990, detailing the total compensation for the Grantee's executive leadership teams, to the Grant Manager no later than January 31 of each Agreement year. Total compensation must include salary, bonuses, cashed-in leave, cash equivalents, severance pay, retirement benefits, deferred compensation, real-property gifts, and any other payout. If Grantee is exempt from filing IRS Form 990, submit Attachment II without including the IRS Form 990, to the Department. All Annual Compensation Reports must indicate what percent of compensation comes directly from State or Federal funding allocations given to Grantee. In addition, Grantee, by executing this Agreement, which includes any subsequent amendments, agrees to inform the Department of any changes in total executive compensation specified in Grantee's submitted Annual Compensation Reports.

2) **Budget**: Expenditures must be supported by an approved budget summary and budget narrative for the initial period of the Agreement. For each subsequent agreement year, the budget summary and budget narrative must be submitted to the Grant Manager for approval by May 1. Any revisions to the budget summary and budget justification must be submitted to the Grant Manager for review and approval prior to implementation.

3) **Quarterly Financial Report**: The Grantee must submit a Quarterly Financial Report at the conclusion of the first through third quarters of each Agreement year. Each Quarterly Financial Report must state, by line item, all Agreement fund expenditures made by Grantee to complete the deliverables under this Agreement. The Grantee must submit a Quarterly Financial Report to the Grant Manager within 30 calendar days following the end of each quarter. For the fourth quarter of each Agreement year, the Grantee must submit the Annual Financial Report within 45 days following the end of the agreement year. Each Quarterly Financial Report and the Annual Financial Report must state, by line item, all Agreement fund expenditures made by Grantee to complete the deliverables under this Agreement.

E. **Special Provisions**:

1) **Allowable Costs**: The Grantee may expend funds only for allowable costs resulting from obligations incurred during the Agreement term. Allowable costs are those that were approved in the final project budget.

2) **Return of Funds**: The Grantee will return to the Department any overpayments due to unearned funds or funds disallowed. In the event that Florida State University, or its independent auditor discovers that an overpayment has been made, Florida State University, will repay the overpayment within 40 calendar days without prior notification from the Department. In the event that the Department first discovers an overpayment has been made, the Department will notify the Grantee, in writing of such a finding. Any balance of unobligated funds advanced or paid must be refunded to the Department.

3) **Monitoring**: The Grantee must permit persons duly authorized by the Department to inspect any records, papers, documents, facilities, or goods and services of the Grantee that are relevant to this grant, and interview any clients, sub-contractors, 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 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 Agreement; or 3) the termination of this grant.

4) **Duties of Designated Grant Manager**: The Grant Manager designated by the Department shall reconcile and verify all funds received against all funds expended during the term of this Agreement period and produce a final reconciliation report. The final report for this project must identify any funds paid in excess of the expenditures incurred by the Grantee or Sub-recipient.

5) **Sovereign Immunity**: Nothing herein is intended to serve as a waiver of sovereign immunity pursuant to section 768.28, Florida Statutes, nor construed as consent by a state agency or subdivision (as defined by section 768.28, Florida Statutes) to be sued by third parties in any matter arising out of this Agreement.

6) **Governing Law and Venue**: This Agreement is executed and entered into in the State of Florida and will be construed and performed under the laws, rules, and regulations of the State of Florida. Venue must be in Leon County, Florida, to the exclusion of all other jurisdictions.

7) **Indemnification**: This section is not applicable to agreements executed with State agencies or subdivisions, as defined in section 768.28, Florida Statutes.

Grantee will be liable for, and indemnify, defend, and hold the Department harmless from and against all claims, demands, suits, judgments, or damages, including, but not limited to, court costs and attorneys' fees and damages resulting from personal injury, including death or damage to property, arising out of the negligence, intentional or unintentional acts or omissions of the Grantee, and the Grantee's agents, assignees, sub-contractors, and employees, that may arise during the course of the operation of this Agreement, or that arise out of or relating to the subject property, the Project, or the use of grant money.

8) **Modification**: This Agreement may only be amended in writing and upon mutual agreement by the Parties.

9) **Termination**:

a. **Termination Because of Lack of Funds**: It is agreed that in the event funds to finance this Agreement, or part of this Agreement, become unavailable, the obligations of each Party, hereunder may be terminated upon no less than 24 hours' notice in writing to the other Party. Said notice will 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 of state funds, and how any remaining funds will be allocated among Grantees.

b. **Termination for Breach**: Unless the Grantee's breach is excused by the Department, the Department may provide written notice to the Grantee specifically setting forth the breach and allow a 30-calendar day period whereby the Grantee may cure any such breach. The Department may terminate any part or the whole of this Agreement in any of the following circumstances:

i. If Grantee fails to provide services called for by this Agreement within the time specified herein or any extension thereof.

ii. If Grantee fails to perform any of the other provisions of this Agreement.

iii. Except as set forth above, termination will be upon no less than 24 hours' notice in writing delivered by certified mail, return receipt requested, or in person with proof of delivery.

c. All provisions of this Agreement that were not terminated, amended, or modified will remain in full effect and Grantee will continue performance under any remaining provisions.

d. After receipt of a notice of termination, and except as otherwise directed in writing, the Grantee will:

i. Stop work under this Agreement on the date and to the extent specified in the notice of termination and take any other actions as directed in writing from the Department.

ii. Place no further orders or contracts for materials, services, or facilities except as may be necessary for completion of such portion of work under the Agreement as is not terminated.

iii. Terminate all outstanding orders and contracts to the extent that they relate to the performance of work under this Agreement.

iv. Prepare all necessary reports and documents required under the terms of this Agreement. Documents must be prepared up to the date of termination and include the final report due upon completion of this Agreement. The Department will provide no additional funds for administrative fees or for the completion of final reports after the date of termination.

v. Notwithstanding anything to the contrary set forth herein, upon termination of this Agreement, the Grantee may continue work on the Project that is the subject of this MOA so long as such work is funded by sources other than the Department.

10) **Notice**: Any notices given by either party to the other party under this Agreement will be in writing and sent either: via email to the designated email address, by overnight courier, with a verified receipt; or by registered or certified United States Mail, postage prepaid. Either party's specified point of contacts may be changed by notifying the other party a minimum of one week prior to such change. Notice will be deemed sufficiently given upon receipt at the following addresses:

Department: Mike Mason
4052 Bald Cypress Way, Bin A-06
Tallahassee, FL 32399
Mike.Mason@flhealth.gov

Grantee: Institution Representative
Address
Email

11) **Cooperation with Inspectors General**: To the extent applicable, the Parties will cooperate with the inspector general in any investigation, audit, inspection, review, or hearing pursuant to section 20.055(5), Florida Statutes.

12) **Public Records**: The Grantee must keep and maintain public records, as defined in Chapter 119, Florida Statutes that are required by the Department to perform the services required by the grant. Questions regarding the application of Chapter 119, Florida Statutes, and its duty to provide public records relating to this Agreement, contact the custodian of public records at (850) 245-4005, PublicRecordsRequest@flhealth.gov or 4052 Bald Cypress Way, Bin A02, Tallahassee, FL 32399.

SECTION V: AUTHORIZATION

IN WITNESS THEREOF, the Parties hereto have caused this 7-page Agreement to be executed by their undersigned, duly authorized, officials:

_____ Date: _____
Name:
Title:

Florida Department of Health

_____ Date: _____
Name: Mike Mason
Title: Assistant Deputy Secretary of Health