pennsylvania
DEPARTMENT OF HEALTH

July 18, 2018

Dear Potential Applicant:

You are invited to submit an application to the Pennsylvania Department of Health for collaborative research on opioid abuse and the overdose crisis in accordance with the enclosed Request for Applications RFA67-76. The effective date for the Grant will be June 1, 2019.

All questions regarding this RFA must be directed in writing to the Manager, Health Research Program, through email at ra-healthresearch@pa.gov no later than 2:30 p.m. on July 31, 2018. All questions should include the specific section of the RFA about which the potential applicant is questioning. A pre-application conference will be held on **August 7, 2018 at 8:00 a.m. in conference room 129, Health and Welfare Building, 625 Forster Street, Harrisburg, PA 17120-0701.** Since facilities are limited, it is requested that you limit your representation to two individuals. Applicant attendance is optional. Pre-registration is not required. 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 shall be submitted to the Director, Division of Public Health Procurement, Bureau of Procurement and Contract Management, Shared Services for Health and Human Services, Room 824, Health and Welfare Building, 625 Forster Street, Harrisburg, Pennsylvania 17120-0701. The Letter of Intent shall be prepared using the Letter of Intent form provided in Part Two, Appendix G of this RFA. The Letter of Intent shall arrive in the designated room at the above address no later than **2:30 p.m. on August 14, 2018**. Faxed Letters of Intent will not be accepted. **If the Letter of Intent is not received using the form provided on or before this date and time, your application will not be accepted.**

Please submit your application in the following format:

1. Five CD-R/DVDs containing an electronic copy of the following parts of the application: Appendix A – Attachment 1, Cover Page, submitted in Microsoft Word; Appendix A – Attachment 2, Research Proposal, submitted in PDF; Appendix A – Attachment 3, Letters of Support, submitted in PDF; and Appendix C – Budget submitted in Microsoft Excel.
2. One original and four complete paper copies of the remaining parts of the application (all documents listed in Part Two of the RFA except Appendix A and Appendix C).

Your application must arrive in the designated room at the following address no later than 2:30 p.m. on Wednesday, **August 22, 2018.**

RFA67-76
Director, Division of Public Health Procurement
Bureau of Procurement and Contract Management
Shared Services for Health and Human Services
Room 824, Health and Welfare Building
625 Forster Street
Harrisburg, Pennsylvania 17120-0701

LATE APPLICATIONS WILL NOT BE ACCEPTED REGARDLESS OF THE REASON.

Please write "APPLICATION ENCLOSED RFA67-76" in large block letters on the envelope or overnight/priority mail label.

We expect that the evaluation of applications and the selection of grantees will be completed within eight weeks of the submission due date.

Sincerely,

Lori Diehl
Director
Division of Public Health Procurement

Enclosure

Request for Application

Collaborative Research on Opioid Abuse and the Overdose Crisis

RFA67-76

Date of Issuance
July 18, 2018

Issuing Office:

Pennsylvania Department of Health
Bureau of Procurement and Contract Management
Shared Services for Health and Human Services
Division of Public Health Procurement
Room 824, Health and Welfare Building
625 Forster Street
Harrisburg, Pennsylvania 17120-0701

RFA Project Officer:

Sylvia Golas
Pennsylvania Department of Health
Health Research Office
Room 833, Health and Welfare Building
625 Forster Street
Harrisburg, Pennsylvania 17120-0701
Email address: ra-healthresearch@pa.gov

Collaborative Research on Opioid Abuse and the Overdose Crisis

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Preface

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 is 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.

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.

The intent of this Request for Applications (RFA) is to fund Collaborative Research on Opioid Abuse and the Overdose Crisis. An application must include plans for conducting only one research project that shall be focused on opioid abuse and the overdose crisis. 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 primary goal of this RFA is to fund collaborative research on opioid abuse and the overdose crisis. 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. The RFA provides support for research infrastructure to keep Pennsylvania research institutions in the forefront of these advances. It also will afford the opportunity for the training of researchers and undergraduate, graduate and postgraduate students through participation in the research project.

The specific objectives are:

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

Funding will go to the most scientifically meritorious proposals, which are submitted by the most qualified group or groups of collaborating persons or organizations.

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

All research applications submitted in response to this RFA must identify and address disparities in health status, outcome, prevention or treatment, and should relate to a national health objective (that is, Healthy People 2020).

All research projects must be consistent with the research priorities 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 must:

1. Address a health-related issue that has significant impact on the health of Pennsylvanians.

2. Place emphasis on a health-related issue that disproportionately affects vulnerable segments of the population.

3. Be inclusive of all populations that are at high risk for the health-related issue.

4. Focus on studies with the potential for prevention and control including the identification of risks and etiology for the health-related issue.

5. Promote collaboration among Pennsylvania institutions including smaller colleges and universities and other non-academic medical centers as well as major research institutions.

Research Priority

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

State Fiscal Year 2018-19 Priority for Nonformula Funded Research, Chapter 9, Act 2001-77

For the purpose of priority setting, the Health Research Advisory Committee recommends combining the two nonformula funding categories of clinical and health services research and other research. At least 50 percent of the funds must be spent on clinical research or health services research or both clinical research and health services research. The research priority for SFY 2018-19 nonformula funded research is:

Collaborative Research on Opioid Abuse and the Overdose Crisis

One of the most devastating health crises to have emerged during the past decade has been the widespread prevalence of opioid and heroin abuse and addiction, contributing to a dramatic rise in overdose deaths across the United States. From 2000-2015, one-half million deaths nationwide have been due to overdose, with 60 percent of these emanating from opioid or heroin use. The opioid epidemic in Pennsylvania is especially problematic, registering the eighth highest overdose death rate in the country at nearly 22 deaths per 100,000 people in 2014. Nationwide in 2014, Pennsylvania had the third highest number of opioid deaths with 2,732 behind only California with 4,521 and Ohio with 2,744.

Pennsylvania's rural areas are overwhelmed with the challenges of meeting the needs of overdose victims. Rural communities face limited availability of mental health services and few options for dealing with dependency. Since 2014, the Center for Rural Pennsylvania has held 11 public hearings on confronting the heroin and opioid epidemic in Pennsylvania and on the impacts this epidemic is having on rural counties.

Pennsylvania's largest urban areas are also experiencing surges in overdoses. In Philadelphia, the number of opioid deaths increased by almost 30 percent from 2015 to 2016, with a total amount of 900 deaths. Allegheny County had a 44 percent increase in opioid overdose deaths from 2015-2016, with opioids factoring into over 60 percent of its 613 overdose deaths. Allegheny County emergency room visits for overdoses doubled during that year, to a total of 5,698 visits.

There are two overarching pathways to opioid addiction that are driving the surge in deaths. One relates to the prevalence of prescription use, evolving to addiction, overdose and death; the other relates to behavioral and mental health issues that result in drug dependency, also leading to overdoses and deaths. Further concerns relate to the challenges associated with treating individuals who have become dependent on opioids. There is currently no cure for opioid addiction; rather, the option available for treatment involves combining medication, counseling, and recovery meetings to support individuals to maintain sobriety. This approach necessitates a deepening of research to improve health care delivery systems, including the role that precision medicine, data analytics and telehealth may have on mitigating the impacts of the crisis.

Research for this priority may include, but is not limited to, the following areas:

- Research to investigate the use of precision medicine in the prevention, treatment and recovery from opioid use disorder;
- Research to identify the barriers and best practices needed to evaluate methods for improved pain management or opioid use disorder or both and its consequences;

- Research related to restructuring the health care delivery system, including attention to pain or opioid disorder in primary care or both; and
- Research related to broad population approaches to address the rising prevalence of opioid use disorder.

Research in the following areas will not be considered:

- Research focused on drug discovery to identify or develop new agents for treating pain or opioid addiction or both.
- Research focused on the benefit of opioids
- Research focused exclusively on any other substance of addiction, for example, other illicit drugs, cannabinoids, alcohol, tobacco and food

The research should hold the potential for addressing the health needs of underserved segments of the population, including rural, urban, racial/ethnic minorities, older adults and/or other high-risk constituencies in the Commonwealth. To foster cross-institutional collaborative research among organizations across the Commonwealth, an applicant must conduct research in collaboration with other research institutions and organizations. To the extent possible, organizations that are not academic medical centers, such as smaller colleges and universities, businesses and local public health agencies, should be included in addition to major research institutions. Collaborations with organizations already focused on the opioid epidemic are strongly encouraged. Collaboration with a minority-serving academic institution or a minority-serving community-based organization in Pennsylvania is strongly encouraged, and should include the mentoring and training of students. All research collaborators must play a substantive and meaningful role in multiple aspects of the proposed research. Research proposals must be organized around specific focused topics or issues rather than a wide range of unrelated projects. Health services research must include objective evidence of outcomes. Research must test at least one hypothesis, not be merely descriptive or hypothesis-generating.

PART ONE

Collaborative Research on Opioid Abuse and the Overdose Crisis

General Information

A. Information for Applicants

Through this RFA process, the Pennsylvania Department of Health (Department) is soliciting health research applications from Pennsylvania institutions and organizations. The Department is interested in funding collaborative research on opioid abuse and the overdose crisis. The overall goal of this funding is to promote the health of all Pennsylvanians.

Applications are welcomed from eligible applicants, as specified in Paragraph 2 below. Additional information about how to apply, relevant and specific restrictions, evaluation of applications and deliverables are noted and outlined in Section B. Applicants are encouraged to be innovative and creative in their approach.

This RFA provides interested institutions, organizations and persons with information to prepare and submit applications to the Department. Questions about this RFA must be directed to the Manager, Health Research Program through e-mail at ra-healthresearch@pa.gov by the deadline contained in the cover letter to this RFA. The answers to questions asked by all applicants will be posted at www.emarketplace.state.pa.us. Each applicant shall be responsible to monitor the website for new or revised RFA information. The Department shall not be bound by any information that is not either contained within the RFA or formally issued as an addendum by the Department.

In order to do business with the Commonwealth of Pennsylvania providers are required to enroll in the SAP system. Applicants may enroll at www.vendorregistration.state.pa.us/, or by calling toll free at 1-877-435-7363 or locally at (717) 346-2676.

1. Introduction

The Department has between $11 and $12 million to fund collaborative research projects that are consistent with the research priority listed in the Preface. The Department expects to award three Grants, and expects awards not to exceed $4 million. If an applicant requests more than $4 million, the application must show clear and strong justification of the need for additional funding in excess of $4 million.

The following parts of the application (Appendix A – Attachment 1, Cover Page; Appendix A – Attachment 2, Research Proposal; Appendix Attachment 3, Letters of Support; and Appendix C - Budget) must be submitted electronically on a CD or DVD. Copies of the forms for the Cover Page, Research Proposal and Budget may be obtained by calling 717-231-2825 or emailing ra-healthresearch@pa.gov.

2. Who May Apply

Eligible applicants must be located in the Commonwealth of Pennsylvania 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 Care 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 Commonwealth), 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 the preface of this RFA. The applicant and collaborating organizations must be separate institutions. The applicant must be a legal entity that will receive all Grant funds and shall be responsible for the fiscal aspects and all other aspects of this Grant. The applicant and all collaborating organizations (which have a meaningful and substantive role in the research project) must be located in Pennsylvania. Lead applicants and collaborating organizations must conduct 98 percent of the research proposed in the Grant application at Pennsylvania-based facilities. Subcontractors that are not considered collaborating partners and have a minor role in the research project may be non-Pennsylvania-based institutions which are located outside of Pennsylvania. However, if out-of-state subcontractors participate on the project team, the application should clearly describe how any barriers to communication and close collaborative research work will be overcome. The principal investigator (PI) on the research project may reside outside of Pennsylvania; however, the applicant or collaborating institution where the PI works must be located in Pennsylvania. Consultants who have a minor role in the research project may be located outside of Pennsylvania. The total cost of out-of-state subcontractors, consultants, fee-for-service providers and vendors and the cost of research conducted outside of Pennsylvania by the lead applicant and collaborating organizations must not exceed two percent of the total Grant 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 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.

3. 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 one research project.

The goal of this funding is to discover scientific knowledge that can be applied toward improving the health of Pennsylvanians. In order to achieve this goal, the research project shall 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-projects or studies that are proposed to address each aim of the overall research project or address a different aspect of the overall goal. The studies should be closely related to each other and the overall goal. The proposal should only include studies that will be completed within the Grant period.

All research applications submitted in response to this RFA must be consistent with the research priority listed in the Preface 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 should be the design of scientifically meritorious research that will lead to improving the health of Pennsylvanians.

c) Train minority students -- All research applications must include the involvement of minority college students in research through the development 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. 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 student summer internships or academic semester internships or both:

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.

If a minority graduate student training is supported with Grant 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. Physically disabled persons, women and medically underserved populations are not considered minorities. A post-baccalaureate program designed to prepare students for biomedical research training programs is considered to be a graduate student training program.

Students must be involved in some aspect of the research project, 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 should begin no later than September 1, 2019. 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 period. Grant funds may also be used to train non-minority students.

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.

4. Use of Funds – Limitations and Additional Requirements

All research projects must be consistent with the research priority listed in the Preface.

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

- 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, and (3) research on the delivery of health care services to reduce health risks and transfer research advances to community use.

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.

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

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

Funds may not be used to establish registries, patient databases or tissue banks unless the research project includes at least one specific hypothesis-driven research study that uses the registry, patient database or tissue bank and is completed within the Grant period.

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

Funds may 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 may not be used for international travel.

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

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

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

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

All other personnel are professional personnel and are non-infrastructure costs. Research equipment is not infrastructure. Research equipment may be purchased as part of an approved research project funded under 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 should describe the location of the facilities and potential users of the facilities both at the host institution and other institutions. Sharing of infrastructure facilities among universities and public and private research organizations is encouraged. Personnel (technicians) to operate equipment and facilities may not be requested as part of a research facilities construction or renovation project.

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

Indirect costs must not be charged against items in Categories II and III of the budget (Consultant and Subcontract Services). A subcontractor also must not charge indirect costs against items in Categories II and III. The Department does not specify which budget categories can be included in indirect costs. The indirect costs specified in Appendix C - Budget must not be greater than 20 percent of the sum of total direct costs less Categories II and III of the budget (Consultant and Subcontract Services) costs. Indirect costs must be supported by a uniform method to equitably allocate and distribute indirect costs across all projects. The applicant must be able to support the indirect cost rate with an allocation plan if requested. The indirect cost rate cannot be increased at any time for the duration of the Grant Agreement.

Small businesses are encouraged to apply and may use Grant funds for a reasonable profit or fee provided that the profit or fee is included in the budget. The profit or fee cannot be increased above the rate specified in the Grant Agreement for the duration of the Agreement. The fee is intended to be a reasonable profit for businesses

involved in health research and development work. The profit or fee rate specified in the Grant Agreement shall be no greater than seven percent of the sum of total costs (direct and indirect) less Category II and III costs.

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

For the duration of the Grant Agreement, hourly rates and fringe benefit rates for all personnel except union-covered positions cannot be increased above the rates specified in the Budget of the Grant Agreement. Hourly rates and fringe benefit rates may be increased only for union-covered positions and only when those increases are negotiated as part of an approved collective bargaining unit agreement that was put into place after the Grant Agreement was approved.

None of the Grant funds shall be used to pay an individual at a rate in excess of $97.20/hour. None of the grant funds shall be used to pay an individual to manage or administer the grant.

Upon execution, the Grant Agreement, including this supplemental information, will be accessible to the public through 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 Grant Agreement on the Web, the Department will redact (black out) confidential and proprietary information. Applicants must clearly identify all proprietary or confidential text with highlighting and adding a statement that the highlighted text is considered to be confidential or proprietary.

5. Technical Reporting and Accountability Requirements

All successful applicants are required to submit to the Department annual reports, a final report, and copies of any publications and reports published based on research funded by this award. These reporting requirements and others are specified in "Appendix D, Attachment 7 - Agreement Regarding Fiscal and Other Requirements" in Part Two of this document.

6. Grant Agreement Payment Provisions and Fiscal Reporting Requirements

The Applicant shall submit to the Department an annual expenditure report for each state fiscal year (ending June 30) within 30 calendar days after the end of the state fiscal year and a final report within 60 calendar days of the Grant Agreement's termination date. The expenditure reports shall be submitted using the forms contained in Part Two, Appendix B, Attachments 1 - 5.

Funds awarded for the state fiscal year 2018-19 must be spent by the institution by the termination date of the Grant award. Any unspent funds still available at the end of the Grant award period must be returned to the Commonwealth.

7. Use of Existing Health Data

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

8. Effective and Termination Dates for Grants

In preparing the application, the effective date contained in the cover letter to this RFA should be used as the effective date for the Grant. The applicant must determine the duration of the Grant award and specify the duration of the award in the application. According to Section 904 of Act 77 of 2001, Grants may be awarded for a period not to exceed four years. Therefore, the termination date as specified in the application must not exceed 48 months from the effective date (June 1, 2019), as specified in the cover letter to the RFA. The Department may, by written notice, extend the Grant Agreement term, but the extended termination date still may not exceed 48 months from the effective date.

B. Application Procedures

1. General

a. Applications must be received by the Department by the time and date stated in the cover letter. 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 on the DGS website.
c. The decision of the Department with regard to selection of applicants is final. The Department reserves the right to reject any and all applications received as a result of this request and to negotiate separately with competing applicants.
d. Grantees whose applications are selected are not permitted to issue news releases pertaining to this project prior to official written notification of award by the Department. Any subsequent publication or media release issued by the Grantee throughout the life of the Grant using funding from this Grant must acknowledge the Department as the granting agency. Any subsequent media release must also be approved in writing by the Department.
e. Grantees must use blue or black ink when signing all documents and ensure it is legible and able to be compared to printed name on documents requiring signature.

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 on the basis of 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 a Review Committee comprised of Department staff. The Department Review Committee will review applications that meet the requirements in this RFA. The applications will be ranked according to the peer review scientific and technical merit score assigned during the first stage of the review. 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 Department Review Committee will use the rankings and 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.

The Department may request written clarification or schedule an oral presentation if additional clarification of an application is needed.

3. Awards

The Grant payment will be made in accordance with the payment provisions contained in Part Two, Appendix B - Department of Health Grant Agreement Payment Provisions. Awards will be made to the lead agency of the collaborative research project.

The Grant Agreement between the Grantee and the Department will consist substantially of the documents contained in Part Two of this RFA.

All Grants funded in response to this RFA will be administered by the Department.

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 reviewer panel's written comments on their application. Comparisons 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. All requests for peer review comments 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.

4. Deliverables

a. The Grantee shall submit an annual report of progress and expenditures to the Department within 30 calendar days after the end of the state fiscal year (June 30) and 60 calendar days after the Grant end date. Any changes to the scope of research during the term of the Grant Agreement must be approved in writing by the Department.
b. The Grantee shall submit an interim written progress report 12-15 months after the start date of the Grant.
c. The Grantee shall submit a final written progress and expenditure report within 60 calendar days after the Grant end date.
d. The Grantee shall submit a written response to the performance review report within 30 calendar days after the Department provides the grantee with a copy of the performance review report.
e. The Grantee shall inform the Department of any changes in principal investigator or administrative officer, within 14 calendar days after the change.

C. Application Instructions and Required Format

1. Application Instructions

The following is a list of requirements.

a. A Letter of Intent shall be submitted to the Director, Division of Public Health Procurement, Bureau of Procurement and Contract Management, Shared Services for Health and Human Services, Room 824, Health and Welfare Building, 625 Forster Street, Harrisburg, Pennsylvania 17120-0701. The Letter of Intent shall be prepared using the Letter of Intent form provided in Part Two, Appendix G of this RFA. The Letter of Intent shall arrive in the designated room at the above address on or before the time and date specified in the cover letter to this RFA. Faxed Letters of Intent will not be accepted. **If the Letter**

of Intent is not received using the Letter of Intent form provided on or before this date and time, your application will not be accepted.

b. The application shall consist of: (1) electronic documents (Appendices A and C) and (2) paper documents (all documents as required in Part Two of the RFA except Appendices A and C).

(1) Electronic documents – The applicant must provide five CD-R or DVD of the required electronic documents in the following format. Each CD or DVD must contain a copy of: Appendix A – Attachment 1, Cover Page, submitted in Microsoft Word; Appendix A – Attachment 2, Research Proposal, submitted in PDF; Appendix A – Attachment 3, Letters of Support, submitted in PDF; and Appendix C – Budgets for the applicant organization and each subcontractor, submitted in Microsoft Excel.

The Research Proposal should be submitted as a directly created PDF file, not the result of scanning.

Each CD or DVD should be labeled with RFA67-76, the name of the principal investigator, applicant institution, and research project title.

(2) Paper copies – The applicant must provide an original application and four complete paper copies of all documents required in Part Two of the RFA except Appendices A and C. The application must be single-sided. Attach a cover page to the original application that indicates it is the original copy. The application and all copies should be secured only with rubber bands or binder clips. Do not use tabbed dividers to separate sections of the application; if needed, colored paper may be used as section dividers.

c. The application shall be received by mail or in person at the Division of Public Health Procurement, Bureau of Procurement and Contract Management, Shared Services for Health and Human Services, Room 824, Health and Welfare Building, 625 Forster Street, Harrisburg, Pennsylvania 17120-0701 on or before the time and date specified in the cover letter. If, due to inclement weather, natural disaster, or any other cause, the Commonwealth office location to which applications are to be returned is closed on the application response date, the deadline for submission will be automatically extended until the next Commonwealth business day on which the office is open, unless the Department otherwise notifies Applicants. The hour for submission of applications shall remain the same. The Department will reject, unopened, any late applications. Applicants mailing applications should allow sufficient mail delivery time to ensure timely receipt. **Late applications will not be accepted regardless of the reason.**

d. The application must be submitted using the format described in subsection 2. - Application Format.

e. The Certifications Form must be completed and signed by an official authorized to bind the organization to the application.

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 applicants must submit documents in the order shown below and in the Application Checklist, which is located in Part Two, Appendix F of this RFA. Do not insert the name of the Principal Investigator anywhere on any of the application documents unless indicated. Do not insert SAP number on any forms. The Department will add the SAP number to the appropriate documents when the application is submitted.

The entire RFA is available in PDF. All forms are available as fillable forms. The Cover Page and Research Proposal are available in Microsoft Word, while the budget is available in Microsoft Excel. Copies may be obtained by calling 717-231-2825 or emailing ra-healthresearch@pa.gov.

Forms requiring signatures -- Only original signatures of authorized persons will be accepted; proxy signatures will not be accepted. Do not use correction fluid or correction tape on these forms. Do not submit forms containing handwritten corrections. Do not attach labels containing the title(s) of the person(s) who signed the forms.

Legal name of applicant organization – On all applications 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. All forms that do not contain the legal name of the applicant organization will be returned to be re-signed and re-dated.

The instructions for completing the application are as follows:

a. **Signature Page:** The Signature Page must include the applicant's complete legal name and be signed and dated by an official authorized to bind the applicant's organization to the agreement. If the applicant is a corporate entity, the signature page must be signed by the President or Vice President AND the Secretary/Assistant Secretary or Treasurer/Assistant Treasurer of the corporation or other properly authorized individual. If any other person has authority to execute agreements, that person may sign, but a copy of the document conferring that authority (such as by-laws or corporate resolution) must be sent with this agreement when returning the application to the Department. The copy of the by-laws or corporate resolution should be identifiably specific to the entity and shall be dated currently. Do not complete the SAP number on the top of the form. The number will be added when the application is submitted to the Department. Do not add a page number on this document.

b. **Grant Agreement between the Pennsylvania Department of Health and the Grant Applicant:** Read and return this document with the application. The required information will be added when the application is submitted to the Department.

c. **Appendix A, Attachment 1 - Cover Page:**
   1. Do not add a page number on this document.
   2. An electronic copy of this document must be submitted in Microsoft Word on a CD-R/DVD. Electronic copies of this form may be obtained by calling 717-231-2825 or emailing ra-healthresearch@pa.gov.
   3. Complete as follows:
      a) Applicant Name: Insert the legal name of the applicant organization exactly as it is registered with the Department of State.
      b) Type of Legal Entity: Insert the type of legal entity of the applicant organization, that is., Corporation, Partnership, Limited Liability Company, or Sole Proprietorship.
      c) Grant Amount: Enter the full amount of funds requested.
      d) Grant Start Date: The effective date of the Grant is expected to be June 1, 2019.
      e) SAP Vendor #: Indicate vendor number, which is a number assigned by the Commonwealth of Pennsylvania.
      f) Grant End Date: Enter the anticipated end date of grant. The applicant must determine the duration of the Grant award; however the end date must not exceed 48 months from effective date of the grant. The effective date of the Grant is expected to be June 1, 2019; therefore, the end date must be on or before May 31, 2023.

g) Address: Provide a complete mailing address that corresponds to the vendor number for your organization. Provide the 5-digit Zip Code; do not include a 4-digit extension.
h) Item 1: Indicate the amount of funds requested for clinical and health services research, as defined in the Preface to the RFA. 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. The amount must be consistent with the Research Proposal, Item XI., Allocation of Costs for Biomedical, Clinical and Health Services Research.
i) Item 2a: Provide the name of the principal investigator who will be the primary contact person with the Department of Health for all grant-related activities.
j) Item 2b: Indicate up to three academic and professional degrees or other credentials and licenses held by the project coordinator/principal investigator.
k) Item 2c: Provide the academic or professional title of the project coordinator/principal investigator. If there is more than one title, provide the title that is most relevant to the planned research project.
l) Item 2d: Provide complete mailing address for the project coordinator/principal investigator (including room number, building and street address) necessary for postal delivery.
m) Item 2e: Provide the telephone number and email address for the project coordinator/principal investigator. The individual's direct email address is preferred over a shared departmental email address.
n) Item 3a: Provide the name and degrees for the principal investigator's primary point of contact to be copied on emails from the Department of Health. The primary point of contact may be the administrative or research assistant who will assist the principal investigator on all grant-related activities.
o) Item 3b: Provide the telephone number and email address for the principal investigator's primary contact person. The individual's direct email address is preferred over a shared departmental email address.
p) Item 3c: Provide the title of the position held by the primary contact person for the principal investigator.
q) Item 4: Indicate the name and title of the applicant institution's administrative official to be notified when the funds are made available. Provide a complete address for postal delivery, the telephone number and email address. The individual's direct email address is preferred over a shared departmental email address.

d. **Appendix A, Attachment 2 - Research Proposal:** Applicants must submit the Research Proposal using the form and instructions contained in Part Two of the RFA. An electronic copy of this document must be submitted in a directly created PDF document on a CD-R/DVD. Electronic copies of the Research Proposal form may be obtained by calling 717-231-2825 or emailing ra-healthresearch@pa.gov.

e. **Appendix A, Attachment 3 – Letters of Support:** Letters of support from collaborating organizations and consultants should be scanned and submitted as one electronic document in PDF on a CD-R/DVD.

f. **Appendix B - Grant Agreement Payment Provisions and Attachments 1 through 5 (Annual Expenditure Report, Report of Infrastructure Expenditures, Report of Interest Earned and Expenditures on Interest Earned, Certificate of Compliance with Investment Requirements, and Nonformula Grant Report of Expenditures by Type of Research):** Read and return these documents with the application. Applicant should not complete the attachments to this appendix at this time. The attachments will be completed by the applicant and submitted with annual and final expenditure reports. Do not change the page numbers on this document.

g. **Appendix C - Budget:** An electronic copy of this document must be submitted in Excel on the CD-R/DVD. The Budget must be completed using the Excel budget file that was provided by email with this application. The Excel budget file contains detailed instructions. The Excel budget file also contains formulas, which create the required totals in order to make the preparation process easier. If the institution needs another copy of the Excel budget file, please call 717-231-2825 or email ra-healthresearch@pa.gov.

1) Applicants must complete a budget for the entire Grant period. The budget will consist of a Budget Summary and nine budget categories: (I) Personnel Services (which includes fringe benefits), (II) Consultant Services, (III) Subcontract Services, (IV) Patient Services, (V) Equipment, (VI) Supplies, (VII) Travel, (VIII) Laboratory or Building Construction or Renovations and (IX) Other Costs. 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.
2) Refer to detailed instructions in the Excel spreadsheet. Use those instructions, along with the following instructions, to complete the budget.
3) Include indirect costs in the "Other Costs" budget category. The indirect cost shall be no greater than 20 percent of the sum of total direct costs less Categories II (Consultants) and III (Subcontracts) costs. A subcontractor may charge an indirect cost rate of no greater than 20 percent of the sum of total direct costs less Categories II and III costs.
4) On each budget page, insert the amount of funds, which are considered "infrastructure" in the column labeled "Infrastructure Funds." Infrastructure is defined as including the following items: office equipment, office supplies, nonprofessional personnel, and laboratory or building construction or renovations used to conduct research. The total costs for infrastructure must not exceed 50 percent of the total budget. Secretaries, clerks and administrative assistants are nonprofessional personnel and, therefore, considered infrastructure. All other personnel are professional personnel and are non-infrastructure costs. Note that the definition of infrastructure is set forth in Act 2002-149. The definition is not the same as the National Institutes of Health (NIH) definition of indirect costs [Facilities and Administrative (F&A) costs]. In the 'Non-Infrastructure Funds" column, insert the amount of funds that are not considered to be infrastructure. For each line, the amount shown in the "Full Project Costs" column should equal the sum of the infrastructure and non-infrastructure amounts.
5) 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.

(a) Budget Summary
   (1) For the lead applicant: Insert the legal name of the Grantee and the effective and termination dates for the Grant at the top of the page. Do not insert the SAP #. The Department will add this number when the application is submitted.
   (2) For each subcontractor: Insert "Subcontractor:" followed by the name of the subcontractor at the top of the page.

(b) Category I - Personnel: The personnel section shall identify each position by the role of each person on the project, hourly rate, and the number of hours allocated to the Grant. Fringe benefits are to be shown as a separate line item by percentage and shall include a detailed listing of the benefits covered. Specific instructions for subsections A and B include:

(c) Category I, Subsection A. Staff Personnel
   (1) Starting with the principal investigator, list the name followed by the role of applicant organization's employees who will be funded by this Grant. Include employees of other

institutions in the subcontractor's budget or consultant category, as appropriate. If staff has not been hired, use the title of the position followed by "To Be Announced" (TBA) in place of names.

(2) Hourly Rate and Number of Hours – For each position, provide hourly rate rounded to the nearest cent. Do not enter macros or formulas in the work sheet. Applicants that pay their faculty and staff using salaries rather than hourly rates must convert salaries to an hourly rate and, in so doing, must determine the number of hours per week used to calculate the hourly rate. Enter number of hours rounded to the nearest hundredth (for example, 20.33, not 20.333).

(3) Full Project Cost column - The spreadsheet contains formulas that multiply hourly rate and number of hours.

(4) Infrastructure and non-infrastructure columns - If the position is a clerk, secretary or administrative assistant, copy the cost for the position from the Full Project Costs column into the infrastructure column. Costs for all other positions are considered non-infrastructure costs and should be copied into the non-infrastructure column.

(5) Total Cost of Personnel - The spreadsheet will do the calculation.

(d) Category I, Subsection B. Fringe Benefits

(1) Rate – for each position indicate the fringe benefit rate, rounded to the nearest one hundredth (for example, 33.33 percent, not 33.333 percent).

(2) Under the cell labeled "Specify the benefits included in this rate" - Specify the types of benefits that are covered by the fringe benefit rate (for example, health insurance, FICA, and workers compensation).

(3) Full Project Costs - The spreadsheet contains formulas that multiply the fringe benefit rate times the amount of the salaries.

(4) Infrastructure and non-infrastructure columns - If the position is a clerk, secretary or administrative assistant, copy the cost for the position from the Full Project Costs column to the infrastructure column. Costs for all other positions are considered non-infrastructure and should be copied into the non-infrastructure column.

(5) Total Cost of Fringe Benefits - The spreadsheet will calculate the fringe benefit lines listed separately above the total cost cell.

(e) Category II - Consultant Services: This budget category shall identify each consultant by classification, hourly rate and number of hours to be utilized under this Grant.

(1) The total cost of out-of-state consultants and subcontractors must not exceed two percent of the total Grant costs.

(2) For each consultant, specify the city and state where the consultant is located.

(3) Follow the same instructions as for Category I. A. – Staff Personnel.

(4) Total Cost of Consultants - The spreadsheet will do the calculation.

(f) Category III - Subcontract Services: This budget category shall identify each subcontract to be utilized under this Grant. If the subcontractor is not known at this time, please indicate by saying "To Be Determined" along with a description of the work to be performed and hourly rate, if applicable.

(1) The total cost of out-of-state consultants and subcontractors must not exceed 2 percent of the total Grant costs.

(2) Subcontract Services - List the name of the subcontractor and indicate the service to be provided in parentheses. Specify the city and state where the subcontractor is located.

(3) Full Project Costs column - Insert total cost of subcontract in this column.

(4) Infrastructure and non-infrastructure columns - Subcontractor costs must be broken down into infrastructure and non-infrastructure costs.
(5) Total Cost of Subcontract Services - The spreadsheet will do the calculation.

(g) Category IV - Patient Services: This budget category shall reflect funding dedicated for patient services.
(1) Describe the service, rate and number of patients to be served in the left column.
(2) Full Project Costs column -Insert the total cost.
(3) Infrastructure and non-infrastructure columns - Patient services are non-infrastructure costs. Copy costs from the Full Project Costs column into the non-infrastructure column.
(4) Total Cost of Patient Services - The spreadsheet will do the calculation.

(h) Category V - Equipment: This budget category shall reflect the actual or projected cost of any piece of equipment costing $5,000 or higher. Equipment items costing less than $5,000 should be listed in the Supplies category.
(1) Describe each item of equipment, the quantity and unit cost of each item. Equipment maintenance and services costs should be placed in Category IX, Other Costs.
(2) Full Project Costs column - The spreadsheet contains formulas that multiply the quantity and unit cost.
(3) Infrastructure and non-infrastructure columns - Only office equipment costs are infrastructure costs. Computers and computer software that are used primarily and specifically to conduct the research, not as a piece of office equipment are considered non-infrastructure costs. Copy office equipment costs from the Full Project Costs column into the infrastructure column. Copy non-office equipment costs from the Full Project Costs column into the non-infrastructure column.
(4) Total Cost of Equipment - The spreadsheet will do the calculation.

(i) Category VI - Supplies: This budget category shall reflect expected costs for general office supplies including personal computers and facsimile machines valued at less than $5,000 per item needed to support this Grant.
(1) List types of supplies separately, for example, office supplies, laboratory supplies, etc.
(2) Full Project Costs column - Insert the total cost.
(3) Infrastructure and non-infrastructure columns - Only office supplies costs are infrastructure costs. Copy office supplies costs from the Full Project Costs column into the infrastructure column. Copy non-office supplies costs from the Full Project Costs column into the non-infrastructure column.
(4) Total Cost of Supplies - The spreadsheet will do the calculation.

(j) Category VII- Travel: This budget category shall include anticipated expenditures for travel including mileage, hotels and meals.
(1) Funds may not be used for international travel.
(2) Break down costs by mileage, airfare, lodging, subsistence, parking/tolls and ground transportation. Ground transportation includes costs for taxis, airport limousines, trains, subways, buses, streetcars, and vehicle rentals. Mileage includes costs to reimburse personal vehicle mileage incurred during the conduct of grant-related activities.
(3) Full Project Costs column - Insert the total cost.
(4) Infrastructure and non-infrastructure columns - Travel costs are non-infrastructure costs. Copy costs from the Full Project Costs column into the non-infrastructure column.
(5) Total Cost of Travel - The spreadsheet will do the calculation.

(k) Category VIII - Laboratory or Building Construction or Renovations
   (1) List the construction/renovation project(s).
   (2) Full Project Costs column - Insert the total cost.
   (3) Infrastructure and non-infrastructure columns - Construction and renovations costs are infrastructure costs. Copy costs from the Full Project Costs column into the infrastructure column.
   (4) Total Cost of Construction/Renovation - The spreadsheet will do the calculation.

(l) Category IX - Other Costs: This budget category shall be used for anticipated expenditures that do not fit into any other budget categories such as telephone, printing, postage, and indirect costs (overhead, general and administrative).
   (1) List all other costs not classified elsewhere.
   (2) Indirect costs - Indirect costs must not be charged against items in Categories II and III (Consultant or Subcontract Services). At the bottom of the list, include a line for indirect costs. Specify the indirect cost rate, the Category of the budget items to which it applies, and the cost of the budget items to which it applies [for example, Indirect costs = Up to 20 percent of $15,456 (all costs except Categories II & III)]. Also, list the specific items that the indirect costs are paying for [for example, facilities and grounds maintenance and administrative and support services]. Indirect costs may be listed in both the infrastructure and non-infrastructure columns OR they may go only in the non-infrastructure column, depending on how much of the indirect costs are infrastructure costs as defined in Part One, Section A.4. of this RFA (that is, only that portion of indirect costs that are for office equipment, offices supplies, nonprofessional personnel and laboratory or building construction or renovations, used to conduct research, should be placed in the infrastructure column). For example, if the budget for laboratory renovations is $100,000 (infrastructure cost), the budget for research personnel is $100,000 (non-infrastructure cost) and the indirect costs are $40,000 (20 percent of total direct costs less Categories II & III). The applicant reviews its methods for determining the indirect cost rate and determines that 8 percent of the costs that comprise the indirect costs are for nonprofessional personnel used to conduct research. None of the other costs that comprise indirect costs are for the other items defined as infrastructure by this RFA. Therefore, only 8 percent of indirect costs ($3,200) would be placed in the infrastructure column and the remaining 92 percent of indirect costs ($36,800) would be placed in the non-infrastructure column. Note: If any indirect costs are listed in the infrastructure column, those costs must be reported on the annual Report of Infrastructure Expenditures, Part Two, Attachment 2, not as indirect costs, but itemized as office equipment, office supplies, nonprofessional personnel (secretaries, administrative assistants and clerks) or laboratory construction.
   (3) Full Project Costs column - Insert the total cost.
   (4) Infrastructure and non-infrastructure columns - The only costs that should be placed in the infrastructure column are those indirect costs as indicated above.
   (5) Total Cost of Other Costs - The spreadsheet will do the calculation.

h. **Appendix D, Attachment 1 - Certifications:** The official who is authorized to bind the organization to its application must sign this form. Do not add a page number to this document.

i. **Appendix D, Attachment 2 - Certifications for the Protection of Human Subjects and Regarding the Use of Human Embryonic Stem Cell Research:** 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. However, 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. Do not change the page numbers on this document. If the research project involves the use of human embryonic stem cells, only human embryonic stem cell lines that are approved by the National Institutes of Health and derived from outside of Pennsylvania can be used.

j. **Appendix D, Attachment 3 - Certifications for the Containment of Recombinant DNA Research and the Care and Treatment of Vertebrate Laboratory Animals:** 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. However, all such research must be approved by the applicant's review committee *prior to the initiation of such research and use of Grant funds* to pay such research.

k. **Appendix D, Attachment 4 - Form HD1013F: Application to the Pennsylvania Department of Health Institutional Review Board:** 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 as follows and submitted with the application.
   1) Complete items 1-8.
   2) Complete item 9. Check Box C and: (1) complete the name of the institutional review board that reviewed the project, (2) indicate the type of review, (3) specify the date when IRB approved the project or exempted it from review, and (4) attach copy of document indicating that the IRB approved project or exempted it from review.
   3) If your institution's IRB determined that the project was exempt from review, please answer 10 by checking the appropriate box. If the project was not exempt from review, skip item 10.
   4) Complete items 11-22.
   5) DO NOT complete items 23-29.
   6) Do not change the page numbers on this document.

l. **Appendix D, Attachment 5 - 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. Do not add a page number on this document.

m. **Appendix D, Attachment 6 - Agreement Regarding Construction:** The official who is authorized to bind the organization to its application must sign this form. Do not complete the SAP number on the form. This number will be added when the application is submitted to the Department. Do not add a page number to this form.

n. **Appendix D, Attachment 7 - Agreement Regarding Fiscal and Other Requirements:** The official who is authorized to bind the organization to its application must sign this form. Do not complete the SAP number on page 1 of the form. This number will be added when the application is submitted to the Department. Do not change the page numbers on this document.

o. **Appendix E - Form W-9 and Instructions:** Complete the Internal Revenue Service W-9 form and enclose with the application. The W-9 form and instructions for completing the form are available at the website http://www.irs.gov. Do not add a page number to this document.

p. **Appendix F - Application Checklist:** Use this checklist to ensure that your application contains all necessary documents.

q. **Appendix G - Letter of Intent:** Do not submit the Letter of Intent with the application. The Letter of Intent shall be submitted prior to the application, on or before the time and date specified in the cover letter. **If the Letter of Intent is not submitted on the form contained in the RFA on or before the time and date specified in the cover letter, the application will not be accepted.**

PART TWO

Pennsylvania Department of Health
Health Research Office

Collaborative Research on Opioid Abuse and the Overdose Crisis

Request for Applications (RFA67-76)

pennsylvania
DEPARTMENT OF HEALTH

Tom Wolf, Governor

Rachel L. Levine, MD, Secretary of Health

Mailing Label:

THIS LABEL MAY BE USED FOR MAILING THE APPLICATION. THIS LABEL MAY BE CUT OUT AND FIRMLY AFFIXED TO THE APPLICATION PACKAGE, OR COPY THIS EXACT FORMAT FOR THE MAILING LABEL.

FROM:

APPLICATION ENCLOSED RFA67-76

BID

TO: DIRECTOR
DIVISION OF PUBLIC HEALTH PROCUREMENT
BUREAU OF PROCUREMENT AND CONTRACT MANAGEMENT
SHARED SERVICES FOR HEALTH AND HUMAN SERVICES
ROOM 824, HEALTH AND WELFARE BUILDING
625 FORSTER STREET
HARRISBURG, PA 17120-0701

SAP# _____

AGREEMENT BETWEEN THE PENNSYLVANIA DEPARTMENT OF HEALTH AND

_____

(Name)

WHEREFORE, in witness of the covenants set forth below on the attached pages, the parties have affixed their signatures hereto:

BY: _____ DATE: _____

Signature of Vendor

_____ _____

Print/Type Title Print/Type Name

BY: _____ DATE: _____

Signature of Vendor

_____ _____

Print/Type Title Print/Type Name

BY: _____ DATE: _____

Pennsylvania Department of Health

Approved as to form and legality:

BY: _____ DATE: _____

Office of Legal Counsel
Pennsylvania Department of Health

AND

BY: _____ DATE: _____

Office of General Counsel
Commonwealth of Pennsylvania

AND

BY: _____ DATE: _____

Office of Attorney General
Commonwealth of Pennsylvania

I hereby certify that funds are available in the amount(s) and in the appropriation symbol(s) as shown below:

_____

_____

BY: _____ DATE: _____

Comptroller

SIGNATURE REQUIREMENTS

Note: The name(s) and title(s) of the individual(s) signing the agreement must also be printed or typed in the appropriate place on the agreement.

CORPORATION (including Professional Corporation)

- Two signatures are required: either the President or Vice President and either the Secretary, Assistant Secretary, Treasurer, or Assistant Treasurer of the Corporation must sign.
- If any other person has authority to execute agreements on behalf of the Corporation, that person may sign, but a copy of the document conferring that authority (such as by-laws or corporate resolution) must be sent with the agreement when it is returned to the Department for processing.

NOTE: Pennsylvania law requires a for-profit corporation to have a corporate designation such as "Inc.," "Corp.," "Co.," "Ltd.," or "P.C." as part of the corporate name. A not-for-profit corporation under Pennsylvania law might or might not have such a designation as part of the name. When reviewing the corporate name on the agreement, you should make certain it is complete and correct. If a correction to the corporate name is made on the agreement, that correction must be initialed and dated by the same person(s) who sign the agreement.

PARTNERSHIP

- General Partnership – the agreement must be signed by a partner. The title line should indicate "Partner."
- Limited Partnership – only a general partner is authorized to sign on behalf of the partnership. The title line should indicate "General Partner."
- If the partner signing is a corporate entity, corporation signature requirements above apply to the signature of the corporate partner.

NOTE: Partnerships of either kind (general or limited) may register as "limited liability partnerships." This does not affect the signature requirements noted above.

LIMITED LIABILITY COMPANY (LLC)

- Member-Managed LLC – the agreement must be signed by a member. The title line should indicate "Member."
- Manager-Managed LLC – the agreement must be signed by a manager. The title line should indicate "Manager."
- If the member or manager signing is a corporate entity, corporation signature requirements above apply to the signature of the corporate member or manager.

SOLE PROPRIETORSHIP

- The owner should sign the agreement. The title line may be left blank.

DOING BUSINESS AS (d/b/a), or TRADING AS (t/a)

- Corporation operating under a fictitious name – the agreement must be signed according to the instructions provided under "CORPORATION."
- Partnership operating under a fictitious name – the agreement must be signed according to the instructions under "PARTNERSHIP."
- LLC operating under a fictitious name – the agreement must be signed according to the instructions under "LIMITED LIABILITY COMPANY."
- Sole proprietorship operating under a registered fictitious name – the agreement must be signed according to the instructions provided under "SOLE PROPRIETORSHIP."
- The name must include the name of the person(s) or entity(ies) owning and registering the fictitious name, followed by the fictitious name.
- Examples include:

Sole Proprietorship	Partnership	Corporation
John Doe	John Doe and Jane Doe	Doe, Inc.
d/b/a The Coffee Shop	d/b/a The Coffee Shop	d/b/a The Coffee Shop

COUNTIES

- For all counties except home rule charter counties: signature of at least two of the County's three Commissioners shall be affixed; signatures shall be attested to by the Chief Clerk; county seal shall be affixed.
- Home rule charter counties shall execute contracts in accordance with their charters, administrative codes, or as directed in writing by their solicitors.

Sylvia Golas, Project Officer
(717) 231-2825

Susan Guy, Alternate Project Officer
(717) 231-2825

SAP# :[Insert Number]

GRANT AGREEMENT BETWEEN THE PENNSYLVANIA DEPARTMENT OF HEALTH

AND
[INSERT VENDOR NAME]

THIS GRANT AGREEMENT, hereinafter referred to as "Grant Agreement" or "Agreement", is made by and between the Commonwealth of Pennsylvania, Department of Health, hereinafter referred to as "the Department", and [Insert Vendor Name] hereinafter referred to as "Grantee."

WHEREAS, the Department has the power and duty to protect the health of the people of this Commonwealth, and to determine and employ the most efficient and practical means for the prevention and suppression of disease pursuant to 71 P.S. §532; and

WHEREAS, this Agreement is a Grant Agreement and not subject to the Commonwealth Procurement Code, P.L. 358, No. 57, May 15, 1998, 62 Pa.C.S.A. §101 et seq., (Act 57).

WHEREAS, the Department is in receipt of or anticipates receipt of Federal funds or state funds or both pursuant to Tobacco Settlement Act, Act 2001-77, 35 P.S. §5701.101 et seq., to provide for the purposes of this Grant Agreement, and this Grant Agreement is contingent upon appropriation and receipt of such funds.

NOW, THEREFORE, the parties, intending to be legally bound, hereby agree as follows:

I. GRANT AGREEMENT TERM

A. This Grant Agreement shall be effective from June 1, 2019 through [Insert termination date], subject to its other provisions, and the availability of funds, whether state or Federal unless terminated earlier by either party according to the termination provisions of this Grant Agreement.

B. No-Cost Extension. The term of this Grant Agreement may be extended with no additional funding by a written notice signed by the Department in order to allow the Grantee to continue to use the funds to perform the work of this Grant Agreement at the same terms and conditions as this Grant Agreement for an additional period of time. For the purpose of this extension, the funding amount is limited to the funds not spent by the Grantee by the end of the Budget period. At no time will the length of this Grant Agreement exceed 4 years including any extension.

C. Renewal.

☐ At the Department's discretion and by letter notice, the Department may renew this Grant Agreement for the following term: [insert renewal term].

1. In the event of a renewal, the Department may choose to renew the Grant Agreement as follows:

   a) At the Grant Agreement's original terms or conditions; or

   b) To increase or decrease the grant amount or salaries, hourly wages or fringe benefits to reflect cost increases so long as that increase does not exceed [insert percentage]% of the original amount or rates. Nothing in this subparagraph is intended to permit an alteration in the scope of work of the original agreement in the renewal; or

c) To include the increase or decrease in work or change to amount, salaries, wages, or fringe benefits included in an amendment to the original Grant Agreement, including SAFs, Budget Revisions, or formal Amendments. The increase or decrease of work shall be limited to deliverables established in the amendment. Nothing in this paragraph shall be read to permit the scope of work of the Grant Agreement to be changed.

2. The Department is not obligated to increase the amount of the Grant award.

3. Any renewal terms are subject to the other provisions of this Grant Agreement, and the availability of funds.

☒ Renewals are not applicable to this Agreement

II. GRANT AGREEMENT AMOUNT

Subject to the availability of funds, whether state or Federal, and the other terms and conditions of this Grant Agreement, the Department will make payments in accordance with the Grant Agreement payment provisions, Appendix B and the grant Budget, Appendix C, up to the maximum Grant Agreement amount of [Insert total grant amount].

III. FUNDING SOURCE(S)

Pursuant to Management Directive 305.21, *Payments to Local Governments and Other Subrecipients*, the Department must identify the amounts of Federal and state funding it provides to Grantees. This identification follows and includes the breakdown of Federal and state dollars provided and the related Federal and state financial assistance program name and number:
This Agreement is funded 100% with State funds.

IV. WORK STATEMENT

The Grantee shall provide program activities and related services as specified in Appendix A, Work Statement, and its Attachment(s), if any.

V. APPENDICES AND ATTACHMENTS

The following Appendices and Attachments are incorporated into and made part of this Grant Agreement and the parties agree to be bound by these Appendices and Attachments:

A. Appendix A - Work Statement
1. Attachment 1 - Cover Page
2. Attachment 2- Research Proposal
3. Attachment 3 - Letters of Support

B. Appendix B – Payment Provisions
1. Attachment 1 - Annual Expenditure Report
2. Attachment 2 - Report of Infrastructure Expenditures
3. Attachment 3 - Report of Interest Earned and Expenditures on Interest Earned
4. Attachment 4 - Certificate of Compliance with Investment Requirements
5. Attachment 5 – Nonformula Grant Report of Expenditures by Type of Research

C. Appendix C – Budget

D. Appendix D – Program Specific Provisions and Attachments 1-9

1. Attachment 1 - Certifications
2. Attachment 2 - Certifications for the Protection of Human Subjects and Regarding the Use of Human Embryonic Stem Cell Research
3. Attachment 3 - Certifications for the Containment of Recombinant DNA Research and the Care and Treatment of Vertebrate Laboratory Animals
4. Attachment 4 - Form HD1013F: 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
5. Attachment 5 - - Memorandum of Understanding Regarding Ethical Standards As Required By 35 P.S. § 5701.905(f)
6. Attachment 6 - Agreement Regarding Construction
7. Attachment 7 - Agreement Regarding Fiscal and Other Requirements

E. Appendix E - W-9 Form and Instructions

F. Appendix F – Application Checklist

G. Appendix G – Letters of Intent

VI. INCORPORATED DOCUMENTS

Grantee acknowledges having reviewed a copy of the following documents, which are available at http://www.health.pa.gov/vendors. These documents are incorporated by reference into and made a part of this Grant Agreement:

A. Standard General Terms and Conditions (Rev. 3/15)

B. Audit Requirements (Rev. 2/15)

C. Commonwealth Travel and Subsistence Rates (Rev. 4/15)

D. Federal Lobbying Certification and Disclosure (Rev. 12/05)

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

F. Block Grant Provisions (Rev. 12/05)

☐ Maternal and Child Health Block Grant Provisions

☐ Preventive Health and Health Services Block Grant Provisions

☒ Block Grant Provisions are not applicable to this agreement

G. HIPAA Business Associate Agreement and Attachment 1 (Rev. 5/13)

☐ The HIPAA Business Associate Agreement is applicable to this agreement

☒ The HIPAA Business Associate Agreement is not applicable to this agreement

VII. APPLICATION

The Grantee's application:

☒ dated [Insert date] and entitled Nonformula Health Research is attached and incorporated herein.

☐ dated [Insert date] and entitled [Insert title] is hereby incorporated by reference into and made a part of this Grant Agreement.

☐ is not applicable; sole source approval has been obtained.

In the event that there is a conflict between the Department's Request for Application number 67-49, the Grantee's application, and this Grant Agreement, the order of precedence shall be first, this Grant Agreement; second, the Department's Request for Application; third, the Grantee's application.

VIII. ADDITION OF SUBSEQUENTLY AVAILABLE FUNDS

If, during the term of this Grant Agreement, additional funds become available to provide additional or expanded services or activities under the scope of this Grant Agreement, the Department may advise Grantee, in writing, of the availability and purpose of such funds. The Department also will inform Grantee of any additional conditions or requirements of the additional funds. Grantee hereby agrees to accept the funds for the stated purpose and agrees to use the additional funds as stated by the Department. Grantee shall provide the Department with a written Work Statement detailing the manner in which Grantee will use the additional funds in accordance with the stated requirements. Grantee shall provide the Department with a detailed revised overall Grant Agreement Budget showing the current Budget, the Budget for the additional funds and a revised total Budget. The Department may choose to provide Grantee with a Budget format on which to submit the revised Budget information. The additional funds, and the new Budget, shall be subject to the terms and conditions of the initial Grant Agreement, as well as to any additional conditions and requirements of the additional funds. Grantee's Work Statement, revised Budget and any new conditions or requirements of the additional funds shall be incorporated into and become a part of this document by reference. To be effective, documentation describing the additional funds and any additional conditions or requirements shall be signed by the Department and the Agency Comptroller.

IX. DECREASE IN FUNDING

If the Department determines that the Grantee is unable to spend the funding included in this Grant Agreement in a timely manner and that the Grantee is therefore unable to fully carry out the work required under the Agreement in the timeframe required by the Agreement, the Department reserves the right to decrease funding to the Grantee from any Budget year set out in Appendix C of this Grant Agreement by prior written notice signed by the Department and the Comptroller. The decrease in funding shall be reflected by a revised Budget and if necessary, shall also include a revised Work Statement showing any reduction in work resulting from the decrease in funding. The decision to decrease funding is solely within the discretion of the Department.

X. MEANING OF TERMS "CONTRACT" AND "CONTRACTOR"

The parties understand that the use of the terms "Contract" and "Contractor" throughout this Agreement shall mean "Grant Agreement" and "Grantee" respectively.

XI. FINAL GRANT AGREEMENT APPROVAL

This Grant Agreement shall not be legally binding until all signatories, including those signing their approvals for form and legality, have signed the Agreement and the Commonwealth provides a fully signed copy to the Grantee.

Appendix A

WORK STATEMENT

The Work Statement consists of three Attachments:

Attachment 1 - Cover Page

Attachment 2 - Research Proposal

Attachment 3 – Letters of Support

SAP # _____

APPENDIX A, Attachment 1

COVER PAGE

Collaborative Research on Opioid Abuse and the Overdose Crisis

RFA67-76

Applicant Name: _____

(Organization or Institution)

Type of Legal Entity: _____

(Corporation, Partnership, Professional Corporation, Sole Proprietorship, etc.)

Grant Amount: $_____ **Grant Start Date:** _____

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

Address: _____

_____

City: _____ **County:** _____ **State:** _____ **Zip Code:** _____

Type of Grant: Health Research Nonformula Grant

1. FUNDS REQUESTED FOR CLINICAL AND HEALTH SERVICES RESEARCH: _____	
2. GRANT COORDINATOR (PRINCIPAL INVESTIGATOR)	
2a. NAME (First Name MI Last Name)	2b. DEGREE(S)
2c. POSITION TITLE	2d. MAILING ADDRESS (Street, City, State, Zip Code)
2e. TELEPHONE # (Area code, number and extension), and EMAIL ADDRESS Telephone: E-mail:	
3. PRIMARY CONTACT FOR THE PRINCIPAL INVESTIGATOR	
3a. NAME (First Name MI Last Name, Degrees)	3b. TELEPHONE # and EMAIL ADDRESS 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:	

SAP # _____
APPENDIX A, Attachment 2

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 Web, 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 Times New Roman typeface with a font size of 12 points or larger or in an Arial, Helvetica, Palatino Linotype or Georgia typeface with a font size of 11 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 (for example: ☐ **Yes** ☐ **No)** with images or an 'X'. To change an unchecked box to a checked box: select the box, right click, select Properties, and click on the "checked" radial button.

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.

Section	Page Numbers
Introduction	1
I. Table of Contents	2
II. Abbreviations	
III. Research Project Title, Purpose and Inclusion of Proprietary Information	
IV. Research Project Overview	
V. Expected Research Outcomes and Benefits	
VI. Health Disparities	
VII. Management and Staffing Plan	
VIII. Key Research Personnel	
IX. Research Plan	
A. Specific Aims	
B. Background and Significance	
C. Preliminary Studies	
D. Research Design and Methods	
Specific Aim 1	
Specific Aim 2	
Specific Aim 3	
E. Timeline and Milestones	
X. Other Sources of Support	
XI. Research Project Performance Sites	
XII. Facilities and Resources	
XIII. Allocation of Costs for Biomedical, Clinical and Health Services Research	
XIV. Budget Narrative	
XV. Curriculum Vitae, Resumes and Biographical Sketches	
XVI. Evaluation Component and Research Evaluative Procedures	
XVII. Research Subjects and Materials	
XVIII. Protection of Human Subjects	
XIX. Clinical Trials and Data Safety Monitoring Plan	
XX. Targeted/Planned Enrollment Table	
XXI. Consortium/Contractual Agreements	
XXII. Consultants	
XXIII. Literature Cited	
XXIV. Reporting Requirements	

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. The specific objective related to minority research training should be listed after the other research objectives. 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 Institutional Review Board (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 Contract 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 (Principal Investigator) on Appendix A, Attachment 1, 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 name of the person and 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, "Susan Black, Co-Investigator" should 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 Times New Roman font that is no smaller than 12-point type, and left aligned.: **DO NOT** replace **Yes/No Check boxes (for example: ☐ Yes ☐ No)**with images or an 'X.' To change an unchecked box to a checked box: select the box, right click, select Properties, and click on the "checked" radial button.

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

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

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

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

IX. Research Plan - The research plan should 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 should be on the actual research to be conducted, that is, the data that will be collected and analyzed and methods that will be developed to test hypotheses and generate new knowledge that is intended to lead to improvements health related technologies, treatments, services or preventive interventions. The Research Plan must describe only the research to be accomplished within the Grant award period of funding, which may not exceed 48 months. No-cost extensions beyond 48 months are not permitted.

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

The entire Research Plan must not exceed 40 single-spaced, single-sided pages. This page of instructions is not counted in the 40-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). The Research Plan must contain a specific aim related to minority training. The specific aim related to minority training should be listed after the other research aims. 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 the minority training aim, describe recruitment plans and methods, including sources and availability of student trainees; anticipated number of students to be trained; and criteria and procedures by which students will be selected. Describe how students will be involved in the conduct of the research specific aims. Describe a plan to evaluate the training program including a method to obtain training program graduates' recommendations on how to improve the program. Include a method to track the impact of the program on training program graduates' applications for additional higher education and careers in the health sciences and research fields. 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 XVIII.** 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 #__
6/1/19 - 6/30/19	
7/1/19 - 6/30/20	
7/1/20 - 6/30/21	
7/1/21 - 6/30/22	
7/1/22 - 5/31/23	

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 in Attachment 3.

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, Aim 3 minority research training program. 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 the Preface to 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 (Appendix C). 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 – Laboratory or Building Construction or Renovations, provide an explanation of the need for the new facility, including why the proposed work cannot be conducted in existing research facilities.
(J) For each line listed in Category IX – Other Costs, provide an explanation of the costs, a rationale for number of items needed and any other information which explains the budget line item.

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 Contract Principal Investigator, other key personnel at the lead applicant organization and each subcontractor's key personnel. Biographical sketches are recommended, but not required, for external advisory committee members and consultants. On the top of the first page of the biographical sketches of subcontractor key personnel, insert the name of the subcontractor. On the top of the first pages of the biographical sketches of the external advisory committee members and consultants, insert "External Advisory Committee" or "Consultant," as appropriate. Do not exceed five pages per biographical sketch. There is no required format for providing the information. NIH grant application biosketches are compatible with the required information and may be used.

The biographical sketch must include the following items and may not exceed 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 Times New Roman font that is no smaller than 12-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, Item 3. 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 (for example: ☐ Yes ☐ No)** with images or an 'X.' To change an unchecked box to a checked box: select the box, right click, select Properties, and click on the "checked" radial button.

Complete items (A) – (E) below.

(A) Does the project involve the conduct of human subjects research as defined in Appendix D, Attachment 4 - Form HD1013F: 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 you answered Yes, complete Appendix D, Attachment 4 and submit documentation of IRB approval or exemption from review. If the project includes de-identified human specimens, include documentation that an IRB determined the research does not constitute human subjects research and is exempt from review.

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

(C) Does the project conduct research using 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 conduct research involving recombinant DNA? ☐ Yes ☐ No

(E) Does the project conduct research involving 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 Appendix D, Attachment 2 of Part Two of this 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 (Part Two, Appendix D, Attachment 4) 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 you 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, do not complete (a) - (j) below.*

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

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

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

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

(e) **Informed consent**:
(Enter response here)

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

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

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

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

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

If you 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 you answered "Yes" to Item XVII (B), you must describe a data safety and monitoring plan 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 Appendix A, Attachment 3, Letters of Support. The Grantee 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 her/her role in the project. Place the letters in Appendix A, Attachment 3 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 applicant agrees to the following reporting and accountability requirements.

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

1. An Annual Progress Report is due 30 calendar days after the end of each state fiscal year or 60 calendar days after the end of the Grant in the year that the Grant 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 state fiscal year and other information as required by the Department. Annual Progress Reports are posted to the Department's C.U.R.E website in November as part of the Annual Report to the Legislature.

2. A Final Progress Report is due 60 calendar days after the ending 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 Commonwealth 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
        (4) the extent of penetration of the studies throughout the region or the Commonwealth.

    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.

3. A Response to a Performance Review Report is due 30 calendar days after the Department provides the Grantee with a copy of the Performance Review Report.

   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 Department will conduct a performance review upon the completion of the research Grant, 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. The evaluation criteria are available on the CURE website, **www.cure.pa.gov**, under the CURE Final Reports and Performance Review link.

   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 Grantee 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 Grantee must provide an electronic copy of a written Response to the Performance Review Report within 30 calendar days after the Grantee receives the Performance Review Report.

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

   The Final Performance Review Report, as well as the Grantee'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.

In addition to written reports, applicants may also be required to provide oral reports to an advisory committee to the Department at the request of the Program Manager in the Health Research Office.

SAP # _____

APPENDIX A, Attachment 3

LETTERS OF SUPPORT

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

SAP # _____

APPENDIX B

DEPARTMENT OF HEALTH
GRANT AGREEMENT PAYMENT PROVISIONS

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

A. Subject to the availability of state funds and the other terms and conditions of this Grant Agreement, the Department will pay Grantee the total Grant Agreement amount in accordance with Appendix C and any subsequent amendments thereto.

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

1. One payment will be made to the Grantee at the beginning of the Grant Agreement. State funds received under this Grant Agreement shall be promptly deposited by the Grantee in an insured interest-bearing account or invested according to the following investment requirements. All interest derived by the Grantee from the use of state funds during the Grant Agreement shall be utilized to provide additional health research services pertaining to the research project funded by this Grant Agreement.

   Investment Requirements:

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

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

Investment Policy Guidelines include the following:

(a) At least 50 percent of the Pool will be comprised of Federal Obligations or repurchase agreements secured by the same.
(b) At least 30 percent of the Pool will consist of U.S. Treasuries or repurchase agreements secured by U.S. Treasuries.
(c) All other things being equal, preference will be given to investments offered in or through Pennsylvania corporations and financial institutions.

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

3. The Grantee shall submit to the Department an annual expenditure report (Appendix B, Attachment 1) for each state fiscal year ending June 30 within 30 calendar days after the end of the state fiscal year, and a final expenditure report within 60 calendar days of the Grant Agreement's termination date. The Grantee shall submit to the Department a corrected annual or final expenditure report within 30 calendar days of a request for correction from the Department. The reports shall be sent by the Grantee directly to: **Administrative Officer, Pennsylvania Department of Health, Office of Health Research, Room 833 Health and Welfare Building, 625 Forster Street, Harrisburg, PA 17120-0701**. The report shall show Grant number, Federal identification number, date when submitted, name of person preparing report, reporting period, and total expense amount. The report shall include a detailed report of infrastructure expenditures (Appendix B, Attachment 2) and a report of interest earned to date and expenditures on the interest earned (Appendix B, Attachment 3). The Department will not require Grantees to submit detailed documentation with the expenditure reports. However, the Grantee must maintain all detailed documents, records and invoices that support claimed expenditures for a four-year period after the termination date of the Grant. Detailed documentation must be provided (usually within 15 calendar days) upon request by the Commonwealth or its authorized representatives.

4. No more than 50 percent of the total Grant and interest earned on the Grant award may be expended on infrastructure, which is defined as including the following items: office equipment, office supplies, nonprofessional personnel, laboratory or building construction or renovations, used to conduct research.

5. Funds must be spent by the institution within the term of the Grant Agreement. Any unspent funds at the termination of the Grant Agreement, including interest earned but not expended on the research project funded by the Grant Agreement, shall be returned to the Commonwealth no more than 10 work days after the Department has approved the final expenditure report.

   If monies are due the Department, correspondence from the Grantee shall include a breakdown of the funds being returned and the Department's agreement number. A check in this amount shall be made payable to the "Commonwealth of Pennsylvania, Department of Health."

   The check and the unaudited financial report shall be submitted to the Administrative Officer, Pennsylvania Department of Health, Health Research Office, Room 833 Health and Welfare Building, 625 Forster Street, Harrisburg, PA 17120-0701. Funds returned must include interest earned on the unspent funds during the time period of the Grant as well as the time period from termination of the Grant Agreement until the date that the return check is submitted to the Department. Correspondence provided with the check must specify the amount of unspent interest earned prior to the end date of the Grant Agreement and the amount of interest earned from the end date of the Grant to the date of the check preparation.

6. The Commonwealth will make payments through the Automated Clearing House (ACH) Network. The Pennsylvania Electronic Payment Program (PEPP) establishes the Automated Clearing House Network as the preferred method of payment in lieu of issuing checks. The PEPP enrollment form may be obtained at: www.vendorregistration.state.pa.us/cvmu/paper/Forms/ACH-EFTenrollmentform.pdf and can be completed online, as applicable.

a. Within 10 work days of award of the Contract or Purchase Order, the Contractor must submit or must have submitted its ACH information within its user profile in the Commonwealth's procurement system (SRM). At the time of submitting ACH information, the Contractor will also be able to enroll to receive remittances via electronic addenda. Within 10 work days of award of the Grant Agreement, the Contractor must submit or must have already submitted its ACH information and electronic addenda information, if desired, to the Commonwealth's Payable Service Center, Vendor Data Management Unit at 717-214-0140 (FAX) or by mail to the Office of Comptroller Operations, Bureau of Payable Services, Payable Service Center, Vendor Data Management Unit, 555 Walnut Street – 9th Floor, Harrisburg, PA 17101.

b. It is the responsibility of the Contractor to ensure that the ACH information contained in SRM (for Contracts or Purchase Orders) or in the Commonwealth's Central Vendor Master File (for Grant Agreements) is accurate and complete. Failure to maintain accurate and complete information may result in delays in payments.

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

SAP # _____
APPENDIX B, Attachment 1

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.	LABORATORY OR BUILDING CONSTRUCTION OR RENOVATIONS			
IX.	OTHER COSTS (Including Indirect Costs)			
	TOTAL COSTS			

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

_____ Date: _____
(Department's Authorized Signature)

SAP # _____
APPENDIX B, Attachment 2

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		
LABORATORY OR BUILDING CONSTRUCTION OR RENOVATIONS		
OTHER COSTS (include only that portion of Indirect Costs that cover the costs of nonprofessional personnel, office equipment, office supplies, and laboratory construction or renovation)		
TOTAL INFRASTRUCTURE COSTS		

SAP # _____
APPENDIX B, Attachment 3

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, Appendix B, Attachment 1, 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.	LABORATORY OR BUILDING CONSTRUCTION OR RENOVATIONS		
IX.	OTHER COSTS (Including Indirect Costs)		
	TOTAL COSTS		

SAP # _____
APPENDIX B, Attachment 4

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 Section B.1 of Appendix B to the Grant Agreement.

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:	Check "Yes" if funds were not invested during the reporting period for the acceptable reason. Check "No" if funds were not invested during the reporting period for the acceptable reason.	
	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:_____		

SAP # _____
APPENDIX B, Attachment 5

Nonformula Grant Report of Expenditures by Type of Research

Nonformula 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	

APPENDIX C

BUDGET

(Insert Vendor Name)

(Insert SAP #)

(Insert Budget Period)

CATEGORIES	Infra-Structure Funds	Non-Infra-Structure Funds	Full Project Costs
I. PERSONNEL SERVICES			
II. CONSULTANT SERVICES			
III. SUBCONTRACT SERVICES			
IV. PATIENT SERVICES			
V. EQUIPMENT			
VI. SUPPLIES			
VII. TRAVEL			
VIII. LABORATORY OR BUILDING CONSTRUCTION OR RENOVATIONS			
IX. OTHER COSTS (Including Indirect Costs)			
TOTAL			

(Insert Vendor Name)

(Insert SAP #)

(Insert Budget Period)

Categories			Infra-structure Funds	Non-Infra-structure Funds	Full Project Costs
I. PERSONNEL SERVICES					
A. Staff Personnel	Hourly Rate	Number of Hours			
Sub-Total					

(Insert Vendor Name)

(Insert SAP #)

(Insert Budget Period)

Categories			Infra-structure Funds	Non-Infra-structure Funds	Full Project Costs
I. PERSONNEL SERVICES					
B. Fringe Benefits	**Salary**	**Rate**			
Specify the benefits included in this rate:					
Sub-Total					
Total					

(Insert Vendor Name)

(Insert SAP #)

(Insert Budget Period)

Categories			Infra-structure Funds	Non-Infra-structure Funds	Full Project Costs
II. CONSULTANT SERVICES					
	Hourly Rate	**Number of Hours**			
Total					
III. SUBCONTRACT SERVICES					
Total					

(Insert Vendor Name)

(Insert SAP #)

(Insert Budget Period)

Categories			Infra-structure Funds	Non-Infra-structure Funds	Full Project Costs
IV. PATIENT SERVICES					
Total					
V. EQUIPMENT					
	Quantity	Unit Cost			
Total					

(Insert Vendor Name)

(Insert SAP #)

(Insert Budget Period)

Categories	Infra-structure Funds	Non-Infra-structure Funds	Full Project Costs
VI. SUPPLIES			
Total			
VII. TRAVEL			
Mileage **Lodging** **Airfare** **Subsistence** **Parking / Tolls** **Ground Transportation**			
Total			

(Insert Vendor Name)

(Insert SAP #)

(Insert Budget Period)

Categories	Infra-structure Funds	Non-Infra-structure Funds	Full Project Costs
VIII. LABORATORY OR BUILDING CONSTRUCTION OR RENOVATIONS			
Total			
Categories	**Infra-structure Funds**	**Non-Infra-structure Funds**	**Full Project Costs**
IX. OTHER COSTS			
Indirect Costs*			
Total			

*Specify the Indirect Costs rate, the budget categories to which it applies, and cost of those categories. List the specific items that the indirect costs pay for.

APPENDIX D - PROGRAM SPECIFIC PROVISIONS

Attachment 1 - Certifications

Attachment 2 - Certifications for the Protection of Human Subjects and Regarding the Use of Human Embryonic Stem Cell Research

Attachment 3 - Certifications for the Containment of Recombinant DNA Research and the Care and Treatment of Vertebrate Laboratory Animals

Attachment 4 - Form HD1013F: 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

Attachment 5 - Memorandum of Understanding Regarding Ethical Standards As Required By 35 P.S. § 5701.905(f)

Attachment 6 - Agreement Regarding Construction

Attachment 7 - Agreement Regarding Fiscal and Other Requirements

(REV. 2/15)

SAP # _____

APPENDIX D, Attachment 1

CERTIFICATIONS

1. **Certification Regarding Debarment and Suspension**

   a. The Contractor certifies, in writing, for itself and all its subcontractors required to be disclosed or approved by the Commonwealth, that as of the date of its execution of this Bid/Contract, that neither the Contractor, nor any such subcontractors, are under suspension or debarment by the Commonwealth or any governmental entity, instrumentality, or authority and, if the Contractor cannot so certify, then it agrees to submit, along with its Bid/Contract, a written explanation of why such certification cannot be made.

   b. The Contractor also certifies, in writing, that as of the date of its execution of this Bid/Contract it has no tax liabilities or other Commonwealth obligations, or has filed a timely administrative or judicial appeal if such liabilities or obligations exist, or is subject to a duly approved deferred payment plan if such liabilities exist.

   c. The Contractor's obligations pursuant to these provisions are ongoing from and after the effective date of the Contract through the termination date thereof. Accordingly, the Contractor shall have an obligation to inform the Commonwealth if, at any time during the term of the Contract, it becomes delinquent in the payment of taxes, or other Commonwealth obligations, or if it or, to the best knowledge of the Contractor, any of its subcontractors are suspended or debarred by the Commonwealth, the Federal government, or any other state or governmental entity. Such notification shall be made within 15 days of the date of suspension or debarment.

   d. The failure of the Contractor to notify the Commonwealth of its suspension or debarment by the Commonwealth, any other state, or the Federal government shall constitute an event of default of the Contract with the Commonwealth.

   e. The Contractor agrees to reimburse the Commonwealth for the reasonable costs of investigation incurred by the Office of State Inspector General for investigations of the Contractor's compliance with the terms of this or any other Agreement between the Contractor and the Commonwealth that results in the suspension or debarment of the Contractor. Such costs shall include, but shall not be limited to, salaries of investigators, including overtime; travel and lodging expenses; and expert witness and documentary fees. The Contractor shall not be responsible for investigative costs for investigations that do not result in the Contractor's suspension or debarment.

   f. The Contractor may obtain a current list of suspended and debarred Commonwealth Contractors by either searching the Internet at http://www.dgs.state.pa.us/ or contacting the:

      Department of General Services
      Office of Chief Counsel
      603 North Office Building
      Harrisburg, PA 17125
      Telephone No: (717) 783-6472
      FAX No: (717) 787-9138

   IF THE CONTRACTOR INTENDS TO USE ANY SUBCONTRACTORS, LIST THEIR NAMES(S), ADDRESS(ES), AND FEDERAL IDENTIFICATION OR SOCIAL SECURITY NUMBER(S) IN THE SPACE BELOW.

2. **Certification Regarding Application/Proposal/Bid Validity**

   This application/proposal/bid shall be valid for a period of 60 days following the time and date designated for bid opening of applications/proposals/bids received in response to this Request for Application/Request for Proposal/Invitation for Bid # RFA67-76.

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

SIGNATURE OF AUTHORIZED CERTIFYING OFFICIAL	TITLE
APPLICANT ORGANIZATION	ADDRESS OF ORGANIZATION
DATE SUBMITTED	CONTRACTOR'S FEDERAL I.D. OR S.S. NUMBER

SAP # _____

APPENDIX D, Attachment 2

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 form number HD1013F. 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 Application to Pennsylvania Department of Health Institutional Review Board on form number HD1013F.

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

SAP # _____

APPENDIX D, Attachment 3

CERTIFICATIONS FOR THE CONTAINMENT OF RECOMBINANT DNA RESEARCH 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 RECOMBINANT DNA RESEARCH

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

Please check the appropriate statement:

☐ This research does not involve any use of recombinant DNA molecules as defined by current NIH guidelines.

☐ This research involves the use of recombinant DNA molecules as defined by current NIH guidelines. This is to certify that the proposed activities involving recombinant DNA 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 DNA molecules as defined by current NIH guidelines. This is to certify that the proposed activities involving recombinant DNA 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 DNA molecules will adhere to policies set out in the current National Institutes of Health (NIH) Guidelines for Research Involving DNA Molecules, and that prior to the initiation of research involving recombinant DNA and the use of Health Research Formula 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 Formula Funds to pay for any of the research expenses, the applicant will obtain prior written approval of an appropriate IACUC.

NAME OF AUTHORIZED INSTITUTIONAL OFFICIAL	TITLE
SIGNATURE	DATE

HD1013F

SAP # _____

APPENDIX D, Attachment 4

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

Policy: The following types of research projects involving human subjects require the review of the Department of Health's Institutional Review Board (IRB): (1) grants for which a Department of Health program is applying; (2) grants awarded by the Department of Health to grantees; (3) research conducted by the Department of Health; or (4) entities using Department of Health biological specimens and/or data. A human subject is a living person about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual or (2) personally identifiable information.

1. Project Name	2. Project Status ☐ New ☐ Continuing

Principal Investigator Information

3. Name	5. Name and Address of Institution	6. Phone
4. Title		7. Fax
		8. E-mail Address

9. Anticipated Level of Review (check one)

☐ A. Project apparently requires IRB review. *Complete items 11-22.*

☐ B. Project is exempt from IRB for the reasons indicated in question 10 below and has not been previously reviewed by another IRB. *Complete items 10-22.*

☐ C. IRB review has been conducted by another IRB. *Attach copy of approval or exemption and complete items 17-22.*

Name of other IRB_____

Type of Review: ☐ Full Review ☐ Expedited Review ☐ Exempt from Review

Date of IRB Action_____

10. Request for Exemption from Review (check any of the following which apply)

☐ A. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (1) research on regular and special education instructional strategies, or (2) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ B. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (1) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (2) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

☐ C. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph B above, if: (1) the human subjects are elected or appointed public officials or candidates for public office; or (2) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

☐ D. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

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

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

Project Detail

11. Required Attachments

The following attachments are included with the submission of this form:

- ☐ Research protocol
- ☐ Grant application form (if applicable)
- ☐ Informed consent statements
- ☐ Contact letters
- ☐ Questionnaires/survey instruments
- ☐ Other_____

12. Project Purpose (in addition to the attachments, provide brief explanation in layman's terms)

13. Research Design (in addition to the attachments, provide brief explanation in layman's terms)

14. Anticipated Time Period for Conducting the Research

From_____ To_____

15. Anticipated Source of Funding	16. Anticipated Level of Funding

Signature

The official signing below certifies that the information provided above and in any related attachments is correct and that, as required, future reviews will be requested and certification will be provided.

17. Name of Official	18. Title
19. Signature	20. Date
21. Phone	22. Fax

Department of Health Institutional Review Board Approval

23. Exemption from Review

Project is exempt from Department of Health IRB review: ☐ Yes ☐ No

If yes, determination is based on this criteria in question 10 above: ☐ A ☐ B ☐ C ☐ D ☐ E ☐ F

24. Name of Signatory	25. Title of Signatory
26. Type of Review ☐ Full Review ☐ Expedited Review	27. Approval ☐ Approved ☐ Disapproved
28. Signature	29. Date

SAP # _____

APPENDIX D, Attachment 5

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

SAP # _____

APPENDIX D, Attachment 6

Agreement Regarding Construction

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

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

APPLICANT ORGANIZATION	
NAME OF AUTHORIZED OFFICIAL	TITLE OF AUTHORIZED OFFICIAL
SIGNATURE OF APPLICANT'S AUTHORIZED OFFICIAL	DATE

Agreement Regarding Fiscal and Other Requirements

Section 12. RECORDS RETENTION REQUIREMENTS of the Standard General Terms and Conditions (Rev 3/15) is hereby deleted in its entirety and replaced with the following:

RECORD RETENTION REQUIREMENTS.

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

A. The Contractor shall preserve and make available its records for a period of four years from the termination date of this Agreement, and for such period, if any, as is required by applicable statute, by any other paragraph of this Agreement, or by sub-paragraphs (1) or (2) below.

(1) If this Agreement is completely or partially terminated, the records relating to the work terminated shall be preserved and made available for a period of five years from the date of any resulting final payment.

(2) Records which relate to litigation or the settlement of claims arising out of the performance of this Agreement, or costs and expenses of this Agreement as to which exception has been taken by the auditors, shall be retained by the Contractor until such litigation, claims, or exceptions have been disposed of.

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

Section 15. PROGRAM CHANGES of the Standard General Terms and Conditions (Rev 3/15) is hereby deleted in its entirety and replaced with the following:

PROGRAM CHANGES.

The DOH Project Officer may, by written order, make changes to the Grant Agreement provided such changes are consistent with the research priorities and that the requirements for human subjects protections, recombinant DNA research and vertebrate laboratory animals are met and provided further that the total cost of this Agreement is not exceeded. Applicants may request to discontinue research project(s) or add a new research project(s) to the Grant. All research projects must be approved in writing in advance by the DOH Project Officer prior to the initiation of the research. Research involving human subjects, laboratory animals and recombinant DNA must be reviewed and approved by the applicant's appropriate institutional review board prior to the initiation of the research and use of Grant funds to pay for any research expenses. If the proposed research project involves human subjects, the application to the Pennsylvania Department of Health Institutional Review Board and documentation of IRB exemption or approval must be submitted to the DOH Project Officer prior to initiation of the research. The DOH Project Officer and the Grantee shall mutually determine whether the ordered changes can be accomplished within the total Grant cost and the extent of change, if any in the delivery schedules required by the ordered changes.

Section 17. KEY PERSONNEL of the Standard General Terms and Conditions (Rev 3/15) is hereby deleted in its entirety.

Section 18. INSPECTION AND ACCEPTANCE of the Standard General Terms and Conditions (Rev 3/15) is hereby deleted in its entirety.

Section 20. OWNERSHIP RIGHTS of the Standard General Terms and Conditions (Rev 3/15) is hereby deleted in its entirety and replaced with the following:

DATA, COPYRIGHTS, AND DISCLOSURE

The Commonwealth of Pennsylvania shall have a royalty-free, non-exclusive, irrevocable license to use any patented or copyrighted invention developed with direct funding support from this Grant, for non-commercial, public health practice or research conducted by the Department directly, or through a contractor on its behalf. Except in accordance with the foregoing, this right shall not be sublicensable or transferable. The terms contained in this paragraph shall take precedence over any provision to the contrary appearing elsewhere in this agreement.

All notices, publications, informational pamphlets, press releases, research reports and similar public notices prepared and released by the Contractor, shall include the statement, "This project is funded, in part, under a Grant with the Pennsylvania Department of Health. The Department specifically disclaims responsibility for any analyses, interpretations or conclusions."

Section 24. COLLECTION OR RECORDING OF INFORMATION of the Standard General Terms and Conditions (Rev 3/15) is hereby deleted in its entirety.

Section 37. DISPOSITION OF EQUIPMENT AND OTHER MATERIAL paragraphs B through G of the Standard General Terms and Conditions (Rev 3/15) is hereby deleted in its entirety.

REPORTING AND ACCOUNTABILITY

The applicant agrees to the following reporting and accountability requirements.

Applicants are required to submit to the Department a copy of the following written reports in electronic form.

1. An Annual Progress Report is due 30 calendar days after the end of each state fiscal year or 60 calendar days after the end of the Grant in the year that the Grant 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 state fiscal year and other information as required by the Department. Annual Progress Reports are posted to the Department's C.U.R.E website in November as part of the Annual Report to the Legislature.

2. A Final Progress Report is due 60 calendar days after the ending date of the Grant award. The final report shall be provided in a format to be determined by the Department and 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 Commonwealth 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
(4) the extent of penetration of the studies throughout the region or the Commonwealth.

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.

3. A Response to a Performance Review Report is due 30 calendar days after the Department provides the Grantee with a copy of the Performance Review Report.

An applicant that receives a health research Grant under the Tobacco Settlement Act, 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 Department will conduct a performance review upon the completion of the research Grant, 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 to conduct the review.

Upon completion of the performance review process, the Department will provide each Grantee 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 Grantee must provide an electronic copy of

a written Response to the Performance Review Report within 30 calendar days after the Grantee receives the Performance Review Report.

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

The Final Performance Review Report, as well as the Grantee'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.

In addition to written reports, applicants may also be required to provide oral reports to an advisory committee to the Department at the request of the Program Manager in the Health Research Office.

Finally, an electronic copy of each publication and report published based on research funded by this award must be provided to the Department, without charge, at the time of publication, even after the award period has been completed.

COMPLIANCE WITH ETHICAL STANDARDS

In accordance with Section 905(f) of the Pennsylvania Tobacco Settlement Act, the research to be performed and all individuals performing such research shall be subject to Federal ethical and procedural standards of conduct as prescribed by the NIH. By signing this Grant Agreement, Grantee certifies that it will conduct the research funded by this Grant in accordance with Federal ethical and procedural standards regulating research and research findings, including publications and patents, which are observed under NIH extramural funding requirements and NIH grants policy statements and applicable sections of 45 CFR Pt 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 Pt. 92 (relating to uniform administrative requirements for grants and cooperative agreements to state and local governments).

ADDITIONAL AUDIT REQUIREMENTS

This Agreement is subject to audit in accordance with the Audit Requirements (Rev. 2/15) located on the Internet at: http://www.health.pa.gov/vendors. The following terms supplement the audit requirements previously referenced. However, where there may be a conflict between the terms referenced below and the previously mentioned audit requirements, the terms referenced below will take precedence in such instances.

Records must be retained for four years after the end of the Grant Agreement period.

Audit periods shall coincide with state fiscal years, but shall not be less than six months or greater than 18 months. Specifically, the contractor shall have an audit performed when it expends $500,000 or more of state funds received under this contract within the 13-month period immediately following the effective date of the

contract (June 1, 2019) or when it expends $500,000 or more of state funds received under this contract within any successive 12-month period thereafter, unless notified in writing by the Department prior to the termination of the applicable audit period that the audit requirement has been waived. If the contract or any successive period is for a period of less than 12 months, but the contract amount expended by the contractor during said period includes $500,000 or more of state funds, the contractor is also required to have an audit performed for the entire contract or successive period, unless notified in writing by the Department prior to the termination of the applicable audit period that the audit requirement has been waived.

Contractor must submit a program specific audit in accordance with the provisions of Department's audit requirements referenced above.

The contractor shall preserve all books, records and documents related to this contract for a minimum of four years from the termination date of the Grant Agreement; or until all findings, questioned costs or activities have been resolved to the satisfaction of the Commonwealth; or as required by applicable Federal laws and regulations, whichever is longer, unless this contract elsewhere provides for a shorter period; or unless the Department otherwise separately agrees in writing to a shorter period. The contractor shall provide Federal and state agencies or their designees access to such books, records and documents for inspection, audit or reproduction.

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

Submit one electronic copy to:	**Submit one electronic copy to:**
David DePeau, Audit Resolution Section	CURE Program Analyst
Pennsylvania Department of Human Services	Health Research Office
Bureau of Financial Operations	Pennsylvania Department of Health
DGS Annex, 3 Ginko Drive	Room 833 Health and Welfare Building
Hilltop Building, Rm 213	625 Forster Street
Harrisburg, Pennsylvania 17110	Harrisburg, Pennsylvania 17120-0701
Email: ra-dhprogramaudit@pa.gov	Email: ra-healthresearch@pa.gov
Phone #: (717) 705-2288	Phone #: (717) 231-2825

TERMINATION PROVISIONS

The Department shall have the right to terminate the Grant if the research conducted by Grantee and funded by this Grant Agreement does not conform to Federal ethical standards in accordance with the Memorandum of Understanding (MOU) Regarding Ethical Standards or research that is not within the scope of research described in the strategic research plans that have been approved in writing in advance by the Department Project Officer prior to the initiation of the research or for violations of the terms and conditions of the Nondiscrimination/Sexual Harassment Clause (found below) or Contractor Integrity Provisions as specified in the Standard General Terms and Conditions (Rev. 3/15; found at http://www.health.pa.gov/vendors).

NONDISCRIMINATION/SEXUAL HARASSMENT CLAUSE

The following language replaces Paragraph 35 of the Standard General Terms and Conditions (Rev. 3/15) in its entirety:

The Grantee agrees:

1. In the hiring of any employee(s) for the manufacture of supplies, performance of work, or any other activity required under the Grant Agreement or any subgrant Agreement, Contract, or subcontract, the Grantee, a subgrantee, a Contractor, a subcontractor, or any person acting on behalf of the Grantee shall not discriminate by reason of race, gender, creed, color, sexual orientation, gender identity or expression, or in violation of the *Pennsylvania Human Relations Act* (PHRA) and applicable Federal laws, against any citizen of this Commonwealth who is qualified and available to perform the work to which the employment relates.
2. The Grantee, any subgrantee, Contractor or any subcontractor or any person on their behalf shall not in any manner discriminate by reason of race, gender, creed, color, sexual orientation, gender identity or expression, or in violation of the PHRA and applicable Federal laws against or intimidate any of its employees.
3. The Grantee, any subgrantee, Contractor or any subcontractor shall establish and maintain a written nondiscrimination and sexual harassment policy and shall inform their employees of the policy. The policy must contain a provision that sexual harassment will not be tolerated and employees who practice it will be disciplined. Posting this Nondiscrimination/Sexual Harassment Clause conspicuously in easily-accessible and well-lighted places customarily frequented by employees and at or near where the Grant services are performed shall satisfy this requirement for employees with an established work site.
4. The Grantee, any subgrantee, Contractor or any subcontractor shall not discriminate by reason of race, gender, creed, color, sexual orientation, gender identity or expression, or in violation of the PHRA and applicable Federal laws against any subgrantee, Contractor, subcontractor or supplier who is qualified to perform the work to which the Grant relates.
5. The Grantee and each subgrantee, Contractor and subcontractor represents that it is presently in compliance with and will maintain compliance with all applicable Federal, state, and local laws and regulations relating to nondiscrimination and sexual harassment. The Grantee and each subgrantee, Contractor and subcontractor further represents that is has filed a Standard Form 100 Employer Information Report ("EEO-1") with the U.S. Equal Employment Opportunity Commission ("EEOC") and shall file an annual EEO-1 report with the EEOC as required for employers subject to *Title VII* of the *Civil Rights Act of 1964,* as amended, that have 100 or more employees and employers that have Federal government Contracts of first-tier subcontracts and have 50 or more employees. The Grantee, any subgrantee, any Contractor or any subcontractor shall, upon request and within the time periods requested by the Commonwealth, furnish all necessary employment documents and records, including EEO-1 reports, and permit access to their books, records, and accounts by the granting agency and the Bureau of Diversity, Inclusion and Small Business Opportunities, for purpose of ascertaining compliance with provisions of this Nondiscrimination/Sexual Harassment Clause.
6. The Grantee, any subgrantee, Contractor or any subcontractor shall include the provisions of this Nondiscrimination/Sexual Harassment Clause in every subgrant Agreement, Contract or subcontract so that those provisions applicable to subgrantees, Contractors or subcontractors will be binding upon each subgrantee, Contractor or subcontractor.
7. The Granter's and each subgrantee's, Contractor's and subcontractor's obligations pursuant to these provisions are ongoing from and after the effective date of the Grant Agreement through the termination date thereof. Accordingly, the Grantee and each subgrantee, Contractor and subcontractor shall have an obligation to inform the Commonwealth if, at any time during the term of the Grant Agreement, it becomes aware of any actions or occurrences that would result in violation of these provisions.
8. The Commonwealth may cancel or terminate the Grant Agreement and all money due or to become due under the Grant Agreement may be forfeited for a violation of the terms and conditions of this Nondiscrimination/Sexual Harassment Clause. In addition, the granting agency may proceed with

debarment or suspension and may place the Grantee, subgrantee, Contractor, or subcontractor in the Contractor Responsibility File.

ADDITIONAL PROVISIONS RELATING TO NONDISCRIMINATION/SEXUAL HARASSMENT

The following language replaces Paragraph 36 of the Standard General Terms and Conditions (Rev. 3/15) in its entirety:

The Grantee agrees:

1. In the hiring of any employee(s) for the manufacture of supplies, performance of work, or any other activity required under the Contract or any subcontract, the Contractor each subcontractor, or any person acting on behalf of the Contractor or subcontractor shall not discriminate by reason of religion, age, handicap or national origin, against any citizen of this Commonwealth who is qualified and available to perform the work to which the employment relates.
2. Neither the Contractor nor any subcontractor or any person on their behalf shall in any manner discriminate against or intimidate any of its employees on account of religion, age, handicap or national origin.
3. The Grantee, any subgrantee, Contractor or any subcontractor shall not discriminate by reason of religion, age, handicap or national origin against any subgrantee, contractor, subcontractor or supplier who is qualified to perform the work to which the contracts relates.
4. The Contractor and any subcontractors shall ensure that any services or benefits available to the public or other third parties by way of this Contract shall not be denied or restricted for such persons due to race, creed, color, religion, gender, sexual orientation, gender identity or expression, age, handicap, or national origin (national origin protections include persons who are limited English proficient) consistent with the provisions of Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, Title II of the Americans with Disabilities Act and The Age Discrimination Act of 1975 as well as applicable provisions of the Omnibus Reconciliation Act of 1981.
5. The Contractor and each subcontractor shall furnish all necessary employment documents and records to and permit access to its books, records, and accounts by the contracting officer and the Department of General Services' Bureau of Diversity, Inclusion and Small Business Opportunities for purposes of investigation to ascertain compliance with the provisions of this Additional Provisions relating to Nondiscrimination/Sexual Harassment Clause. If the Contractor or any subcontractor does not possess documents or records reflecting the necessary information requested, it shall furnish such information on reporting forms supplied by the contracting officer or the Bureau of Diversity, Inclusion and Small Business Opportunities.
6. The Commonwealth may cancel or terminate the Grant Agreement and all money due or to become due under the Grant Agreement may be forfeited for a violation of the terms and conditions of this Section II, Additional Provisions Relating To Nondiscrimination/Sexual Harassment Clause. In addition, the granting agency may proceed with debarment or suspension and may place the Grantee, subgrantee, Contractor, or subcontractor in the Contractor Responsibility File.

PENALTY FOR VIOLATING THE GRANT AGREEMENT TERMS

The Department may require repayment of Grant funds for the conduct of research that does not conform to the Federal ethical standards in accordance with the Memorandum of Understanding (MOU) Regarding Ethical Standards or research that is not within the scope of research described in the Research Proposal, which have been approved in writing in advance by the Department Project Officer prior to the initiation of the research.

PENALTY FOR VIOLATING REPORTING REQUIREMENTS

If the Grantee fails to submit to the Department an annual progress report in the required format within 30 calendar days after its due date, or a final progress report in the required format within 30 calendar days after its due date, or the Grantee fails to submit a corrected annual or final progress report in the required format within 30 calendar days of a request by the Department, the Grant may receive an unfavorable final performance review rating. For grants consisting of more than one project, each project for which the final progress report is not submitted in the required format within 30 calendar days after its due date may receive an unfavorable final performance review rating. Two consecutive overall grant-level unfavorable performance review ratings will make the Grantee ineligible to apply for nonformula funds and will result in a reduction in formula funds in the next funding cycle.

If the Grantee fails to submit a response to the final performance review report within 60 calendar days after its due date, the Department may post the final performance review report on the CURE website with a notice that the Grantee failed to submit a response to the final performance review.

LIQUIDATED DAMAGES

The Grantee acknowledges that failure to submit expenditure reports, audit reports or unspent funds including interest, as referenced in previous sections of this Appendix, by the due date(s) shall constitute a material breach of this agreement. Such material breach of this agreement may subject the Grantee to liquidated damages in the amount of up to $100 per day until the outstanding report or repayment of unspent funds is submitted to the Department. Future health research formula awards may be offset by damages owed as a result of material breaches in prior Health Research Grants.

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

APPLICANT ORGANIZATION	
NAME OF AUTHORIZED OFFICIAL	TITLE OF AUTHORIZED OFFICIAL
SIGNATURE OF APPLICANT'S AUTHORIZED OFFICIAL	DATE

SAP # _____

APPENDIX E

W-9 FORM AND INSTRUCTIONS

Provide a copy of the completed Internal Revenue Service form W-9. The W-9 form and instructions for completing the form are available at the website http://www.irs.gov.

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APPENDIX F

APPLICATION CHECKLIST

Include this page when submitting the Grant application.

The documents in the paper copy of the Grant application should be placed in the following order.

- ☐ **Completed and SIGNED** Signature Page
- ☐ Documentation of Signature Authority (if applicable)
- ☐ Grant Agreement between the Pennsylvania Department of Health and Grant Applicant
- ☐ Appendix B - Department of Health Grant Agreement Payment Provisions and Attachments 1 through 5 (Annual Expenditure Report, Report of Infrastructure Expenditures, Report of Interest Earned and Expenditures on Interest Earned, Certificate of Compliance with Investment Requirements, and Nonformula Grant Report of Expenditures by Type of Research)
- ☐ Appendix D, Program Specific Provisions, Attachment 1 - **Completed and SIGNED** Certifications
- ☐ Appendix D, Program Specific Provisions, Attachment 2 - **Completed and SIGNED** Certifications for the Protection of Human Subjects and Regarding the Use of Human Embryonic Stem Cell Research
- ☐ Appendix D, Program Specific Provisions, Attachment 3 - **Completed and SIGNED** Certifications for the Containment of Recombinant DNA Research, and the Care and Treatment of Vertebrate Laboratory Animals
- ☐ Appendix D, Program Specific Provisions, Attachment 4 - **Completed and SIGNED** Form HD1013F: Application to the Pennsylvania Department of Health Institutional Review Board (if applicable)
- ☐ Appendix D, Program Specific Provisions, Attachment 5 - **Completed and SIGNED** Memorandum of Understanding Regarding Ethical Standards As Required By 35 P.S. § 5701.905(f)
- ☐ Appendix D, Program Specific Provisions, Attachment 6 - **Completed and SIGNED** Agreement Regarding Construction
- ☐ Appendix D, Program Specific Provisions, Attachment 7 - **Completed and SIGNED** Agreement Regarding Fiscal and Other Requirements
- ☐ Appendix E - **Completed and SIGNED** W-9 Form and Instructions
- ☐ Appendix F - Application Checklist

The following electronic documents should be placed on a CD-R or DVD:

- ☐ Appendix A, Work Statement, Attachment 1 - Cover Page in Microsoft Word
- ☐ Appendix A, Work Statement, Attachment 2 - Research Proposal in PDF. The Research Proposal should be submitted as a directly created PDF file, not the result of scanning. Each CD-R/DVD should be labeled with RFA67-76, the name of the principal investigator, applicant institution, and research project title.
- ☐ Appendix A, Work Statement, Attachment 3 – Letters of Support in PDF
- ☐ Appendix C - Budget in Excel for applicant and all subcontractors

SAP# _____

APPENDIX G

Letter of Intent

Pennsylvania Department of Health **Letter of Intent to Submit an Application for Collaborative Research on Opioid Abuse and the Overdose Crisis** *In Response to* **Request For Applications (RFA67-76)**	**Deliver to:** Division of Contracts Pennsylvania Department of Health Room 824, Health and Welfare Building 625 Forster Street Harrisburg, PA 17120-0701 Telephone: (717) 787-1022 **Faxed Letters of Intent will not be accepted.** **Due date:** on or before the time and date 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*)