

Center for AIDS Research Spring 2016 Request for Applications - General HIV/AIDS Proposals



APPLICATION DEADLINE: June 24th, 2016 by 5 PM EST

Purpose

To support a broad range of highly innovative research projects and pilot studies to address key gaps in our understanding of HIV/AIDS and that **address the NIH HIV/AIDS High Priority Research Topics** that have been designated by National Institutes of Health ([NIH](#)) and Office of AIDS Research ([OAR](#)) (see attached list).

Background

The mission of the CFAR is to provide leadership, services and infrastructure necessary to: establish multidisciplinary collaborations that achieve high-impact discoveries; support the early career development of diverse young HIV/AIDS investigators; and to establish a distinctive scientific identity, placing the University of Rochester at the forefront of HIV/AIDS research.

Eligibility

- University of Rochester Associate Professors, Assistant Professors, or Research Assistant Professors whose primary field is in HIV/AIDS, but who have not received an NIH R01 award or equivalent as PI/MPI in HIV/AIDS (New Investigators working in HIV/AIDS)
- University of Rochester Assistant or Research Assistant Professors whose primary field is not in HIV/AIDS, have not received an NIH R01 award or equivalent as PI/MPI in HIV/AIDS, and have enlisted an established HIV/AIDS researcher as Co-I/Mentor on the application (new investigators new to HIV/AIDS collaborating with an established HIV/AIDS researcher)
- University of Rochester Full or Associate Professors with no history of NIH funding in HIV/AIDS research (established investigators new to HIV/AIDS research)
- **Please note: T32 awardees are not eligible to have effort on CFAR Pilot awards and K awardees are not eligible to receive salary support from a CFAR pilot award. Please contact [Laura Enders](#) for further information.**

Projects will receive the highest priority if they:

- Have strong potential for follow up funding by national, state or private agencies
- Are interdisciplinary and create new collaborations involving multiple departments

Awards

Up to 2 awards will be made for a one-year period with maximum funding of **\$25,000** in Direct Costs.

Application Instructions

Applications must be submitted to Laura Enders, Laura_Enders@urmc.rochester.edu, before or on **June 24th, by 5 PM EST**. Applicants are encouraged to submit electronically as an attachment in pdf format.

Application Requirements:

- CFAR Proposal sign-off form
- Draft Cost Sharing form signed by PI and department (fully signed forms will be required for pilots selected for funding)
- Modified PHS 398 face page (page 4 of these guidelines)
- Abstract

- Identification of the **High Priority Research Topic** that this application will focus on (see the attached NIH HIV/AIDS Research Priorities list as designated by NIH and OAR)
- NIH-format biosketch for PI, co-investigators and mentors
- Updated Other Support for PI only
- Research Plan (limited to 3 pages):

The Research Plan consists of items noted below, as applicable. It should be self-contained and include sufficient information to evaluate the project, independent of any other document (e.g., previous application). Be specific and informative, and avoid redundancies.

 - Specific Aims
 - Research Strategy (Significance, Innovation and Approach)
 - Timeline
- Human Subjects and Animals (no limit):

The Human Subjects and Animals Plan consists of items noted below, as applicable. It should be self-contained and include sufficient information to evaluate the project, independent of any other document (e.g., previous application). Be specific and informative, and avoid redundancies.

 - Protection of Human Subjects
 - Vertebrate Animals
- Plans for Future Funding (limited to 1 page):
 - Provide a short outline of how the pilot will develop into a NIH-funded grant. It should include the proposed hypothesis and specific aims intended for a NIH grant application as well as the projected timeline for submission.
- Data Analysis Plan (half-page limit):
 - Provide a brief data analysis plan and identify if bioinformatics support is needed for data collection and management.
- Mentoring Plan (if applicable):
 - Identify a primary mentor and provide a clearly delineated mentoring plan, including frequency and methods. The plan should identify long-term needs and goals in order to establish a successful independent academic career within the next 2 to 5 years.
- Budget (limited to 1 page using PHS 398 Form Page 4, providing a detailed description of supplies and other expenses within the form page):
 - Limited to **\$25,000** direct costs.
 - Unless exceptional circumstances, funds may not be used to support faculty salary but the budget must identify the proposed effort.
 - Funds may not be used for travel to professional meetings or equipment.
 - Funds may be used to support research supplies and expenses, travel to collect data and other non-faculty salary.
 - If applicable, identify other sources of support that will be used to complete the pilot project.
- Bibliography

Submission and Review Process

This is an internal competition for NIH-funds already awarded to the CFAR. **ORPA review and sign-off is not required but departmental review and approval should be sought through the CFAR sign-off form.**

Proposals will be reviewed by a faculty committee and will be assigned a priority score in accordance with these 6 categories:

- Significance (including scientific premise and hypothesis)
- PI, Scientific Team & Environment
- Innovation and Multidisciplinary Approach
- Experimental Approach (including methods and authentication of key biological and/or chemical resources, if applicable)
- Responsiveness to the terms of this RFA
- Probability of future NIH funding

A summary of the reviewers' comments will be provided once the review process has been completed

Award Process

CFAR will notify selected investigators via email within 2-3 weeks of the application deadline. Funding will not be released until all UR and NIH regulatory requirements have been met including IRB, IBC and IACUC approvals as applicable. Upon receipt of all required documentation, the CFAR will issue a formal internal Notice of Award.

Reporting Requirements

The pilot PI will be required to present the status of the pilot project work to the CFAR Steering or Mentoring Committee.

CFAR is required to report the outcome of this award to NIH for a period of no less than 5 years. Routine reporting is thus required of the investigator and should be comprised of a written report, which must include the following:

- Status of the work supported by pilot grant
- Statement regarding resulting grant applications, publications, presentations and inventions
- Update regarding plans for future funding resulting from the project

Awardees may also be asked to present their projects and results at a CFAR sponsored event and/or annual World AIDS Day Scientific Symposium.

Inquiries:

CFAR Director – [Steve Dewhurst](#)

CFAR co-Director – [Mike Keefer](#)

Administrator – [Laura Enders](#)

P: 585-273-2939

F: 585-473-9573

<http://www.urmc.rochester.edu/cfar/>

NIH HIV/AIDS Research Priorities and Guidelines for Determining AIDS Funding

Notice Number: NOT-OD-15-137

Key Dates

Release Date: August 12, 2015

Related Announcements

[NOT-HL-15-281](#)

[NOT-HL-15-280](#)

Issued by

National Institutes of Health ([NIH](#))

Office of AIDS Research ([OAR](#))

Purpose:

The NIH supports a comprehensive portfolio of biomedical, behavioral, and social science research on HIV and its associated coinfections, comorbidities, and other complications. The Office of AIDS Research (OAR), a component of the NIH Office of the Director, is legislatively mandated to coordinate, plan, evaluate, and budget for the NIH AIDS research program. Building on the most recent scientific progress and scientific opportunities to most likely contribute to ending the AIDS pandemic, developing a cure for HIV/AIDS, and achieving an AIDS-free generation, NIH has identified the highest HIV/AIDS research priorities for the next 3-5 years. NIH will use these guidelines to ensure that AIDS resources are supporting the highest HIV/AIDS research priorities. The overarching NIH HIV/AIDS research priorities are: 1) research to reduce the incidence of HIV/AIDS, including the development of safe and effective HIV/AIDS vaccines; 2) development of the next generation of HIV therapies with improved safety and ease of use; 3) research towards a cure for HIV/AIDS; and 4) HIV-associated comorbidities and co-infections. Basic research, health disparities, and training that cross-cut these priorities also will be supported. These priorities were informed by the OAR Advisory Council's recommendations, the Annual Trans-NIH Plan for HIV-Related Research, and input from NIH leadership. Implementation of these priorities will begin with fiscal year 2016 funding of HIV/AIDS research.

The NIH has developed a series of guidelines for determining whether a research project has a high-, medium-, or low-priority for receiving AIDS-designated funding. These guidelines do not assess/determine the scientific and technical merit of a project only the priority for receiving AIDS-designated funds. A description of these priority topics and examples of each are provided below.

High Priority topics of research for support using AIDS-designated funds

- Reducing Incidence of HIV/AIDS including: developing and testing promising vaccines, developing and testing microbicide and pre-exposure prophylaxis candidates and methods of delivery, especially those that mitigate adherence issues; and developing, testing, and implementing strategies to improve HIV testing and entry into prevention services.
- Next generation of HIV therapies with better safety and ease of use including: developing and testing HIV treatments that are less toxic, longer acting, have fewer side effects and complications, and easier to take and adhere to than current regimens. Additionally, implementation research to ensure initiation of treatment as soon as diagnosis has been made, retention and engagement in these services, and achievement and maintenance of optimal prevention and treatment responses.
- Research toward a cure including: developing novel approaches and strategies to identify and eliminate viral reservoirs that could lead toward a cure or lifelong remission of HIV infection, including studies of viral persistence, latency, reactivation, and eradication.
- HIV-associated comorbidities, coinfections, and complications including: addressing the impact of HIV-associated comorbidities, including tuberculosis, malignancies; cardiovascular, neurological, and metabolic complications; and premature aging associated with long-term HIV disease and antiretroviral therapy.
- Cross cutting areas: Basic research, health disparities, and training including:

- Basic Research: understanding the basic biology of HIV transmission and pathogenesis; immune dysfunction and chronic inflammation; host microbiome and genetic determinants; and other fundamental issues that underpin the development of high priority HIV prevention, cure, co-morbidities, and treatment strategies.
- Research to Reduce Health Disparities in the incidence of new HIV infections or in treatment outcomes of those living with HIV/AIDS.
- Research Training of the workforce required to conduct High Priority HIV/AIDS or HIV/AIDS-related research.

Further information can be found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-137.html>

**Grant Application
UR CFAR
Grant Application**

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| 1a. TITLE OF PROJECT |
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| 2a. PRINCIPAL INVESTIGATOR | 2b. DEGREE(S) | 2c. NEW INVESTIGATOR <input type="checkbox"/> No <input type="checkbox"/> Yes |
| 2d. POSITION TITLE | 2e. DEPARTMENT, MAJOR SUBDIVISION (if applicable) | |
| 2f. TELEPHONE TEL ext: Email: | 2g. MENTOR | |

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| 3. ADDITIONAL INVESTIGATORS (if applicable) | |
| NAME | DEPARTMENT, MAJOR SUBDIVISION (if applicable) |
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| 4a. HUMAN SUBJECTS RESEARCH <input type="checkbox"/> No <input type="checkbox"/> Yes | 4b. RESEARCH EXEMPT <input type="checkbox"/> No <input type="checkbox"/> Yes If yes, exemption # |
| 4c. STATUS OF IRB SUBMISSION/APPROVAL <input type="checkbox"/> Approved <input type="checkbox"/> Submitted, review pending <input type="checkbox"/> Not yet submitted | 4d. CLINICAL TRIAL <input type="checkbox"/> No <input type="checkbox"/> Yes |

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| 5a. VERTEBRATE ANIMALS <input type="checkbox"/> No <input type="checkbox"/> Yes | 5b. STATUS OF IACUC SUBMISSION/APPROVAL <input type="checkbox"/> Approved <input type="checkbox"/> Submitted <input type="checkbox"/> Not yet submitted |
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| 6a. BIOHAZARD SAFETY Will the project use any materials that would require IBC approval: <input type="checkbox"/> No <input type="checkbox"/> Yes | 6b. HUMAN EMBRYONIC STEM CELL <input type="checkbox"/> No <input type="checkbox"/> Yes |
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| 7a. PROPOSED PROJECT PERIOD | 7b. FUNDS REQUESTED | 7c. PROPOSED SUBCONTRACT <input type="checkbox"/> No <input type="checkbox"/> Yes |
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CFAR PROPOSAL SIGN-OFF FORM

THIS FORM MUST BE COMPLETED AND SUBMITTED TO THE UR-CFAR WITH YOUR PILOT PROPOSAL AFTER ALL NECESSARY SIGNATURES HAVE BEEN OBTAINED. THIS FORM DOES NOT NEED TO BE SUBMITTED TO ORPA.

Principal Investigator (PI)/Contact PI _____ UR Financials _____ UR Financials _____
Please check if this is a Multiple PI project (as defined by NIH) Company 040 Cost Center CC 12193-000 (DCFAR)
Other Multiple PIs/Co-PIs: _____ Project Sponsor CFAR
Project Title _____
Funding Op (Number/Title) _____ Award mechanism (R01, K08, CAREER) _____
Proposed Start Date _____ End Date _____ Total Project Budget Requested _____ Deadline _____
Proposal Type: New Continuation Supplement Resubmission Renewal Current UR Financials FAO (if applicable): GR _____
F&A (Indirect) Rate _____ Award Type: Grant Contract Subcontract/subaward
Purpose: Research Clinical Research Training Fellowship Service Other
Project Location: On-Campus Off-Campus If off-campus, location _____

ADMINISTRATIVE AND POLICY CONSIDERATIONS (MUST BE COMPLETED BY PI) - Please explain "yes" responses on additional sheets

NOTE: All Co-Investigators, and other named investigators, MUST complete Section A ("Additional Signatures Certification")

| Yes | No | | Yes | N/A | |
|----------------------------|----------------------------|--|----------------------------|----------------------------|--|
| <input type="checkbox"/> y | <input type="checkbox"/> n | 1. Does this project contain a clinical research component with clinical procedures? If "Yes", complete Section B (on page 4). | <input type="checkbox"/> y | <input type="checkbox"/> n | 13. If you have acquired new financial interests since your last disclosure, have you reported these to the institution? |
| <input type="checkbox"/> y | <input type="checkbox"/> n | 2. Does this project require additional/new space or renovation/modification of current space or facilities? Check all that apply: Equipment/Utility support _____ Additional, New or Renovated Space _____ If yes, include an explanation on amount of space needed, cost and source of funds. | <input type="checkbox"/> y | <input type="checkbox"/> n | 14. For NIH proposals, do all investigators agree to comply with the NIH Public Access Policy? Please see the NIH Policy for details. |
| <input type="checkbox"/> y | <input type="checkbox"/> n | 3. Does this proposal involve cost sharing or matching funds? If yes, complete below: -Total Amount of cost sharing _____ -Type of cost being shared _____ -Planned cost share UR Financials FAO(s) _____ -If the cost sharing is Third Party Cost Sharing , attach a Pre-award THIRD PARTY COST SHARING FORM | <input type="checkbox"/> y | <input type="checkbox"/> n | 15. Is this an Individual NRSA (F-awards) Fellowship? If yes, complete the Individual Fellow and Faculty Mentor Certification for NIH F-awards Certification Individual Fellow and Faculty Mentor Certification for NIH F-awards . |
| <input type="checkbox"/> y | <input type="checkbox"/> n | 4. Will research use human subjects? | <input type="checkbox"/> y | <input type="checkbox"/> n | 16. Are you currently debarred or suspended from doing business with the federal government or excluded from Medicare or other federal/state health care programs, or are you currently in default on any federal student loans? |
| <input type="checkbox"/> y | <input type="checkbox"/> n | 5. Will research use animals? | <input type="checkbox"/> y | <input type="checkbox"/> n | 17. Have you engaged in lobbying activities using federal funds to influence any federal employee in connection with this proposal? |
| <input type="checkbox"/> y | <input type="checkbox"/> n | 6. Will research use radioactive materials or isotopes? | <input type="checkbox"/> y | <input type="checkbox"/> n | 18. If funded, will other individuals be authorized to sign for purchases necessary for the project? If yes, name authorized individuals: _____ |
| <input type="checkbox"/> y | <input type="checkbox"/> n | 7. Will research use human embryonic stem cells? | <input type="checkbox"/> y | <input type="checkbox"/> n | 19. Is this proposal a collaborative inter-school/college program with sharing of indirect cost recovery? If yes, attach completed copy of Sharing of Indirect Cost Recovery form. |
| <input type="checkbox"/> y | <input type="checkbox"/> n | 8. Are you requesting less than the maximum F&A costs as allowed by the sponsor's written policy? | <input type="checkbox"/> y | <input type="checkbox"/> n | 20. Does the project involve international partnerships or activities in foreign countries? Country name: _____ |
| <input type="checkbox"/> y | <input type="checkbox"/> n | 9. Will there be subcontracts to other institutions? Number? _____ | <input type="checkbox"/> y | <input type="checkbox"/> n | 21. Will the work involve the transfer of technology and/or materials overseas? |
| <input type="checkbox"/> y | <input type="checkbox"/> n | 10. Is any program income anticipated under this project? | <input type="checkbox"/> y | <input type="checkbox"/> n | 22. Identify the CLASP-certified individual(s) who will have functional responsibility for oversight of this project, should it be funded. (Signature or initials of this individual recommended) |
| <input type="checkbox"/> y | <input type="checkbox"/> n | 11. Do you have consulting arrangements, line management responsibilities, substantial equity holdings with the sponsor, subcontractor, or potential vendor? | | | |
| <input type="checkbox"/> y | <input type="checkbox"/> n | 12. Have you submitted an annual conflict of interest disclosure statement? | | | |

PRINCIPAL INVESTIGATORS' CERTIFICATION

In signing below the Principal Investigator(s) (PIs) certify that the above is accurate and complete to the best of the PIs' knowledge. **This certification must also include signatures of all investigators in Section A (page 3 of this form).** The PI certifies the proposal (including any subsequent supplemental material) is compliant with sponsor requirements. In addition, the PI(s) understand that any false, fictitious, or fraudulent statements or claims made in the accompanying submission may subject the PI(s) personally to criminal, civil, or administrative penalties. The PI(s) agrees to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.

Principal Investigator(s): _____ Date: _____

REQUIRED SIGNATURES: (PLEASE SEE REVERSE FOR ADDITIONAL SIGNATURES WHICH MAY BE REQUIRED)

Dept Chair: _____ Date: _____ Cost Center Chief: _____ Date: _____
Director of Medical Center
Dean: _____ Date: _____ Space Planning: _____ Date: _____
(required for Medical Center if "Yes" has been checked on consideration 2 above)

Form Rev 01/01/15

For ORPA use only:

ORPA RA: _____ Date: _____

OBTAIN FOLLOWING SIGNATURES AS APPLICABLE TO THIS PROPOSAL:

- | | |
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| <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> | <p><input type="checkbox"/> y <input type="checkbox"/> n A. Is proposed project using space or facilities of Strong Memorial Hospital? If yes, obtain Signature of SMH Senior Director for Finance (x5-3033 – Room 1-2412): _____</p> <p><input type="checkbox"/> y <input type="checkbox"/> n B. Will project require resources of the University Vivarium? If yes, please list the animal species _____ and the estimated maximum number of each species housed at one time _____ and send a copy of the signoff form to the attention of the Vivarium Director, Box 674.</p> <p><input type="checkbox"/> y <input type="checkbox"/> n C. Will project require resources of the CRC? If yes, obtain Signature of CRC Director: _____</p> <p><input type="checkbox"/> y <input type="checkbox"/> n D. Will project require services of the Department of Biostatistics and Computational Biology? If yes, obtain Signature of Chair, Department of Biostatistics and Computational Biology: _____</p> <p><input type="checkbox"/> y <input type="checkbox"/> n E (a). Will this project include pathogens, recombinant DNA, human blood, body fluids or tissue, virus vectors, human cell lines or generation of transgenic animals via recombinant DNA technology or interbreeding? For additional information, consult the IBC Webpage.</p> <p><input type="checkbox"/> y <input type="checkbox"/> n E (b). Will this project involve an OSHA recognized carcinogen? (2-Acetylaminofluorene, 4-Aminodiphenyl, Benzidine, bis-Chloromethyl ether, 3,3'-Dichlorobenzidine (and its salts), 4-Dimethylaminoazo-benezene, Ethyleneimine, methyl chloromethyl ether, alpha-Naphthylamine, beta-Naphthylamine, 4-Nitrophenyl, N-Nitrosodimethylamine, beta-Propiolactone)</p> <p style="padding-left: 40px;">If answer to question E(a) or E(b) is marked "Yes", please send a copy of this completed signoff form to the attention of the IBC Program Coordinator, Environmental Health & Safety, RC Box 278878.</p> <p><input type="checkbox"/> y <input type="checkbox"/> n F. Will faculty or staff from other University departments, divisions, or units participate in this project or will resources of another department, unit or office (see below) be used? If yes, obtain signature of Participating Department Chair(s), Dean(s), or Director(s):</p> |
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| | |
|----------------------------------|-----------|
| Faculty and Dept. Name (printed) | Signature |
| Faculty and Dept. Name (printed) | Signature |
| Faculty and Dept. Name (printed) | Signature |

DESCRIPTION OF PROPOSAL SIGN-OFF RESPONSIBILITIES

PRINCIPAL INVESTIGATOR/MULTIPLE PI: The PI/Multiple PI is the initiator and director of the proposed program. The PI's/Multiple's PIs' signature(s) indicates that he/she/they will adhere to University and sponsor policies affecting the project, including completion of an Employee Intellectual Property Agreement and conflict of interest disclosure, monitoring of expenditures and the submission of reports required by the sponsor and the University.

DEPARTMENT CHAIR, DIVISION/UNIT CHIEF: These signatures mean that agreement has been reached regarding the amount and type of departmental resources that will be required to assist a PI in completing a project. If new space, personnel, or renovations are required, further discussion with the appropriate Dean's office will be necessary. This signature also confirms receipt of the annual conflict of interest disclosure and, where required, the supplemental disclosure and certifies that review will be complete and conflicts resolved, if any, prior to award.

DEAN: The Dean's signature means that agreement has been reached regarding the amount of School/College resources required to support the program. The Dean ensures that appropriate salary and pooled costs are requested in the proposal. As well, the Dean participates in discussions of new space or renovations required to complete a project.

THIRD PARTY COST SHARING: A complete Pre-Award Third Party Cost Sharing is required at the time of proposal to indicate the Third Party's concurrence with their cost sharing responsibilities.

ADDITIONAL REVIEW AND/OR OTHER SIGNATURES WHICH MAY BE REQUIRED DEPENDING UPON THE NATURE OF THE RESEARCH:

RESOURCES OF OTHER DEPARTMENTS, UNITS OR OFFICES: Projects that require resources of other University departments or offices require approval of the appropriate signatory. At the Medical Center, examples include Blackboard Online Learning, Curricular Affairs/Office of Medical Education, etc.

VIVARIUM: All University projects using animals must be reviewed by the University Committee of Animal Resources (UCAR, x5-1693).

BIOHAZARDS: Projects which propose the use of potential biohazards, including recombinant DNA and carcinogens, must be reviewed by the Executive Secretary of the Biosafety Committee, 685 Mt Hope Ave., x5-3241. This signature is required to comply with federal and state regulations covering biohazards.

BIostatistics and COMPUTATIONAL BIOLOGY SERVICES: Projects that involve biostatistics services must be approved by the Department of Biostatistics and Computational Biology, Saunders Research Bldg. Room 4106, x5-2407. This signature ensures that adequate costs and professional effort have been included to support biostatistical studies.

STRONG MEMORIAL HOSPITAL: Projects which involve facilities, services, or training programs of Strong Memorial Hospital require the signature of the Senior Director for Finance, Room 1-2412, Medical Center, x5-3300.

CLINICAL RESEARCH CENTER: Projects which will require beds, space, or staff of the Clinical Research Center should be reviewed by the Director of the Clinical Research Center. Room 1.502, Saunders Research Building, x5-0674.

EXPLANATION OF THE ITEMS FROM FRONT (use additional sheets)

Section A: Additional Signatures Certification
new, competing, and non-competing (progress reports) applications

In signing below the following Investigators certify that:

- they have submitted an annual conflict of interest disclosure statement;
- there are no new financial interests to report (if there are new financial interests that have not been disclosed, the investigator must report these prior to proposal submission); and
- they are not currently debarred or suspended from doing business with the federal government or excluded from Medicare or other federal/state health care programs, or that they are not currently in default on any federal student Loans.
- In addition, the Investigators understand that any false, fictitious, or fraudulent statements or claims made in the accompanying submission may subject the Investigators personally to criminal, civil, or administrative penalties. The Investigators agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.

| Name | Signature | Role on Project (e.g. PI, Res. Assoc.) |
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SECTION B: Prospective Reimbursement Analysis (PRA) (Note 1)

If Question 1 in the **ADMINISTRATIVE AND POLICY CONSIDERATIONS** section was answered “Yes”, please check one of the appropriate boxes below:

- The clinical research study’s clinical procedures constitute a clinical trial (i.e. there is an investigational drug, device or treatment). ***The PI has signed the following three (3) worksheets (copies are attached to this sign off form): PRA Template, Participant Grid/Billing Plan and Total Budget comparison worksheet (refer to Note 2 and Note 3).***

- The clinical research study’s clinical procedures constitute a clinical trial (i.e. there is an investigational drug, device or treatment) and the sponsor has indicated it will pay for all visits and procedures (i.e. nothing will be billed to third party insurance). ***The PI has signed the following two (2) worksheets (copies are attached to this sign off form): Participant Grid/Billing Plan and Total Budget comparison worksheet (refer to Note 3).***

- The clinical research study is not a clinical trial (i.e. there is not an investigational drug, device or treatment). ***The PI has signed the following two (2) worksheets (copies are attached to this sign off form): Participant Grid/Billing Plan and Total Budget comparison worksheet (refer to Note 3).***

PRINCIPAL INVESTIGATORS’ CERTIFICATION

In signing below the Principal Investigator(s) certify that he/she has completed the Blackboard clinical trial training (Course CT-01).

Principal Investigator(s) Name(s)

Date: _____

- NOTE 1:** The University of Rochester Clinical Research Standard Operating Procedures Regarding Financial Oversight and Billing Compliance defines a Prospective Reimbursement Analysis as “the process of determining and documenting what procedures, items and tests in a protocol are standard of care or strictly related to research. This information is then used to determine the appropriate payer of such activities” (SOP 1.1).

- NOTE 2:** The PRA Template is a questionnaire that assists with the determination whether a clinical trial is a “Qualifying trial” as per Centers for Medicare and Medicaid Services guidelines. The PRA Template is a worksheet within the UR’s Budgeting Workbook for clinical trials, accessible in the Clinical Trial Resources Share Point site (that is accessible through the link on this web page http://www.rochester.edu/ORPA/Clinical_Trial_Resources/index.html).

- NOTE 3:** The Participant Grid/Billing Plan is an EXCEL worksheet on which is documented the proper payer for each clinical procedure for each visit in a clinical research study plan. A Total Budget comparison worksheet allows comparison of the sponsor’s financial offer to the UR’s internally prepared budget and indicates whether a potential deficit or surplus exists. . The Participant Grid/Billing Plan and the Total Budget comparison are worksheets within the UR’s Budgeting Workbook for clinical trials, accessible in the Clinical Trial Resources Share Point site (that is accessible through the link on this web page: http://www.rochester.edu/ORPA/Clinical_Trial_Resources/index.html).