pennsylvania
DEPARTMENT OF HEALTH

April 5, 2023

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) # 67-153.

All questions regarding this RFA must be directed by e-mail to RA-HEALTHRESEARCH@pa.gov, no later than 12:00 p.m. on April 19, 2023. 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 on April 20, 3023. 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. Please type "LOI ENCLOSED RFA # 67-153 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 on May 16, 2023. 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: 2023.04.05 12:03:39 -04'00'

Office of Procurement
For Agency Head

Enclosure

Request for Application

Spinal Cord Injury Research Grant

RFA Number
67-153

Date of Issuance
April 5, 2023

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

RFA Project Officer: Galen Graham
Pennsylvania Department of Health
Health Research Office
Email: galgraham@pa.gov

Spinal Cord Injury Research Grant

CONTENTS

Any Grant Agreement resulting from this RFA will include certain standard terms and conditions, which will either be attached as paper appendices or incorporated by reference and may be found at http://www.health.pa.gov/vendors. These terms and conditions are listed below:

- Payment Provisions (Rev. 10/21)
- Program Specific Provisions
- Standard General Terms and Conditions (Rev. 2/21)
- Audit Requirements (Rev. 8/18)
- 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)

PART ONE

Spinal Cord Injury Research Grant

General Information

A. Information for Applicants

1. Background of Funding Source

In 1998, Pennsylvania's Attorney General along with the Attorneys General from 46 states, five territories and Commonwealths, and the District of Columbia, joined the Tobacco Master Settlement Agreement (MSA) with the five major tobacco manufacturers, which account for almost 99% of the tobacco industry's revenues. The MSA has no termination date and provides a perpetual reimbursement to states for costs incurred as a result of tobacco use. Pennsylvania's share of the MSA funds for the first 25 years of the Agreement is estimated to be approximately $11 billion. Pennsylvania is slated to receive annual payments of between $344 million and $459 million between 1999 and 2025. Pennsylvania's annual computed adjustment amount under the agreement will affect the actual amount received. Adjustments will depend upon levels of inflation and domestic sales of tobacco products.

The Commonwealth of Pennsylvania (Commonwealth) established the Spinal Cord Injury Research Grant Program (Program) in the Department through Act 126 of 2018, which was an amendment to the Tobacco Settlement Act of 2001. Act 126 directed the Department to establish a Grant program for Pennsylvania institutions conducting spinal cord injury research to focus on new and innovative treatments and rehabilitative efforts for the functional improvement of people with spinal cord injuries.

The intent of this RFA is to fund spinal cord injury research Grants with the overall objective of fostering and encouraging innovative research for treatment and rehabilitative techniques for spinal cord injuries. The Department is interested in funding three levels or tiers of spinal cord injury research:

a) Pilot Project Grants;

b) Standard Research Grants; and

c) Clinical/Translational Grant applications addressing the research priorities established by the Department in conjunction with the Spinal Cord Research Advisory Board.

Please read the entire RFA. Additional information about how to apply, relevant and specific restrictions, evaluation of applications and deliverables are noted and outlined in B. Application Procedures.

2. RFA Information

Through this RFA process, the Pennsylvania Department of Health (Department) is soliciting research applications on Spinal Cord Injury. The overall goal of this funding is to promote the functional improvement of people with spinal cord injuries.

The anticipated Grant Agreement effective date is January 1, 2024 subject to the availability of funding. The Grant Agreement term is not to exceed four years, per Section 904 of the Act (35 P.S. § 5701.904).

The Department has identified $1 million annually to fund collaborative research projects that are consistent with the spinal cord injury research priority set forth below in Section D.2., Research Priority.

Applications are welcomed from eligible applicants, as defined in Section 3, "Lead Applicant and Support" below. 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 Health Research Office at RA-HEALTHRESEARCH@pa.gov no later than 12:00 p.m. on April 19, 2023. 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 located in Pennsylvania and must be spinal cord injury research institutions within this Commonwealth that are equipped and actively conducting spinal cord injury research designated by the Secretary of Health to be eligible to receive contributions and must be (1) a nonprofit entity that conducts research, (2) a hospital that conducts research and is established under the Act of July 19, 1979 (P.L. 130, No. 48), known as the Health Care Facilities Act, or (3) an institution of higher education that conducts research. All applicants must have their primary location within Pennsylvania. Entities other than general partnerships and sole proprietorships must be registered with the Pennsylvania Department of State.

If the application involves collaboration among two or more applicants, one applicant must be designated on the application as the lead agency. The applicant must be a legal entity that will receive all Grant funds and shall be responsible for the fiscal aspects and all other aspects of this Grant. Both the applicant and collaborating institutions must have a significant and meaningful role in the proposed research project. The research role of the applicant and each collaborating institution must be clearly described in this application and demonstrate that each institution is contributing substantially to the overall project.The applicant and all collaborating organizations must be located in Pennsylvania.

Lead applicants and collaborating organizations must conduct 98 percent of the research proposed in the application at Pennsylvania-based facilities.

Subcontractors, beyond the collaborating organization(s), shall have a minor role in the research project and are not considered collaborating partners. Subcontractors may be non-Pennsylvania-based institutions which are located outside of Pennsylvania. However, if out-of-state subcontractors participate on the project team, the application must 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 must have only a minor role in the research project and 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 Grant Agreement 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 Grant Agreement 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, for a spinal cord injury research project for Tier 1: Pilot Research Grant and only one application, as a lead agency, for Tier 2: Standard Research Grant and only one application, as lead agency, for Tier 3: Clinical/Translational Research Grant. There is no limit to the number of applications in which an organization is 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 living with spinal cord injuries.

The Research project shall provide the following activities:

a) Conduct research – Design and conduct only one scientifically meritorious research project consistent with the research priority. One research project may consist of several hypothesis-driven sub-aims 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 must be closely related to each other and the overall goal. The proposal must include only studies that will be completed within the Grant Agreement period. All research applications submitted in response to this RFA must be consistent with the research priority listed in Section D.2. Research Priority of this RFA.

Collaboration is not a requirement of this RFA. If collaboration is chosen, the following is applicable:

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 commitment from collaborating organizations are required to be submitted in the application for this RFA to demonstrate this collaborative commitment.

5. Use of Funds – Limitations and Additional Requirements

Funds must be used for one or more of the following types of health research:

a) Biomedical Research - comprehensive research pertaining to the application of the natural sciences to the study and clinical practice of medicine at an institution, including biobehavioral research related to tobacco use.

b) Clinical Research - patient-oriented research which involves direct interaction and study of the mechanisms of human disease, including therapeutic interventions, clinical trials, epidemiological and behavioral studies and the development of new technology.

c) Health Services Research - includes any of the following: (1) research on the promotion and maintenance of health including biobehavioral research, (2) research on the prevention and reduction of disease, and (3) research on the delivery of health care services to reduce health risks and transfer research advances to community use.

All research projects must be consistent with the research priority listed in Section D.2. of this RFA, Research Priority. Funds must be used for one or more of the types of health research described and defined in Section D.1. of this RFA, Research Information; biomedical, clinical, and health services.

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 indirect cost rate shall not be increased at any time for the duration of the Grant Agreement.

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 Grant 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 may 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 support minority undergraduate student research training. Funds may also support minority graduate student research training and non-minority student research training.

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 funded by the 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 (CME) 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 health outcomes.

Funds shall not be used to pay for the costs of regular patient care. Funds may be used to pay for research patient care costs and are limited to no more than $250,000 for the entire Grant Agreement 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 individuals, 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 this 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. Funds allocated for a research laboratory or building construction project may not be used for personnel.

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. Personnel (technicians) to operate equipment and facilities may not be requested as part of a research facilities construction or renovation project.

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)

Funds shall 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.

Grant funds shall not be used to pay an individual at a rate in excess of the Executive Level II ($203,700/year or $97.93/hour) of the 2022 Federal Executive Schedule, in accordance with the National Institutes of Health (NIH) Guide for Grants & Funding. Grant funds shall not be used to pay an individual to manage or administer the Grant.

6. Use of Existing Health Data

Applicants are encouraged to utilize existing health data and resources. Relevant databases such as the Pennsylvania Cancer Registry, hospital discharge, outpatient and ambulatory care, and managed care data already exist. 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.

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 Agreement 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 2001-77, 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 andReporting 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 Certifications Form must be completed and signed by an official authorized to bind the applicant/organization to the application.

f) The Worker Protection and Investment Certification Form (BOP-2201) must be completed and signed by an official authorized to execute the certification on behalf of the applicant, and certify that the applicant is compliant with applicable Pennsylvania state labor and workplace safety laws.

g) 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 67-153Cover 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. (Upload in Microsoft Word format)

b) **Certifications Form** – The Certifications Form must be completed and signed by an official authorized to bind the applicant/organization to the application.

c) **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, and must certify that the applicant is compliant with applicable Pennsylvania state labor and workplace safety laws.

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)

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 Agreement period (upload in Excel format). One budget must be submitted by the lead applicant. This budget must list the costs for all subcontractors under Subcontract services. In addition, a separate budget must be completed for each subcontractor using the Excel budget spreadsheet. 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 term is January 1, 2024 – December 31, 2027. The Grant Agreement term is not to exceed four years, per Section 904 of the Act (35 P.S. § 5701.904). The budget must contain an Overall Summary in addition to a Summary with Budget Details for each year.

   See the Budget Definitions section below for more information.

f) **Certification 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 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) **Certification for the Containment of Recombinant DNA Research, and the Care and Treatment of Vertebrate Laboratory Animals** – Complete and sign the form.

   The authorized institutional official must sign this form. Grants involving recombinant DNA or laboratory animals do have to be approved or exempted from review by the applicant's

appropriate review committee prior to the submission of the application. 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 as Required by 35 P.S. § 5701.905(f):** 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 template.

3. 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). Indirect rates cannot exceed the provider's Federally approved indirect cost rate schedule. 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 Research Priority

1. Research Information

An application must include plans for conducting only one research project that shall be focused on Spinal Cord Injury Research. The research project must involve an applicant and may involve one or more collaborating organizations that cooperate to identify priorities and conduct research. The research project must provide for the sharing of infrastructure, resources and expertise. The applicant and, if applicable, collaborating organization(s), must be separate institutions. The application must describe the roles of the applicant and, if applicable, the collaborating organization(s). If collaborative, the application must also demonstrate that the collaborating partners will be playing real and substantive roles in the research project. The research project must have one common goal, and if collaborative, the collaborating organization(s) must be working together on all phases of the project instead of each collaborating organization working independently on separate phases of the research project.

All responses to this RFA must be consistent with the research priority for non-formula funded research as shown in D.2. Research Priority below.

The ultimate goal of the research should be to improve health status and access. The Department will encourage, through the application process and accountability requirements, research that:

- promotes business and community involvement,
- increases infrastructure and research capacity,
- increases the number of new investigators, new Grants, new discoveries, and new products,
- leverages new and existing research funds, and
- leads to population-based applications that address disparities in health status among various Commonwealth populations and promotes the health of all Pennsylvanians
- allows collaboration.

Institutions receiving Grants under Section 909 of Act 2001-77 shall also comply with the requirements of Section 910., *Accountability procedures* of Act 2001-77 by providing reports as required.

Only the following types of research, as defined by Act 2001-77 below, may be conducted:

a) Biomedical research - comprehensive research pertaining to the application of the natural sciences to the study and clinical practice of medicine at an institution, including biobehavioral research related to tobacco use**.**
b) Clinical research - patient-oriented research which involves direct interaction and study of the mechanisms of human disease, including therapeutic interventions, clinical trials, epidemiological and behavioral studies and the development of new technology.
c) Health services research - includes any of the following: (1) research on the promotion and maintenance of health including biobehavioral research, (2) research on the prevention and reduction of disease, (3) research on the delivery of health care services to reduce health risks and transfer research advances to community use.

If the research is a collaborative project funded by this RFA, the research will bring together established research scientists with proven records of scientific excellence to work with clinicians, non-traditional partners and other researchers, including junior faculty as members of the research team. The collaborating organization(s) will share essential facilities, services, knowledge, and other resources to conduct research designed to improve the health of Pennsylvanians.

2. Research Priority

The research priority for nonformula-funded research is **Spinal Cord Injury Research.**

All Spinal Cord Injury Research projects submitted in response to this RFA must be aligned with the following specific priorities as established by the Department in conjunction with the Spinal Cord Research Advisory Committee.

a) Pharmacologic, biologic, medical device, brain stimulus, and rehabilitative approaches and techniques.

b) Preference will be given to those projects and techniques that seek to change the nature and course of the injury.

c) To ensure funded research addresses the gap in translation of discovery to human study and proposal, further preference will be given to research that is strategically translational or translatable relative to aims and outcomes.

d) Finally, further preference will be given to research strategies that represent either potential or existing collaboration with industry, whether in the development and trial of biologics, pharmacologics, device, or novel therapeutic rehabilitative treatments in combination with these developments.

This RFA provides three funding options aligned to the research priority described above. Each of the three Tiers of funding, which are described below, will have specific maximum allowable budget requests, project requirements and a maximum allowable Grant Agreement period:

Tier 1: Pilot Research Grant:

- Maximum Budget Request: $100,000.
- Project Requirements: This tier will fund applications that propose early research investment aligned with the research priority as the institution applicant prepares to seek a larger research Grant from a Federal program or non-profit organization. Preliminary data is not required for this Tier.

- Grant Agreement Period: January 1, 2024 to December 31, 2027

Tier 2: Standard Research Grant:

- Maximum Budget Request: $150,000.
- Project Requirements: This tier will primarily fund applications for research aligned with the research priority which include supporting and preliminary data for the research proposed. This Tier may also fund pilot research (with no preliminary or supporting detail) if the application justifies the budget for pilot research. Institution applicants are encouraged to attach research papers; in-press, pre-published drafts, and accepted research papers may be cited or submitted separately as an attachment to the application.
- Grant Agreement Period: January 1, 2024 to December 31, 2027

Tier 3: Clinical/Translational Research Grant:

- Maximum Budget Request: $250,000
- Project Requirements: This tier will fund applications which have a concurrent application to, or funding from, Federal or industry sources for projects aligned with the research priority. Preliminary data must be published or in press in a scientific journal and cited or submitted separately as an attachment to the application.
- Grant Agreement Period: January 1, 2024 to December 31, 2027

The funds are awarded based on the tier level identified. The Department's decision on the tier level funding is final.

Research priority shall include the identification of critical research areas, disparities in health status among various Commonwealth populations, expected research outcomes and benefits and disease prevention and treatment methodologies.

Funds must be used for one or more of the types of health research described and defined in Section D.1. of this RFA, Research Information; biomedical, clinical, and health services. Any combination of these research types may be included in an application.
At least 50% of the funds requested must be used for clinical research or health services research or both clinical research and health services research.

PART TWO

Pennsylvania Department of Health
Health Research Office

Spinal Cord Injury Research Grant

Request for Applications (RFA) #67-153

pennsylvania
DEPARTMENT OF HEALTH

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)	

RFA# 67-153
Attachment V

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 (IRB)

Visit IRB (pa.gov) for a current IRB Application.

RFA# **67-153**
Attachment X

Letter of Intent

Pennsylvania Department of Health **Letter of Intent to Submit an Application for Spinal Cord Injury Research Grant** *In Response to* **RFA 67-153**	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**:

Focus of the Research Project *(check one category):* Spinal Cord Injury Research:

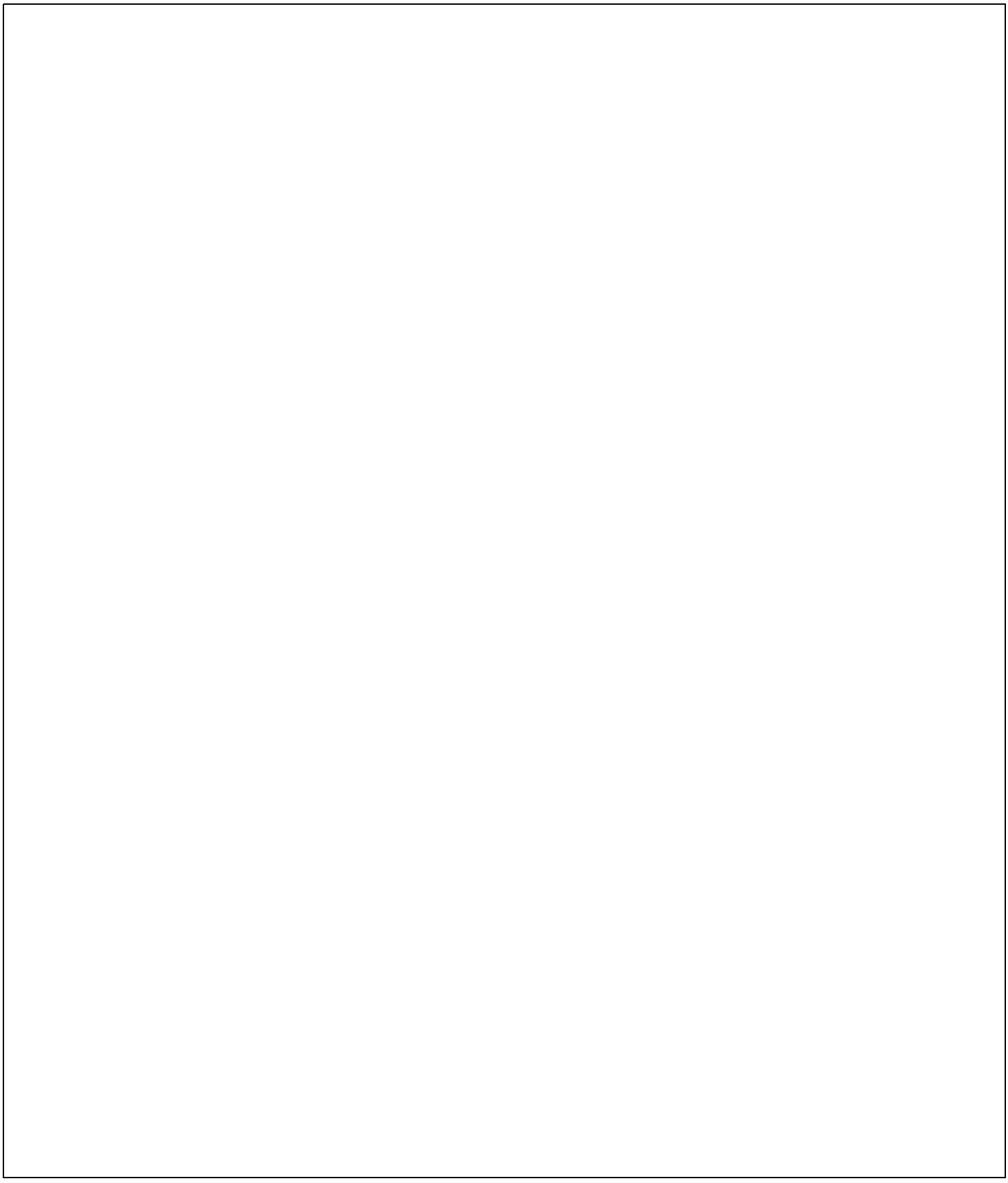
☐ *Tier 1: Pilot Research Grant*

☐ *Tier 2: Standard Research Grant*

☐ *Tier 3: Clinical/ Translational Research Grant*

Title of the Research Project (*no more than 81 characters including spaces and punctuation*):

Research Project Description (*not to exceed 2 pages*)



RFA # 67-153
Attachment XI

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.**

3. 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		

Non-formula Grant Report of Expenditures by Type of Research

Non-formula Grant Requirement:
At least 50 percent of each Grant's funds must be spent on clinical and/or health services research as defined in Act 2001-77; no more than 50 percent of each Grant's funds may be spent on biomedical research, as defined in Act 2001-77.

Act 2001-77 Definitions:
Biomedical research - comprehensive research pertaining to the application of the natural sciences to the study and clinical practice of medicine at an institution, including biobehavioral research related to tobacco use.
Clinical research – patient-oriented research which involves direct interaction and study of the mechanisms of human disease, including therapeutic interventions, clinical trials, epidemiological and behavioral studies and the development of new technology.
Health services research - includes any of the following: (1) research on the promotion and maintenance of health including biobehavioral research, (2) research on the prevention and reduction of disease, (3) research on the delivery of health care services to reduce health risks and transfer research advances to community use.

Institution:

SAP Document #:

SAP Vendor #:

1. **Total costs: $_____**
   This amount will be equal to the total of the "Expenditures to Date" column on the *Annual Expenditure Report*.

2. **Provide a breakdown of costs by two categories of expenditure: (A) biomedical and (B) clinical and/or health services research.**

	CATEGORIES	EXPENDITURES TO DATE
A	Biomedical Research Costs	
B	Clinical Research and/or Health Services Research Costs	
	TOTAL COSTS	

RFA # 67-153

PAYMENT PROVISIONS

The Department agrees to pay the Contractor 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 Contract, the Department will pay the Contractor in accordance with Appendix C, and any subsequent amendments thereto, for the costs incurred in providing the services described in this Contract.

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

a. Investment Requirements:

The Contractor 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 Contractor 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 Contractor that is not in accordance with the terms of this Contract. The Contractor shall reimburse the Commonwealth for any disapproved expenditure.

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

   The report shall show the Contract's SAP number, 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 Contractor by the termination date of the Contract, unless a no cost extension is granted pursuant to the terms of this Contract. Any unspent funds at the end of the Contract, including interest earned but not expended on the services pertaining to the project funded by this Contract, shall be returned to the Commonwealth within 45 days of the Contract'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 Contractor shall also provide a breakdown of the funds being returned and shall include the Contract'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 & Welfare Building,
   625 Forster Street, Harrisburg, PA 17120-0701

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

         B. The Contractor 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 Contract.

         C. Reallocations at or exceeding 20% of the total amount of the Contract 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 Contractor shall notify the Department's Project Officer of any Budget Revision under 20% of the total amount of the Contract in writing, but need not request Department approval, except as provided for in Paragraph 5(a)(i)(B) above.

      (iii) The Contractor 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 Contractor 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 Contractor 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 Contractor is subject to a collective bargaining agreement or other union agreement and, during the term of this Contract, salaries, hourly wages, or fringe benefits under this Contract are increased because of a renegotiation of that collective bargaining agreement or other union agreement. The Contractor 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 Contractor is unable to fill a position that is vacant or becomes vacant at or after the effective date of this Contract. The Contractor 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 Contract, as well as the Contractor'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 Contractor is unable to perform the work of the Contract with the existing positions, titles or classifications of staff. The Contractor may add or change a position, title or classification in order to perform work that is already required. The Contractor 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 Contractor'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 Contract. 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 Contractor may pay beyond the cap with non-Grant funds.

6. The Commonwealth will make payments through the Automated Clearing House (ACH). Within 10 days of award of the Contract or Purchase Order, the Contractor must submit or must have already submitted its ACH information within its user profile in the Commonwealth's procurement system (SRM). Within 10 days of the Grant award, the Grantee must submit or must have already established its ACH information in the Commonwealth's Master Database. The Grantee will also be able to enroll to receive remittance information via electronic addenda and email (e-Remittance). ACH and e-Remittance information is available at https://www.budget.pa.gov/Services/ForVendors/Pages/Direct-Deposit-and-e-Remittance.aspx.

a. The Contractor must submit a unique invoice number with each invoice submitted. The unique invoice number will be listed on the Commonwealth of Pennsylvania's ACH remittance advice to enable the Contractor to properly apply the state agency's payment to the invoice submitted (for Contracts or Purchase Orders) or to the invoice or program (for Grant Agreements).

b. It is the responsibility of the Contractor to ensure that the ACH information contained in SRM (for Contracts or Purchase Orders) or in the Commonwealth's Master Database (for Grant Agreements) 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. Section 12 RECORDS RETENTION REQUIREMENTS of the Standard General Terms and Conditions (Rev. 2/21) is hereby deleted in its entirety and replaced with the following:

RECORD RETENTION REQUIREMENTS

All records kept pursuant to Paragraph 11 shall be retained pursuant to the provisions of this Paragraph 12.

A. The Contractor 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 Contractor 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 Contractor 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 Contractor 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 Contractor 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. Section 15 PROGRAM CHANGES of the Standard General Terms and Conditions (Rev. 2/21) is hereby deleted in its entirety and replaced with the following:

PROGRAM CHANGES

The Project Officer may, by written order, make changes to the Grant Agreement provided such changes are consistent with the research priorities and that the requirements for human subjects protections, recombinant DNA 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 DNA 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 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 Project Officer, 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.

IV. Section 17 KEY PERSONNEL of the Standard General Terms and Conditions (Rev. 2/21) is hereby deleted in its entirety.

V. Section 18 INSPECTION AND ACCEPTANCE of the Standard General Terms and Conditions (Rev. 2/21) is hereby deleted in its entirety.

VI. Section 20 OWNERSHIP RIGHTS of the Standard General Terms and Conditions (Rev. 2/21) 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 Contractor, 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."

VII. Section 24 COLLECTION OR RECORDING OF INFORMATION of the Standard General Terms and Conditions (Rev. 2/21) is hereby deleted in its entirety.

VIII. Section 37 DISPOSITION OF EQUIPMENT AND OTHER MATERIAL paragraphs B through G of the Standard General Terms and Conditions (Rev. 2/21) is hereby deleted in its entirety.

IX. ADDITIONAL AUDIT REQUIREMENTS

This Agreement is subject to audit in accordance with the Audit Requirements (Rev. 8/18) incorporated by reference in 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 contractor shall have an audit performed when it expends $500,000 or more of state funds received under this contract within the 13-month period immediately following the effective date of the contract or when it expends $500,000 or more of state funds received under this contract 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 contract or any successive period is for a period of less than 12 months, but the contract amount expended by the contractor during said period includes $500,000 or more of state funds, the contractor is also required to have an audit performed for the entire contract 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.

Contractor 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 a contract lasting more than 12 months. There will be no exceptions to the 180 calendar days. The contractor 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

X. 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 strategic research plans 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 Contractor Integrity Provisions as specified in the Standard General Terms and Conditions (Rev. 2/21).

XI. 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 Non-formula funds and will result in a reduction in Formula 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 CURE website with a notice that the Grantee failed to submit a response to the final performance review.

XII. 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 Formula Grant awards may be offset by damages owed as a result of material breaches in prior Health Research Formula Grants.