pennsylvania
DEPARTMENT OF HEALTH

Nov. 13, 2020

Dear Potential Institution Applicant:

You are invited to submit an application to the Pennsylvania Department of Health for research on spinal cord injury in accordance with the enclosed Request for Applications (RFA) 67-115. The effective date for the Grant Agreement will be June 1, 2021.

All questions regarding this RFA must be directed in writing to the Director, Health Research Office, through email at ra-healthresearch@pa.gov no later than 12:00 p.m. on **Nov. 19, 2020**. All questions must include the specific section of the RFA about which the potential institution is questioning. Answers to all questions will be posted at www.emarketplace.state.pa.us. Click on 'Solicitations' and search for the above RFA number.

A pre-application conference will be held via Skype on **Nov. 24, 2020** from 2 PM to 3 PM EST. Potential applicants can join by Skype by clicking on this link https://meet.lync.com/pagov/peharris/V2KCFY5Vor by phone at (267) 332-8737. The conference ID is 157674747. If attending by phone, any content shown on Skype call screen will not be visible. Applicant attendance is optional.

A Letter of Intent must be submitted through email to ra-healthresearch@pa.gov. The Letter of Intent must be prepared using the Letter of Intent form provided in Part Two, Appendix F of this RFA. The Letter of Intent must be submitted no later than **2:30 p.m. on Dec. 3, 2020**. **If the Letter of Intent is not received using the form provided on or before this date and time, the application will not be accepted.**

Upon the receipt of the Letter of Intent, the applicant will receive a link to a SharePoint site for submission of the application. The application must be submitted through the SharePoint site link no later than **1:30 p.m. on Dec. 22, 2020. The link will be removed at the submission deadline.**

LATE APPLICATIONS WILL NOT BE ACCEPTED REGARDLESS OF THE REASON.

The Department expects that the evaluation of applications and the selection of Grantees will be completed within six months of the submission due date.

Sincerely,

Lori Diehl
Digitally signed by Lori Diehl
Date: 2020.11.12 11:33:39 -05'00'

Lori Diehl
Director
Office of Procurement

Enclosure

Request for Application

Spinal Cord Injury Research Grant Program

RFA Number
67-115

Date of Issuance
Nov. 13, 2020

Issuing Office: Pennsylvania Department of Health
Office of Procurement
Room 816, Health & Welfare Building
625 Forster Street
Harrisburg, Pennsylvania 17120-0701

RFA Project Officer: Sylvia Golas
Pennsylvania Department of Health
Health Research Office
Room 833, Health & Welfare Building
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Harrisburg, Pennsylvania 17120-0701
Email address: ra-healthresearch@pa.gov

Spinal Cord Injury Research Grant Program

CONTENTS

PART ONE

Spinal Cord Injury Research Grant Program

General Information

A. Information for Institutions

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.

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

The intent of this RFA is to fund Spinal Cord Injury Research Grants with the overall objective to foster and encourage innovative research for treatment and rehabilitative techniques for spinal cord injuries. Through this RFA process, the Department is soliciting Spinal Cord Injury Research Grant applications from Pennsylvania institutions that conduct research on spinal cord injuries. The Department is interested in funding three levels or Tiers of spinal cord research: 1.) Pilot Project Grants, 2.) Standard Research Grants, and 3.) Clinical/Translational Grant applications addressing the research priorities established by the Department in conjunction with the Spinal Cord Research Advisory Board.

The institution 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 institution and any collaborating institutions must be located in Pennsylvania.

This RFA provides interested institutions with information to prepare and submit applications to the Department. Questions about this RFA must be addressed to the Director, Health Research Office 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 institution 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 providers are required to enroll in the SAP system. Institutions shall enroll at www.vendorregistration.state.pa.us/, or by calling toll free at 1(877) 435-7363 or locally at (717) 346-2676.

Additional information about how to apply, relevant and specific restrictions, evaluation of applications and deliverables are noted and outlined in Section B.

1. Introduction

The Department has identified $1 million annually to fund research projects that are consistent with the spinal cord research priority. For this initial RFA 67-115, the total funds are $2 million due to the

combining of funds from state fiscal years 2019-2020 and 2020-2021.

All applications submitted in response to this RFA must be aligned with the following research priorities established by the Department in conjunction with the Spinal Cord Research Advisory Committee:

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

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

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

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

2. Eligible Institutions

An eligible institution must conduct research on spinal cord injuries in the Commonwealth of Pennsylvania and must be (1) a nonprofit entity that conducts research, or (2) a hospital that conducts research and is established under the Act of July 19, 1979 (P.L. 130, No. 48), known as the Health Care Facilities Act, or (3) an institution of higher education that conducts research. All institutions must have their primary location within Pennsylvania. Eligible institutions must be registered with the Pennsylvania Department of State.

3. Use of Funds – Limitations and Additional Requirements

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

Tier 1: Pilot Research Grant:

- **Maximum Budget Request:** $100,000.
- **Project Requirements:** This Tier will fund applications that propose early research investment aligned with the research priority as the institution prepares to seek a potential larger research Grant from a Federal program or non-profit organization. Preliminary data is not required for this Tier.
- **Grant Period:** June 1, 2021 to May 31, 2023 (a one year no-cost extension may be requested and approved with sufficient justification, extending the period to May 31, 2024.)

Tier 2: Standard Research Grant:

- **Maximum Budget Request:** $200,000.
- **Project Requirements:** This Tier will primarily fund applications for research aligned with the research priority which include supporting and preliminary data for the research proposed. This Tier may also fund pilot research (with no preliminary or supporting detail) if the application justifies the budget for pilot research. Applicants are encouraged to attach research papers; in-press, pre-published drafts, and accepted research papers may be cited or submitted separately as

an attachment to the application.
- **Grant Period:** June 1, 2021 to May 31, 2023 (a one year no-cost extension may be requested and approved with sufficient justification, extending the period to May 31, 2024.)

Tier 3: Clinical/Translational Research Grant:
- **Maximum Budget Request:** $400,000
- **Project Requirements:** This Tier will fund institutions which have a concurrent application to, or funding from, Federal or industry sources for projects aligned with the research priority. Preliminary data must be published or in press in a scientific journal and cited or submitted separately as an attachment to the application.
- **Grant Period:** June 1, 2021 to May 31, 2024 (a one year no-cost extension may be requested and approved with sufficient justification, extending the period to May 31, 2025.)

An institution shall apply for a maximum of one Grant only, in each of the three Tiers. If a single institution is submitting multiple applications in response to this RFA, a different Principal Investigator must be identified for each separate application. If multiple applications are submitted under the same Principal Investigator from one institution, all applications submitted from that institution will be deemed ineligible and will not be reviewed.

The Research Proposal must address the project period and funding requested, show the scope of the overall project, and justify how the proposed research will provide new and innovative treatments and rehabilitative efforts for the functional improvement of people with spinal cord injuries. It should also include a justification as to why the project falls within the funding Tier selected. The anticipated Grant Agreement term is June 1, 2021 to May 31, 2023 for all successful applicants for Pilot Project Grant and Standard Research Grant applicants, and June 1, 2021 to May 31, 2024, for Clinical/Translational Grant applicants, subject to the availability of funding.

Funds shall NOT be used:
- for the purchase or lease of motor vehicles or to supplement Federal or other state funds that have been made available for this purpose
- to pay costs incurred prior to the effective date of the Grant
- to establish registries, patient databases or tissue banks
- for international travel
- to indemnify institutions that are performance sites against adverse events associated with the research project
- for tuition or to develop Continuing Medical Education (CME) programs or both
- for educational programs designed to interest school children in research careers
- to pay honoraria to individuals asked to serve on advisory committees or to reimburse advisory committee members for travel expenses related to attendance at advisory committee meetings or both
- to pay costs for consultants or speakers related to the research project or for personnel to perform statistical and data analyses
- to develop or implement patient, professional or community educational programs designed to change patient or health care provider behaviors
- to pay for the costs of regular or research patient care
- for licensing or option fees, attorney's fees for preparing or submitting patent proposals, and fees paid to the U.S. Patent and Trademark Office for patent proposal, patent maintenance, or recordation of patent-related information
- for laboratory or building construction or renovations or any infrastructure expenses to include

office equipment (computer hardware and software), office supplies, non-professional, support personnel (secretaries, administrative assistants, and clerks)

Personnel, other than non-professional support personnel, are professional research personnel. Research equipment may be purchased as part of an approved research project funded under this Grant. Sharing of facilities among universities and public and private research institutions is encouraged.

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

Indirect costs shall not be charged against items in Categories II (Consultant Services), III (Subcontract Services) and V (Equipment) of the budget. A subcontractor shall not charge indirect costs against items in Categories II, III and V. The indirect costs specified in Appendix C - Budget shall not be greater than 5 percent of the sum of total direct costs less the costs of Categories II, III and V. The applicant must be able to support the indirect cost rate with an allocation plan if requested. The indirect cost rate shall not be increased at any time for the duration of the Grant Agreement.

For the duration of the Grant Agreement, hourly rates and fringe benefit rates for all personnel except union-covered positions shall not 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.

Grant funds shall not be used to pay an individual at a rate in excess of the Executive Level II ($197.300/year or $101.17/hour) of the 2020 Federal Executive Schedule, in accordance with the National Institutes of Health (NIH) Guide for Grants & Funding. Grant funds shall not be used to pay an individual to manage or administer the Grant.

4. Technical Reporting and Accountability Requirements

Awardees shall submit, to the Department an Annual Progress Report at the end of each state fiscal year (SFY) by July 31st. A Final Progress Report, and copies of any publications and reports published based on research funded by this award are due within 60 calendar days of the Grant Agreement's termination date. These reporting requirements and others are specified in "Appendix D, Attachment 7 - Agreement Regarding Fiscal and Other Requirements" in Part Two of this document.

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 website, the Department will redact (blackout) 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. Grant Agreement Payment Provisions and Fiscal Reporting Requirements

Awardees shall submit, to the Department, an Annual Expenditure Report at the end of each SFY by July 31st and a Final Expenditure Report within 60 calendar days of the Grant Agreement's termination date. The expenditure reports must be submitted using the forms contained in Part Two, Appendix B, Attachments 1 - 5.

Funds awarded for this RFA must be spent in accordance with the terms and conditions of the Grant Agreement including Appendix B (Payment Provisions) and Appendix C (Budget) and by the termination date of the Grant Agreement. Any unspent funds remaining at the end of the Grant Agreement award period must be returned to the Commonwealth. The full payment provisions are found in Appendix B.

6. Use of Existing Health Data

Applicants must use existing health data and resources to the greatest extent possible. Relevant databases such as the Pennsylvania Cancer Registry, and hospital discharge, outpatient and ambulatory care, and managed care data already exist. Other state agencies such as the Pennsylvania Health Care Cost Containment Council and health care researchers in Pennsylvania have already undertaken significant work with these resources.

7. Effective and Termination Dates for Grants

In preparing the application, the effective date contained in the cover letter to this RFA, June 1, 2021, must be used as the effective date for the Grant. The applicant must determine the duration of the Grant award based on the Tier as listed in *Part One, A. Information for Institutions, 3. Use of Funds – Limitations and Additional Requirements* and specify the duration of the award in the application.

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 Department of General Services (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) Institutions 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.

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.

This RFA is a competitive RFA. Grants will be awarded based upon the Tier applied for in each application: Tier 1, Tier 2 or Tier 3. Applications in each Tier will be evaluated together with other applications in the same Tier according to the process described below.

Following the requirements of Act 2001-77, applications in each Tier 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, scientific need, scientific method, research design, adequacy of the facility and qualifications of the research personnel. The applications will be ranked within the Tier according to the peer review scientific and technical merit score assigned during this review.

The second stage of the review will be conducted by the Spinal Cord Research Advisory Committee with Department staff (Committee). This Committee will review applications that meet the requirements in this RFA. The selection of research projects to be funded will be based on the rankings developed from the peer review process. In making its selection, this Committee will use the rankings, avoid unnecessary duplication, ensure relevance to the research priority, focus on changing the nature and course of spinal cord injury, address the gap in translation of discovery to human study and application, and encourage potential or existing collaboration with industry.

If the Committee needs additional clarification of an application, Health Research Office staff and staff from the Office of Procurement will schedule an oral presentation or assign a due date for the submission of a written clarification or both.

The Secretary of Health will make the final selection of applications to be funded.

3. Awards

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 applications. 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 applications. 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 awarded institution shall submit an Annual Progress Report and an Annual Expenditure Report to the Department by July 31st each SFY and 60 calendar days after the Grant Agreement termination date. Any changes including the scope or methodology of the research during the term of the Grant Agreement must be approved in writing by the Department.

b) The awarded institution shall submit an Interim Report of progress 12-15 months after the start date of the Grant. This Interim report will be requested by the Health Research Office. A presentation shall be provided to a peer review panel scheduled by the Health Research Office.

c) The awarded institution shall submit a Final Report of progress and a Final Expenditure Report within 60 calendar days after the Grant Agreement termination date. The progress achieved during the Grant Agreement term will be evaluated by a peer review panel. The panel will provide a Performance Review Report.

d) The awarded institution will receive the Performance Review Report and shall submit a Performance Review Response Report within 30 calendar days after the Department provides the Grantee with the Performance Review Report. ..

e) The awarded institution shall inform the Department of any changes to the primary contacts of 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) The Letter of Intent shall be prepared using the Letter of Intent form provided in Part Two, Appendix F of this RFA. The Letter of Intent shall arrive on or before the time and date specified in the cover letter. Faxed Letters of Intent will not be accepted. **If the Letter of Intent is not received via the above email address, using the Letter of Intent form provided, on or before this date and time, the application will not be accepted.**

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

c) The application shall consist of: Appendix A – Attachment 1, Cover Page (Word document); Appendix A – Attachment 2, Research Proposal (**created** PDF); Appendix C, Budgets for the applicant institution and for each subcontractor (Excel document(s)); and PDF for all other documents as required in Part Two of the RFA except Appendices A and C.

d) Submit documents via SharePoint using the following naming convention:
- Appendix A-1_CoverPage_2020NF-SC_InstitutionName;
- Appendix A-2_ResearchProposal_2020NF-SC_InstitutionName;
- Appendix C_Budget_2020NF-SC_InstitutionName.
  - If additional budgets are needed for subcontractors: Appendix C_Budget_2020NF-SC_InstitutionName_SubcontractorInitials; and
- 00_ApplicationForms_2020NF-SC_InstitutionName.

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

f) The application must be submitted using the format described in Subsection 2. - Application Format.

g) The Certifications Form must be completed and signed by an official authorized to bind the institution to the application.

h) 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 upload documents identified into the SharePoint document set in the order shown below and in the

Application Checklist, which is located in Part Two, Appendix E of this RFA. Applicants must not insert the name of the Principal Investigator anywhere on any of the application documents unless indicated. Applicants must not insert the SAP number on any forms. The Department will add the SAP number to the appropriate documents when the application is submitted.

Upon receipt of the Letter of Intent, all fillable forms will be provided to the applicant with the SharePoint link and instructions email. The Cover Page and Research Proposal section are available in Microsoft Word. The budget is available in Microsoft Excel. The Application to the Pennsylvania Department of Health Institutional Review Board is available in PDF.

Forms requiring signatures – Signatures must adhere to the signature requirements (found in Part Two of the RFA). Only signatures of authorized persons will be accepted; proxy signatures will not be accepted. Applicants must not use correction fluid or correction tape on these forms. Applicants must not submit forms containing handwritten corrections. Applicants must not attach labels containing the title(s) of the person(s) who signed the forms.

Legal name of institution organization – On all application forms, the name of the institution must be identical to the legal name of the institution exactly as registered with the Department of State. All forms that do not contain the legal name of the institution 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 institution's complete legal name and be signed and dated by an official authorized to bind the institution to the Agreement. If the institution 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. Applicants must not complete the SAP number on the top of the form. The number will be added when the application is submitted to the Department. Applicants must not add a page number on this document.

b) **Signature Authority:** A copy of the document conferring signatory authority (such as by-laws or corporate resolution) must be sent with the application and dated within 5 years.

c) **Grant Agreement Between the Pennsylvania Department of Health and the Grant Institution:** Return this document with the application. The required information will be added when the application is submitted to the Department.

d) **Appendix A, Attachment 1 - Cover Page:**

1. Do not add a page number on this document.

2. Complete as follows:
   a. Institution Name: Insert the legal name of the institution exactly as it is registered with the Department of State.

   b. Type of Legal Entity: Insert the type of legal entity of the institution, that is, Corporation, Partnership, Limited Liability Company, or Sole Proprietorship.

c. Grant Amount: Enter the full amount of funds requested. The amount is equal to or less than the amount identified for the chosen Tier. Indicate the amount of funds requested based on the Tier level presented in the application, as defined in Part One, section A. Information for Institutions 3. Use of Funds. The amount must be consistent with the Research Application, Item XIII., Allocation of Costs for Spinal Cord Injury Research.

d. Grant Start Date: The effective date of the Grant is expected to be June 1, 2021

e. SAP Vendor #: Indicate vendor number, which is a number assigned by the Commonwealth.

f. Grant End Date: Enter the anticipated end date of Grant. The duration of the Grant award is based on the chosen Tier identified in the application

g. Address: The mailing address provided should be the same as the vendor billing address that is listed in the SAP system for the associated vendor number. In order to do business with the Commonwealth, providers are required to enroll in the SAP system. Institutions enroll in the SAP system at www.vendorregistration.state.pa.us/, or by calling toll free 1-877-435- 7363 or locally at (717) 346-2676.

h. Item 1a: Provide the name of the Principal Investigator who will be the primary contact person with the Department for all Grant-related activities.

i. Item 1b: Indicate up to three academic and professional degrees or other credentials and licenses held by the Principal Investigator.

j. Item 1c: Provide the academic or professional title of the Principal Investigator. If there is more than one title, provide the title that is most relevant to the planned research project.

k. Item 1d: Provide complete mailing address for the Principal Investigator.

l. Item 1e: Provide the telephone number and email address for the Principal Investigator. The individual's direct email address is preferred over a shared departmental email address.

m. Item 2a: Provide the name and degrees for the Principal Investigator's primary point of contact to be copied on emails from the Department. The primary point of contact may be the administrative or research assistant who will assist the Principal Investigator on all Grant-related activities.

n. Item 2b: 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.

o. Item 2c: Provide the title of the position held by the primary contact person for the Principal Investigator.

p. Item 3: Indicate the name and title of the 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.

e) **Appendix A, Attachment 2 - Research Proposal:** Applicants must submit the Research Proposal using the form and instructions contained in Part Two of the RFA.

f) **Appendix A, Attachment 3 – Research Documentation**: Citations for the institution's research to support Tier 2 or Tier 3 Research Proposal must be provided.

g) **Appendix A, Attachment 4 – Letters of Support:** Letters of Support from collaborating institutions and consultants must be provided.

h) **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 Non-Formula Grant Report of Expenditures by Type of Research):** Return these documents with the application. Applicants do not complete the attachments to this Appendix, at this time. The attachments will be completed by the institution and submitted as Annual and Final Expenditure Reports. Applicants must not change the page numbers on this document.

i) **Appendix C - Budget:** The Budget must be completed using the Excel budget workbook provided with this application. This workbook contains detailed instructions and formulas, which create the required totals in order to make the preparation process easier.

1. Applicants must complete a budget for the entire Grant period. The budget will consist of a Budget Summary and eight budget categories: (I) Personnel Services (which includes fringe benefits), (II) Consultant Services, (III) Subcontract Services, (IV) Patient Services, (V) Equipment, (VI) Supplies, (VII) Travel and (VIII) Other Costs. One budget must be submitted by the lead institution. 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 the *Instructions* tab within the Excel budget workbook . Use those instructions to complete the budget.

3. For the purposes of this Grant, all expenses are considered non-infrastructure and should be listed in the *Non-Infrastructure Funds* column.

4. 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.

j) **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.

k) **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 institution's Institutional Review Board (IRB) prior to the submission of the application. However, all research involving human subjects must be approved by the institution'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 institution'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 NIH and derived from outside of Pennsylvania can be used.

l) **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 institution's appropriate review committee prior to the submission of the application. However, all such research must be approved by the institution's review committee ***prior to the initiation of such research and use of Grant funds*** to pay for such research.

m) **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:**

1. If the research project does not involve human subjects, this Appendix form does not need to be completed.

2. If the research involves human subjects and has not been approved or exempted from review by the institution's IRB, this Appendix must not be submitted with the application. However, the Appendix must be submitted ***prior to the initiation of such research and use of Grant funds to pay for research involving human subjects***.

3. If the research involves human subjects and it has already been approved or exempted from review by the institution's IRB, this Appendix must be completed and submitted with the Grant application and include documentation that the institution's IRB either approved or exempted the research from review. This form must be the version that was provided with this application and submitted via SharePoint. The Appendix contains detailed instructions that are embedded within the body of the form, itself, for completing the form. Electronic copies of the Application to the Pennsylvania Department of Health IRB form may be obtained by emailing ra-healthresearch@pa.gov.

4. Note on the use of human specimens or data: If the institution checked "No human subjects will be used in any of the proposed research" on Appendix D, Attachment 2 – Certifications for the Protection of Human Subjects and Regarding the Use of Human Embryonic Stem Cell Research, but the institution's application proposes using human specimens or data, this Appendix must be completed and submitted prior to any research involving the human specimens and must include documentation from the institution's IRB stating that the research does not constitute human subjects research.

n) **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.

o) **Appendix D, Attachment 6 - 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 one 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.

p) **Appendix D, Attachment 7 – Audit Requirements (Rev. 8/18)**

q) **Appendix E - Application Checklist:** Use this checklist to ensure that the application contains all necessary documents.

r) **Appendix F - Letter of Intent:** Do not submit the Letter of Intent with the application. The Letter of Intent must 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

Spinal Cord Injury Research Grant Program

Request for Applications (RFA 67-115)

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. Documents are permitted to be signed electronically. If the documents are not signed electronically, the original ink signatures are required.

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	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.
- Home rule charter counties shall execute contracts in accordance with their charters, administrative codes, or as directed in writing by their solicitors.

XXXXXXXX, Project Officer
(717) 000-0000

XXXXX, Alternate Project Officer
(717) 000-0000

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;

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); and

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, 2021 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 Institutions. 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 – Research Documentation
4. Attachment 4 – 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

C. Appendix C – Budget

D. Appendix D – Program Specific Provisions and Attachments 1-8

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 - 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 Fiscal and Other Requirements
7. Attachment 7 – Audit Requirements (Rev. 8/18)

E. Appendix E – Application Checklist

F. Appendix F – Letter 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. 1/19)

B. Commonwealth Travel and Subsistence Rates (Rev. 8/18)

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

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

E. 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

F. 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 Non-formula Spinal Cord Injury 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 67-115, 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. FUNDING REDUCTION CHANGE ORDER (FRCO)

In the event that there is a reduction in the availability of state funds, including the elimination of all state funding, the Department may reduce the amount of funds available in this Agreement through a FRCO. The FRCO shall include a revised Budget reflecting the changes to the funding included in the original Agreement. If necessary, the FRCO shall also include a revised Work Statement showing any reduction in work resulting from the funding reduction or elimination. The FRCO shall require no signatures other than those of the Agency Head and the Comptroller.

X. DECREASE IN FUNDING (DIF)

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 DIF 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 DIF. The decision to decrease funding is solely within the discretion of the Department.

XI. 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.

XII. 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 four Attachments:

Attachment 1 – Cover Page

Attachment 2 – Research Proposal

Attachment 3 – Research Documentation

Attachment 4 – Letters of Support

SAP # _____
APPENDIX A, Attachment 1

COVER PAGE

Spinal Cord Injury Research Grant
RFA 67-115

Institution Name: _____
(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:**_____

1. PRINCIPAL INVESTIGATOR	
1a. NAME (First Name MI Last Name)	1b. DEGREE(S)
1c. POSITION TITLE	1d. MAILING ADDRESS (Street, City, State, Zip Code)
1e. TELEPHONE # (Area code, number and extension), and EMAIL ADDRESS Telephone: E-mail:	
2. PRIMARY CONTACT FOR THE PRINCIPAL INVESTIGATOR	
2a. NAME (First Name MI Last Name, Degrees)	2b. TELEPHONE # and EMAIL ADDRESS Telephone: E-mail:
2c. POSITION TITLE	
3. 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 institution, must 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 uploading the Research Proposal on the website, the Department will redact (black out) confidential and proprietary information. It is the institution's responsibility to 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.

Do not insert the name of the Principal Investigator on the top of any pages.

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.

Appendices to the Research Proposal are not allowed.

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

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

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

(A) Title – The title of the research project should not exceed 81 characters including spaces and punctuation. Use Mixed Title Case, 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 institution or Center of Excellence or both.

Insert Title here:

(B) Purpose – The purpose should emphasize the research studies that will be undertaken as related to the Spinal Cord Injury Research Program. The purpose should not exceed eight lines of text. Responses must be single-spaced, left aligned and in font styles and sizes as specified in the Introduction (first page) of the Research Proposal.

Insert Purpose here:

(C) Inclusion of Proprietary or Confidential Information

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

☐Yes ☐No

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

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

IV. Research Project Overview – State the broad research objectives, specific research aims and subaims. The research aims and subaims must be listed here and be the same as the aims and subaims contained in Item IX. (A) of the Research Plan. Describe the methods for achieving the aims and subaims. Do not include information about the qualifications of the researchers to perform the research or expectations that the research will lead to publications and Grant awards. Information concerning publications and Grant awards should be placed in Item XVI. (B) Performance Measures. Responses must be single-spaced, left aligned, not exceed 25 lines of text, and in the font styles and sizes specified in the Introduction to the Research Proposal. Spell out acronyms the first time they are used. Do not include the names of investigators, footnotes, references to literature, graphics, or proprietary or confidential information.

(Insert Research Project Overview here):

V. Expected Research Outcomes and Benefits – Describe the expected outcomes and benefits of the research project. Include information on how the project will address the functional improvement of people with spinal cord injuries. 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 may 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. 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 institutions and subcontractors and describe their specific roles in the project. A substantive and meaningful role must be described for every collaborating organization.
(B) Provide a diagram and a management plan that describes how the organizational units and Principal Investigators for each specific aim will communicate and work together.
(C) Include a description of personnel responsible for oversight of IRB protocols, oversight of supported research, mentoring of junior investigators, administrative and fiscal responsibilities and communication with the Department.

Insert Management and Staffing Plan below.

VIII. Key Research Personnel - Use the separate forms provided below to provide required information for the Contact Principal Investigator at the lead institution, other key personnel at the lead institution, key personnel at subcontractor institutions, 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 institution 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 institution 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 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. Fill in Yes/No boxes by clicking in the space.

CONTACT PRINCIPAL INVESTIGATOR AT LEAD INSTITUTION	
NAME (First Name MI Last Name)	DEGREE(S)
RESEARCH ROLE ON PROJECT Contact Principal Investigator	NAME OF EMPLOYER (INSTITUTION 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 INSTITUTION	
NAME (First Name MI Last Name)	DEGREE(S)
RESEARCH ROLE ON PROJECT (specify role on project and include aims on which person will work)	
Percentage of effort on the project:	Will any Grant funds be used for this position? ☐Yes ☐No
NAME (First Name MI Last Name)	DEGREE(S)
RESEARCH ROLE ON PROJECT (specify role on project and include aims on which person will work)	
Percentage of effort on the project:	Will any Grant funds be used for this position? ☐Yes ☐No
NAME (First Name MI Last Name)	DEGREE(S)
RESEARCH ROLE ON PROJECT (specify role on project and include aims on which person will work)	
Percentage of effort on the project:	Will any Grant funds be used for this position? ☐Yes ☐No
NAME (First Name MI Last Name)	DEGREE(S)
RESEARCH ROLE ON PROJECT (specify role on project and include aims on which person will work)	
Percentage of effort on the project:	Will any Grant funds be used for this position? ☐Yes ☐No
NAME (First Name MI Last Name)	DEGREE(S)
RESEARCH ROLE ON PROJECT (specify role on project and include aims on which person will work)	
Percentage of effort on the project:	Will any Grant funds be used for this position? ☐Yes ☐No
NAME (First Name MI Last Name)	DEGREE(S)
RESEARCH ROLE ON PROJECT (specify role on project and include aims on which person will work)	
Percentage of effort on the project:	Will any Grant funds be used for this position? ☐Yes ☐No

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

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

IX. Research Plan - The research plan must describe spinal cord injury research addressing the priorities identified in Part One, General Information, A. Introduction. The focus and emphasis must be on the 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 functional improvement of people with spinal cord injuries . The Research Plan must describe only the research to be accomplished within the Grant award period of funding based on the Tier, without any anticipation for a no cost extension.

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

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

(A) Specific Aims - List the research objectives and specific research aims that will be achieved during the Grant period as part of the research to be conducted. State the specific hypotheses to be tested and research objectives (for example, to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop a product or new technology). . Do not exceed two pages.
(B) Background and Significance - Summarize the background leading to the project. Evaluate existing knowledge and identify the gaps in knowledge that will be addressed by the research project. Identify the significance of the research project and the contribution that it will make to improvements in functioning. 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 proposal. If the project involves human subjects, describe pilot studies which demonstrate feasibility of the project, including the feasibility of recruitment strategies and anticipated retention rates. Provide information that will enable reviewers to assess the Principal Investigator's experience pertinent to the project and the experience of staff responsible for study recruitment and enrollment. Do not include copies of publications. Do not exceed five pages.
(D) Research Design and Methods - Describe the conceptual framework, research design and limitations of the research design, definition and measurement of key variables, data collection methods, data sources and quality, randomization, analysis plan, sample size estimate, statistical power. Describe any new methodologies and their advantage over existing methodologies. Describe novel approaches, technologies, tools, and concepts. Discuss potential problems and alternative strategies to be used, if needed, to achieve the specific aims. For aim(s) involving human subjects, describe inclusion and exclusion criteria; outreach and recruitment methods; sites for recruiting subjects and the demographics of the clientele at those sites; alternative strategies to boost recruitment if problems occur; justification for anticipated enrollment and retention rates; staff responsible for recruitment and enrollment; justification of anticipated differences in outcomes between experimental and control groups; and data management plan including where the data will be maintained and confidentiality procedures. For clinical trials, describe expected gender, race, and ethnicity differences in intervention effect and include supporting evidence from animal studies, clinical observations, epidemiology or other relevant studies. Include data analysis plans to determine intervention effect.
(E) Timeline and Milestones - For each specific aim, include a timeline, using the format shown below, to show specific, measurable milestone(s) that will be accomplished by the end of each state fiscal year. If there are subaims or more than one study under a specific aim, specify the number of the subaim or name of the study to which each milestone applies. **Do not change the time periods in the timeline shown below. These time periods are the reporting periods for the annual progress report as explained in Item XVIII. Use only the timelines that match the maximum allowable grant period.** 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 #_
6/1/21 - 6/30/21	
7/1/21 - 6/30/22	
7/1/22- 6/30/23	
7/1/23 - 6/30/24	
7/1/24 - 5/31/25	

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

(A) Are other sources of funding 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 4.

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

PROJECT SITE PRIMARY LOCATION
NAME OF INSTITUTION 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 Spinal Cord Injury 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.

Specific aims	EXAMPLE Total cost to complete the aim	Cost of research to complete the aim
Specific aim 1	$150,000	$0
Specific aim 2, study/subaim 1	$150,000	$0
Specific aim 2, study/subaim 2	$100,000	$0
Specific aim 3	$600,000	$0
Total budget	$1,000,000	$0

XIV. Budget Narrative - Provide a separate, detailed narrative for the budget of the lead institution 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 institution.
(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, NOT APPLICABLE for the Spinal Cord Injury Research Program.
(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 institution 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. There is no required format for providing the information. NIH Grant applications bio-sketches 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). Fill in Yes/No boxes by clicking in the space.

Complete items (A) – (E) below.

(A) Does the project involve the conduct of human subjects' research as defined in 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?

☐Yes ☐No

If answered Yes, complete Appendix D, Attachment 4 and submit documentation of IRB approval or exemption from review. If answered No, but the project involves human specimens or data, complete Appendix D, Attachment 4 and include documentation from your IRB stating that the research does not constitute human subjects research.

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

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

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

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

(C) Does the project conduct research using human embryonic stem cells (HESC)? ☐Yes ☐No

Only HESC lines that are approved by the NIH 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 – Institutions 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 institution'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 institution 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 answered Yes to Item XVII (A), insert Protection of Human Subjects information in (a) – (j) below. *Exception: if your IRB determined that your project is exempt from IRB review because it uses de-identified human specimens or data, do not complete (a) - (j) below.*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Specific Aim #:

Study Title:

Total Planned Enrollment:

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino			
Not Hispanic or Latino			
Other			
Ethnic Category: Total of All Subjects *			
Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
Other or Unknown			
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 institutions 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 the consultant's role in the project. Place the letters in Appendix A, Attachment 3 Letters of Support.

Institution is not required to provide information in this section.

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

XXIV. Reporting Requirements

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

Awarded institutions are required to submit to the Department the following reports in electronic form.

1. An Annual Progress Report is due to the Department by July 31st each SFY and 60 calendar days after the Grant Agreement termination date. The progress report shall be provided in a format to be determined by the Department. The report shall include a detailed summary of research completed during the SFY and other information as required by the Department. Annual Progress Reports are posted to the Department's Commonwealth Universal Research Enhancement (CURE) website in November as part of the Annual Report to the Legislature.

2. An Interim Progress Report is due to the Department 12-15 months after the start date of the Grant. This will be requested by the Health Research Office. A presentation shall be provided to a peer review panel scheduled by the Health Research Office. Following the presentation, the awarded institution will receive an Interim Review Report. A Response to the Interim Review Report is due to the Department 30 calendar says after the Department provides the Grantee with the Interim Review Report.

3. A Final Progress Report is due to the Department 60 calendar days after the Grant Agreement termination date. The 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 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, as appropriate:

        (1) the number of treatment, prevention and diagnostic studies initiated and completed;

        (2) the number of hospital and health care professionals involved in the research project;

        (3) the number of subjects relative to targeted goals; and

        (4) the extent of penetration of the studies throughout the region or 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.

4. An institution that receives a spinal cord injury research Grant is subject to a performance review evaluation by the Department upon completion of the 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 Spinal Cord Research Advisory Committee. The evaluation criteria are available on the CURE website, https://www.health.pa.gov/topics/Research/CURE/Pages/CURE.aspx, under the CURE Final Reports and Performance Review link.

   As part of the performance review process, a 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 conduct the review using the institution's strategic research plan, Annual Progress Reports, Final Progress Report and publications that resulted from the project and acknowledge Department funding.

   Upon completion of the performance review process, the Department will provide the Grantee with the Performance Review Report containing the outcome of the review (outstanding, favorable, or unfavorable) for the Grant, strengths and weaknesses, and recommendations for future improvement. The Grantee must submit a Response to the Performance Review Report within 30 calendar days after the Grantee receives the Performance Review Report.

   An institution that receives an unfavorable performance review by the Department may be subject to a reduction in funding, become ineligible for future health research funding 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 Response to the 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 institution may also be required to provide other reports such as a brief progress report during the conduct of performance reviews.

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

In addition to reports, institutions 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

RESEARCH DOCUMENTATION

Provide citations below for additional information for Tier 2 or Tier 3. Documents that cannot be cited are inserted after this page.

LETTERS OF SUPPORT

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

SAP # _____

APPENDIX B

DEPARTMENT OF HEALTH
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 the 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 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 institution 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 has the option to reallocate funds between and within budget categories (Budget Revision), subject to the following criteria:

a. General Conditions for Budget Revisions

i. *Budget Revisions At or Exceeding 20%.*

A. The Grantee shall not reallocate funds between budget categories in an amount at or exceeding 20% of the total amount of the Grant Agreement per Grant Term as set forth in Appendix C Budget without prior written approval of the Department's Project Officer.

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

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

ii. *Budget Revisions Under 20%.* The Grantee shall notify the Department's Project Officer of any Budget Reallocation under 20% of the total amount of the Grant Agreement during the Grant Term in writing, but need not request Department approval, except as provided for in Paragraph 6 (a) (i) (B) above.

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

iv. The Grantee shall provide the Department's Project Officer with notice or make a request for approval prior to the submission of the next annual/final expenditure report based on these changes.

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

b. Budget Revisions Relating to Personnel

i. Any change to funds in the Personnel Category requires the approval of the Department's Project Officer, and any such change at 20% or over as set forth in Paragraph 6 (a) shall be counted as one Budget Reallocation under that paragraph.

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

A. The Grantee is subject to a collective bargaining agreement or other union agreement and, during the term of this Grant Agreement, salaries, hourly wages, or fringe benefits under this Grant Agreement are increased because of a renegotiation of that collective bargaining agreement or other union agreement. The

Grantee shall submit to the Department's Project Officer written documentation of the new collective bargaining or other union agreement, which necessitates such reallocation.

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

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

iii. The Department's determination regarding the validity of any justification is final or of any request for approval under this Appendix B (Payment Provisions) is final.

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

v. This paragraph is not intended to restrict any employee from receiving an increase in salary based on the employer's fee schedule for the job classification.

4. 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 & 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 Institutions 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.

5. 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.

6. 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 & 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.

7. 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.

C. The Department's determination regarding the validity of any justification or of any request for approval under this Appendix B (Payment Provisions) is final.

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

SAP # _____
APPENDIX B, Attachment 3

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 because:	Check appropriate reason(s):	
	YES	NO
(1) Grant funds were received less than 10 days prior to the end of the reporting period. Specify date funds were received:_____		
(2) Funds were maintained in cash or cash balances during the entire reporting period. Specify maximum cash balance maintained during the reporting period:_____		

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	N/A		
II. CONSULTANT SERVICES	N/A		
III. SUBCONTRACT SERVICES	N/A		
IV. PATIENT SERVICES	N/A		
V. EQUIPMENT	N/A		
VI. SUPPLIES	N/A		
VII. TRAVEL	N/A		
VIII. LABORATORY OR BUILDING CONSTRUCTION OR RENOVATIONS	N/A	N/A	N/A
IX. OTHER COSTS (Including Indirect Costs)	N/A		
TOTAL	N/A		

(Insert Vendor Name)

(Insert SAP #)

(Insert Budget Period)

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

(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**	N/A		
			N/A		
Specify the benefits included in this rate:			N/A		
Sub-Total			N/A		
Total			N/A		

(Insert Vendor Name)

(Insert SAP #)

(Insert Budget Period)

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

(Insert Vendor Name)

(Insert SAP #)

(Insert Budget Period)

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

(Insert Vendor Name)

(Insert SAP #)

(Insert Budget Period)

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

(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			
	N/A	N/A	N/A
Total	N/A	N/A	N/A
Categories	**Infra-structure Funds**	**Non-Infra-structure Funds**	**Full Project Costs**
IX. OTHER COSTS			
Indirect Costs*	N/A		
Total	N/A		

*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 - 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 (if applicable)

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

Attachment 6 - Agreement Regarding Fiscal and Other Requirements

Attachment 7 – Audit Requirements (Rev. 8/18)

(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 # RFA 67-115.

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

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

CERTIFICATION REGARDING THE USE OF HUMAN EMBRYONIC STEM CELL RESEARCH

Please check the appropriate statement:

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

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

NAME OF AUTHORIZED INSTITUTIONAL OFFICIAL	TITLE
SIGNATURE	DATE

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 institution 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 institution 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 institution assures the humane care and use of vertebrate animals, that the institution 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 institution will obtain prior written approval of an appropriate IACUC.

NAME OF AUTHORIZED INSTITUTIONAL OFFICIAL	TITLE
SIGNATURE	DATE

pennsylvania
DEPARTMENT OF HEALTH

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 institutions; (3) research conducted by the Department of Health; or (4) entities using Department of Health biological specimens and/or data; (5) research to be conducted at a DOH licensed/approved nursing home or long-term care facility. 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.

Project Name:

Principal Investigator Information (Please Attach Proof of Training)

Name:	Name and address of institution:	Phone:
Title:		Fax:
		Email address:

Co-investigators (Please attach proof of training for each investigator.)

Name:	Email:	Phone:
Name:	Email:	Phone:
Name:	Email:	Phone:
Name:	Email:	Phone:
Name:	Email:	Phone:
Name:	Email:	Phone:
Name:	Email:	Phone:
Name:	Email:	Phone:
Name:	Email:	Phone:
Name:	Email:	Phone:

Reason for Submission to DOH IRB

There are several characteristics of research that require a researcher to submit an application to the DOH IRB. These characteristics are listed in the policy at the top of the application. Please select which of the following characteristics applies to this project:

☐ Research involving Grants for which Department of Health programs are applying

☐ Research involving Grants awarded by the Department of Health to institutions

☐ Research conducted by the Department of Health

☐ Research involving the use of Department of Health biological specimens and/or data

☐ Research to be conducted at a DOH licensed/approved nursing home or long-term care facility

Anticipated Level of Review (Check one.)

☐ A. Project requires full IRB review.

☐ B. Project requires expedited IRB review for the reasons indicated below.

☐ C. Project is exempt from IRB for the reasons indicated below. **Following this point, complete only project detail and signature sections.**

☐ D. IRB review has been conducted by another IRB. Attach copy of approval or exemption and continue to fill out application in accordance with the type of review you are requesting.

Name of other IRB_____

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

Date of IRB action:_____

Request for Exemption from Review (Check any of the following that 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 that 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

Request for Expedited Review (Check any of the following that apply.)

☐ A. Clinical studies of drugs and medical devices when an investigational new drug proposal is not required

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

☐ C. Collection of blood samples by finger stick, heel stick, ear stick or venipuncture from:

- ☐ Healthy, nonpregnant adults who weigh at least 110 pounds, for which subjects the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week
- ☐ Other adults and children for which subjects the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week

☐ D. Prospective collection of biological specimens for research purposes by noninvasive means

☐ E. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis)

☐ F. Collection of data from voice, video, digital or image recordings made for research purposes

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

☐ H. Continuing review of research previously approved by the convened IRB as follows:

- ☐ The research is permanently closed to the enrollment of new subjects.
- ☐ All subjects have completed all research related interventions.
- ☐ The research remains active only for long-term follow-up of subjects.
- ☐ No subjects have been enrolled and no additional risks have been identified.
- ☐ The remaining research activities are limited to data analysis.

Project Detail

Describe the project purpose. (Provide a brief explanation in layman's terms.)

Are you requesting to obtain any data from the Department? Please provide a detailed description of any data you are seeking from the Department of Health and what the data will be used for. Specify if the Department of Health data will be linked to any other data. Attach data sharing agreements if applicable

Describe the research methods. (Provide a brief explanation in layman's terms.) Attach copies of any printed materials, scripts and surveys that will be used.)

Anticipated time period for conducting the research

From_____ To_____

Anticipated source of funding:	Anticipated level of funding:

pennsylvania
DEPARTMENT OF HEALTH

Information About Subjects

Approximately how many subjects do you anticipate enrolling in this study? If it becomes necessary to enroll more subjects in this study, a change of protocol request form must be submitted.

Please provide a description of the subjects you will be enrolling in the study. (Example characteristics include age range, gender, geographical region, etc.)

Will you be studying or including any of the following in your subject pool? Check all that apply:

- ☐ Abortion materials
- ☐ Tissues
- ☐ In vitro fertilization

Will subjects in your study belong to any of the following vulnerable populations? Check all that apply.

- ☐ Pregnant women
- ☐ Neonates
- ☐ Fetuses
- ☐ Prisoners
- ☐ Children
- ☐ Mentally disabled individuals
- ☐ General population, which may Include any of the above vulnerable populations

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

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

Subject Recruitment

How do you plan on identifying potential subjects in order to recruit them into your study? In other words, what methods will you use to find people who fit the characteristics of subjects you described in the Information About Subjects section?

How will you recruit subjects? Please specify the methods and the medium through which these methods will be disseminated. Also, provide a copy of any recruitment materials including oral scripts, posters, advertisements for any medium, letters and any other material you will be using to recruit subjects.

If applicable, describe where in regard to a specific location, region or organization the recruitment will take place.

Will an incentive be offered for participation? If so, please describe it here.

Data Privacy

Will any personally identifiable information be collected? If yes, please list any type of personally identifiable data you plan to collect and how you plan to collect it.

Will your data be stored via:

☐ Electronic records

☐ Hard copies

☐ Both

Describe how the data will be stored in a secure way. Include a description of any encryption methods that may be used.

Who will have access to the data collected in this study?

Will the data collected in the study and/or borrowed from the Department of Health be linked to any other data? If so, please specify how it will be linked and if there are any precautions that will ensure the data is still deidentified.

How long will the data be stored?

If applicable, describe how the data will be disposed of.

Informed Consent

Will informed consent be collected?

☐ Yes

☐ No. Please explain why informed consent is not necessary for your study.

What process will you use to obtain consent (examples include informed consent, assent, parental permission, etc.)? Attach any forms or copies of any verbal scripts that will be used in the consent process.

Anticipated Benefits and Risks

How will the research potentially benefit the population of potential subjects for this study?

How will the research potentially benefit society as a whole?

What potential risks could affect participants in this study? Please include any possible risks you have considered even if they are unlikely.

How do you plan to minimize the risk subjects could incur from participation in this study?

Signature

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

Name of official	Title
Signature	Date

pennsylvania
DEPARTMENT OF HEALTH

Phone	Fax

Department of Health Institutional Review Board Approval

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

If yes, determination is based on this this exemption criteria: ☐ A ☐ B ☐ C ☐ D ☐ E ☐ F

Project underwent expedited review: ☐ Yes ☐ No

If yes, determination is based on this expedited review criteria: ☐ A ☐ B ☐ C ☐ D ☐ E ☐ F ☐ G ☐ H

Project underwent full review: ☐ Yes ☐ No

Approval:

☐ Approved ☐ Approved with conditions ☐ Disapproved

Name of signatory	Title of signatory
Signature	Date

Application Checklist

Mandatory documents:

☐ IRB application

☐ Research protocol

☐ Copies of certification of appropriate research training

Other documents that are required if applicable to this project:

☐ Any questionnaires and/or surveys that will be used

☐ Any printed materials the subjects will be shown

☐ Script of what will be said to subjects during the experiment

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

☐ Copies of all recruitment materials

☐ Consent document(s)

☐ Approval form from another IRB

☐ Data sharing agreements

☐ Any other supporting material you believe will better help the IRB understand your research

DOH Office Use Only:

☐ Reviewed Outcome:_____Date: _____

SAP # _____

APPENDIX D, Attachment 5

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

The institution 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 institutions, and commercial institutions; 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 INSTITUTION, BY ITS AUTHORIZED SIGNATORY, IS BINDING ITSELF TO THE ABOVE AGREEMENT.

INSTITUTION ORGANIZATION	
SIGNATURE OF FORMULA FUND INSTITUTION'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 Fiscal and Other Requirements

Section 12. RECORDS RETENTION REQUIREMENTS of the Standard General Terms and Conditions (Rev 1/19) 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 1/19) 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. Institutions 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 institution'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 IRB 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 1/19) is hereby deleted in its entirety.

Section 18. INSPECTION AND ACCEPTANCE of the Standard General Terms and Conditions (Rev 1/19) is hereby deleted in its entirety.

Section 20. OWNERSHIP RIGHTS of the Standard General Terms and Conditions (Rev 1/19) 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 1/19) 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 1/19) is hereby deleted in its entirety.

REPORTING AND ACCOUNTABILITY

The institution agrees to the following reporting and accountability requirements.
Institutions are required to submit to the Department a copy of the following written reports in electronic form.

1. An Annual Progress Report is due July 31st of each SFY and 60 calendar days after the Grant Agreement's termination date. The progress report shall be provided in a format to be determined by the Department. The report shall include a detailed summary of research completed during the SFY and other information as required by the Department. Annual Progress Reports are posted to the Department's CURE website in November as part of

the Annual Report to the Legislature.

2. A Final Progress Report is due to the Department 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. The Grantee will receive a Performance Review Report and shall submit a Performance Review Response Report within 30 calendar days after the Department provides the Grantee with report.

   An applicant that receives a spinal cord injury 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 the Performance Review Report containing the outcome of the review (outstanding, favorable, or unfavorable) for the Grant as a whole, strengths and weaknesses and recommendations for future improvement. The Grantee must provide the Response to the Performance Review Report within 30 calendar days after the Grantee receives the Performance Review Report.

A Grantee 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 institution may also be required to provide other reports such as a brief progress report or a report during the conduct of performance reviews.

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

In addition to documentation, a Grantee 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 institutions, and commercial institutions; 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. 8/18) Appendix D, Attachment 8 of this document. The following terms supplement the audit requirements previously referenced. However, where there may be a conflict between the terms referenced below and the previously mentioned audit requirements, the terms referenced below will take precedence in such instances.

Audit periods shall coincide with state fiscal years but shall not be less than six months or greater than 18 months. Specifically, the contractor shall have an audit performed when it expends $500,000 or more of state funds received under this contract within the 13-month period immediately following the effective date of the contract (June 1, 2021) or when it expends $500,000 or more of state funds received under this contract within any successive 12-month period thereafter, unless notified in writing by the Department prior to the termination of the applicable audit period that the audit requirement has been waived. If the contract or any successive period is for a period of less than 12 months, but the contract amount expended by the contractor during said period includes $500,000 or more of state funds, the contractor is also required to have an audit performed for the entire contract or successive period, unless notified in writing by the Department prior to the termination of the applicable audit period that the audit requirement has been waived.

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

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

Submit one electronic copy to:	**Submit one electronic copy to:**
Mr. David D. DePeau, Accountant, Audit Resolution Section	CURE Program Director
Office of Procurement	Health Research Office
Pennsylvania Department of Health	Pennsylvania Department of Health
Room 816 Health & Welfare Building	Room 833 Health & Welfare Building
625 Forster Street	625 Forster Street
Harrisburg, Pennsylvania 17120-0701	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. 1/19; found at http://www.health.pa.gov/vendors).

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 of July 31st, 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. Two consecutive overall Grant-level unfavorable performance review ratings will make the Grantee ineligible to apply for Non-formula funds and will result in a reduction in Formula funds in the next funding cycle.

If the Grantee fails to submit a Performance Review Response Report within 60 calendar days after its due date, the Department may post the 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 Grant awards may be offset by damages owed as a result of material breaches in prior Health Research Grants.

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

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

SAP # _____
APPENDIX D, Attachment 7

AUDIT REQUIREMENTS

I. INTRODUCTION

The Department of Health (Department) provides Federal and state financial assistance to a variety of entities. The Contractor/Grantee must comply with all applicable Federal and state Grant requirements including *The Single Audit Act Amendments of 1996; 2 CFR Part 200 as amended;* and any other applicable law or regulation, and any amendment to such other applicable law or regulation which may be enacted or promulgated by the Federal government.

Audit requirements may be either a Federal mandate or a Department mandate. **The audit requirements that are applicable to this Contract/Grant are determined by the source(s) of the Contract/Grant funding as described in the following Sections of this Appendix:**

- Section II - Contracts/Grants funded 100 percent by Federal funds
- Section III – Contracts/Grants funded 100 percent by state funds
- Section IV – Contracts/Grants funded by Federal and state funds

Also, audit exemption conditions are described in Section V of this Appendix. Additionally, general audit provisions that are applicable to ALL Contracts/Grants are described in Section VI of this Appendix.

II. CONTRACTS/GRANTS FUNDED 100 PERCENT BY FEDERAL FUNDS - (Federally Mandated Audits)

A. General Requirements

If the Contractor/Grantee is a local government or non-profit organization and expends total Federal awards of $750,000 or more during its fiscal year, received either directly from the Federal government or indirectly from a recipient of Federal funds, the Contractor/Grantee is required to provide the appropriate single or program-specific audit in accordance with the provisions outlined in *2 CFR Part 200.501*.

If the Contractor/Grantee expends total Federal awards of less than the threshold established by *2 CFR 200.501*, it is exempt from Federal audit requirements for that year, but records must be available for review or audit by appropriate officials (or designees) of the Federal agency, pass-through entity, and Government Accountability Office (GAO).

If the Contractor/Grantee is a for-profit entity, it is not subject to the auditing and reporting requirements of *2 CFR Part 200, Subpart F – Audit Requirements (Subpart F)*. However, the Department is responsible for establishing requirements, as necessary, to ensure compliance by for-profit Contractors/Institutions. To accomplish this, the Department reserves the right to perform monitoring during the Contract/Grant and require the following at its discretion:

1. Pre-award audits; and

2. Post-award audits. The post-award audits may be in the form of a financial audit conducted in accordance with *Government Auditing Standards*, or a single audit report or a program-specific audit report in accordance with *Subpart F*. However, if a post-award audit is required by the Department, it must be directly submitted to the Department. Only single audit reports for local governmental and non-profit Contractors/Institutions are electronically submitted to the Federal Audit Clearinghouse.

In instances where a Federal program-specific audit guide is available, the audit report package for a program-specific audit should be prepared in accordance with the appropriate audit guide, *Government Auditing* Standards, and *Subpart F*.

B. Additional Components of the Single Audit Reporting Package

In addition to the requirements of *Subpart F*, the Department requires that the single audit report packages include the following additional components in the Schedule of Expenditures of Federal Awards (SEFA), or supplemental schedules:

1. A breakdown of Federal funds passed through the Department by Federal Grantor, *Catalog of Federal Domestic Assistance* (CFDA) number, CFDA name and state program name (if different from CFDA name), state program year, and state Contract/Grant number (if applicable);

2. Contract/Grant period beginning and ending dates for Federal funds passed through the Department, by Contract/Grant;

3. Program or award amount for each Department Contract/Grant;

4. Total received during the year for each Department Contract/Grant;

5. Accrued or deferred revenue at the beginning of the year for each Department Contract/Grant;

6. Revenue recognized during the year for each Department Contract/Grant;

7. Accrued or deferred revenue at the end of the year for each Department Contract/Grant.

C. Submission of the Audit Report

The Contractor/Grantee must submit an electronic copy of the audit reporting package to the Federal Audit Clearinghouse, which shall include the elements outlined in *Subpart F*.

D. Submission of the Federal Audit Clearinghouse Confirmation

The Contractor/Grantee must send a copy of the confirmation from the Federal Audit Clearinghouse to the resource account *RA-BOASingleAudit@pa.gov*.

III. CONTRACTS/GRANTS FUNDED 100 PERCENT BY STATE FUNDS - (Department Mandated Audits)

A. General Requirements

The Contractor/Grantee shall have a program-specific audit performed when it expends $500,000 or more of state funds under this Contract/Grant during the state fiscal year (i.e., July 1 through June 30), or 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 Contractor/Grantee's Contract/Grant or any successive period is for a period shorter than the state fiscal year, but the Contract/Grant amount expended by the Contractor/Grantee during said period includes $500,000 or more of state funds, the Contractor/Grantee is also required to have a program-specific audit performed for the entire Contract/Grant or successive period, unless notified in writing by the Department prior to the termination of the applicable audit period that the program-specific audit requirement has been waived.

If the body of the Contractor/Grantee's Contract/Grant with the Department contains language superseding the dollar threshold for Department mandated audits identified in this Appendix, the superseding language takes precedence and must be used by the Contractor/Grantee when determining whether the Contractor/Grantee is required to have an audit performed.

When the Contractor/Grantee is required to have a program-specific audit performed, it must be a financial audit conducted in accordance with auditing standards generally accepted in the United States of America and *Government Auditing Standards*, issued by the Government Accountability Office (GAO). The audit shall meet the audit requirements of the laws and regulations governing the program(s) in which the Contractor/Grantee participates, and the terms of this Contract/Grant. With the written consent of the Department, the Contractor/Grantee may be permitted to vary the audit period for these audits.

The costs of program-specific audits performed in accordance with the provisions of Section III of this Appendix shall be reimbursed by the Department **when said costs are specifically budgeted in the Contract/Grant budget as audit expenses.**

B. Minimum Audit Reporting Requirements

When a program-specific audit is performed, the audit report must include the following at a minimum:

1. A Statement of Financial Position (balance sheet) for each Contract/Grant the Contractor/Grantee includes in the program-specific audit. Said statement of financial position shall identify any unexpended/unused funds at the end of the audit period.

2. A separate Statement of Contractual Performance, which shall reflect the Contract/Grant budget and reporting period and include a comparison of budgeted to actual expenditures/services, must be prepared for each Contract/Grant the Contractor/Grantee includes in the program-specific audit. Said schedule(s) must reconcile to the state fiscal year(s) affected.

3. Notes to the financial statements. The following must be included:

a. Definition of the reporting entity

b. Summary of significant accounting policies used in preparing the statements

c. Other informative disclosures (as necessary)

4. Auditor's report on the financial statements and any additional statements required in the terms of this Contract/Grant. The report must identify each Contract/Grant included in the program–specific audit by its Department Contract/Grant number.

5. Auditor's report on internal control, including (where applicable) references to Contract/Grant requirements and Department audit guidance. The report must identify each Contract/Grant included in the program–specific audit by its Department Contract/Grant number. This report shall describe the scope of testing of internal control and the results of the tests, and, where applicable, refer to the separate Schedule of Findings and Questioned Costs described below.

6. Auditor's report on compliance with laws, regulations, and the provisions of this Contract/Grant, noncompliance with which could have a material effect on the financial statements. The report must identify each Contract/Grant included in the program–specific audit by its Department Contract/Grant number. This report shall include (where applicable) references to Contract/Grant requirements and Department audit guidance.

7. Schedule of Findings and Questioned Costs (if applicable). This schedule shall include the views of responsible officials of the Contractor/Grantee concerning the auditors' findings, conclusions, and recommendations. This schedule shall contain all findings and questioned costs for the financial statements which are required to be reported under *Government Auditing Standards*. Specifically, the auditor shall report the following as audit findings in this schedule:

a. Reportable conditions in internal control over the program(s) (state and/or Federal) that provide funding under this Contract/Grant. The auditor shall identify reportable conditions which are individually or cumulatively material weaknesses.

b. Material noncompliance with the provision of laws, regulations, and the provisions of this Contract/Grant.

c. Questioned costs specifically identified by the auditor (known questioned costs). In evaluating the effect of the questioned costs, the auditor shall consider the best estimate of total costs questioned (likely questioned costs), not just the known questioned costs. In reporting questioned costs, the auditor shall include information to provide proper perspective for judging the prevalence and consequences of the questioned costs.

d. Known fraud that has a material effect on the financial statements.

8. Corrective Action Plan (if applicable). At the completion of the audit, the Contractor/Grantee shall prepare a corrective action plan (CAP) to address each audit finding included in the audit report. The CAP shall provide the name(s) of the contact person(s) responsible for corrective action(s), the corrective action(s) planned, and the anticipated completion date(s) for the corrective action(s) planned. Further, if the Contractor/Grantee does not agree with an audit finding, it must clearly and completely explain the nature of its disagreement with the finding in the CAP. Finally, if the Contractor/Grantee believes that corrective action is not required, it must provide the specific reason(s) in the CAP.

9. Status of Prior Audit Findings and Recommendations (if applicable). The auditor shall report the status of uncorrected material findings and recommendations from prior audits that affect the current audit.

10. Management Letter (if applicable). If a letter is issued to management disclosing non-reportable conditions or other matters that warrant the attention of management, it must be furnished to the Department with the audit report.

11. Subcontractor/Subgrantee Audit Requirements. As applicable, the Contractor/Grantee shall have subcontractors/subinstitutions obtain audits of their Contracts/Grants in accordance with Section III of this Appendix. The Contractor/Grantee shall make the requirements of Section III of this Appendix applicable to any subcontractor/subgrantee expending $500,000 or more of state funds under this Contract/Grant during the state fiscal year (i.e., July 1 through June 30), or expending $500,000 or more of state funds under this Contract/Grant within any successive state fiscal year. If the subcontract/subgrant or any successive period is for a period shorter than the state fiscal year, but the subcontractor/subgrantee expends $500,000 or more of state funds under this Contract/Grant during said period, the Contractor/Grantee is also required to make the requirements of Section III of this Appendix applicable to the subcontractor/subgrantee. The Contractor/Grantee, NOT the Department, shall be responsible for the receipt, review, and resolution of such audits. The Contractor/Grantee shall follow up on all findings disclosed in the audit report(s). The Contractor/Grantee shall retain such audits for a period of time which is the greater of four years after termination of the Contractor/Grantee's Contract/Grant with the subcontractor/subgrantee or until resolution of any audit exceptions or other claims or actions involving a subcontract/subgrant.

If the body of the Contractor/Grantee's Contract/Grant with the Department contains language superseding the dollar threshold for Department mandated audits identified in this Appendix, the superseding language takes precedence and must be used by the Contractor/Grantee when determining whether the subcontractors/subinstitutions are required to have an audit performed of their Contracts/Grants**.**

C. Submission of Audit Reports

When the Contractor/Grantee is responsible for obtaining a program-specific audit in accordance with Section III of this Appendix, the audit report must be completed and submitted within 120 days of the end of the state fiscal year (i.e., June 30) or 120 days following the end of each state fiscal year in case of a Contract/Grant lasting more than twelve months. The Department will accept electronic submission of program-specific audit reporting packages. **Electronic submission is required for the state fiscal year ending June 30, 2015 and subsequent reporting periods.** The reporting package must be submitted electronically in single Portable Document Format (PDF) file to both the cognizant Project Officer for the Contract/Grant and to the e-mail resource account RA-DHPROGRAMAUDIT@pa.gov.

Steps for electronic submission:

- Complete the Program-Specific Audit Reporting Package Checklist to ensure your package contains all required elements.

- Upload the **completed** Program-Specific Audit Reporting Package along with the checklist in a **single** PDF file to an e-mail addressed to both the cognizant Project Officer for the Contract/Grant and to the e-mail resource account RA-DHPROGRAMAUDIT@pa.gov. In the subject line of the e-mail you must identify the exact name on the Program-Specific Audit Reporting Package and the period end date to which the package applies.

- You will receive an e-mail to confirm the receipt of your Program-Specific Audit Reporting Package, including the completed checklist.

  Technical assistance with respect to program-specific audits performed in accordance with Section III of this Appendix will be provided by the Department's Audit Resolution Section at the following address and telephone number.

Pennsylvania Department of Health
Office of Procurement
Audit Resolution Section
Room 816Health & Welfare Building
625 Forster Street
Harrisburg, PA 17120-0701
Phone: (717) 705-2288

IV. CONTRACTS FUNDED BY FEDERAL AND STATE FUNDS

Conditions Requiring an Audit

- The Contractor/Grantee is required to have a Federally mandated audit made in accordance with the requirements of Section II of this Appendix when the Contractor/Grantee expends more than $750,000 of total Federal awards received from ALL sources during its fiscal year, regardless of the amount of state funds received under this Contract/Grant during the state fiscal year.

- The Contractor/Grantee is required to have a program-specific audit made in accordance with the requirements of Section III of this Appendix, if the Contractor expends $500,000 or more of state funds received under this Contract/Grant during the state fiscal year and the Contractor/Grantee is not required to have a Federally mandated audit(s) in accordance with this Appendix that covers the entire state fiscal year.

  If the body of the Contractor/Grantee's Contract/Grant with the Department contains language superseding the dollar threshold for Department mandated audits identified in this Appendix, the superseding language takes precedence and must be used by the Contractor/Grantee when determining whether the Contractor/Grantee is required to have an audit performed in accordance with the condition described above**.**

V. AUDIT EXEMPTION CONDITIONS

Unless stated otherwise in the terms of this Contract/Grant, the Contractor/Grantee is not required to have an audit performed when EITHER of the following conditions is applicable:

- The Contractor/Grantee expends less than $500,000 of state funds received under this Contract/Grant during the state fiscal year (i.e., July 1 through June 30) (for Department mandated audits) AND it expends less than $750,000 of total Federal awards received from ALL sources during its fiscal year.

  If the body of the Contractor/Grantee's Contract/Grant with the Department contains language superseding the dollar threshold for Department mandated audits identified in this Appendix, the superseding language takes precedence and must be used by the Contractor/Grantee when determining whether the Contractor/Grantee is required to have an audit performed.

- The Contract/Grant is funded by either state or Federal funds, and all Contract/Grant monies expended during either the Contractor/Grantee's fiscal year (for Federally mandated audits) or during the state fiscal year (i.e., July 1 through June 30) (for Department mandated audits) are received on a strictly fee for service basis.

However, even if the Contractor/Grantee is not required to have an audit performed, the Contractor/Grantee is required to maintain auditable records of Federal awards and any state funds which supplement such awards, and to provide access to such records by Federal and state agencies or their designees.

VI. GENERAL AUDIT PROVISIONS

A. Auditor Selection

The Contractor/Grantee is responsible for obtaining the necessary audit and securing the services of a certified public accountant or independent governmental auditor.

The Office of the Budget, Office of Comptroller Operations, Bureau of Audits (Bureau of Audits) may decide to perform program-specific audits that are required under Section III of this Appendix. The Contractor/Grantee will be given written notification if the Bureau of Audits makes this decision. In the event that the Bureau of Audits does perform the program-specific audit, any audit costs included in the Contract/Grant will revert to the Department. However, unless notified as provided above, the Contractor/Grantee is required to arrange for the audit as described above.

B. Questioned Costs

Any questioned costs identified as such in audit reports of either the Contractor/Grantee or its subcontractors/subinstitutions shall be returned to the cognizant Federal and/or state agencies providing the financial assistance, unless resolved to the satisfaction of said entities.

C. Sanctions (Remedies for Noncompliance with Audit Requirements)

The Contractor/Grantee's failure to provide an acceptable audit in accordance with the requirements of this Appendix may result in the Department initiating sanctions against the Contractor/Grantee including, but not limited to, the following actions:

1. Disallow the cost of the audit.

2. Withhold a percentage of the Contract/Grant funding.

3. Withhold or disallow administrative/overhead costs.

4. Suspend subsequent Contract/Grant funding.

D. Additional Audits

The commonwealth reserves the right for Federal and state agencies or their authorized representatives to perform additional audits of a financial or performance nature, if deemed necessary by commonwealth or Federal agencies. Any such additional audit work will rely on work already performed by the Contractor/Grantee's auditor and the costs for any additional work performed by the Federal or state agencies will be borne by those agencies at no additional expense to the Contractor/Grantee.

E. Audit Working Papers and Reports

Audit documentation and audit reports must be retained by the Contractor/Grantee’s auditor for a minimum of five years from the date of issuance of the audit report, unless the Contractor/Grantee’s auditor is notified in writing by the commonwealth, the cognizant Federal agency for audit, or the oversight Federal agency for audit to extend the retention period. Audit documentation will be made available upon request to authorized representatives of the commonwealth, the cognizant Federal agency for audit, the oversight Federal agency for audit, the Federal funding agency, or the Government Accountability Office (GAO).

F. Records Retention

The Contractor/Grantee is required to maintain records of state funds and Federal awards. The Contractor/Grantee shall preserve all books, records and documents related to this Contract/Grant for a minimum of four years from the date of final payment under this Contract/Grant; 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/Grant elsewhere provides for a shorter period; or unless the Department otherwise separately agrees in

writing to a shorter period. The Contractor/Grantee shall provide Federal and state agencies or their designees access to such books, records and documents for inspection, audit or reproduction.

G. Funding Source(s)

The audit report must identify the amounts of Federal and state funding that is included in the report. This identification must include the breakdown of Federal and state dollars provided and the related Federal and state financial assistance program name and number. This identifying information is provided in Section III, FUNDING SOURCE(S), of the Contract/Grant.

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APPENDIX E

APPLICATION CHECKLIST

Include this page when submitting the Grant application.

- ☐ **Completed and SIGNED** Signature Page
- ☐ Documentation of Signature Authority (if applicable)
- ☐ Grant Agreement between the Pennsylvania Department of Health and Grant Institution
- ☐ 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 Non-formula 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** 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 D, Program Specific Provisions, Attachment 8 – Audit Requirements (Rev. 8/18)
- ☐ Appendix E - Application Checklist
- ☐

The following documents should be uploaded individually in the format identified:

- ☐ 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 RFA67-115, the name of the Principal Investigator, institution, and research project title.

  Appendix A, Work Statement, Attachment 3 – Research Documentation in PDF
- ☐ Appendix A, Work Statement, Attachment 4 – Letter of Support in PDF
- ☐ Appendix C - Budget in Excel for institution and all subcontractors

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APPENDIX F

Letter of Intent

Pennsylvania Department of Health **Letter of Intent to Submit an Application for Collaborative Research on Spinal Cord Injury** In Response to **Request for Applications (RFA 67-115)**	**Email to:** ra-healthresearch@pa.gov Health Research Office Pennsylvania Department of Health Room 833, Health and Welfare Building 625 Forster Street Harrisburg, PA 17120-0701 Telephone: (717) 231-2825 **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.	
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*)	