Pennsylvania
Department of Health

September 24, 2025

Dear Potential Applicant:

You are invited to submit an application to the Pennsylvania Department of Health in accordance with the enclosed Request for Applications (RFA) 67-205.

All questions regarding this RFA must be directed by e-mail to ra-healthresearch@pa.gov with an email subject line of "PA DOH RFA #67-205 QUESTIONS", no later than 12:00 p.m. ET on October 7, 2025. All questions must include the specific section of the RFA about which the potential applicant is requesting clarification. Answers to all questions will be posted at www.emarketplace.state.pa.us. Click on 'Solicitations' and search for the above RFA number.

A Letter of Intent (LOI) must be submitted by email to ra-healthresearch@pa.gov. The Letter of Intent must be prepared using the Letter of Intent form provided in Part Two of this RFA. The Letter of Intent must be submitted no later than 1:30 pm ET on **November 3, 2025**. If the Letter of Intent is not received using the form provided on or before this date and time, the application will not be accepted. Type "LOI ENCLOSED RFA #(67-205)" as the subject line of your e-mail submission.

Upon receipt of the Letter of Intent, the applicant will receive a link to a SharePoint site for submission of the application. The application must be submitted through the SharePoint site link no later than 1:30 pm ET on **November 24, 2025**. As the link will be removed at the submission deadline, applicants are encouraged to not wait until this closing date and time.

LATE APPLICATIONS WILL NOT BE ACCEPTED REGARDLESS OF THE REASON.

We expect that the evaluation of applications and the selection of Grantees will be completed within six months of the submission due date.

Sincerely,

Rebekah Gregorowicz
Digitally signed by Rebekah Gregorowicz
Date: 2025.09.24 09:18:43 -04'00'
Office of Procurement
For Agency Head

Enclosure

Request for Application

Research to Cure and Prevent Type 1 (Juvenile) Diabetes

RFA Number
67-205

Date of Issuance
September 24, 2025

Issuing Office: Pennsylvania Department of Health
Office of Procurement
Email: RA-DHHEALTH_DEPT_DOC@pa.gov

RFA Project Officer: Sylvia Golas
Pennsylvania Department of Health
Health Research Office
Email: ra-healthresearch@pa.gov

Research to Cure and Prevent Type 1 (Juvenile) Diabetes

CONTENTS

Any Grant Agreement resulting from this RFA will include certain standard terms and conditions that will be attached as appendices and will be part of the agreement, which may either be found at http://www.health.pa.gov/vendors or

are attachments to this RFA. These terms and conditions are not negotiable and are listed below:

- Payment Provisions (Rev. 10/21)
- Program Specific Provisions
- Commonwealth Standard General Terms and Conditions (Grant) (Rev. 10/1/23)
- Department Standard General Terms and Conditions (Grant) (Rev. 12/24)
- Audit Requirements (Rev. 10/24)
- Commonwealth Travel and Subsistence Rates (Rev. 8/18)
- Federal Lobbying Certification and Disclosure (Rev. 12/05)
- Minimum Personal Computer Hardware, Software, and Peripherals Requirements (Rev. 1/19)
- Pro-Children Act of 1994 (Rev. 12/05)
- Federal Standard Terms and Conditions (Grant) (Rev. 12/24)

PART ONE

Research to Cure and Prevent Type 1 (Juvenile) Diabetes

General Information

A. Information for Applicants

1. Background of Funding Source

The Juvenile Diabetes Cure Research Tax Check-off Program was created in September 2004 with the passage of Act 133, Juvenile Diabetes Cure Research. The Act created a state income tax check-off option for individuals to contribute a portion of their state tax refund to support research for Type 1 (Juvenile) Diabetes.

Pennsylvania's use of Juvenile Diabetes Cure Research Tax Check-off Program funds to support health research in Pennsylvania helps direct research efforts to state-defined health research objectives that improve the health of all Pennsylvanians.

For this RFA, funds will be awarded to applicants located within the Commonwealth of Pennsylvania (Commonwealth). By supporting Pennsylvania-based researchers with Juvenile Diabetes Cure Research Tax Check-off Program funds, the Commonwealth's intent is to help attract additional research funds from other sources and to achieve health and economic goals that existing revenues could not underwrite.

All research applications submitted in response to this RFA must identify and address disparities in health status, outcome, prevention or treatment, and should relate to the Pennsylvania Department of Health's (Department) goal to improve the health status and life expectancy of Pennsylvanians and eliminate health inequities (that is, PA State Health Improvement Plan 2023 - 2028).

All research projects must be consistent with the research priorities listed in Part One, Section D.

This RFA is subject to applicable sections of the Tax Reform Code of 1971 (P.L. 6, No 2), P.S. § 315.7, Act 133 (Act) as amended 2004.

2. RFA Information

Through this RFA process, the Department is soliciting research applications to cure and prevent Type 1 (Juvenile) Diabetes. The overall goal of this funding is to promote the health of children and adolescents in Pennsylvania. The anticipated Grant Agreement effective date is July 1, 2026 subject to the availability of funding. The Grant Agreement term is not to exceed four years.

The Department has approximately $237,955 to fund a research project that is consistent with the research priorities set forth below in Section D. Research Priorities. Pursuant to the applicable sections of the Tax Reform Code of 1971 (P.L. 6, No 2), P.S. § 315.7, Act 133 (Act) as amended 2004, the Department expects to award one Grant Agreement and expects the award not to exceed $237,955.00.

At the Department's discretion and by letter notice, the Department may extend the resulting Grant Agreement as follows:

Extension. Upon notice to the Grantee, without the need for a formal amendment, the Department may, for any reason, exercise an extension that extends the term of the agreement, the period of performance, or both. The aggregate duration for all extension periods, exclusive of the 3-month extension, cannot extend the term of the agreement more than four years from the effective date. The same terms and conditions apply to an extension unless otherwise stated. The extension is part of the agreement and subject to its provisions.

1. **No-Cost**. The Department may issue a no-cost extension of the agreement for any reason. The no-cost extension only extends the time period when the Grantee is permitted to use remaining funds and does not extend the agreement beyond four

years from the agreement's effective date. The Department shall provide the Grantee written notice of its decision to issue a no-cost extension. No additional funding is awarded to Grantee in a no-cost extension.

2. **3-Month**. The 3-month extension extends the agreement for up to three months.

Applications are welcomed from institutions of higher education and independent research institutes located within the Commonwealth of Pennsylvania. Funding will be awarded to the most scientifically meritorious proposal, which is submitted by the most qualified organization. Additional information about how to apply, relevant and specific restrictions, and stated preferences regarding applicants are noted and outlined in Section B. Applicants are encouraged to be innovative and creative in their approach.

This RFA provides interested and eligible parties with information to prepare and submit applications to the Department. Questions about this RFA can be directed to the contact listed in the potential applicant letter (which is the first page of this RFA) by the date and time listed therein. All questions must include the specific section of the RFA about which the potential applicant is requesting clarification. Answers to all questions will be posted under the RFA Solicitation at www.emarketplace.state.pa.us. Each applicant shall be responsible to monitor the website for new or revised RFA information. The Department shall not be bound by any information that is not either contained within the RFA or formally issued as an addendum by the Department.

In order to do business with the Commonwealth of Pennsylvania providers are required to enroll in the SAP system. Applicants may enroll by selecting "Non-Procurement" at: https://www.budget.pa.gov/Services/ForVendors/Pages/Vendor-Registration.aspx or by calling toll free at 1-877-435-7363. The PDF and MP4 embedded links next to "Non-Procurement" provide guidance on enrolling.

3. Lead Applicant and Support

Eligible applicants must be institutions of higher education and independent research institutes located within the Commonwealth of Pennsylvania. All applicants must have their primary location within Pennsylvania. Applicants must be registered with the Pennsylvania Department of State as required by Pennsylvania law.

For the purposes of this RFA, a collaborative research project is defined as two or more organizations that are committed to working together, as collaborating applicants, to jointly conduct a single research project. Letters of support from collaborating organizations are required to be submitted in the application for this RFA to demonstrate this collaborative commitment.

If the application involves collaboration among two or more organizations, one organization must be designated on the application as the lead agency. The applicant shall be a legal entity to be eligible to receive all potential Grant Agreement funds and shall be responsible for the fiscal aspects and all other aspects of the resulting Grant Agreement. The applicant and all collaborating organizations (which have a meaningful and substantive role in the research project) must be located within Pennsylvania. Lead applicants and collaborating organizations must conduct 98% of the research proposed in the application at Pennsylvania-based facilities. Subcontractors that are not considered collaborating partners and have a minor role in the research project may be non-Pennsylvania-based institutions which are located outside of Pennsylvania. However, if subcontractors from other states participate on the project team, the application should clearly describe how any barriers to communication and close collaborative research work will be overcome. The principal investigator (PI) on the research project may reside outside of Pennsylvania; however, the applicant or collaborating institution where the PI works must be located in Pennsylvania. Consultants who have a minor role in the research project may be located outside of Pennsylvania. The total cost of out-of-state subcontractors, consultants, fee-for-service providers and vendors and the cost of research conducted outside of Pennsylvania by the lead applicant and

collaborating organizations must not exceed two percent of the total budgeted costs. If a product or service that is essential for conducting the research is not available in Pennsylvania, the total cost of the out-of-state subcontractor or vendor which will provide the service or product may exceed two percent of the total budgeted costs, provided that the application contains adequate justification that the service or product is essential to the conduct of the research and evidence that the service or product is not available in Pennsylvania. An organization may submit only one application, as a lead agency in response to this RFA. There is no limit to the number of applications in which an organization can be listed as a collaborating organization.

4. Requirements of the Research Project

The goal of this funding is to discover scientific knowledge that can be applied toward improving the health of Pennsylvanians. In order to achieve this goal, the research project shall design and conduct only one scientifically meritorious research project consistent with the research priority. One research project may consist of several hypothesis-driven sub-projects or studies that are proposed to address each aim of the overall research project or address a different aspect of the overall goal. The studies should be closely related to each other and the overall goal. The application should only include studies that will be completed within the anticipated term outlined in Part One, Section C.2.d.

All research applications submitted in response to this RFA must be consistent with the research priority listed in Part One, Section D. of this RFA. The extent to which an application is consistent with the research priority will be determined by peer reviewers who will review and rank the application based on the scientific and technical merit of the research project. Each application will be evaluated based on criteria as stated in Part One, Section B.2.

5. Use of Funds – Limitations and Additional Requirements

Funds may only be used for Type 1 (Juvenile) Diabetes cure research related to: (1) restoring normal blood sugar levels; (2) preventing and reversing complications; or (3) preventing Type 1 (Juvenile) Diabetes as defined by Act 2004-133. Activities that are not Type 1 (Juvenile) Diabetes research as defined by Act 2004-133 will not be considered.

Funds are awarded for a specifically defined purpose and must be used for implementation and management of the research project. Funds shall not be used for mini-grants or sub-grants or pilot studies that are not clearly specified in detail in the application. Research aims, research design and research methodology must be described for every study included in the application.

Funds shall not be used to pay costs incurred prior to the effective date of the Grant.

Funds shall not be used to establish registries, patient databases or tissue banks.

Funds may support personnel and services directly related to the research project and may be used to purchase computer hardware and software.

Funds shall not be used for the purchase or lease of motor vehicles or to supplant Federal or other state funds that have been made available for this purpose.

Funds shall not be used for international travel.

Funds shall not be used to indemnify institutions that are performance sites against adverse events associated with the research project.

Funds may be used for tuition, but only for those investigators who are directly involved in carrying out research to be funded by the resulting Grant Agreement. Funds may not be used for educational

programs designed to interest school children in careers in biomedical, health services or clinical research.

Funds shall not be used to pay honoraria to individuals asked to serve on advisory committees.

Funds may be used to reimburse advisory committee members for travel expenses related to attendance at advisory committee meetings.

Funds may be used to pay costs for consultants or speakers related to the research project.

Funds shall not be used to develop Continuing Medical Education programs. Funds shall not be used to develop or implement patient, professional or community educational programs designed to change patient or health care provider behaviors unless such programs are part of a rigorously designed scientific trial to evaluate the effectiveness of the education intervention on behaviors to improve healthcare outcomes, morbidity or mortality.

Funds may not be used to pay for the costs of regular patient care. Funds may be used to pay for research patient care costs limited to no more than $400,000 for the entire budget period. Research patient care costs are costs of routine and ancillary services provided by hospitals and other health care service providers to patients participating in research projects. Research patient care costs do not include: (1) the otherwise allowable items of personal expense reimbursement, such as patient travel or subsistence, consulting physician fees, or any other direct payments related to all classes of patients, including inpatients, outpatients, subjects, volunteers, and donors and (2) costs of ancillary tests performed in facilities outside the hospital on a fee-for-services basis (for example, in an independent, privately owned laboratory) or in an affiliated medical school/university, based on an institutional fee schedule.

No more than 50 percent of the funds may be used for infrastructure. Infrastructure is defined as:

- Office equipment
- Office supplies
- Nonprofessional personnel (secretaries, administrative assistants, and clerks)
- Laboratory or Building construction or renovations, used to conduct research.

All other personnel are professional personnel and are non-infrastructure costs. Research equipment is not infrastructure. Research equipment may be purchased as part of an approved research project funded under the resulting Grant Agreement or as part of a research infrastructure project involving research facilities construction or renovation. Costs of equipment purchased as part of a research infrastructure project must not exceed 50 percent of the entire project costs.

Applications containing requests for infrastructure funds should describe the location of the facilities and potential users of the facilities both at the host institution and other institutions. Sharing of infrastructure facilities among universities and public and private research organizations is encouraged. Necessary support personnel (technicians) to operate equipment and facilities may be requested, but the project plan must explain how these operating costs would be funded after the termination of the resulting Grant Agreement.

The applicant must adhere to applicable Federal, state and local standards and laws for the construction and renovation of research facilities. (See http://grants.nih.gov/grants/policy/policy.htm)

Indirect costs shall not be charged against items in Categories II (Consultant Services), III (Subcontract Services) and V (Equipment) of the budget. A subcontractor shall not charge indirect costs against items in Categories II, III and V. The indirect costs specified in Appendix C - Budget shall not be greater than 20 percent of the sum of total direct costs less the costs of Categories II, III and V. The applicant must be

able to support the indirect cost rate with an allocation plan if requested. The indirect cost rate shall not be increased at any time for the duration of the resulting Grant Agreement.

Small businesses are encouraged to apply and may use potential Grant Agreement funds for a reasonable profit or fee provided that the profit or fee is included in the budget. The profit or fee cannot be increased above the rate specified in the resulting Grant Agreement for the duration of the Grant Agreement. The fee is intended to be a reasonable profit for businesses involved in health research and development work. The profit or fee rate specified in the resulting Grant Agreement shall be no greater than seven percent of the sum of total costs (direct and indirect) less Category II and III costs.

Funds may not be used for licensing or option fees, attorney's fees for preparing or submitting patent applications, and fees paid to the U.S. Patent and Trademark Office for patent application, patent maintenance, or recordation of patent-related information.

Funds shall not be used to pay an individual at a rate in excess of the Executive Level II ($221,900/year or $106.68/hour) of the 2024 Federal Executive Schedule, in accordance with the National Institutes of Health (NIH) Guide for Grants & Funding.

Funds shall not be used to pay an individual to manage or administer the resulting Grant Agreement.

Funds shall not be used for research projects focused primarily or exclusively on program planning and evaluation.

No more than 10 percent of the budget may be used for personnel to perform statistical and data analyses.

6. Use of Existing Health Data

Applicants are encouraged to utilize existing health data and resources. Relevant databases such as the Behavioral Risk Factor Surveillance System, hospital discharge, outpatient and ambulatory care, and managed care data already exist, and other state agencies such as the Pennsylvania Health Care Cost Containment Council and health care researchers in Pennsylvania have already undertaken significant work with these resources. Applicants are encouraged to utilize existing data sets and expertise to the extent feasible.

7. Effective and Termination Dates for Grant

In preparing the application, the effective date contained in the cover letter to this RFA should be used as the effective date for the resulting Grant Agreement. The applicant must determine the duration of the grant award and specify the duration of the award in the application. The total project period for the resulting Grant Agreement may not exceed four years. Therefore, the termination date as specified in the application must not exceed 48 months from the effective date (July 1, 2026), as specified in the cover letter to the RFA. The Department may, by written notice, extend the resulting Grant Agreement term, but the extended termination date still may not exceed 48 months from the effective date.

B. Application Procedures

1. General

a) Applications must be received by the Department by the time and date stated in the cover letter. The Department will reject any late applications. The decision of the Department with regard to timeliness of submission is final. No changes, Amendments, supplements, alterations or additions of any nature to the application or any additional letters or materials of any kind will be accepted after the application due date as stated in the cover letter.

b) If it becomes necessary to revise any part of the application guidelines, an amendment will be posted under the RFA Solicitation at www.emarketplace.state.pa.us.
c) The decision of the Department with regard to selection of applicants is final. The Department reserves the right, in its sole and complete discretion, to reject any and all applications received as a result of this request and to negotiate separately with competing applicants.
d) The Department is not liable for any costs the applicant incurs in preparation and submission of its application, in participating in the RFA process or in anticipation of award of the resulting Grant Agreement(s).
e) The Department reserves the right to cancel the RFA at any time up until the full execution of the resulting Grant Agreement(s).
f) Awarded applicants and non-selected applicants shall not be permitted to issue news releases pertaining to this project prior to official written notification of award by the Department review committee. Any subsequent publication or media release issued by the Grantee throughout the life of the Grant using funding from this Grant Agreement must acknowledge the Department as the granting agency and be approved in writing by the Department.

2. Evaluation of Applications

All applications meeting stated requirements in this RFA and received by the designated date and time, will be reviewed and evaluated by the Department as follows:

Following the requirements of Act 2004-133, applications will be reviewed and evaluated through a two-stage review process. The first stage will be a peer evaluation of the scientific and technical merit of the application by a committee of impartial reviewers with expertise in the proposed research topic. Each application will be evaluated individually against the following criteria: scientific and technical merit based on scientific need, scientific method, research design, adequacy of the facility and qualifications of the research personnel.

The second stage of the review will be conducted by the Department Review Committee (Committee) comprised of Department staff. The Committee will review applications that meet the requirements in this RFA. The selection of research projects to be funded will be based on the rankings developed from the peer review process. In making its selection, the Committee will use the rankings, avoid unnecessary duplication, ensure relevance to the research priority, encourage collaboration between applicants and provide for the development of a complementary statewide research program. The Secretary of Health will make the final selection of applications to be funded.

If the Committee determines that additional clarification of an application is needed, the Department will schedule an oral presentation, either in person or via a conference call, or assign a due date for the submission of a written clarification, or both.

3. Awards

Grants will be administered through the Department. Payment will be made in accordance with the Payment Provisions contained in Part Two of the RFA. Awards will be made to the lead agency of the collaborative research project.

All applicants will receive official written notification of the status of their application from the Department. Unsuccessful applicants may request a report containing the peer review panel's written comments on their application. This request must be in writing and must be received by the Health Research Office within 30 calendar days of the written official notification of the status of the application. Comparison of applications will not be provided. Applicants will not be given any information regarding the evaluation other than the peer review comments on their individual application.

4. Deliverables and Reporting Requirements

See Section XXIV of Research Proposal , which is Attachment IV in Part Two of the RFA.

C. Application Instructions and Required Format

1. Application Instructions

The following is a list of requirements.

a) A Letter of Intent shall be submitted by email to RA-HEALTHRESEARCH@pa.gov on or before the date and time specified in the cover letter using the form provided in Part Two, Attachment XI of this RFA. The Department cannot accept secure or encrypted emails. Any submission via secure or encrypted email will be immediately discarded.

b) The Letter of Intent must be received by the date and time specified in the cover letter, using the form provided, or the application will not be accepted. Applicants should consider that technical difficulties could arise and allow sufficient time to ensure timely email receipt. **(Late submissions will be rejected, regardless of the reason). The Letter of Intent can be submitted as soon as it is ready for submission; to prevent late submissions, applicants are encouraged to not wait until the date and time in the cover letter.**

c) Upon successful submission of a Letter of Intent, the Department will provide a link and instructions for uploading to the SharePoint site for submission of the application.

d) The application must be submitted using the format described in subsection 2, below – Application Format.

e) The application must be submitted via the SharePoint link provided to the applicant on or before the time and date specified in the cover letter. The SharePoint link will be disconnected at that date and time. **Late applications will not be accepted regardless of the reason.**

Applicants are strongly encouraged to be brief and clear in the presentation of ideas.

2. Application Format

Applicants must follow the format as described below to complete Part Two of this RFA. All required forms can be found in Part Two. When uploading, the following naming convention must be followed: Keep the file name as is and add the applicant's name at the end. For example: RFA 67-205 Cover Page, Applicant Name. On all forms, the name of the applicant must be identical to the legal name of the applicant organization exactly as registered with the Department of State. Forms that do not contain the legal name of the applicant organization will be returned.

a) **Cover Page** – Complete the form. This form must be signed by an official authorized to bind the applicant/organization to the application.

b) **Worker Protection and Investment Certification Form (BOP-2201)** – BOP-2201 must be completed and signed by an official authorized to execute the certification on behalf of the applicant.

c) **Lobbying Certification Form (BOP-1307)** - BOP-1307 must be completed and signed by an official authorized to execute the certification on behalf of the applicant.

d) **Research Proposal** – The research proposal consists of the following two sections:

i. Section One – Research Proposal (upload in PDF format; must be a directly created PDF and not the result of scanning)

ii. Section Two – Letters of Support (upload in PDF format; letters of support from collaborating organizations, subcontractors and consultants should be submitted as one electronic document in PDF format)

e) **Budget Detail** – Use the downloadable format to present your budget request. Instructions regarding completion of the budget can be found in the last worksheet of the downloadable excel budget file. Must be completed for applicant and all subcontractors for the entire Grant period (upload in Excel format). NOTE: Based on the number of applications and the amount of Grant funds available, the Department may ask applicants to submit a revised budget prior to the issuance of the Grant award.
The anticipated Grant Agreement effective date is July 1, 2026 and shall not exceed four years, subject to the availability of funding. The The overall budget shall not exceed $237,955. The budget must contain an Overall Summary in addition to a Summary with Budget Details shown for the full time period in the Budget Details tab of the downloadable excel budget file.
See the Budget Definitions section below for more information.

f) **Certifications for the Protection of Human Subjects and Regarding the Use of Human Embryonic Stem Cell Research** – Complete and sign the form.
The authorized institutional official must sign this form. Grants involving human subjects do not have to be approved or exempted from review by the applicant's Institutional Review Board (IRB) prior to the submission of the application. All research involving human subjects must be approved by the applicant's IRB ***prior to the initiation of the research involving human subjects and prior to the use of Grant funds*** to pay for research involving human subjects. If the research project involves human subjects and approval is pending from the applicant's IRB, check the third option on the first page of this form. If the research project involves the use of human embryonic stem cells, only human embryonic stem cell lines that are approved by the NIH and derived from outside of Pennsylvania can be used.

g) **Certifications for the Containment of Research Involving Recombinant or Synthetic Nucleic Acid Molecules (r/sNA) and the Care and Treatment of Vertebrate Laboratory Animals** – The authorized institutional official must complete and sign this form.
Grants involving recombinant recombinant or synthetic nucleic acid molecules or laboratory animals do not have to be approved or exempted from review by the applicant's appropriate review committee prior to the submission of the application. However, all such research must be approved by the applicant's review committee ***prior to the initiation of such research and use of Grant funds*** to pay for such research.

h) **Application to the Pennsylvania Department of Health Institutional Review Board** – Instructions and an electronic copy of the form may be obtained at https://www.health.pa.gov/topics/Research/Pages/IRB.aspx by selecting IRB Application.

- If the research project does not involve human subjects, this application form does not need to be completed.
- If the research involves human subjects and has not been approved or exempted from review by the applicant's IRB, this form must not be submitted with the application. However, it must be submitted ***prior to the initiation of such research and use of Grant funds to pay for research involving human subjects***. If the research involves human subjects and it has already been approved or exempted from review by the applicant's IRB, this form must be completed and submitted with the RFA application and

include documentation that the applicant's IRB either approved or exempted the research from review.

- Note on the use of human specimens or data: If the applicant checks "No human subjects will be used in any of the proposed research" on the Certification for the Protection of Human Subjects and Regarding the Use of Human Embryonic Stem Cell Research (above), but the application proposes using human specimens or data, this form must be completed and submitted with the RFA application and must include documentation from the applicant's IRB stating that the research does not constitute human subjects research

i) **Memorandum of Understanding Regarding Ethical Standards:** The official who is authorized to bind the organization to its application must sign this form.

j) **Letter of Intent Form:** Do not submit the Letter of Intent with the application; see instructions above in C.1. Application Instructions.

k) **Annual Expenditure Report:** Do not submit the Annual Expenditure Report with the application; see instructions in Section XXIV of the Research Proposal (Attachment IV in Part Two of the RFA).

3. Definitions

a) **Budget Definitions:**

Personnel: This budget category shall identify each position by research role on the project, hourly rate, and the number of hours per year allocated to the project, starting with the principal investigator. Fringe benefits are to be shown as a separate line-item by percentage and shall include a detailed listing of the benefits being covered.

Consultant Services: This budget category shall identify the services to be provided by each consultant including hourly rate and number of hours to be utilized under this Grant Agreement.

Subcontract Services: This budget category shall identify the services to be provided by each subcontractor under this Grant Agreement.

Patient Services: This budget category shall reflect funding dedicated for patient services.

Equipment: This budget category shall reflect the actual or projected cost of any equipment $5,000 or greater. Justification for the purchase of any equipment must be included. Purchase of equipment is not a priority of the Department.

Supplies: This budget category shall reflect expected costs for general office supplies including personal computers and facsimile machines and other types of supplies valued at less than $5,000, needed to support this project. List types of supplies separately, for example, office supplies, laboratory supplies and so on.

Travel: This budget category shall include anticipated expenditures for travel including mileage, hotels and meals.

Other: This budget category shall be used for anticipated expenditures that do not fit into any of the other budget categories such as telephone, printing, postage, and indirect costs (overhead, general, and administrative). The indirect cost rate must NOT exceed 20%. In the description area under

OTHER COSTS include the % that the rate reflects, identify the budget categories to which the rate was applied, and list the specific items that the indirect is paying for.

Laboratory or Building Construction or Renovations: This budget category shall be used for construction or renovation project(s), if any. Construction and renovation costs are infrastructure costs.

When filling out the budget, refer to the instructions tab within the Excel budget file, as well as the limitations noted above in Part One, A.5. Use of Funds – Limitations and Restrictions.

D. Research Information and Priority

All research projects submitted in response to this RFA must be consistent with the following research priorities.

State Fiscal Year 2023-2024 Priority for Juvenile Diabetes Cure Funded Research, Act 133 of 2004

The research priority for Juvenile Diabetes Cure Funded Research is:

Prevention and Treatment of Type 1 (Juvenile) Diabetes
Research related to preventing Type 1 (Juvenile) Diabetes, restoring normal blood sugar levels and preventing and reversing complications of Type 1 (Juvenile) Diabetes.

The Research Proposal must show the scope of the overall project and justify how the proposed research will provide new and innovative prevention and treatments for children and adolescents with Type 1 diabetes.

Activities that are not Type 1 (Juvenile) Diabetes research related to restoring normal blood sugar levels; preventing and reversing complications or preventing Type 1 (Juvenile) Diabetes will not be considered.

PART TWO

Pennsylvania Department of Health
Health Research Office

Research to Cure and Prevent Type 1 (Juvenile) Diabetes

Request for Applications (RFA) #67-205

Pennsylvania
Department of Health

COVER PAGE
Research to Cure and Prevent Type 1 (Juvenile) Diabetes

Applicant Name: _____
(Legal Name of Organization or Institution, exactly as registered with Dept. of State)

Type of Legal Entity_____
(Corporation, Partnership, Professional Corporation, Sole Proprietorship, etc.)

Grant Amount: $_____ **Grant Effective Date: July 1, 2026**

SAP Vendor #:_____ **Grant End Date:** _____

Address:_____

_____

City_____**County**_____**State**_____**Zip Code**_____

(Complete billing address that corresponds to the organization or institution's vendor number; this should be the same as the billing address listed in SAP for the associated vendor number)

Type of Grant: Health Research Juvenile Diabetes Cure Research Tax Check-off Program Grant

1. RESEARCH PRIORITY: Prevention and Treatment of Type 1 (Juvenile) Diabetes	
2. GRANT COORDINATOR (CONTACT PRINCIPAL INVESTIGATOR)	
2a. NAME (First Name MI Last Name)	**2b. DEGREE(S) (*Maximum three*)**
2c. POSITION TITLE *(Academic or professional; if there is more than one title, provide the one most relevant to the planned research project)*	**2d. MAILING ADDRESS (Street, City, State, Zip Code)**
2e. TELEPHONE # (Area code, number and extension), and EMAIL ADDRESS (*Direct rather than a shared departmental e-mail*) **Telephone:** **E-mail:**	
3. SECONDARY CONTACT FOR THE GRANT COORDINATOR	
3a. NAME (First Name MI Last Name, Degrees)	**3b. TELEPHONE # and EMAIL ADDRESS (*Direct rather than a shared departmental e-mail*)** **Telephone:** **E-mail:**
3c. POSITION TITLE	

4. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED WHEN FUNDS BECOME

AVAILABLE Name (First Name MI Last Name, Degrees):

Title:

Address:

Telephone:

E-mail:

Applications/proposals/bids received shall remain valid, unless deemed unresponsive, until such time that final award(s) is or are made.

BY SIGNING BELOW, THE APPLICANT, BY ITS AUTHORIZED SIGNATORY, IS BINDING ITSELF TO THE APPLICATION AND REPRESENTING THAT ALL THE INFORMATION SUBMITTED IS TRUE AND CORRECT TO THEIR BEST KNOWLEDGE, INFORMATION AND BELIEF.

SIGNATURE OF AUTHORIZED CERTIFYING OFFICIAL	TITLE
	DATE

WORKER PROTECTION AND INVESTMENT CERTIFICATION FORM

A. Pursuant to Executive Order 2021-06, *Worker Protection and Investment* (October 21, 2021), the Commonwealth is responsible for ensuring that every worker in Pennsylvania has a safe and healthy work environment and the protections afforded them through labor laws. To that end, contractors and grantees of the Commonwealth must certify that they are in compliance with Pennsylvania's Unemployment Compensation Law, Workers' Compensation Law, and all applicable Pennsylvania state labor and workforce safety laws including, but not limited to:

1. Construction Workplace Misclassification Act
2. Employment of Minors Child Labor Act
3. Minimum Wage Act
4. Prevailing Wage Act
5. Equal Pay Law
6. Employer to Pay Employment Medical Examination Fee Act
7. Seasonal Farm Labor Act
8. Wage Payment and Collection Law
9. Industrial Homework Law
10. Construction Industry Employee Verification Act
11. Act 102: Prohibition on Excessive Overtime in Healthcare
12. Apprenticeship and Training Act
13. Inspection of Employment Records Law

B. Pennsylvania law establishes penalties for providing false certifications, including contract termination; and three-year ineligibility to bid on contracts under 62 Pa. C.S. § 531 (Debarment or suspension).

CERTIFICATION

I, the official named below, certify I am duly authorized to execute this certification on behalf of the contractor/grantee identified below, and certify that the contractor/grantee identified below is compliant with applicable Pennsylvania state labor and workplace safety laws, including, but not limited to, those listed in Paragraph A, above. I understand that I must report any change in the contractor/grantee's compliance status to the Purchasing Agency immediately. I further confirm and understand that this Certification is subject to the provisions and penalties of 18 Pa. C.S. § 4904 (Unsworn falsification to authorities).

Signature	***Date***
Name (Printed)	
Title of Certifying Official (Printed)	
Contractor/Grantee Name (Printed)	

LOBBYING CERTIFICATION FORM

Certification for Contracts, Grants, Loans, and Cooperative Agreements

The undersigned certifies, to the best of his or her knowledge and belief, that:

(1) No federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a member of Congress, an officer or employee of Congress, or an employee of a member of Congress in connection with the awarding of any federal contract, the making of any federal grant, the making of any federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any federal contract, grant, loan, or cooperative agreement.

(2) If any funds other than federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a member of Congress, an officer or employee of Congress, or an employee of a member of Congress in connection with this federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form-LLL, Disclosure of Lobbying Activities, which can be found at:

http://www.whitehouse.gov/sites/default/files/omb/assets/omb/grants/sflllin.pdf

(3) The undersigned shall require that the language of this certification be included in the award documents for all sub-awards at all tiers (including subcontracts, sub-grants, and contracts under grants, loans, and cooperative agreements) and that all sub-recipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed under *Section 1352, Title 31, U. S. Code.* Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than **$100,000** for such failure.

SIGNATURE: _____

TITLE: _____ DATE: _____

RESEARCH PROPOSAL

Introduction

Patentable ideas, trade secrets, privileged or confidential commercial or financial information, disclosure of which may harm the applicant, should be included in applications only when such information is necessary to convey an understanding of the proposed project. If selected for funding, the Grant Agreement, including the Research Proposal, will be accessible to the public though a Commonwealth website pursuant to the amendment to the Right to Know law (Act 2008-3; 65 P.S.§67.101 et seq.). Prior to placing the Research Proposal on the website, the Department will redact (black out) confidential and proprietary information. Applicants must clearly identify all proprietary or confidential information that they desire to be redacted by marking the proprietary or confidential text with highlighting and adding a statement that the highlighted text is considered to be confidential or proprietary.

Items II-IV of the Research Proposal will become part of the annual report to the legislature and will be posted on the Department's website if this application is selected for funding. **Do not include proprietary or confidential information or past accomplishments in these items**. Do not repeat the same information in items II-IV. Do not include the names of the investigators or references to literature in Items II-IV. Spell out acronyms when first used. If a term is not universally known, spell out the term the first time it is used in the text and note the appropriate abbreviation in parentheses.

Do not delete or change, in any way, the instructions, headings or any information contained in this form. This first page should not be numbered. Subsequent pages should be numbered consecutively beginning with - 2 - at the bottom center of the page. Do not use suffixes, such as 3a and 3b, for page numbers.

Do not insert the name of the principal investigator on the top of any pages.

Except where otherwise noted, responses must not exceed the space indicated. Blank lines do not count as a line of text when determining whether or not text exceeds the line number limitation specified for some items.

The Research Proposal must be completed in Arial typeface with a font size of 10 points or larger. (A Symbol font may be used to insert Greek letters or special characters; the font size requirement still applies. A smaller font may be used for figures, graphs, diagrams, charts, tables, figure legends and footnotes, but the type must follow the font typeface and be readily legible.) Use black font color for text. Color may be used for figures. Type density, including character and spaces, must be not more than 15 characters per inch. Type must be not more than six lines per inch. Do not replace Yes/No Check boxes with images or an 'X'.

Use standard paper size (8½ x 11 inches) with at least ½ inch top, bottom, left and right margins.

Internet website addresses (URLs) should not be used to provide information necessary to the review of the Research Proposal. Reviewers are not required or advised to view the internet sites.

Appendices to the Research Proposal are not allowed.

I. Table of Contents – On the table below, specify the page numbers where information appears in the research proposal. If a section exceeds one page, insert the page number where the section begins and the page number where it ends. In the research design and methods section, list the page numbers for each specific aim. Add or delete lines for specific aims below, as needed.

II. Abbreviations – Provide an alphabetical list of abbreviations used in the Research Proposal. After each abbreviation spell out the words that the abbreviation stands for, for example, “ASD - autism spectrum disorders, MRSA - Methicillin-resistant *Staphylococcus aureus*, *c. difficile* – *Clostridium difficile*.” There are no space limitations. *Insert list below*.

III. Research Project Title, Purpose and Inclusion of Proprietary Information

(A) Title – The title of the research project should not exceed 81 characters including spaces and punctuation. Use Mixed Title Case, not UPPER CASE, for example, "Identification of ABC Binding Protein." The research project title should convey the purpose of the research to be conducted and exclude the name of the applicant and Center of Excellence.

Insert Title here:

(B) Purpose – The purpose should emphasize the research studies that will be undertaken to discover new knowledge leading to new prevention or treatment approaches, rather that the establishment of a center of excellence. The purpose should not exceed eight lines of text. Responses must be single-spaced, left aligned and in font styles and sizes as specified in the Introduction (first page) of the Research Proposal.

Insert Purpose here:

(C) Inclusion of Proprietary or Confidential Information

Does the Research Proposal contain proprietary or confidential information that you desire to be redacted?

☐ Yes ☐ No

If yes, specify the page numbers in the Research Proposal that contain proprietary and confidential information: _____

In the Research Proposal, applicants must highlight all proprietary and confidential information and add a statement that the highlighted text is considered to be confidential or proprietary.

IV. Research Project Overview – State the broad research objectives, specific research aims and subaims. The research aims and subaims must be listed here and be the same as the aims and subaims contained in Item IX. (A) of the Research Plan. Describe the methods for achieving the objectives, aims and subaims. Responses must be single-spaced, left aligned, not exceed 25 lines of text, and in the font styles and sizes specified in the Introduction to the Research Proposal. Spell out acronyms the first time they are used. Do not include the names of investigators, footnotes, references to literature, graphics, or proprietary or confidential information.

(Insert Research Project Overview here):

V. Expected Research Outcomes and Benefits – Describe the expected outcomes and benefits of the research project. Include information on how the project will improve health status. Do not include information about the qualifications of the researchers to perform the research or expectations that the research will lead to publications and Grant awards. Information concerning publications and Grant awards should be placed in Item XVI. (B) Performance Measures. Do not repeat sentences contained in Items III and IV. Responses must be single-spaced, left aligned, not exceed 20 lines of text, and in the font styles and sizes specified in the Introduction to the Research Proposal. Do not include the names of investigators, footnotes, references to literature, graphics, or proprietary or confidential information.

(Insert Expected Research Outcomes and Benefits here):

VI. Health Disparities – Describe briefly how the research project will identify and address disparities in health status, outcome, prevention or treatment. Health disparities are differences in the incidence, prevalence, mortality and burden of disease or injury and related adverse events that exist among minority groups, rural populations, urban populations and other specific population groups. The research priority states that the research project should hold the potential for addressing the health needs of underserved segments of the population, including rural, urban, racial and ethnic minorities, or other high-risk populations. In order to address health disparities, applicants should conduct research on populations that are at high risk for the condition. By identifying risk factors and interventions that work with high-risk populations to reduce the burden of disease, the research should help to reduce health disparities. Responses must be single-spaced, not exceed 25 lines of text, and in the font styles and sizes specified in the Introduction to the Research Proposal.

(Insert Health Disparities here):

VII. Management and Staffing Plan – This section should be informative to scientists, researchers, clinicians and physicians who are working the same field as the proposed research. There is no required format for providing the information. Do not exceed two pages, including this page.

The Management and Staffing Plan must include the following items:

(A) Identify collaborating organizations and subcontractors and describe their specific roles in the project. A substantive and meaningful role must be described for every collaborating organization.

(B) Provide a diagram and a management plan that describes how the organizational units and principal investigators for each specific aim will communicate and work together.

(C) Include a description of personnel responsible for oversight of IRB protocols, oversight of supported research, mentoring of junior investigators, administrative and fiscal responsibilities and communication with the Department.

Insert Management and Staffing Plan below.

VIII. Key Research Personnel - Use the separate forms provided below to provide required information for the Contact Principal Investigator at the lead applicant organization, other key personnel at the lead applicant organization, key personnel at subcontractor organizations, and external consultants and advisory committee members (if the project includes an external advisory committee).

Key research personnel are defined as persons who contribute in a substantive way to the scientific development and execution of the research activities. Persons responsible for subject recruitment and enrollment are considered to be key research personnel. Typically, key personnel have doctoral or other professional degrees, although persons with masters or baccalaureate degrees should be included if their involvement meets the definition. External consultants who are not employed by the applicant organization or subcontractors should be included only if their involvement meets the definition. Those persons providing technical or administrative services are not considered key research personnel.

The Contact Principal Investigator is the principal point of contact for all Grant-related reports and is responsible for ensuring compliance with all Grant provisions. The Contact Principal Investigator must be employed by the lead applicant organization at the time that the application is submitted to the Department. The research project may designate multiple Principal Investigators; however, one person must be designated as the Contact Principal Investigator. The Contact Principal Investigator must be listed as Grant Coordinator (Contact Principal Investigator) on the Cover Page.

For each position listed, provide the name (first name, middle initial, last name) and no more than three degrees (for example, Jane E. Smith, MD, PhD, MPH – **DO NOT** put periods in the degrees). Describe the specific role of the person on the research project's various specific aims, for example, principal investigator (PI) for aim 1, co-principal investigator (co-PI) for aims 2 and 4, project director for aim 3, biostatistician for entire project, project coordinator for study recruitment/enrollment in aim 1, research associate for aim 1, research assistant for aim 2, research technician for aim 1, external advisory committee member for entire project, external consultant for aim 2. **DO NOT** use "Postdoctoral Fellow," "Doctoral Student" or "Graduate Student" because these titles do not adequately describe the person's research role on the project. If any Grant funds will be used for a position as indicated by checking "Yes" below, the position must be listed in the budget. The role of the person in the budget and on this form must be the same. For example: if Susan Black, PhD is listed as a Co-Investigator and the "Yes" box is checked below, "Co-Investigator" should be listed in the budget. Names should not be listed in the budget.

Indicate the percentage of effort that will be provided by each position to the research project. If the percentage varies by year, break down the percentage by year, for example, Years 1 & 2 – 20 percent, Year 3 – 15 percent, Year 4 – 5 percent.

Add or delete space as needed on the appropriate form in order to provide information on all key personnel.

List all employees for a subcontractor together.

Responses must be single-spaced, in Arial font that is no smaller than 10-point type and left aligned.
DO NOT replace **Yes/No Check boxes** with images or an 'X.'

CONTACT PRINCIPAL INVESTIGATOR AT LEAD APPLICANT ORGANIZATION	
NAME (First Name MI Last Name)	DEGREE(S)
RESEARCH ROLE ON PROJECT Contact Principal Investigator	NAME OF EMPLOYER (APPLICANT ORGANIZATION)
EMAIL ADDRESS	MAILING ADDRESS (Street, City, State, Zip Code)
Percentage of effort on the project:	Will any Grant funds be used for this position? ☐Yes ☐No

OTHER KEY PERSONNEL AT LEAD APPLICANT ORGANIZATION	
NAME (First Name MI Last Name)	DEGREE(S)
RESEARCH ROLE ON PROJECT (specify role on project and include aims on which person will work)	
Percentage of effort on the project:	Will any Grant funds be used for this position? ☐Yes ☐No
NAME (First Name MI Last Name)	DEGREE(S)
RESEARCH ROLE ON PROJECT (specify role on project and include aims on which person will work)	
Percentage of effort on the project:	Will any Grant funds be used for this position? ☐Yes ☐No
NAME (First Name MI Last Name)	DEGREE(S)
RESEARCH ROLE ON PROJECT (specify role on project and include aims on which person will work)	
Percentage of effort on the project:	Will any Grant funds be used for this position? ☐Yes ☐No
NAME (First Name MI Last Name)	DEGREE(S)
RESEARCH ROLE ON PROJECT (specify role on project and include aims on which person will work)	
Percentage of effort on the project:	Will any Grant funds be used for this position? ☐Yes ☐No
NAME (First Name MI Last Name)	DEGREE(S)
RESEARCH ROLE ON PROJECT (specify role on project and include aims on which person will work)	
Percentage of effort on the project:	Will any Grant funds be used for this position? ☐Yes ☐No
NAME (First Name MI Last Name)	DEGREE(S)
RESEARCH ROLE ON PROJECT (specify role on project and include aims on which person will work)	
Percentage of effort on the project:	Will any Grant funds be used for this position? ☐Yes ☐No

KEY PERSONNEL FOR SUBCONTRACTOR(S) List all the employees of a subcontractor together.	
NAME (First Name MI Last Name)	DEGREE(S)
RESEARCH ROLE ON PROJECT (include aims person will work on)	NAME OF EMPLOYER (SUBCONTRACTOR)
Percentage of effort on the project:	Will any Grant funds be used for this position? ☐Yes ☐No
NAME (First Name MI Last Name)	DEGREE(S)
RESEARCH ROLE ON PROJECT (include aims person will work on)	NAME OF EMPLOYER (SUBCONTRACTOR)
Percentage of effort on the project:	Will any Grant funds be used for this position? ☐ Yes ☐ No
NAME (First Name MI Last Name)	DEGREE(S)
RESEARCH ROLE ON PROJECT (include aims person will work on)	NAME OF EMPLOYER (SUBCONTRACTOR)
Percentage of effort on the project:	Will any Grant funds be used for this position? ☐ Yes ☐ No
NAME (First Name MI Last Name)	DEGREE(S)
RESEARCH ROLE ON PROJECT (include aims person will work on)	NAME OF EMPLOYER (SUBCONTRACTOR)
Percentage of effort on the project:	Will any Grant funds be used for this position? ☐ Yes ☐ No
NAME (First Name MI Last Name)	DEGREE(S)
RESEARCH ROLE ON PROJECT (include aims person will work on)	NAME OF EMPLOYER (SUBCONTRACTOR)
Percentage of effort on the project:	Will any Grant funds be used for this position? ☐Yes ☐ No
NAME (First Name MI Last Name)	DEGREE(S)
RESEARCH ROLE ON PROJECT (include aims person will work on)	NAME OF EMPLOYER (SUBCONTRACTOR)
Percentage of effort on the project:	Will any Grant funds be used for this position? ☐ Yes ☐No

EXTERNAL CONSULTANTS AND ADVISORY COMMITTEE MEMBERS:	
NAME (First Name MI Last Name)	DEGREE(S)
RESEARCH ROLE ON PROJECT	NAME OF EMPLOYER
NAME (First Name MI Last Name)	DEGREE(S)
RESEARCH ROLE ON PROJECT	NAME OF EMPLOYER
NAME (First Name MI Last Name)	DEGREE(S)
RESEARCH ROLE ON PROJECT	NAME OF EMPLOYER
NAME (First Name MI Last Name)	DEGREE(S)
RESEARCH ROLE ON PROJECT	NAME OF EMPLOYER
NAME (First Name MI Last Name)	DEGREE(S)
RESEARCH ROLE ON PROJECT	NAME OF EMPLOYER
NAME (First Name MI Last Name)	DEGREE(S)
RESEARCH ROLE ON PROJECT	NAME OF EMPLOYER
NAME (First Name MI Last Name)	DEGREE(S)
RESEARCH ROLE ON PROJECT	NAME OF EMPLOYER
NAME (First Name MI Last Name)	DEGREE(S)
RESEARCH ROLE ON PROJECT	NAME OF EMPLOYER

IX. Research Plan - The research plan must describe health research leading to the discovery of scientific knowledge that can be applied to improve health status. The research plan may include information on the development of cores or other research-capacity building activities; however, the focus and emphasis must be on the actual research to be conducted, that is, the data that will be collected and analyzed and methods that will be developed to test hypotheses and generate new knowledge that is intended to lead to improvements health related technologies, treatments, services or preventive interventions. The Research Plan must describe only the research to be accomplished within the Grant award period of funding, which may not exceed 48 months. No-cost extensions beyond 48 months are not permitted.

The Research Plan consists of the following sections: (A) Specific Aims, (B) Background and Significance, (C) Preliminary Studies, and (D) Research Design and Methods and (E) Timeline and Milestones.

The entire Research Plan must not exceed 40 single-spaced, single-sided pages. This page of instructions is not counted in the 25-page limit. Specific page limitations are provided for sections A, B and C.

(A) Specific Aims - List the research objectives and specific research aims that will be achieved during the Grant period as part of the research to be conducted. State the specific hypotheses to be tested and research objectives (for example, to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop a product or new technology). Do not exceed two pages.
(B) Background and Significance **-** Summarize the background leading to the project. Evaluate existing knowledge and identify the gaps in knowledge that will be addressed by the research project. Identify the significance of the research project and the contribution that it will make to improvements in clinical practice and health services. Do not exceed three pages.
(C) Preliminary Studies - Describe prior research and preliminary studies that are relevant to the proposed project and that have been completed by the Principal Investigator and key research personnel. Describe pilot studies that have been conducted to test and refine the methods proposed in this application. Include experience with and outreach to the racial and ethnic populations that are targeted by the research project. If the project involves human subjects, describe pilot studies which demonstrate feasibility of the project, including the feasibility of recruitment strategies and anticipated retention rates. Provide information that will enable reviewers to assess the Principal Investigator's experience pertinent to the project and the experience of staff responsible for study recruitment and enrollment. Do not include copies of publications. Do not exceed five pages.
(D) Research Design and Methods - Describe the conceptual framework, research design and limitations of the research design, definition and measurement of key variables, data collection methods, data sources and quality, randomization, analysis plan, sample size estimate, statistical power. Describe any new methodologies and their advantage over existing methodologies. Describe novel approaches, technologies, tools, and concepts. Discuss potential problems and alternative strategies to be used, if needed, to achieve the specific aims. For aim(s) involving human subjects, describe inclusion and exclusion criteria; outreach and recruitment methods; sites for recruiting subjects and the demographics of the clientele at those sites; alternative strategies to boost recruitment if problems occur; justification for anticipated enrollment and retention rates; staff responsible for recruitment and enrollment; justification of anticipated differences in outcomes between experimental and control groups; and data management plan including where the data will be maintained and confidentiality procedures. For clinical trials, describe expected gender, race, and ethnicity differences in intervention effect and include supporting evidence from animal studies, clinical observations, epidemiology or other relevant studies. Include data analysis plans to determine intervention effect.
(E) Timeline and Milestones - For each specific aim, include a timeline, using the format shown below, to show specific, measurable milestone(s) that will be accomplished by the end of each state fiscal year. If there are subaims or more than one study under a specific aim, specify the number of the subaim or name of the study to which each milestone applies. **Do not change the time periods in the timeline shown below. These time periods are the reporting periods for the annual progress report.** For aim(s) involving human subjects indicate on the timeline the number of persons to be recruited as cases and controls for each reporting period and the start and end dates for recruiting subjects.

State Fiscal Year	Milestones for Specific Aim #
7/1/26 – 6/30/27	
7/1/27 – 6/30/28	
7/1/28 – 6/30/29	
7/1/29 – 6/30/30	

X. Other Sources of Support – Indicate other sources of support for the project.

(A) Are other funds being sought for this project? ☐ Yes ☐ No

If yes, specify other sources of funding **being sought** here:

Name of organization from which other funds are being sought	**Amount of funding being sought**

(B) Do other funds currently support this project? ☐ Yes ☐ No

If yes, specify sources and amounts of other **current funding** and how the proposed project differs from currently funded research efforts:

Name of organization providing funding	**Amount of funding**	**How does the proposed project differ from the currently funded research supported by this source?**

(C) Do you have letters of support for the project and / or letters indicating commitment of funds from other sources for this proposed project? ☐ Yes ☐ No

If yes, include copies of letters of support per the RFA, as Section Two to the Research Proposal using the Letters of Support form provided.

XI. Research Project Performance Sites – Beginning with the lead applicant organization, indicate the sites where the work described in the Research Plan will be performed. Explain the role(s) of the site in the project, for example, overall project coordination and Aim 1 clinical trial, Aim 2 animal study. Indicate county in Pennsylvania where the site is located. For the additional project sites, indicate the mailing address of the organization. Add or delete space, as needed, following the format for
Additional Project Site Location.

PROJECT SITE PRIMARY LOCATION
NAME OF APPLICANT ORGANIZATION
ROLE ON PROJECT
COUNTY

ADDITIONAL PROJECT SITE LOCATION	
NAME OF ORGANIZATION	
ROLE ON PROJECT	
COUNTY	MAILING ADDRESS (Street, City, State, Zip Code)

ADDITIONAL PROJECT SITE LOCATION	
NAME OF ORGANIZATION	
ROLE ON PROJECT	
COUNTY	MAILING ADDRESS (Street, City, State, Zip Code)

ADDITIONAL PROJECT SITE LOCATION	
NAME OF ORGANIZATION	
ROLE ON PROJECT	
COUNTY	MAILING ADDRESS (Street, City, State, Zip Code)

XII. Facilities and Resources – Describe the existing facilities and resources available to conduct the proposed research at all performance sites in the same order as the sites are listed in Research Project Performance Site Section. Describe the capabilities, capacities, and extent of availability to the project for only those facilities and resources that are applicable and will be used for the proposed work. This information will be used by reviewers to evaluate the adequacy of the facilities and resources to perform the proposed research. There is no required format for providing the information, and there are no space limitations, but be succinct.

The description of currently existing facilities and resources must include the following items:

(A) Performance Site. Indicate name of organization.
(B) Laboratory facilities and resources
(C) Clinical facilities and resources
(D) Animal facilities and resources
(E) Computer facilities and resources
(F) Office(s)
(G) Major Equipment. List important equipment to be used, noting location and capabilities.

Insert the Facilities and Resource information after this page.

XIII. Allocation of Costs for Research by Specific Aim - Using the following format and example, provide a breakdown by specific aim of expenditures for the entire project. For each specific aim, specify the total costs. **If a specific aim consists of more than one study or subaim, list each study and subaim separately, as shown in the example below**. Do not include indirect and overall project management costs under one specific aim; distribute these costs across all specific aims.

Specific aims	Total cost to complete the aim	Percent of total budget
Specific aim 1 (one study)	$157,897	19.2%
Specific aim 2, study/subaim 1)	$64,876	7.89%
Specific aim 2, study/subaim 2)	$100,000	12.15%
Specific aim 3 (one study)	$500,000	60.77%
Total budget	$822,773	100%

XIV. Budget Narrative - Provide a separate, detailed narrative for the budget of the lead applicant organization and each subcontractor. The narrative must be for the entire budget period, rather than a narrative for the first year of the project. Include an explanation for each budget line in the Excel budget. The dollar amount specified in the budget narrative must equal the amount for that budget line in the Excel budget. Do not provide a separate budget narrative for each specific aim. There are no space limitations for this section. The budget narrative must include the following items.

(A) Indicate the name of the organization.
(B) For each position listed in Category I A - Staff Personnel, provide the name of the person and a description of the person's work on various specific aims. Include this information for "To Be Announced (TBA)" positions. Explain rationale if the percent of effort varies by year. Do not include information on the person's qualifications or experience here. The Contact Principal Investigator must be included in the budget for the applicant organization.
(C) For each line listed in Category II – Consultant Services, provide the name of the consultant and a description of the services that the consultant will perform on various specific aims. If the consultant is from out-of-state, explain rationale for not using an in-state consultant.
(D) For each line listed in Category III – Subcontract Services, provide the name of the subcontractor and a description of the subcontractor's work on various specific aims. If the subcontractor is from out-of-state, explain rationale for not using an in-state subcontractor.
(E) For each line listed in Category IV - Patient services, provide a narrative explaining the tests and services to be provided per patient. Explain number of tests with regard to number of participants in the experimental and control groups, pre-tests, and post-tests.
(F) For each line listed in Category V – Equipment, provide a justification of the need for the equipment. Allowable items are limited to research equipment and apparatus not already available for the conduct of the proposed research. Equipment is defined as an item of property that has an acquisition cost of $5,000 or more.
(G) For each line listed in Category VI – Supplies, provide a justification of the number of supplies needed relative to the number of subjects or laboratory animals involved in the research project, as appropriate.
(H) For Category VII – Travel, provide justification for travel by explaining the purpose of various trips, for example, travel to train personnel at performance sites and travel to present papers. For trips involving airfare, include the number of separate trips and their purpose, destination and number of individuals for each trip.
(I) For each line listed in Category VIII – Other Costs / Laboratory or Building Construction or Renovations, provide an explanation of the other costs, a rationale for number of items needed and any other information which explains the budget line item. Provide an explanation of the need for the new facility, including why the proposed work cannot be conducted in existing research facilities.

XV. Curriculum Vitae, Resumes or Biographical Sketches – Provide the following information for key personnel **in the same order as they are listed in Research Personnel section**. Biographical sketches are required for the Contact Principal Investigator, other key personnel at the lead applicant organization and each subcontractor's key personnel. Biographical sketches are recommended, but not required, for external advisory committee members and consultants. On the top of the first page of the biographical sketches of subcontractor key personnel, insert the name of the subcontractor. On the top of the first pages of the biographical sketches of the external advisory committee members and consultants, insert "External Advisory Committee" or "Consultant," as appropriate. Do not exceed five pages per biographical sketch. There is no required format for providing the information. NIH Grant application biosketches are compatible with the required information and may be used.

The biographical sketch must include the following items and may not exceed five pages:
(A) Name of Researcher (First, MI, Last)
(B) Position title. Indicate the current title of the position held at the researcher's current place of employment.
(C) Education and training. Include degree(s), year(s) awarded and field(s) of study.
(D) Selected peer review publications. Do not include publications submitted or in preparation. URLs may accompany references only if the publication is available to the public. Reviewers are not required or advised to view the internet sites.
(E) Research support. List research support received for current research projects or projects completed within the past three years. Begin with projects which are the most relevant to the proposed research project. Indicate goals of projects and researcher's role on the project.

Insert biographical sketches after this page.

XVI. Evaluation Component and Research Evaluative Procedures – Explain the evaluative procedures of the research project. Responses must be single-spaced, in Arial font that is no smaller than 10- point type and left aligned and must not exceed 40 lines of text.

(A) Oversight and Statistical Tests – Describe project oversight and evaluation by other researchers, and statistical tests to be used, if any.

(Insert oversight and statistical tests here):

(B) Performance Measures – Describe performance measures to be used to determine the impact and success of the research project. Performance measures may include publications, changes in risk factors, Grant awards obtained based on preliminary data obtained from the project and other measures of the project's outcome, impact or effectiveness.

(Insert performance measures here):

(C) Evaluation/Performance Review – The research project will be evaluated by means of the performance review process. See Section XXIV, Reporting Requirements. This section requires no response.

XVII. Research Subjects and Materials - Research performed under this Grant Agreement and all individuals performing such research must adhere to Federal ethical and procedural standards for conduct of research as prescribed by the National Institutes of Health (NIH). **DO NOT** replace **Yes/No Check boxes** with an X. Click in the box to fill. Only complete one check box.

Complete items (A) – (E) below.

(A) Does the project involve human subjects research as defined in Application to the Pennsylvania Department of Health Institutional Review Board for Approval of Research Project under the Federal Policy for the Protection of Human Subjects?

☐Yes ☐No

If answered Yes, complete Application to the Pennsylvania Department of Health Institutional Review Board (see Attachment VIII) and submit documentation of IRB approval or exemption from review. If answered No, but the project involves human specimens or data, complete Application to the Pennsylvania Department of Health Institutional Review Board (see Attachment VIII) and include documentation from your IRB stating that the research does not constitute human subjects research.

If answered Yes, include a response to Item XVIII. Protection of Human Subjects.

(B) Does the project conduct a clinical trial as defined by the NIH? ☐Yes ☐No

NIH defines a clinical trial as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. An intervention is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related processes and/or endpoints. Examples include, but are not limited, to: drugs/small molecules/compounds, biologics, devices; procedures; delivery systems (for example, telemedicine, face-to-face); strategies to change health-related behavior (for example, diet, cognitive therapy); and treatment, prevention, and diagnostic strategies. A health-related biomedical or behavioral outcome is defined as the pre-specified effect of an intervention on the study subjects. Examples include positive or negative changes to physiological or biological parameters; psychological or neurodevelopmental parameters; disease processes; health-related behavior; and well-being or quality of life.

If answered Yes, include a detailed data safety monitoring plan in Item XIX.

(C) Does the project's research use human embryonic stem cells (HESC)? ☐Yes ☐No

Only HESC lines that are approved by the National Institutes of Health and derived from outside of Pennsylvania may be used in the research project.

(D) Does the project's research involve recombinant or synthetic nucleic acid molecules? ☐Yes ☐No

(E) Does the project's research involve vertebrate laboratory animals? ☐ Yes ☐No

XVIII. Protection of Human Subjects – Applicants are responsible for safeguarding the rights and welfare of individuals who participate in research activities. All research involving human subjects must be reviewed and approved by the applicant's appropriate institutional review board prior to the initiation of such research and use of Grant funds to pay for such research. The Certifications form for the Protection of Human Subjects and Regarding the Use of Human Embryonic Stem Cell Research is Attachment VI of Part Two of the RFA. The applicant is not required to file an Assurance of Certification with the National Institute of Health's Office for Protection of Research Risks. If the research project involves human subjects, the Application to the Pennsylvania Department of Health Institutional Review Board (see Attachment VIII of Part Two of the RFA) must also be completed.

The following information must be provided in detail for each study involving research on human subjects. For this section of the application, use the same headings as listed in items (a) – (j) and include information on each item.
(a) Number of specific aim and study title
(b) Risks to human subjects
(c) Adequacy of protection against risks
(d) Recruitment of subjects
(e) Informed consent
(f) Data confidentiality and provision for medical or professional intervention, if needed.
(g) Potential benefits of the research to the subjects
(h) Importance of knowledge to be gained.
(i) Inclusion of women and minorities - Women and members of minority groups and their subpopulations must be included in Department-supported clinical research or health services research projects unless their inclusion is inappropriate due to the purpose of the research project or the health of the subjects. If women or minorities are excluded, describe the rationale for the exclusion.
(j) Inclusion of children - Children (that is, individuals under the age of 21) must be included in Department- supported clinical research or health services research projects unless their inclusion is inappropriate due to the purpose of the research project or the health of the subjects. If children are excluded, describe the rationale for the exclusion.

There are no space limitations for this section. *Insert required information for each applicable study below.*

If answered Yes to Item XVII (A), insert Protection of Human Subjects information in (a) – (j) below. *Exception: if your IRB determined that your project is exempt from IRB review because it uses de-identified human specimens or data, do not complete (a) - (j) below.*

(a) Number of specific aim and study title:
(Enter response here)

(b) Risks to subjects:
(Enter response here)

(c) Adequacy of protection against risks:
(Enter response here)

(d) Recruitment of subjects:
(Enter response here)

(e) Informed consent:
(Enter response here)

(f) Data confidentiality and provision of medical or professional intervention, if needed:
(Enter response here)

(g) Potential benefits of the research to subjects:
(Enter response here)

(h) Importance of knowledge to be gained:
(Enter response here)

(i) **Inclusion of women and minorities in the research:**
(Enter response here)

(i) **Inclusion of children in the research:**
(Enter response here)

If answered Yes to Item XVII (B), include a detailed Data Safety Monitoring Plan in Item XIX.

XIX. Clinical Trials and Data Safety Monitoring Plan: Federal Public Law 110-85 mandates registration and results reporting of "applicable clinical trials" in ClinicalTrials.gov. Under the statute these trials generally include: (1) *Trials of Drugs and Biologics*, including controlled, clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation; and (2) *Trials of Devices*, including controlled trials with health outcomes, other than small feasibility studies, and pediatric postmarket surveillance. The Department encourages registration of all clinical trials whether required under the Federal law or not.

For all Department-supported clinical trials, a detailed data safety and monitoring plan is required to provide oversight of the trial and ensure the safety of participants and the validity and integrity of the data. Include a plan which describes procedures for reporting adverse events, ensuring participant safety and maintaining the integrity of the data. A Data and Safety Monitoring Board (DSMB) is required for a multi-site clinical trial. If a DSMB is proposed, include the list of members and frequency of meetings. There are no space limitations for this section. If answered “Yes” to Item XVII (B), a data safety and monitoring plan must be described here.

(Enter response here)

XX. Targeted/Planned Enrollment Table – The table must be submitted in the following format for specific aim(s) involving clinical research and health services research, including outcomes research. Complete a separate table for each applicable study. Label each table with the number of the specific aim and study title.

Specific Aim #:

Study Title:

Total Planned Enrollment:

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino			
Not Hispanic or Latino			
Ethnic Category: Total of All Subjects *			
Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
Racial Categories: Total of All Subjects *			

* The “Ethnic Category: Total of All Subjects” must be equal to the “Racial Categories: Total of All Subjects.”

XXI. Consortium/Contractual Agreements - Explain specific fiscal, programmatic and administrative arrangements with collaborative organizations and subcontractors that will carry out any of the research project activities. Include qualifications of subcontractors. The subcontractor investigator and the authorized official of the subcontractor must provide, in the application, a signed statement or confirming letter that the appropriate programmatic and administrative personnel are aware of the Department of Health requirements contained in the Grant Agreement and that they are prepared to establish the necessary inter-institutional Agreements consistent with Department Grant requirements. Place the signed statements or confirming letters in Section Two of Attachment III Letters of Support. The awarded applicant is responsible for assuring that the subcontractor adheres to Department Grant requirements.

There are no space limitations to this section but be succinct. *Insert requested information on consortium and contractual Agreements below*.

XXII. Consultants – If consultants are included in the application, attach a letter from each consultant confirming the consultant's role in the project. Place the letters in Section Two of Attachment III, Letters of Support.

Applicant is not required to provide information in this section.

XXIII. Literature Cited – There are no space limitations for this section. *List references for literature cited in the Research Plan below*.

XXIV. Reporting Requirements

The awarded applicant agrees to the following reporting and accountability requirements.

Awarded applicants are required to submit to the Department one copy of the following reports in electronic form.

1. A written Annual Progress Report is due 30 calendar days after the end of each state fiscal year (SFY) or 60 calendar days after the end of the Grant Agreement in the year that the Grant Agreement ends. The progress report shall be provided in a format to be determined by the Department. The report shall include a detailed summary of research completed during the SFY and other information as required by the Department. Annual Progress Reports are posted to the Department's Health Research Office website in November as part of the Annual Report to the Legislature.

2. Any changes to the scope of research during the term of the Grant Agreement must be approved in writing by the Department.

3. A written Final Progress Report and copies of any publications based on research funded by this award is due 60 calendar days after the end date of the Grant Agreement. The final report shall provide a detailed summary of the progress achieved over the entire award period. The report shall include a detailed description of the methods and findings and evidence of the data that were generated and analyzed including appropriate tables, graphs and figures. In addition, the final report shall contain the following information and other information as required by the Department such as collaborative research activities, business and community involvement, research activities that lead to population-based applications addressing disparities in health status and access among various Pennsylvania populations, improvements in infrastructure and increased research capacity including new investigators, new Grants, new discoveries, and new products.

    a. Progress made in achieving expected research outcomes and benefits.

    b. (If the project involves clinical research) Extent of clinical activities initiated and completed, including:

        (1) the number of treatment, prevention and diagnostic studies initiated and completed;
        (2) the number of hospital and health care professionals involved in the research project;
        (3) the number of subjects relative to targeted goals; and
        (4) the extent of penetration of the studies throughout the region or Pennsylvania.

    c. Number of peer-reviewed publications released.

d. Number of inventions and patents filed, including commercial development opportunities initiated and completed.

e. Any changes in risk factors; services provided; incidence of disease; death from disease; stage of disease at time of diagnosis; or other relevant measures of outcome, impact and effectiveness of the research being conducted.

f. Any major discoveries, new drugs and new approaches for prevention, diagnosis and treatment, which are attributable to the completed research project.

4. A written response to a Performance Review Report is due 30 calendar days after the Department provides the awarded applicant with a copy of the Performance Review Report.

5. An Annual Expenditure Report for each SFY is due by July 31st and a final expenditure report within 60 calendar days after the end date of the Grant Agreement. The expenditure reports must be submitted using the forms contained in Part Two, Attachment XI of the RFA.

6. The awarded applicant(s) shall submit to the Department's Project Officer an annual assessment report once per calendar year throughout the term of the Grant Agreement, using the "CLAS Self-Assessment Tool for Grantees" template that can be found at the following link: https://www.pa.gov/en/agencies/health/resources/contractor-grantee.html. The annual report shall summarize in detail how the awarded applicant(s) have met the Health Equity requirements contained in paragraph 22 of the Department Standard General Terms and Conditions (Grant) (Rev. 12/24).

An applicant that receives a health research Grant under the Juvenile Diabetes Cure Research Act 2004-133, is subject to an evaluation via a performance review by the Department upon completion of the research project, or more often if deemed necessary by the Department. The performance review is based on the criteria developed by the Department in consultation with the Health Research Advisory Committee for health research grants.

As part of the performance review process, each research project funded as part of the Grant is reviewed by at least three experts who are physicians, scientists or researchers. Reviewers are from the same or similar discipline as the research project under review and are not from Pennsylvania. Reviewers use the applicant's strategic research plan, Annual Progress Reports, Final Progress Report and publications that resulted from the project and acknowledge Department funding to conduct the review.

Upon completion of the performance review process, the Department will provide each awarded applicant with a copy of the Performance Review Report containing the outcome of the review (outstanding, favorable, or unfavorable) for each project

and for the Grant as a whole, strengths and weaknesses of each research project, and recommendations for future improvement. The awarded applicant must provide an electronic copy of a written Response to the Performance Review Report within 30 calendar days after the awarded applicant receives the Performance Review Report.

An applicant that receives an unfavorable final performance review by the Department may be subject to a reduction in funding, become ineligible for health research funding in the future or may be required to remit some or all of the funding for a Grant that received an unfavorable final performance review.

The Final Performance Review Report, as well as the awarded applicant's written response to the Final Performance Review Report and the Final Progress Report will be posted on the Health Research Office website approximately 12-16 months after the end of the Grant.

The awarded applicant may also be required to provide other written reports such as a brief progress report or a written report during the conduct of performance reviews.

In addition to written reports, the Department may request other information as needed and may conduct one or more site visits to review the progress of the health research project.

Awarded applicants may also be required to provide oral reports to an advisory committee to the Department at the request of the Department.

The awarded applicant shall inform the Department of any changes in principal investigator or administrative officer, within 14 calendar days after the change.

RFA # 67-205
Attachment IV (Section Two)

LETTERS OF SUPPORT

Letters of support from collaborating organizations, subcontractors and consultants should be submitted as one electronic document in PDF format.

Budget Template

See Part One, General Information; Section C, Application Instructions and Required Format; Subsection 2e Budget for completion instructions.

CERTIFICATIONS FOR THE PROTECTION OF HUMAN SUBJECTS AND REGARDING THE USE OF HUMAN EMBRYONIC STEM CELL RESEARCH

PRINCIPAL INVESTIGATOR NAME	TITLE OF PRINCIPAL INVESTIGATOR
TITLE OF RESEARCH PROJECT	INSTITUTION

CERTIFICATION FOR THE PROTECTION OF HUMAN SUBJECTS

It is the responsibility of the research institution to assure that the rights and welfare of all human subjects used in any Pennsylvania Department of Health sponsored research are protected. Any research involving human subjects must be reviewed and approved by an appropriate institutional review board.

The applicant agrees to safeguard the rights and welfare of individuals who participate in research activities. The applicant agrees that all experimentation with human subjects shall be prohibited unless the applicant certifies that the prior written approval of its Institutional Review Board (IRB) is obtained or is not required, subject to all applicable laws, including but not limited to 42 U.S.C. Section 3515 (b) (relating to prohibitions on funding certain experiments involving human participants) and the regulations thereunder. In addition, such experimentation or research projects involving human subjects must be submitted to the Department of Health's IRB on the form entitled, "Application to the Pennsylvania Department of Health Institutional Review Board for Approval of Research Project under the Federal Policy for the Protection of Human Subjects." Further, the written, voluntary, informed consent of each subject must be obtained. If the subject is a minor, or incompetent, the written, voluntary, informed consent of his or her legal guardian shall be required. The applicant shall inform each potential subject prior to his or her consent that refusal shall not result in the loss of any benefits to which the subject is otherwise entitled from the Federal government, the Commonwealth, the applicant, any subcontractor of the applicant, or any third-party insurer.

Please check the appropriate statement:

☐ No human subjects will be used in any of the proposed research.

☐ Human subjects will be used in the proposed research. This is to certify that the proposed activities on human subjects have been reviewed by an institutional review board (IRB) on_____(date) and found to be in accordance with current Department of Health and Human Services (DHHS) policy.

☐ Human subjects will be used in the proposed research. This is to certify that the proposed activities on human subjects have NOT been reviewed by an IRB and that prior to initiating research involving human subjects, the applicant will submit to the Department of Health the form entitled, "Application to the Pennsylvania Department of Health Institutional Review Board for Approval of Research Project under the Federal Policy for the Protection of Human Subjects."

CERTIFICATION REGARDING THE USE OF HUMAN EMBRYONIC STEM CELL RESEARCH

Please check the appropriate statement:

☐ No human embryonic stem cells will be used in any capacity in the proposed research.

☐ Human embryonic stem cells that are approved by the National Institutes of Health and derived from outside of Pennsylvania will be used in the proposed research project.

NAME OF AUTHORIZED INSTITUTIONAL OFFICIAL	TITLE
SIGNATURE	DATE

CERTIFICATIONS FOR THE CONTAINMENT OF RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES (r/sNA) AND THE CARE AND TREATMENT OF VERTEBRATE LABORATORY ANIMALS

PRINCIPAL INVESTIGATOR NAME	TITLE OF PRINCIPAL INVESTIGATOR
TITLE OF RESEARCH PROJECT	INSTITUTION

CERTIFICATION FOR CONTAINMENT OF RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES (r/sNA)

It is the responsibility of the research institution to assure that the physical and biological containment needed for research involving any recombinant or synthetic nucleic acid molecules is within policies set out in the current "National Institutes of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules."

Please check the appropriate statement:

☐ This research does not involve any use of recombinant or synthetic nucleic acid molecules as defined by current NIH guidelines.

☐ This research involves the use of recombinant or synthetic nucleic acid molecules as defined by current NIH guidelines. This is to certify that the proposed activities involving recombinant or synthetic nucleic acid molecules have been reviewed by an institutional biosafety committee on _(date) and found to be in accordance with current NIH guidelines.

☐ This research involves the use of recombinant or synthetic nucleic acid molecules as defined by current NIH guidelines. This is to certify that the proposed activities involving recombinant or synthetic nucleic acid molecules have NOT been reviewed by an institutional biosafety committee, that the applicant assures that the physical and biological containment needed for research involving recombinant or synthetic nucleic acid molecules will adhere to policies set out in the current National Institutes of Health (NIH) Guidelines for Research Involving or Synthetic Nucleic Acid Molecules, and that prior to the initiation of research involving recombinant or synthetic nucleic acid and the use of Health Research Funds to pay for any of the research expenses, the applicant will obtain prior written approval of its biosafety committee.

CERTIFICATION FOR THE CARE AND TREATMENT OF VERTEBRATE LABORATORY ANIMALS

It is the responsibility of the research institution to assure proper care and treatment of all vertebrate laboratory animals used in any Pennsylvania Department of Health sponsored research. Any research involving laboratory animals must be reviewed and approved by an appropriate Institutional Animal Care and Use Committee (IACUC).

Please check the appropriate statement:

☐ No vertebrate laboratory animals will be used in any of the proposed research.

☐ Vertebrate laboratory animals will be used in the proposed research. This is to certify that the proposed activities involving laboratory animals have been approved by an institutional animal care and use committee on _(date) and found to be in accordance with current Public Health Service policy.

☐ Vertebrate laboratory animals will be used in the proposed research. This is to certify that the proposed activities involving laboratory animals have NOT been approved by an appropriate IACUC, that the applicant assures the humane care and use of vertebrate animals, that the applicant will adhere to Federal and state or local laws or regulations for the care and use of laboratory animals and that prior to the initiation of research involving vertebrate animals and the use of Health Research Funds to pay for any of the research expenses, the applicant will obtain prior written approval of an appropriate IACUC.

NAME OF AUTHORIZED OFFICIAL	TITLE
SIGNATURE	DATE

APPLICATION
TO THE
PENNSYLVANIA DEPARTMENT OF HEALTH INSTITUTIONAL REVIEW BOARD
FOR
Approval of Research Project under the Federal Policy for the Protection of Human Subjects

General Policy: A human subject is defined as a living individual about whom an investigator conducting research obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. 45 CFR § 46.102(e)(1).

The following types of research studies involving human subjects require the review of the Pennsylvania Department of Health Institutional Review Board (PA DOH IRB):

(1) Studies involving grants for which a Department of Health program is applying

(2) Studies involving grants awarded by the Department of Health to grantees

(3) Studies conducted by the Department of Health

(4) Studies using Department of Health biological specimens and/or data

(5) Studies conducted at a Department of Health licensed/approved nursing home or long-term care facility

Completed Applications: This application form and all supporting documents must be submitted to the PA DOH IRB Administrator at RA-DHIRB@pa.gov. Please note that the PA DOH IRB will not review an application unless it is accompanied by the following documents:

(1) Complete research protocol

(2) Copies of certification of appropriate research training (CITI Training when appropriate)

(3) Consent forms (if applicable)

(4) Completed waiver of authorization form (if applicable)

(5) Copies of any prior IRB determinations (if applicable)

Study Name

Principal Investigator Information (Please attach proof of training)		
Name:	Name and address of institution:	Email address:
Title:		Phone:
		Fax:

Co-investigator Information (Please attach proof of training for each co-investigator)		
Name:	Email:	Phone:
Name:	Email:	Phone:
Name:	Email:	Phone:
Name:	Email:	Phone:
Name:	Email:	Phone:
Name:	Email:	Phone:
Name:	Email:	Phone:

Study Characteristics
(Please check any of the following that apply)

☐ Study involves grants for which Department of Health programs are applying.

☐ Study involves grants awarded by the Department of Health to grantees.

☐ Study is being conducted by the Department of Health.

☐ Study involves the use of Department of Health biological specimens and/or data.

☐ Study will be conducted at a Department of Health licensed/approved nursing home or long-term care facility.

☐ Principal Investigator (PI) anticipates, or has received, state funding for this study.

☐ PI anticipates, or has received, a combination of state and federal funding for this study.

☐ Study involves vulnerable populations, including but not limited to pregnant women, human fetuses, neonates, children, individuals with impaired decision-making capacity, prisoners, and economically or educationally disadvantaged persons.

Anticipated Level of Review
(Please check one)

☐ A. Study requires full review.

☐ B. Study requires expedited review.
Please ensure that the reason for this level of review is selected in the appropriate section below.

☐ C. Study is exempt from review.
Please ensure that the reason for this exemption is selected in the appropriate section below, after which only the study description and signature sections need to be completed.

Prior IRB Approval/Exemption

If this study has already been reviewed by another IRB, please complete this section and continue to fill out the rest of the application in accordance with the type of review being requested. Remember to attach a copy of the prior approval or documentation of exemption to this application.

Name of IRB that performed prior review:

_____

Type of review performed by this IRB:

☐ Full review ☐ Expedited review ☐ Exempt from review

Date of IRB action: _____

FWA Number: _____

Request for Exemption from Review
(Please check any of the following that apply)

☐ A. Study will be conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.

☐ B. Study is limited to interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, and at least one of the following criteria is met:

(1) the information obtained is recorded in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; or

(2) any disclosure of the human subjects' responses outside the research that would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement.

☐ C. Study is limited to benign behavioral interventions (defined as brief in duration, harmless, painless, not physically invasive, and not likely to have a significant adverse lasting impact on the subjects) in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry), or audiovisual recording if the subject prospectively agrees to the intervention and information collection, and at least one of the following criteria is met:

(1) the information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; or

(2) any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

*Please note that if this study involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

☐ D. Study is limited to secondary research uses of identifiable private information or identifiable biospecimens, and at least one of the following criteria is met:

(1) the identifiable private information or identifiable biospecimens are publicly available;

(2) information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(3) this study involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

(4) this study is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq*.

☐ E. Study is conducted by, or subject to the approval of, the Department of Health and is designed to research, evaluate, improve or otherwise examine: (1) public benefit or service programs; (2) procedures for obtaining benefits or services under those programs; (3) possible changes in or alternatives to those programs or procedures; or (4) possible changes in methods or levels of payment for benefits or services under those programs.

☐ F. Study is limited to taste and food quality evaluation and consumer acceptance studies during which: (1) wholesome foods without additives are consumed; or (2) a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Request for Expedited Review
(Please check any of the following that apply)

☐ A. Study is limited to clinical research of drugs and medical devices for which an investigational new drug application is not required.

☐ B. Study is limited to research on medical devices for which an investigational device exemption application is not required or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

☐ C. Study is limited to the collection of blood samples by finger stick, heel stick, ear stick or venipuncture from:

☐ Healthy, nonpregnant adults who weigh at least 110 pounds, for which subjects the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or

☐ Other adults and children for which subjects the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

☐ D. Study is limited to the collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing.

*Please note that studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.

☐ E. Study is limited to the prospective collection of biological specimens for research purposes by noninvasive means.

☐ F. Study is limited to materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

☐ G. Study is limited to the collection of data from voice, video, digital or image recordings made for research purposes.

☐ H. Study is limited to research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation or quality assurance methodologies.

☐ I. Study is limited to interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) and the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects.

☐ J. Study is limited to benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry), or audiovisual recording if the subject prospectively agrees to the intervention and information collection, and the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects.

Study Description
Describe the purpose of the study in a brief statement.
If the PI is requesting any data from the Department of Health, please provide a detailed description of the data, the intended use of the data, and specify whether this data will be linked to any other data. Remember to attach any applicable data sharing agreements to this application.
Describe the research methodology of the study in a brief statement. Remember to attach copies of any printed materials, scripts, or surveys that will be used to this application.
Anticipated time frame of the study: From: _____ To: _____

Funding	
Anticipated source of funding: _____ Ex. Federal (NIH, CDC etc.), State (Department of Health, C.U.R.E., etc.), or Combination (list all sources of funding) **Grant funding year:** _____ Ex. SFY 2022 or FY 2022	**Anticipated level of funding:** _____ Ex. % of each funding source (State 40% Federal 60%) **Deputate, Bureau, Office, Division etc. distributing funds:** _____ Ex. Long Term Care Facility

Information About Subjects
Approximately how many subjects is the study anticipated to enroll? If it becomes necessary to enroll more subjects in this study, a change of protocol request form must be submitted. _____ subjects

Provide a description of the subjects the study will be enrolling. (For example: age range, gender, geographical region, etc.)

Will the study be researching or including any of the following? Check all that apply:

☐ Abortion materials

☐ Tissues

☐ In vitro fertilization

Will the study be enrolling any of the following vulnerable populations as subjects? Check all that apply:

☐ Pregnant women

☐ Neonates

☐ Fetuses

☐ Prisoners

☐ Children

☐ Individuals with impaired decision-making capacity

☐ Economically or educationally disadvantaged persons

☐ General population, which may Include any of the above vulnerable populations

Explain how the study necessitates or justifies the inclusion of subjects with the characteristics described in the three questions above.

Are there any characteristics that will be used to exclude potential subjects from participating in the study and/or does the PI foresee any reasons an enrolled subject would be removed from the study?

Subject Recruitment
What methods will the study employ to identify potential subjects that fit the characteristics described in the preceding section?
How will the study recruit subjects? Please specify the methods and the medium through which these methods will be disseminated. Remember to provide a copy of any recruitment materials including oral scripts, posters, advertisements for any medium, letters and any other material being used to recruit subjects.
If applicable, describe the specific location, region or organization that recruitment will take place.
Will an incentive be offered for participation? If so, please describe it here.
Data Privacy
Will any personally identifiable information be collected? If so, please list any type of personally identifiable data the study plans to collect and how the study plans to collect it.
Does the study necessitate the collection of protected vital events data from the Department of Health's Division of Vital Records? ☐ Yes ☐ No
How will the data be stored? Check all that apply:

☐ Electronic records ☐ Hard copies
Describe how the data will be stored in a secure way. Please include a description of any encryption methods that may be used.
Who will have access to the data collected in the study?
Will the data collected in the study and/or borrowed from the Department of Health be linked to any other data? If so, please specify how it will be linked and if there are any precautions that will ensure the data is still deidentified.
How long will the data be stored? _____
If applicable, describe how the data will be disposed of.

Informed Consent
Will informed consent be collected? ☐ Yes ☐ No If no, please explain why informed consent is not necessary for the study:
What process will the study use to obtain consent? (For example: informed consent, assent, parental permission, etc.). Remember to attach any forms or copies of verbal scripts that will be used.
Anticipated Benefits and Risks
How will the study potentially benefit the population of potential subjects?
How will the study potentially benefit society as a whole?
What potential risks could affect participants in the study? Please include any possible risks, no matter how unlikely.
How does the PI plan to minimize the risk that subjects could incur from participation in the study?

Signature	
The official signing below certifies that the information provided above and in any related attachments is correct and that, as required, future reviews will be requested and certification will be provided.	
Name of official:	Phone:
Title:	Fax:
Signature:	Date:

Application Checklist

Mandatory documents:

☐ PA DOH IRB application

☐ Research protocol

☐ Copies of certification of appropriate research training (CITI Training when appropriate)

Other documents (required if applicable):

☐ Any questionnaires and/or surveys that will be used

☐ Any printed materials the subjects may see, hear, or read

☐ Script that subjects may hear, see, or read during the research process

☐ Any forms that will be used in the data collection process

☐ Copies of all recruitment materials

☐ Consent document(s)

☐ Approval form from another FWA compliant IRB

☐ Data sharing agreements

☐ Any other supporting material the PI believes will help the PA DOH IRB understand the study

To be completed by PA DOH IRB personnel		
Study is exempt from Department of Health IRB review:	☐ Yes	☐ No
If yes, determination is based on this exemption criteria:	☐ A ☐ B ☐ C ☐ D ☐ E ☐ F	
Study underwent expedited review:	☐ Yes	☐ No
If yes, determination is based on this expedited review criteria:	☐ A ☐ B ☐ C ☐ D ☐ E ☐ F ☐ G ☐ H ☐ I ☐ J	
Study underwent full review:	☐ Yes	☐ No
Institutional Review Board Result: ☐ Approved ☐ Approved with conditions ☐ Disapproved		
_____ Signature		_____ Date

Application to the Pennsylvania Department of Health Institutional Review Board (IRB)

Please visit IRB (pa.gov) for a current IRB Application.

MEMORANDUM OF UNDERSTANDING REGARDING ETHICAL STANDARDS

The applicant agrees that research to be performed under this Grant Agreement and all individuals performing such research shall be subject to Federal ethical and procedural standards of conduct as prescribed by the National Institutes of Health on the date this Memorandum of Understanding Regarding Ethical Standards is executed.

Research funded by this Grant Agreement also shall observe the Federal ethical and procedural standards regulating research and research findings, including publications and patents, which are observed under the National Institutes of Health extramural funding requirements and National Institutes of Health Grants policy statements and applicable sections of 45 CFR Part 74 (relating to uniform administrative requirements for awards and subawards to institutions of higher education, hospitals, other nonprofit organizations, and commercial organizations; and certain Grants and Agreements with states, local governments and Indian tribal governments) and Part 92 (relating to uniform administrative requirements for Grants and cooperative Agreements to state and local governments).

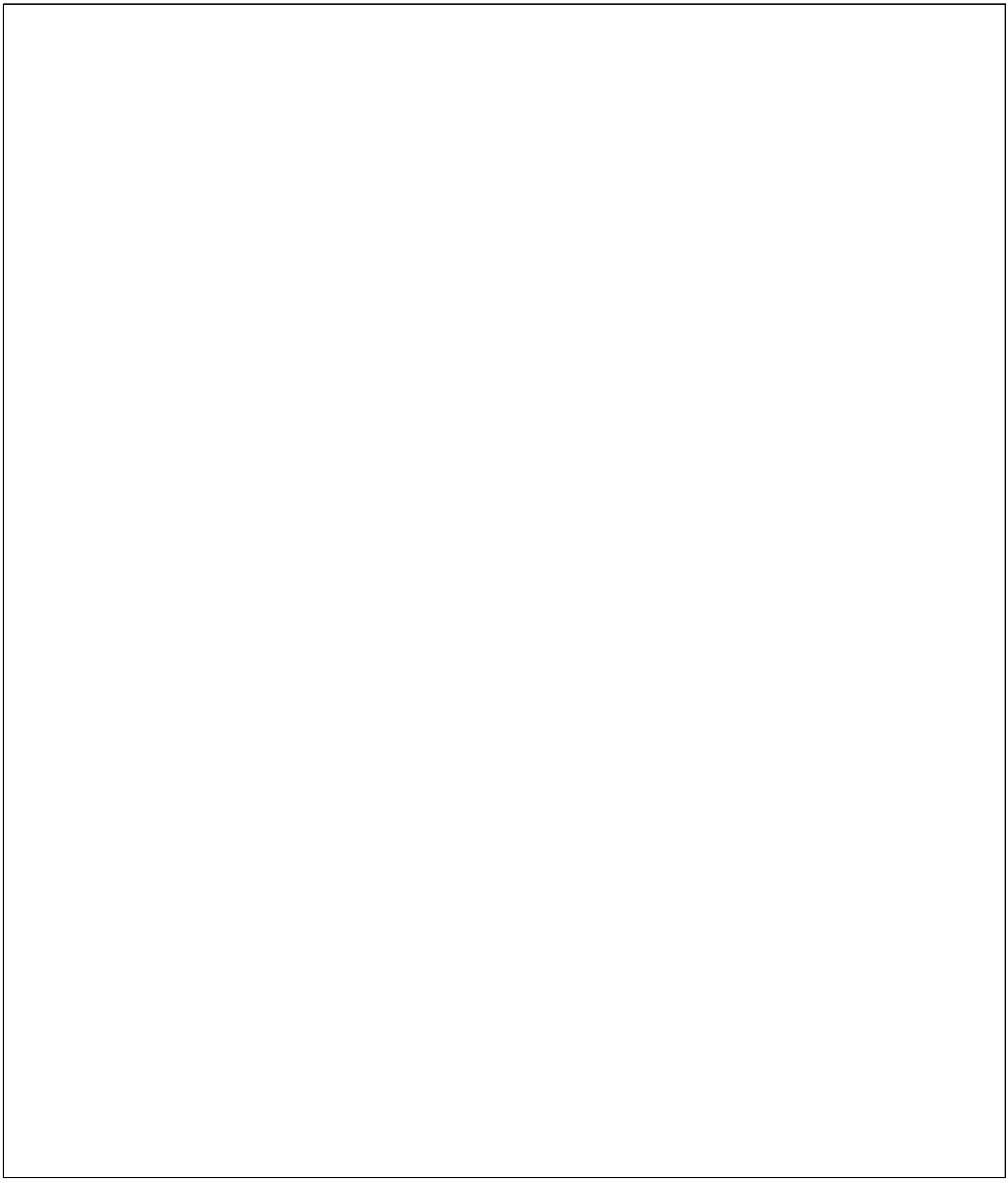
BY SIGNING BELOW, THE APPLICANT, BY ITS AUTHORIZED SIGNATORY, IS BINDING ITSELF TO THE ABOVE AGREEMENT.

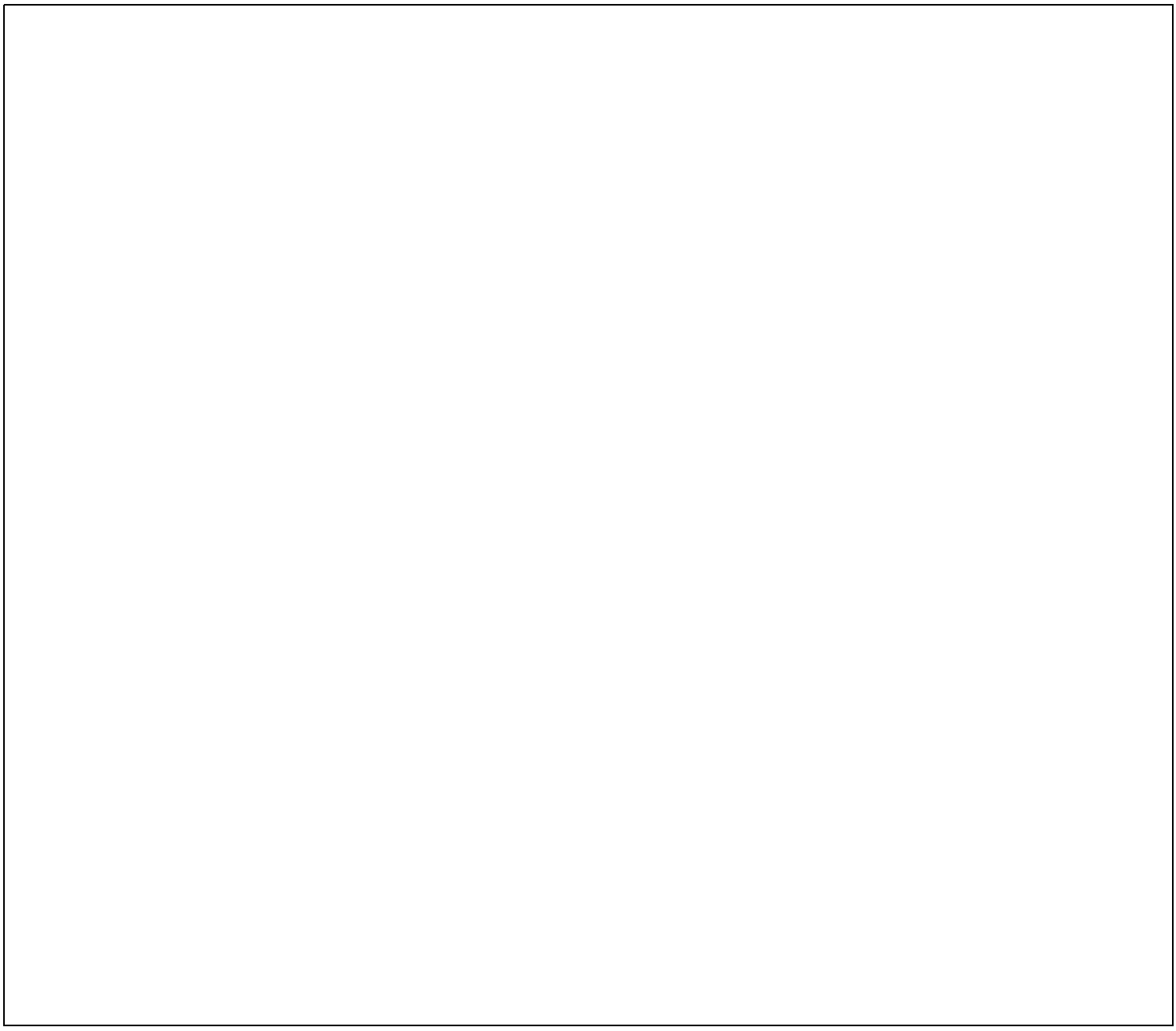
APPLICANT ORGANIZATION	
SIGNATURE OF JUVENILE DIABETES CURE RESEARCH TAX CHECK-OFF PROGRAM FUND- APPLICANT'S AUTHORIZED OFFICIAL	DATE
NAME OF AUTHORIZED OFFICIAL	TITLE OF AUTHORIZED OFFICIAL
SIGNATURE OF SECRETARY OF HEALTH COMMONWEALTH OF PENNSYLVANIA	DATE

RFA# **67-205**
Attachment X

Letter of Intent

Pennsylvania Department of Health **Letter of Intent to Submit an Application for Research to Cure and Prevent Type 1 (Juvenile) Diabetes** *In Response to* **RFA 67-205**	Email to: ra-healthresearch@pa.gov Health Research Office Attention: Administrative Officer Pennsylvania Department of Health 8th Floor West, Health and Welfare Building, 625 Forster Street Harrisburg, PA 17120-0701 Telephone: (717) 547-3103 **Due date:** on or before the date and time specified in the cover letter to the RFA **Typeface and Font size - Use either Times New Roman font size 10 pts. or larger or Arial font size 11 pts. or larger.**
The Principal Investigator of the lead institution and the collaborating institutions, specified in this letter intend to submit an application to the Pennsylvania Department of Health at the time, date and address specified in the cover letter to the RFA. The letter of intent is nonbinding. The letter of intent is used to plan for the peer review process.	
Applicant Institution: **Federal ID (EIN) #**: **Name of Principal Investigator**: **Position Title**: **Telephone**: **Email Address**: **Mailing Address**:	**Collaborating Major Research Organization(s) Located in Pennsylvania and the Name of the Lead Investigator at Each Organization**: **Other Collaborating Institutions and the Name of the Lead Investigator at Each Institution**:
Title of the Research Project (*no more than 81 characters including spaces and punctuation*):	
Research Project Description (*not to exceed 2 pages*)	





Annual Expenditure Report

PROJECT NAME:	
INSTITUTION:	DATE PREPARED:
ADDRESS:	NAME AND TITLE OF CONTACT PERSON:
SSN/FID AND SAP VENDOR NUMBERS: SSN/FID#: SAP VENDOR #:	E-MAIL ADDRESS:
TELEPHONE:	BUDGET PERIOD:
SAP DOCUMENT NUMBER:	REPORTING PERIOD:

	CATEGORIES	**BUDGET AMOUNT**	**EXPENDITURES TO DATE**	**EXPENDITURES FOR REPORTING PERIOD**
I.	PERSONNEL SERVICES			
II.	CONSULTANT SERVICES			
III.	SUBCONTRACT SERVICES			
IV.	PATIENT CARE			
V.	EQUIPMENT			
VI.	SUPPLIES			
VII.	TRAVEL			
VIII.	OTHER COSTS/LABORATORY OR BUILDING CONSTRUCTION OR RENOVATIONS			
	TOTAL COSTS			

Certified by: _____ Date:_____
(Grantee's Authorized Signature)

Reviewed by:

_____
(Department's Authorized Signature)

Report of Interest Earned and Expenditures on Interest Earned

Institution:

SAP Document #:

SAP Vendor #:

1. **Amount of interest earned to date: _____**
   a. **From start of Grant through last date of reporting period.**

2. **Expenditures to date on interest earned: _____**
   a. **From start of Grant through last date of reporting period.**

3. **Expenditures for reporting period on interest earned: _____**
   a. **This amount equals the sum total of both columns below.**
   b. **These expenditures must be included on the Annual Expenditure Report, in the column labeled "EXPENDITURES FOR REPORTING PERIOD."**

	CATEGORIES	**INFRASTRUCTURE EXPENDITURES FOR REPORTING PERIOD**	**NON-INFRASTRUCTURE EXPENDITURES FOR REPORTING PERIOD**
I.	PERSONNEL SERVICES		
	A. Staff Personnel		
	A.1. Nonprofessional Personnel		
	A.2. Other Personnel		
	B. Fringe Benefits		
	B.1. Nonprofessional Personnel		
	B.2. Other Personnel		
II.	CONSULTANT SERVICES		
III.	SUBCONTRACT SERVICES		
IV.	PATIENT CARE		
V.	EQUIPMENT		
	A. Office Equipment		
	B. Non-Office Equipment		
VI.	SUPPLIES		
	A. Office Supplies		
	B. Non-Office Supplies		
VII.	TRAVEL		
VIII.	OTHER COSTS / LABORATORY OR BUILDING CONSTRUCTION OR RENOVATIONS (include Indirect Costs)		
	TOTAL COSTS		

Certificate of Compliance with Investment Requirements

1. **By signing below, the Grantee, by its authorized signatory, confirms that the Health Research Funds were deposited during the reporting period in an insured interest-bearing account or invested according to the Investment Requirements specified in the Payment Provisions.**

ORGANIZATION	SAP DOCUMENT NUMBER
SIGNATURE OF AUTHORIZED OFFICIAL	DATE
NAME OF AUTHORIZED OFFICIAL	TITLE OF AUTHORIZED OFFICIAL

2. **Use the following table to indicate how Grant funds were invested during the reporting period.**

Grant funds were invested in the following Investment Requirement categories during the reporting period:	Check "Yes" if any funds were invested in the category during the reporting period. Check "No" if none of the funds were invested in the category during the reporting period.	
	YES	NO
(1) FDIC-insured interest-bearing account***		
(2) insured money market funds***		
(3) repurchase agreements relating to United States government securities, provided, however, that any such repurchase obligation which is not an "overnight" obligation (hereinafter defined) shall be possessory***		
(4) obligations of, or guaranteed as to interest and principal by, the United States government maturing within one (1) year after investment***		
(5) open market commercial paper of any corporation incorporated under the laws of the United States or any state thereof rated "prime-1" or its equivalent by Moody's Investor Service, Inc., or "A-1+" or its equivalent by Standard & Poor's Corporation (provided that no more than twenty percent (20%) of the Account shall be invested in the commercial paper of any one issuer or its affiliates)***		
(6) certificates of deposit and time deposits maturing within one (1) year after such investment issued by domestic offices of commercial banks organized under the laws of the United States having a combined capital and surplus in excess of one hundred million dollars ($100,000,000)***		
(7) municipal bonds issued by the State of Pennsylvania or any county, city, town, village, municipality, district or political subdivision thereof, if payable by general tax revenues or special assessments, rated "A" or its equivalent by Moody's Investor Service, Inc., or Standard & Poor's Corporation***		

*****In the event of an audit, the Grantee shall provide the Department or its designee with the names of institutions, account numbers, types of government securities and other investment information necessary for inspection, audit or reproduction.**

1. **Complete the following table only if all categories in item 2 above are checked NO.**

Grant funds were not invested in one or more of the Investment Requirement categories during the reporting period because:	Check appropriate reason(s):	
	YES	NO
(1) Grant funds were received less than 10 days prior to the end of the reporting period. Specify date funds were received:_____		
(2) Funds were maintained in cash or cash balances during the entire reporting period. Specify maximum cash balance maintained during the reporting period:_____		

Report of Infrastructure Expenditures

Use the following table to report infrastructure expenditures.

This report must include all infrastructure expenditures incurred during the reporting period and to date. Include infrastructure expenditures on the original Grant award and also on the interest earned, as reported in the column labeled "INFRASTRUCTURE EXPENDITURES FOR REPORTING PERIOD" on the *Report of Interest Earned and Expenditures on Interest Earned*.

Act 149 of 2002 defines infrastructure as follows: "office equipment and supplies, nonprofessional personnel, laboratory or building construction or renovations, used to conduct research." Nonprofessional personnel include secretaries, clerks or administrative assistants.

Institution:

SAP Document #:

SAP Vendor #:

CATEGORIES	**INFRASTRUCTURE EXPENDITURES TO DATE**	**INFRASTRUCTURE EXPENDITURES FOR REPORTING PERIOD**
NONPROFESSIONAL PERSONNEL (secretaries, clerks or administrative assistants)		
OFFICE EQUIPMENT		
OFFICE SUPPLIES		
OTHER COSTS / LABORATORY OR BUILDING CONSTRUCTION OR RENOVATIONS (For Indirect Costs, include only the portion that cover the costs of nonprofessional personnel, office equipment, office supplies, and laboratory construction or renovation)		
TOTAL INFRASTRUCTURE COSTS		

RFA # 67-205

PAYMENT PROVISIONS

The Department agrees to pay the Grantee for services rendered pursuant to this Grant Agreement as follows:

A. Subject to the availability of state and Federal funds and the other terms and conditions of this Agreement, the Department will pay the Grantee in accordance with Appendix C, and any subsequent amendments thereto, for the costs incurred in providing the services described in this Agreement.

B. Payment to the Grantee shall be made in accordance with the Budget set forth in Appendix C and any subsequent amendments thereto, as follows:

1. One payment will be made to the Grantee upon complete execution of the Agreement unless the Grantee has received notice of annual payment. State and Federal funds received under this Agreement shall be promptly deposited by the Grantee in an insured interest-bearing account or invested according to the following investment requirements. All interest derived by the Grantee from the use of state and Federal funds during the Agreement shall be utilized to provide additional services pertaining to the project(s) funded by this Agreement.

   a. Investment Requirements:

      The Grantee shall only invest that portion of the fund which is not maintained in cash or cash balances in the following types of obligations: (i) insured money market funds; (ii) repurchase agreements relating to United States government securities, provided, however, that any such repurchase obligation which is not an "overnight" obligation (hereinafter defined) shall be possessory; (iii) obligations of, or guaranteed as to interest and principal by, the United States government maturing within one year after investment; (iv) open market commercial paper of any corporation incorporated under the laws of the United States or any state thereof rated "prime-1" or its equivalent by Moody's Investor Service, Inc., or "A-1+" or its equivalent by Standard & Poor's Corporation (provided that no more than twenty percent (20%) of the Account shall be invested in the commercial paper of any one issuer or its affiliates); (v) certificates of deposit and time deposits maturing within one year after such investment issued by domestic offices of commercial banks organized under the laws of the United States having a combined capital and surplus in excess of one hundred million dollars ($100,000,000); and (vi) municipal bonds issued by the State of Pennsylvania or any county, city, town, village, municipality, district or political subdivision thereof, if payable by general tax revenues or special assessments, rated "A" or its equivalent by Moody's Investor Service, Inc., or Standard & Poor's Corporation. For purposes of this paragraph, repurchase agreements shall be considered to be "overnight" obligations only if they mature or are otherwise to be repurchased on the next Business Day immediately following the date of purchase. The term "Business Day" shall mean any day other than (i) a Saturday, Sunday, or legal holiday, or (ii) a day on which banking institutions are authorized by law to close.

      The following are some securities the Grantee may buy:
      (i) United States Treasury securities ("Treasuries") and United States Agency securities ("Agencies"; Treasuries and Agencies are, collectively, "Federal Obligations") which mature within two years of the date of issue;
      (ii) Short-term commercial paper issued by industrial, common carrier or finance companies which bears a rating of "P-1" from Moody's or "A-1" from Standard & Poor's;
      (iii) Uncollateralized or collateralized certificates of deposit of Pennsylvania-based commercial banks, savings banks, and savings and loans up to a level equal to 20% of the institution's capital and surplus or net worth (refer to limitations imposed under Investment Policy Guidelines below);
      (iv) Repurchase agreements secured by Federal Obligations;
      (v) Banker's Acceptances written by domestic commercial banks whose debt is rated "Aa" or better by Moody's or its equivalent by either Standard & Poor's or Fitch's Rating Service.

   b. Investment Policy Guidelines include the following:

      (i) At least 50 percent of the Pool will be comprised of Federal Obligations or repurchase agreements secured by the same.
      (ii) At least 30 percent of the Pool will consist of U.S. Treasuries or repurchase agreements secured by U.S. Treasuries.

(iii) All other things being equal, preference will be given to investments offered in or through Pennsylvania corporations and financial institutions.

2. The Department shall have the right to disapprove any expenditure made by the Grantee that is not in accordance with the terms of this Agreement. The Grantee shall reimburse the Commonwealth for any disapproved expenditure.

3. The Grantee shall submit to the Department a final expenditure report within 60 days of the Agreement's termination date. The report shall be sent by the Grantee to the Health Research Office SharePoint site.

   The report shall show the Agreement's SAP number, the Grantee's Federal identification number, date when submitted, name of person preparing the report and total expense amount. The report shall include detailed records to substantiate the report, a detailed report of expenditures, and a report of interest earned to date and expenditures on the interest earned.

4. Funds must be spent by the Grantee by the termination date of the Agreement, unless a no cost extension is granted pursuant to the terms of this Agreement. Any unspent funds at the end of the Agreement, including interest earned but not expended on the services pertaining to the project funded by this Agreement, shall be returned to the Commonwealth within 45 days of the Agreement's termination date. A check in the amount due to the Commonwealth shall be made payable to the "Commonwealth of Pennsylvania, Department of Health". The Grantee shall also provide a breakdown of the funds being returned and shall include the Agreement's SAP number. The check and correspondence shall be mailed to:

   Pennsylvania Department of Health
   Attention: Administrative Officer
   Health Research Office, 8th Floor West, Health & Human Services Building
   625 Forster Street, Harrisburg, PA 17120-0701

5. The Grantee has the option to reallocate funds between and within budget categories (Budget Revision), subject to the following criteria:

   a. General Conditions for Budget Revisions

      (i) Budget Revisions At or Exceeding 20%.

         A. The Grantee shall not reallocate funds between budget categories in an amount at or exceeding 20% of the total amount of the Agreement as set forth in *Appendix C Budget*, and any subsequent amendments thereto, without prior written approval of the Department's Project Officer.

         B. The Grantee shall request prior written approval from the Department's Project Officer when the cumulative total of all prior Budget revisions is 20% or greater of the total amount of the Agreement.

         C. Reallocations at or exceeding 20% of the total amount of the Agreement may not occur more than once unless the Department's Project Officer finds that there is good cause for approving one additional request. The Project Officer's determination of good cause shall be final.

      (ii) *Budget Revisions Under 20%*. The Grantee shall notify the Department's Project Officer of any Budget Revision under 20% of the total amount of the Agreement in writing, but need not request Department approval, except as provided for in Paragraph 5(a)(i)(B) above.

      (iii) The Grantee shall obtain written approval from the Department's Project Officer prior to reallocating funding into a previously unfunded budget category or prior to eliminating all funding from an existing budget category, regardless of the percentage amount.

      (iv) The Grantee shall provide the Department's Project Officer with notice or make a request for approval prior to the submission of the next Annual or Final Expenditure Report based on these changes.

      (v) At no time can Administrative/Indirect cost rates be increased via a Budget Revision.

   b. Budget Revisions Relating to Personnel

(i) Any change to funds in the Personnel Category requires written approval of the Department's Project Officer, and any such change at 20% or over as set forth in Paragraph 5(a)(i) shall be counted as one Budget Revision under that paragraph

(ii) The Grantee may not reallocate funds to, or move funds within, the Personnel Services Category of the Budget (Appendix C), and any subsequent amendments thereto, to increase staff personnel or fringe benefit line items unless one of the following circumstances apply:

A. The Grantee is subject to a collective bargaining agreement or other union agreement and, during the term of this Agreement, salaries, hourly wages, or fringe benefits under this Agreement are increased because of a renegotiation of that collective bargaining agreement or other union agreement. The Grantee shall submit to the Department's Project Officer written documentation of the new collective bargaining or other union agreement, which necessitates such reallocation.

B. The Grantee is unable to fill a position that is vacant or becomes vacant at or after the effective date of this Agreement. The Grantee shall submit to the Department's Project Officer written justification for the request to increase rates and reallocation of funds in connection with filling such a position in sufficient detail for the Department to evaluate the impact of that reallocation on the performance of the work of the Agreement, as well as the Grantee's inability to fill the position at the existing rates. Justification may include, for example, documentation of salaries for the same or similar positions in the same geographic area. No increase relating to a position may exceed 10% of the original rate.

C. The Grantee is unable to perform the work of the Agreement with the existing positions, titles or classifications of staff. The Grantee may add or change a position, title or classification in order to perform work that is already required. The Grantee shall submit to the Department's Project Officer for his or her approval written justification for the request to increase rates and reallocation of funds in connection with changing or adding a position, title or classification, in sufficient detail for the Department to evaluate the impact of that reallocation on the performance of the work of the contract, as well as the Grantee's inability to fill current position. Justification may include, for example, documentation of salaries for the same or similar positions in the same geographic area. No increase relating to an addition or change may exceed 10% of the rate for the original position.

(iii) The Department's determination regarding the validity of any justification is final.

(iv) All increases are subject to the availability of funds awarded under this Agreement. The Commonwealth is not obligated to increase the amount of award.

(v) This paragraph is not intended to restrict any employee from receiving an increase in salary based on the employer's fee schedule for the job classification. The Grantee may pay beyond the cap with non-Grant funds.

6. The Commonwealth shall make payments to the Grantee through the Automated Clearing House (ACH). Within 10 days of the grant, the Grantee must submit or must have submitted its ACH information within its user profile in the Commonwealth's Master Database. The Grantee may enroll to receive remittance information via electronic addenda and email (e-Remittance). ACH and e-Remittance information is available at the following:

https://www.budget.pa.gov/Services/ForVendors/Pages/Direct-Deposit-and-e-Remittance.aspx.

a. The Grantee must submit a unique invoice number with each invoice submitted. The Commonwealth shall list the Grantee's unique invoice number on its ACH remittance advice to enable the Grantee to properly apply the state agency's payment to the respective invoice or program.

b. The Grantee shall ensure that the ACH information contained in the Commonwealth's Master Database is accurate and complete. Failure to maintain accurate and complete information may result in delays in payments.

c. In the event this language conflicts with language contained elsewhere in this agreement, the language contained herein shall control.

C. The Department's determination regarding the validity of any justification or of any request for approval under these Payment Provisions is final.

PROGRAM SPECIFIC PROVISIONS

I. The applicant agrees to adhere to applicable Federal, state and local standards and laws for the construction and renovation of research facilities.

II. Paragraph 25 RECORDS RETENTION REQUIREMENTS of the Department Standard General Terms and Conditions (Grant) (Rev. 12/24) is hereby deleted in its entirety and replaced with the following:

RECORD RETENTION REQUIREMENTS

All records kept pursuant to Paragraph 24 shall be retained pursuant to the provisions of this Paragraph 25.

A. The Grantee shall preserve and make available all books, records, and documents related to this Grant Agreement for a minimum of four years from the termination date of this Agreement; or as required by applicable Federal laws and regulations, whichever is longer. The Grantee shall provide Federal and state agencies or their designee access to such books, records and documents for inspection, audit or reproduction. and for such period, if any, as is required by applicable statute, by any other paragraph of this Agreement, or by sub-paragraphs 1 or 2 below.

   1. If this Agreement is completely or partially terminated, the records relating to the work terminated shall be preserved and made available for a period of five years from the date of any resulting final payment.
   2. Records which relate to litigation or the settlement of claims arising out of the performance of this Agreement, or costs and expenses of this Agreement as to which exception has been taken by the auditors, shall be retained by the Grantee until such litigation, claims, or exceptions have been disposed of or until all findings, questioned costs or activities have been resolved to the satisfaction of the Commonwealth.

B. Except for the records described in sub-paragraph A.2 above, the Grantee may, in fulfillment of its obligation to retain its records as required by this paragraph, substitute photographs, microphotographs, or other authentic reproductions of such records, after the expiration of two years following the last day of the month of reimbursement to the Grantee of the invoice or voucher to which such records relate, unless a shorter period is authorized by the Department, with the concurrence of the auditors.

III. Paragraph 29 CHANGE LETTER of the Department Standard General Terms and Conditions (Grant) (Rev. 12/24) is hereby deleted in its entirety and replaced with the following:

CHANGE LETTER

The Department may make changes in the Work Statement or Grant Agreement by issuing to the Grantee a change letter, signed by the Department, provided such changes are consistent with the research priorities and that the requirements for human subjects protections, recombinant or Synthetic Nucleic Acid Molecules research and vertebrate laboratory animals are met and provided further that the total cost of this Agreement is not exceeded. Research involving human subjects, laboratory animals and recombinant or Synthetic Nucleic Acid Molecules must be reviewed and approved by the applicant's appropriate institutional review board prior to the initiation of the research and use of Grant funds to pay for any research expenses. If the change to the Work Statement or Grant Agreement involves human subjects, the Application to the Pennsylvania Department of Health Institutional Review Board and documentation of IRB exemption or approval must be submitted to the DOH IRB prior to initiation of the research. The Department, PA DOH IRB and the Grantee shall mutually determine whether the ordered changes can be accomplished within the total Grant cost and the extent of change, if any in the delivery schedules required by the ordered changes. The change letter is effective as of the date of the change letter unless the change letter specifies a later date of effectiveness. Grantee shall comply

with the change letter. Any dispute by the Grantee in regard to the performance under the change letter is handled through the Grant Controversies paragraph of the Department Standard General Terms and Conditions (Grant) (Rev. 12/24). The change letter is part of this agreement and subject to its provisions.

IV. Paragraph 27 KEY PERSONNEL of the Department Standard General Terms and Conditions (Grant) (Rev. 12/24) is hereby deleted in its entirety.

V. Paragraph 34 OWNERSHIP RIGHTS of the Department Standard General Terms and Conditions (Grant) (Rev. 12/24) is hereby deleted in its entirety and replaced with the following:

DATA, COPYRIGHTS and DISCLOSURE

The Commonwealth of Pennsylvania shall have a royalty-free, non-exclusive, irrevocable license to use any patented or copyrighted invention developed with direct funding support from this Grant, for non-commercial, public health practice or research conducted by the Department directly, or through a contractor on its behalf. Except in accordance with the foregoing, this right shall not be sublicensable or transferable. The terms contained in this paragraph shall take precedence over any provision to the contrary appearing elsewhere in this Agreement.
All notices, publications, informational pamphlets, press releases, research reports and similar public notices prepared and released by the Grantee, shall include the statement, "This project is funded, in part, under a Grant with the Pennsylvania Department of Health. The Department specifically disclaims responsibility for any analyses, interpretations or conclusions."

VI. Paragraph 31 COLLECTION OR RECORDING OF INFORMATION of the Department Standard General Terms and Conditions (Grant) (Rev. 12/24) is hereby deleted in its entirety.

VII. Paragraph 33 DISPOSITION OF EQUIPMENT AND OTHER MATERIAL paragraphs B through F of the Department Standard General Terms and Conditions (Grant) (Rev. 12/24) is hereby deleted in its entirety.

VIII. ADDITIONAL AUDIT REQUIREMENTS

This Agreement is subject to audit in accordance with the Audit Requirements (Rev. 10/24) attached to this Agreement. The following terms supplement the audit requirements previously referenced. However, where there may be a conflict between the terms referenced below and the previously mentioned audit requirements, the terms referenced below will take precedence in such instances.

Audit periods shall coincide with state fiscal years but shall not be less than six months or greater than 18 months. Specifically, the Grantee shall have an audit performed when it expends $500,000 or more of state funds received under this Agreement within the 13-month period immediately following the effective date of the Agreement or when it expends $500,000 or more of state funds received under this Agreement within any successive 12-month period thereafter, unless notified in writing by the Department prior to the termination of the applicable audit period that the audit requirement has been waived. If the Agreement or any successive period is for a period of less than 12 months, but the Agreement amount expended by the Grantee during said period includes $500,000 or more of state funds, the Grantee is also required to have an audit performed for the entire Agreement or successive period, unless notified in writing by the Department prior to the termination of the applicable audit period that the audit requirement has been waived.

Grantee must submit a program-specific audit in accordance with the provisions of Department’s audit requirements referenced above.

The audit report must be completed and submitted within 180 calendar days of the termination date of the Grant Agreement or 180 calendar days following the end of each 12-month period (or fraction thereof) in case of an Agreement lasting more than 12 months. There will be no exceptions to the 180 calendar days. The Grantee shall submit electronic copies of the audit report to the Department as follows:

Submit one electronic copy to:	**Submit one electronic copy to:**
Audit Resolution Section	Health Research Office
Email: ra-dhprogramaudit@pa.gov	Email : ra-healthresearch@pa.gov

IX. PENALTY FOR VIOLATING THE GRANT AGREEMENT TERMS

The Department shall have the right to terminate and require repayment of the Grant funds if the research conducted by Grantee and funded by this Grant Agreement does not conform to Federal ethical standards in accordance with the Memorandum of Understanding (MOU) Regarding Ethical Standards or research that is not within the scope of research described in the Research Proposal that have been approved in writing in advance by the Department Project Officer prior to the initiation of the research or for violations of the terms and conditions of the Nondiscrimination/Sexual Harassment Clause or Grantee Integrity Provisions as specified in Commonwealth Standard General Terms and Conditions (Grant) (Rev. 10/1/23).

X. PENALTY FOR VIOLATING REPORTING REQUIREMENTS

If the Grantee fails to submit to the Department an Annual Progress Report in the required format within 30 calendar days after its due date, or a Final Progress Report in the required format within 30 calendar days after its due date, or the Grantee fails to submit a corrected Annual or Final Progress Report in the required format within 30 calendar days of a request by the Department, the Grant may receive an unfavorable final performance review rating. For Grants consisting of more than one project, each project for which the final progress report is not submitted in the required format within 30 calendar days after its due date may receive an unfavorable final performance review rating. Two consecutive overall Grant-level unfavorable performance review ratings will make the Grantee ineligible to apply for Juvenile Diabetes Cure Research Tax Check-off Program funds and will result in a reduction in Juvenile Diabetes Cure Research Tax Check-off Program funds in the next funding cycle.

If the Grantee fails to submit a response to the Final Performance Review Report within 60 calendar days after its due date, the Department may post the Final Performance Review Report on the Health Research Office's website with a notice that the Grantee failed to submit a response to the final performance review.

XI. LIQUIDATED DAMAGES

The Grantee acknowledges that failure to submit expenditure reports, audit reports or unspent funds including interest by the due date(s) shall constitute a material breach of the Grant Agreement. Such material breach may subject the Grantee to liquidated damages in the amount of up to $100 per day until the outstanding report or repayment of unspent funds is submitted to the Department. Future Health Research Juvenile Diabetes Cure Research Tax Check-off Program Grant awards may be offset by damages owed as a result of material breaches in prior Juvenile Diabetes Cure Research Tax Check-off Program Grants.

XII. INSPECTION AND ACCEPTANCE

Final inspection and acceptance of all work required under this Grant Agreement shall be performed by the Project Officer.