pennsylvania
DEPARTMENT OF HEALTH

August 28, 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) #67-157.

All questions regarding this RFA must be directed by e-mail to RA-HEALTHRESEARCH@pa.gov, no later than 12:00 p.m. on September 15, 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 **October 15, 2023**. 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 #67-157" 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 **December 1, 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: 2023.08.28 13:23:08 -04'00'

Office of Procurement
For Agency Head

Enclosure

Request for Application

Support for Immune Cell Therapy, Stem Cell Therapy and Gene Editing Technology Development

RFA Number
67-157
Date of Issuance
August 28, 2023

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

RFA Project Officer: Pamela Brown
Pennsylvania Department of Health
Health Research Office
Email: RA-HEALTHRESEARCH@pa.gov

Support for Immune Cell Therapy, Stem Cell Therapy and Gene Editing Technology Development

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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)
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- Pro-Children Act of 1994 (Rev. 12/05)

PART ONE

Support for Immune Cell Therapy, Stem Cell Therapy and Gene Editing Technology Development

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. Annual computed adjustments to the amount Pennsylvania are to receive under the Agreement will affect the actual amount received. Adjustments will depend upon levels of inflation and domestic sales of tobacco products.

Pennsylvania positioned itself as a national leader by limiting the use of the tobacco settlement funds to initiatives designed to improve the health status of its citizens. The following five principles were developed to guide Pennsylvania's use of the tobacco settlement funds:

a) Make Pennsylvanians healthier.
b) Set aside a portion of the funds so that future generations of Pennsylvanians can benefit from the settlement.
c) Direct the settlement funds to programs and initiatives that can easily be adjusted given the likely fluctuation in payment amounts.
d) Focus on fulfilling or enhancing state government's existing service areas before creating new ones.
e) Focus on initiatives that do not require the significant growth or expansion of government bureaucracies.

Citizen and health advocacy group input received through public hearings and stakeholder meetings was analyzed for consistency with the guiding principles and influenced the establishment of the Health Investment Plan priorities and funding allocation percentages. Of the total amount, a portion is being used for broad-based health research to fund health-related research applications from institutions located in Pennsylvania.

For this RFA, funds will be awarded to applicants located within the Commonwealth of Pennsylvania (Commonwealth). By supporting Pennsylvania-based researchers with tobacco settlement funds, the Pennsylvania Department of Health's (Department) intent is to help attract additional research funds from other sources and to achieve health and economic goals that existing revenues could not underwrite.

Pennsylvania's use of tobacco settlement funds to support broad-based health research in Pennsylvania helps direct research efforts to state-defined health research objectives that improve the health of all Pennsylvanians.

This RFA is subject to applicable sections of the Tobacco Settlement Act, 35 P.S. §§ 5701.901 – 5701.910, Act 2001-77 (Act) and the 2021-2022 and 2022-2023 Pennsylvania Fiscal Code, Act 2022-54, Section 1713-A.1.

Funds for COVID-Public Health Biotechnology Research, Fiscal Code – Omnibus Amendments and Related Repeals act of July 11, 2022 (P.L. 540, No. 54) No. 2022-54; particularly Section 8. Section 151-C. Biotechnology research in the amount of $5 million will be incorporated into this Request for Applications (RFA) as a distinct appropriation for the research priority entitled "Support for Immune Cell Therapy, Stem Cell Therapy and Gene Editing Technology Development," which is described below in Section D.2. Research Priority.

2. RFA Information

Through this RFA process, the Pennsylvania Department of Health (Department) is soliciting research applications on Support for Immune ell Therapy, Stem ell Therapy and Gene Editing Technology Development. The overall goal of this funding is to promote the health of all Pennsylvanians. The anticipated Grant Agreement effective date is June 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 between $7 and $8 million to fund collaborative research projects that are consistent with the research priority set forth below in Section D.2. , Research Priority. The Department expects to award one to two Grant Agreements. Each award shall not exceed $5 million.

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 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 ommonwealth 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 or locally at 717-346-2676. 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 the ommonwealth and must be engaging in biotechnology research and must be (1) a "person", or (2) a nonprofit entity that conducts research, or (3) a hospital that conducts research and is established under the Act of July 19, 1979 (P.L. 130, No. 48), known as the Health are Facilities Act, or (4) an institution of higher education that conducts research, or (5) an entity established under the Act of August 24, 1951 (P.L. 1304, No. 315), known as the Local Health Administration Law. A "person" includes a corporation, partnership, limited liability company, business trust, other association, governmental entity (other than the ommonwealth), estate, trust, foundation or natural person. For-profit organizations including small businesses are encouraged to apply as lead applicants or collaborating organizations. All applicants must have their primary location within Pennsylvania. Entities other than general partnerships and sole proprietorships must be registered with the Department of State.

Although one applicant must be designated on the application as the lead agency, the collaborative research project must consist of at least two organizations that have joined together for the purpose of this RFA to conduct research on the research priority listed in Section D.2. Research Priority of this RFA. The applicant and collaborating organizations must be separate institutions. 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 must be a legal entity that will receive all Grant Agreement funds and shall be responsible for the fiscal aspects and all other aspects of the Grant Agreement. 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 in response to this RFA. There is no limit to the number of applications in which an organization is listed as a collaborating organization.

Collaboration with a minority-serving academic institution or minority-serving community-based organization in Pennsylvania is strongly encouraged, and should include the mentoring and training of students, fellows and junior faculty. Pennsylvania's minority-serving academic institutions are Cheyney University of Pennsylvania and Lincoln University. A minority-serving community-based organization is an organization whose mission is to provide service to minority groups. The application should describe the mission of the minority-serving community-based organization and the racial and ethnic composition of the persons that it serves.

4. Requirements of the Collaborative Research Project

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.

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 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.

b) Foster collaborative research – Facilitate collaboration among multiple disciplines and involve multiple partners and organizations relevant to the research project goals, as demonstrated by letters of commitment from the organizations. The focus of the application must be the design of scientifically meritorious research that will lead to improving the health of Pennsylvanians.

c) Train minority students – All research projects applied for in this RFA must include the involvement of minority undergraduate college students in the research project through the inclusion of a minority research training program for racial and ethnic student populations that are underrepresented in biomedical, health services and clinical research, such as African Americans and Hispanics. Physically disabled persons, women and medically underserved populations are not considered minorities.

- The minority research training program must include, at a minimum undergraduate summer internships or academic semester internships or both. (A graduate student training program for underrepresented minority students is encouraged, but not required.)
- Undergraduate students must be involved in some aspect of the research project through the training program, such as data collection or analysis, and should receive training and mentoring as part of their involvement in the research project. The application must describe a substantive and meaningful role for these students in the actual conduct of the research project.
- The training program for the minority students shall begin no later than September 1, 2024. A minimum of eight undergraduate minority students or, a minimum of four undergraduate minority students and a minimum of four graduate minority students must receive training by the end of the Grant Agreement period.
- Requirements for undergraduate student summer internships or academic semester internships or both are: Summer internships shall provide stipends for undergraduate-level minority students to receive research training, mentoring and involvement in some aspect of the research project such as data collection or analysis. Academic semester internships shall provide research stipends, tuition or course credit, or any combination of these benefits to undergraduate minority students for training, mentoring and involvement in some aspect of the research project during the academic year.
- Although not required, should a minority graduate student training be included in the research project and supported with Grant Agreement funding, it must include some or all of the following: research stipends, tuition, course credit for graduate-level minority students to receive training, mentoring, or involvement in some aspect of the research project during the academic year or the summer. Medical students are considered graduate students for the purpose of this RFA. A post-baccalaureate program designed to prepare students for biomedical research training programs is considered to be a graduate student training program.
- These requirements shall be achieved only by one or more of the following approaches: (1) collaborating with Pennsylvania's Historically Black Colleges and Universities (HBCU), which are Cheyney University and Lincoln University, to develop a minority research program, or (2) developing a minority research program at the applicant's institution, or (3) expanding an existing minority research program at the applicant's institution. The minority research training program at the HBCU may develop research capacity at the HBCU through investments in new technology or research equipment that students and faculty at the HBCU may use for research training or mentoring or both and carrying out components of the research project. Junior faculty at the HBCU shall receive training and mentoring, as needed, from the

applicant to conduct research or train students or both of these activities. The minority research training program shall be evaluated to assess impact of the program on the participating students' academic and non-academic career choices.

5. Use of Funds – Limitations and Additional Requirements

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.

At least 50 percent of the funds requested in the application must be used for clinical research or health services research or both clinical research and health services research as defined in the Act; no more than 50 percent of each grant's funds may be spent on biomedical research, as defined in the Act. Activities that are not biomedical, clinical, or health services research as defined by the Act 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 may support personnel and services directly related to the research project and may be used to purchase computer hardware and software.

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 pay costs incurred prior to the effective date of the Grant Agreement.

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

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 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 $400,000 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 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 must 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)

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 Grant Agreement.

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 ($212,100 /year or $101.97 /hour) of the 2023 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.

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 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 awarded applicant 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 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 and Reporting Requirements

See Section XXIV of Research Proposal , which is Attachment III 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 must 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 IX 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 for the Protection of Human Subjects and Regarding the Use of Human Embryonic Stem Cell Research Form and Certifications for the Containment of Research Involving Recombinant or Synthetic Nucleic Acid Molecules (r/sNA) and the Care and Treatment of Vertebrate Laboratory Animals 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 67-144 Cover Page Applicant Name, I. 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 and must certify that the applicant is compliant with applicable Pennsylvania state labor and workplace safety laws.

c) **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)

d) **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). 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 effective date is June 1, 2024. 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 shown for the full time period in the Budget Details, Year 1 tab of the downloadable excel budget file.

   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 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** – Complete and sign the form.

The authorized institutional official must sign this form. Grants involving recombinant DNA 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. 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 Support for Immune Cell Therapy, Stem Cell Therapy and Gene Editing Technology Development. The collaborative research project must involve an applicant and one or more collaborating organizations that cooperate to identify priorities and conduct research. The collaborative research project must provide for the sharing of infrastructure, resources and expertise. The applicant and collaborating organizations must be separate institutions. The application must describe the roles of the applicant and the collaborating organizations and demonstrate that the collaborating partners will be playing real and substantive roles in the research project. The research project must have one common goal, with the collaborating organizations working together on all phases of the project instead of each collaborating organization working independently on separate phases of the research project.

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.

The collaborative research project funded by this RFA 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. Collaboration among and between universities or academic medical centers, in association with businesses, health care providers, public agencies, smaller colleges and universities and other institutions or organizations that are not academic medical centers is encouraged. The collaborating organizations will share essential facilities, services, knowledge, and other resources to conduct research designed to improve the health of Pennsylvanians.

In recent years, there have been enormous advances in research facilities. This RFA provides support for research and research infrastructure to keep Pennsylvania research institutions in the forefront of these advances.

The specific objectives are:

a) To assist in the elimination or reduction of disparities in health status, outcome, prevention, or treatment.
b) To promote competitive research development and technology transfer in health sciences that are important to Pennsylvania.
c) To foster interdisciplinary research by teams of scientists and others.
d) To promote collaborative efforts among academic, business, advocacy, and public health institutions.
e) To provide a catalyst for funding from philanthropic, Federal, and other non-state government sources.
f) To provide flexibility to foster atypical teams who may not usually seek to affiliate for research.

All applications submitted in response to this RFA must identify and address disparities in health status, outcome, prevention, or treatment, and should relate to a national health objective (that is, Healthy People 2030).

All research projects must be consistent with the research priority established by the Department of Health in conjunction with the Health Research Advisory Committee. 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.

The following guiding principles were adopted by Health Research Advisory Committee on December 3, 2003, for use in establishing the research priorities. The research priority shall:

a) Address a health-related issue that has significant impact on the health of Pennsylvanians;
b) Place emphasis on a health-related issue that disproportionately affects vulnerable segments of the population;
c) Be inclusive of all populations that are at high risk for the health-related issue;
d) Focus on studies with the potential for prevention and control including the identification of risks and etiology for the health-related issue; and,
e) Promote collaboration among Pennsylvania institutions including smaller colleges and universities and other non-academic medical centers as well as major research institutions.

2. Research Priority

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

State Fiscal Year 2021-22 Priority for 25 Percent of Nonformula Funded Research, Chapter 9, Act

2001-77 and for State Fiscal Year 2022 COVID-Public Health Biotechnology Research, Fiscal Code – Omnibus Amendments and Related Repeals act of July 11, 2022 (P.L. 540, No. 54) No. 2022-54; Section 8. Section 151-C.

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. At least 50 percent of each Grant's funds must be spent on clinical or health services research or both 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. Activities that are not biomedical, clinical, or health services research as defined by Act 2001-77 will not be considered. The research priority for nonformula-funded research is:

Support for Immune Cell Therapy, Stem Cell Therapy and Gene Editing Technology Development

Immune cell therapies and stem cell products are two of the most rapidly developing areas of biotechnology. Immune cell engineering seeks innovative solutions to major remaining challenges, such as limitations in target antigen selection, the hostility of the tumor microenvironment and the logistical challenges of generating autologous therapies. Next generation adoptive cell therapies such as dynamic synthetic antigen receptors, combinations of multiple transgenes, or coupling gene-editing technologies to delete critical genes are under development as cellular therapies based on immune cells, hematopoietic stem cells (HSC) and induced pluripotent stem cells (iPSC). Engineered immune cells have had their most significant clinical impact in cancer treatment but other applications being explored include infectious disease and regenerative medicine. The number of stem cell therapeutic clinical trials has grown exponentially over last decade and while a small number were successful, many of the trials were inconclusive or even detrimental to patients. These conflicting results indicate both the tremendous potential of these technologies and the need for continued research and development into design, production and clinical delivery of stem cell products.

The purpose of this RFA is to support university biotechnology research institutions in the Commonwealth of Pennsylvania for the purchase and implementation of equipment and instrumentation that would build the capability to address key challenges in developing and delivering advanced cell therapeutics. This may include equipment and other infrastructure to support: bio banking, design, gene editing, cell purification, characterization/quality control and advanced imaging systems to support research and the use of cell-lines as allowable within Pennsylvania and Federal regulations. Such applications include but are not limited to pharmacokinetics and dynamics studies, cell therapy research, flow cytometry systems for product analysis, bioprinters, in vivo imaging systems, FMRI systems, and other related instrumentation. This type of instrumentation could be aggregated with existing resources to provide, hands on undergraduate and graduate student training in upstream and downstream bioprocess through lab courses, internships, summer bootcamp or workshops and short courses with hands-on training in mammalian cell culture and downstream processing for participants from industry and regional academic partner institutions.

This type of infrastructure could also expand capabilities to support collaborative research with industry partners, allowing universities and their company partners to develop and implement cell therapy processes and optimize and scale-up process development in an integrated upstream and downstream facility using state-of-the-art equipment.

The fully developed proposal will include partnerships with other Commonwealth institutions, including those that serve historically underrepresented minorities in higher education. These partnerships could provide collaborating programs access to the research infrastructure and facilitate collaborative research project development in immune cell therapies and regenerative medicine. It will also provide complimentary training opportunities, including hands-on laboratories and remote distance learning for partnering undergraduate and graduate programs.

PART TWO

Pennsylvania Department of Health
Health Research Office

Support for Immune Cell Therapy, Stem Cell Therapy and Gene Editing Technology Development

Request for Applications (RFA) #67-157

pennsylvania
DEPARTMENT OF HEALTH

COVER PAGE
Support for Immune Cell Therapy, Stem Cell Therapy and Gene Editing Technology Development

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: June 1, 2024**

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 Non-formula Grant

1. FUNDS REQUESTED FOR CLINICAL AND HEALTH SERVICES RESEARCH: _____ **(*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. The amount must be consistent with the Research Proposal, Item III*)**	
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)	

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 aims and subaims. 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. 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
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)
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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 25 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 as explained in Item XXIV.** 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 #
6/1/24 - 6/30/24	
7/1/24 - 6/30/25	
7/1/25 - 6/30/26	
7/1/26 – 6/30/27	
7/1/27 – 5/31/28	

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 Biomedical, Clinical and Health Services Research - Using the following format and example, provide a breakdown by specific aim of expenditures for the entire project. For each specific aim, specify the costs by type of research (biomedical, clinical or health services research) to be conducted. **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. See definitions of biomedical, clinical and health services research in Section D, Research Information and Research Priority of the RFA. Patient oriented (clinical) research is research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator or colleague directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual and studies on animals.

Specific aims	Total cost to complete the aim	Cost of biomedical research to complete the aim	Cost of clinical research to complete the aim	Cost of health services research to complete the aim
Specific aim 1 (one study – 100% biomedical)	$100,000	$100,000	0	0
Specific aim 2, study/subaim 1 (100% health services research)	$100,000	0	0	$100,000
Specific aim 2, study/subaim 2 (50% health services, 50% clinical)	$100,000	0	$50,000	$50,000
Specific aim 3 (one study – 100% health services)	$600,000	0	0	$600,000
Specific aim 4, minority training program (half students involved in health services research, half students involved in clinical research study)	$100,000	0	$50,000	$50,000
Total budget	$1,000,000	$100,000	$100,000	$800,000
Percent of total budget	100%	10%	10%	80%

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 four 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 four 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 VII) 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 VII) 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 DNA? ☐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)

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

- **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.

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 Commonwealth Universal Research Enhancement (CURE) website in November as part of the Annual Report to the Legislature.

2. A written Interim Progress Report is due 12-15 months after the Grant Agreement effective date. The awarded applicant shall present their progress to a peer review panel. The interim report shall, at a minimum, identify if activities are proceeding according to the project plan, and explain any deviations from the project plan. Any changes to the scope of research during the term of the Grant Agreement must be approved in writing by the Department. The awarded applicant shall submit a written response to the interim performance review report within 30 calendar days after the Department provides a copy of the report.

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 applicantI f 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 X of the RFA.

An applicant that receives a health research Grant under the Tobacco Settlement Act 2001-77, 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 requirements specified by Act 2001-77 and criteria developed by the Department in consultation with the Health Research Advisory Committee.

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 awarded 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 CURE website approximately 12-16 months after the end of the Grant.

The 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.

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.

LETTERS OF SUPPORT

Letters of support from subcontractors and consultants are inserted after this page.

RFA 67-157 (DOH will change this to Appendix C, if awarded)

BUDGET SUMMARY

(Insert Vendor Name)
(DOH will insert SAP #, if awarded)
(Insert Budget Period)

CATEGORIES	Original Budget	Amendment Type & Number	Total Budget
I. PERSONNEL SERVICES	-	-	-
II. CONSULTANT SERVICES	-	-	-
III. SUBCONTRACT SERVICES	-	-	-
IV. PATIENT SERVICES	-	-	-
V. EQUIPMENT	-	-	-
VI. SUPPLIES	-	-	-
VII. TRAVEL	-	-	-
VIII. OTHER COSTS / LABORATORY OR BUILDING CONSTRUCTION OR RENOVATION	-	-	-
TOTAL	-	-	-

RFA 67-157 (DOH will change this to Appendix C, if awarded)
(Insert Vendor Name)
(DOH will insert SAP #, if awarded)
(Insert Budget Period)

Categories			Original Budget Infrastructure	Original Budget Non-Infrastructure	Amendment Type & Number Infrastructure	Amendment Type & Number Non-Infrastructure	Total Budget
I. PERSONNEL SERVICES (Infrastructure is clerical, secretarial and administrative assistants positions. Non-Infrastructure is all other positions. See budget instructions tab.)							
A. Staff Personnel	Hourly Rate	Number of Hours					
							-
							-
							-
							-
							-
							-
							-
							-
							-
							-
							-
							-
							-
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							-
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							-
							-
							-
		Sub-Total	-	-	-	-	-

RFA 67-157 (DOH will change this to Appendix C, if awarded)
(Insert Vendor Name)
(DOH will insert SAP #, if awarded)
(Insert Budget Period)

Categories			Original Budget Infrastructure	Original Budget Non-Infrastructure	Amendment Type & Number Infrastructure	Amendment Type & Number Non-Infrastructure	Total Budget
B. Fringe Benefits							
	Salary	Rate					
	-						-
	-						-
	-						-
	-						-
	-						-
	-						-
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	-						-
	-						-
Specify the benefits included in this rate:							
		Sub-Total	-	-	-	-	-
		Total	-	-	-	-	-

RFA 67-157 (DOH will change this to Appendix C, if awarded)
(Insert Vendor Name)
(DOH will insert SAP #, if awarded)
(Insert Budget Period)

Categories			Original Budget Infrastructure	Original Budget Non-Infrastructure	Amendment Type & Number Infrastructure	Amendment Type & Number Non-Infrastructure	Total Budget
II. CONSULTANT SERVICES (see budget instructions tab)							
Consultants	Hourly Rate	Number of Hours					
							-
							-
							-
							-
							-
							-
							-
							-
							-
							-
							-
							-
							-
							-
		Total	-	-	-	-	-
III. SUBCONTRACT SERVICES (see budget instructions tab)							
							-
							-
							-
							-
							-
							-
							-
							-
							-
							-
							-
							-
		Total	-	-	-	-	-

RFA 67-157 (DOH will change this to Appendix C, if awarded)
(Insert Vendor Name)
(DOH will insert SAP #, if awarded)
(Insert Budget Period)

Categories	Original Budget Infrastructure	Original Budget Non-Infrastructure	Amendment Type & Number Infrastructure	Amendment Type & Number Non-Infrastructure	Total Budget
IV. PATIENT SERVICES (Non-Infrastructure only. See budget instructions tab.)					
					-
					-
					-
					-
					-
					-
					-
					-
					-
					-
					-
					-
					-
					-
					-
					-
Total	-	-	-	-	-

V. EQUIPMENT (Infrastructure is office equipment. Non-Infrastructure is non-office equipment such as computers & software. See budget instructions tab.)

	Quantity	Unit Cost				
						-
						-
						-
						-
						-
						-
						-
						-
						-
						-
						-
Total			-	-	-	-

RFA 67-157 (DOH will change this to Appendix C, if awarded)
(Insert Vendor Name)
(DOH will insert SAP #, if awarded)
(Insert Budget Period)

Categories	Original Budget Infrastructure	Original Budget Non-Infrastructure	Amendment Type & Number Infrastructure	Amendment Type & Number Non-Infrastructure	Total Budget
VI. SUPPLIES (Infrastructure is office Supplies such as computers & facsimile machines. Non-Infrastructure is supplies to conduct research. See budget instructions tab.)					
					-
					-
					-
					-
					-
					-
					-
					-
					-
					-
					-
					-
Total	-	-	-	-	-
VII. TRAVEL (Non-Infrastructure only. See budget instructions tab.)					
Cost					-
					-
					-
					-
					-
					-
					-
					-
					-
					-
					-
					-
					-
					-
					-
					-
Total	-	-	-	-	-

RFA 67-157 (DOH will change this to Appendix C, if awarded)
(Insert Vendor Name)
(DOH will insert SAP #, if awarded)
(Insert Budget Period)

Categories	Original Budget Infrastructure	Original Budget Non-Infrastructure	Amendment Type & Number Infrastructure	Amendment Type & Number Non-Infrastructure	Total Budget
VIII. OTHER COSTS / LABORATORY OR BUILDING CONSTRUCTION OR RENOVATION (See budget instructions tab)					
					-
					-
					-
					-
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					-
					-
					-
					-
					-
					-
Total	-	-	-	-	-
TOTAL	-	-	-	-	-

Budget Instructions

General Instructions

- Please copy this file to your hard drive before making any edits. **Do not make any changes to this template.**
- Complete only highlighted areas. All other areas are formula driven and are template protected. Data should only be entered on the "Budget Details" tab. For Base Agreements the Budget Details tab and Summary tab should be used.
- **Rows should not be deleted** (even if a particular category is not being used). If additional rows are needed, please contact the DOH Project Officer.
- Additional columns are available for amendments.
- **This template can also be used for amendments.** When preparing an amendment, start with the original budget information already completed and add the amendment changes within the budget category, directly below the original information. Please indicate the Amendment Type and Number in the appropriate column heading and update the Appendix C reference to indicate the amendment number. **For amendments, the Budget Details and accompanying Budget Summary should be used for submission.**
- **IMPORTANT:** Use "Infrastructure" columns for recording infrastructure budget items and use "Non-infrastructure" columns for recording non-infrastructure budget items. These broken out amounts must equal the "Total Budget" per line, otherwise an ERROR message will reflect. All budget items, except indirect costs, must be considered either infrastructure or non-infrastructure. Indirect costs may include both infrastructure and non-infrastructure costs. Infrastructure costs are defined by law to include only office equipment, office supplies, nonprofessional personnel, and laboratory or building construction or renovations used to conduct research. Secretaries, administrative assistants and clerical personnel are nonprofessional personnel and should be recorded in the infrastructure column. All other personnel are considered to be professional personnel and therefore are non-infrastructure. This budget must be completed by the lead applicant with costs for all subcontractors listed under budget category "III - Subcontract Services."
- Please refer to the additional instructions contained in Part One of the RFA when completing the budget.

Budget Details - I.A. Personnel Services

- Complete all highlighted areas.
- Identify each position by research role on the project to be funded, the hourly rate and number of hours. Do not list personnel names. This calculation will automatically appear under Total Budget. Insert Project Number, if applicable.
- Column A - Starting with the principal investigator, list the position and role on the project of the applicant organization's employees who will be funded by the grant, as well as the project number for each position. Do not include employees of other institutions here; list them in the appropriate subcontractor budget or on the consultant worksheet. Exclude anyone whose salary is NOT funded by the grant, e.g., if the PI's salary is not paid with grant funds, do not list them.
- Complete the costs associated to either the Original Budget or to an Amendment, as applicable. The amount must equal the "Total Budget", otherwise an ERROR message will reflect on the Summary Page.
- Once all personnel costs are completed under Staff Personnel, each staff identified and their full project costs will also automatically appear under Fringe Benefits. Complete the benefit rate for each staff identified. The Total Budget will automatically calculate.
- Identify the fringe rate and specific benefits included in the rate.

Budget Details - II Consultants Services

- List the services to be provided, the hourly rate and number of hours. Do not name the consultant(s) that will be retained. This calculation will automatically appear under Total Budget.
- Complete the costs associated to the Original Budget or to an Amendment, as applicable. The amount must equal the "Total Budget", otherwise an ERROR message will reflect on the Summary Page.

Budget Details - III SubContract Services

- Identify services to be provided. Do not name subcontractor that will be retained.
- Complete costs associated to the Original Budget or Amendment. The Total Budget costs will automatically calculate.

Budget Details - IV Patient Services

- Identify servicesand number of patients to be served under the non-infrastructure column.
- Complete costs associated to the Original Budget or Amendment. The Total Budget costs will automatically calculate.

Budget Details - V Equipment

- Identify equipment, the quantity and unit cost. (Use this category for equipment that is $5,000/unit or greater.) This calculation will automatically appear under Total Budget.
- Complete the costs associated to the Original Budget or to an Amendment, as applicable. The amount must equal the "Total Budget", otherwise an ERROR message will reflect on the Summary Page.

Budget Details - VI Supplies

- Identify supplies (in general terms). Equipment items under $5000 unit cost should be listed here
- Complete costs associated to the Original Budget or Amendment. The Total Budget costs will automatically calculate.

Budget Details - VII Travel

- Identify travel cost by event and show the breakdown for that event to show amounts by Mileage, Lodging, Airfare, Subsistence, Parking/Tolls, and Ground Transportation using the approved rates at https://www.gsa.gov/travel-resources. See example below.

VII. TRAVEL			
Philadelphia Conference	Cost	200.00	200.00
-Lodging	150.00		-
-Mileage	50.00		-

- Speakers, if applicable must be related to the research project.
- Complete costs associated to the Original Budget or Amendment. The Total Budget costs will automatically calculate.

Budget Details - VIII Other Costs / Laboratory or Building Construction or Renovation

- Identify other costs.
- **For laboratory or building construction or renovation: list each separately under infrastructure and list the project number. Infrastructure is construction and renovation.**
- **Indirect costs, if applicable, should be reflected under this category as a % and state which categories it applies to. Example:**
  - Indirect Costs: Up to 20% of all categories except II, III & V • Indirect Costs: Up to 20% of categories I & VI
- **If the indirect cost rate is applied to ONLY one budget Category, the word "only" should be included. Example:**
  - Indirect Costs: Up to 20% of category I **only**
- Indirects cannot exceed 20% and cannot be charged against categories II, III & V (cannot exceed 20% of the sum of the total direct costs less the costs of categories II, III & V). A subcontractor shall also not charge indirect costs against items in categories II, III & V.
- The indirect cost rate shall not be increased at any time for the duration of the Grant Agreement.
- Do not list purchase/lease of vehicles.
- Complete costs associated to the Original Budget or Amendment. The Total Budget costs will automatically calculate.
- Equipment rental/maintenance and service costs should be listed here.
- List each separately under infrastructure and list the project number.

Budget Details - Total

- Totals calculate automatically.

Summary Tab

- All areas are formula driven and password protected. No entry is required on this page.

Budget Details Tab

- Insert the legal name of the entity that will receive the funds (On Budget Details Tab only)
- The SAP # will be inserted by the Department after the budget is submitted.
- After completing all of the worksheets, make sure the total budget amount is equal to the amount of funds that you are eligible to receive, as designated by the Department.

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 Institutional Review Board (IRB)

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

MEMORANDUM OF UNDERSTANDING REGARDING ETHICAL STANDARDS AS REQUIRED BY 35 P.S. § 5701.905(f)

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).

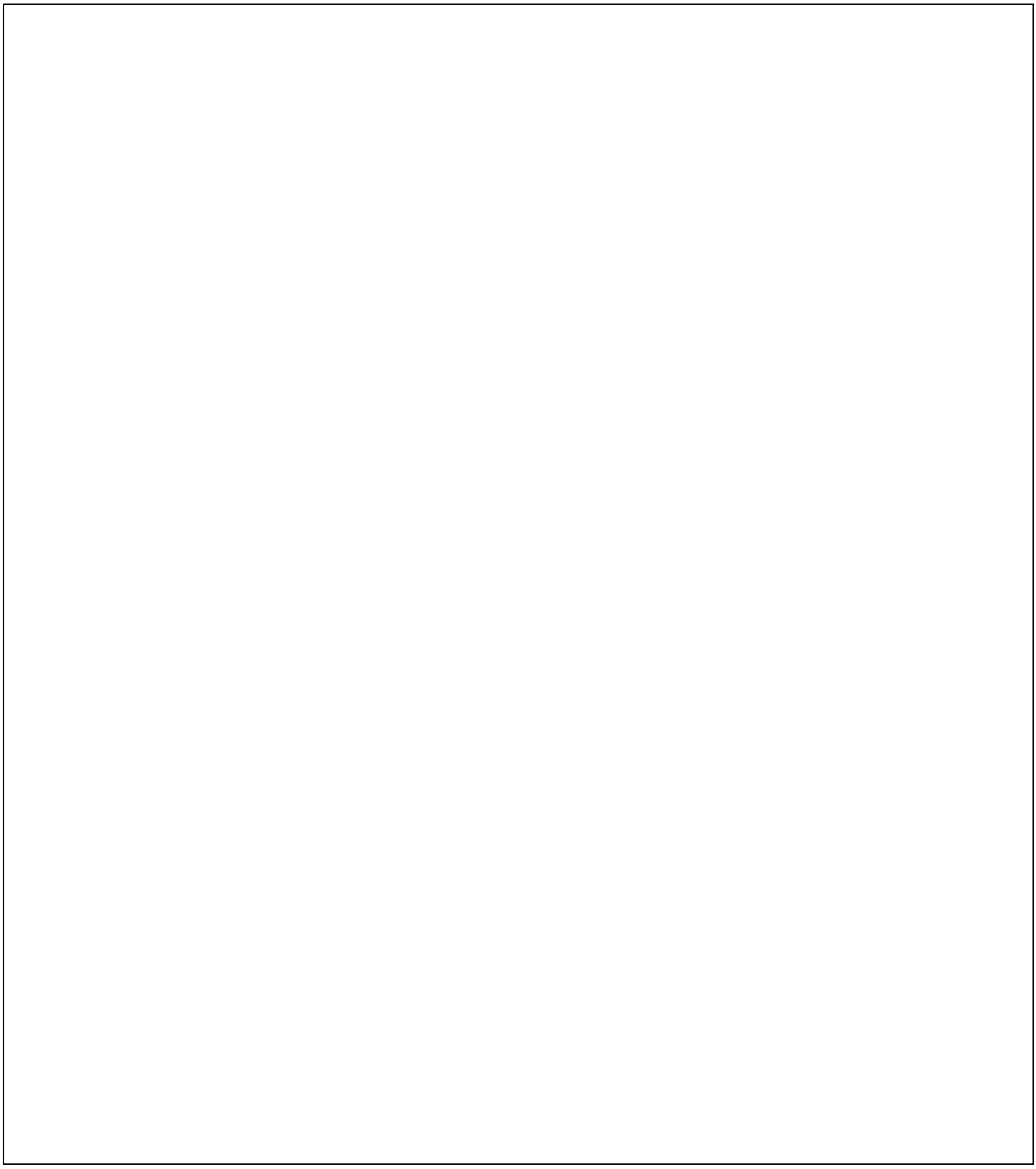
BY SIGNING BELOW, THE APPLICANT, BY ITS AUTHORIZED SIGNATORY, IS BINDING ITSELF TO THE ABOVE AGREEMENT.

APPLICANT ORGANIZATION	
SIGNATURE OF NON-FORMULA FUND APPLICANT'S AUTHORIZED OFFICIAL	DATE
NAME OF AUTHORIZED OFFICIAL	TITLE OF AUTHORIZED OFFICIAL
SIGNATURE OF SECRETARY OF HEALTH COMMONWEALTH OF PENNSYLVANIA	DATE

Letter of Intent

Pennsylvania Department of Health **Support for Immune Cell Therapy, Stem Cell Therapy and Gene Editing Technology Development** *In Response to* **RFA 67-157**	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*)



RFA # 67-157
Attachment X

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	