

Center for AIDS Research
2015 Request for Applications
Major Collaborative Pilot Award



APPLICATION DEADLINE: October 22, 2015 by 5 PM EST

Purpose

The purpose of this pilot funding opportunity is two-fold:

- To support highly innovative research projects that address key gaps in our understanding of HIV/AIDS and in HIV treatment and prevention; *high-risk/high reward science is strongly encouraged, along with studies likely to result in new extramural funding.*
- To facilitate interdisciplinary and inter-professional collaborations between experienced HIV/AIDS researchers and researchers who are new to HIV/AIDS and/or junior investigators.

Background

The Major Collaborative Pilot Award program is new for 2015, and offers \$100k in funds for one year, with the goal of building new collaborations and supporting innovative science that is likely to lead to high-impact discoveries and follow-on funding.

Eligibility

- **Two (or more) CoPIs are required.** Each must have a faculty position within the University of Rochester (UR)
- Each application must include one Co-PI who is an established HIV/AIDS investigator (i.e., who has a prior history of NIH funding in HIV/AIDS research at the R01 level or equivalent) and one Co-PI who is either new to HIV/AIDS research or a junior investigator, as defined below:
 - UR 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*)
 - UR 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 (*new investigators new to HIV/AIDS*)
 - UR Full or Associate Professors with no history of NIH funding in HIV/AIDS research (*established investigators new to HIV/AIDS research*)

Projects will receive the highest priority if they:

- Are highly innovative (including high-risk/high-reward proposals) and have the potential to lead to major discoveries
- Have strong potential for follow up funding by national, state or private agencies
- Are interdisciplinary and create new collaborations involving multiple departments/disciplines

Awards

One award will be made for a one-year period with maximum funding of **\$100,000** in Direct Costs.

Application Instructions

Applications must be submitted to Laura Enders, Laura_Enders@urmc.rochester.edu, before or on **October 22nd, 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 forms will be required for pilots selected for funding)
- Modified PHS 398 face page (page 4 of these guidelines)
- Abstract
- 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 (*applies only to CoPIs who are Assistant Professors or Research Assistant Professors*):
 - 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 **\$100,000** 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 categories:

- Significance
- PI, Scientific Team & Environment
- Innovation and Multidisciplinary
- Approach
- 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 award CoPIs 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/>

**Grant Application
UR CFAR
Grant Application**

1a. TITLE OF PROJECT

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	

3. ADDITIONAL INVESTIGATORS (if applicable)	
NAME	DEPARTMENT, MAJOR SUBDIVISION (if applicable)

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

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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OBTAIN FOLLOWING SIGNATURES AS APPLICABLE TO THIS PROPOSAL:

- | | | |
|--|---|--|
| Yes
<input type="checkbox"/> y | No
<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): _____ |
| <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. |
| <input type="checkbox"/> y | <input type="checkbox"/> n | C. Will project require resources of the CRC? If yes, obtain Signature of CRC Director:
_____ |
| <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:
_____ |
| <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 . |
| <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)

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. |
| <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): |

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 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:

- y 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).***
- y 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).***
- y 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).

_____ Date: _____
Principal Investigator(s) Name(s)

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).