Center for AIDS Research
Spring 2016 Request for Applications - Focused Topic 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.

Scientific Areas of Interest
This RFA is intended to support pilot awards that address one of these three scientific areas of interest. These include:

• **HIV-associated Cardiovascular and Cerebrovascular Disease**: HIV infection and antiretroviral treatment have been associated with increased risk of cardiovascular and cerebrovascular disease, thought to be partially mediated by atherosclerosis. Proposals investigating all aspect of cardiovascular and cerebrovascular disease (in vitro, animal and human studies) are welcomed with strong interest in two common complications: left ventricular diastolic dysfunction and cerebral small vessel disease.

• **Stress, Trauma, and Vulnerable Populations**: Applications should address how experiences of stress and trauma, including stigma, abuse, violence, discrimination, or socioeconomic disadvantage, affect biological, behavioral, and structural factors to: (a) affect PrEP uptake and adherence; (b) impact health-related outcomes for individuals infected with HIV, including HIV-associated comorbidities, co-infections, and complications; (c) impede access, linkage, and retention in HIV care and preventive services; (d) affect interventions to prevent HIV infection; or (e) influence HIV-related health disparities. Studies that focus on members of vulnerable populations, including men who have sex with men (MSM), individuals who abuse alcohol or drugs, justice-involved individuals, sexual and racial minorities, and vulnerable women are especially encouraged.

• **HIV Cure**: The HIV Cure SWG focuses on new basic research and translational approaches to curing HIV, and demonstrating that a cure has taken place. Focus areas include (but are not limited to) identifying mechanisms of viral latency and re-activation, novel biomarkers, therapeutic strategies, and novel diagnostic tools including integrated photonic sensors.

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 3 awards will be made for a one-year period with maximum funding of $40,000 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 $40,000 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/
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
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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: __________________________ Company: 040  Cost Center: CC 12193-000 (DCFAR)

Please check if this is a Multiple PI project (as defined by NIH)

Other Multiple Pls/Co-Pls:______________________________________ 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 FAQ (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 ☐ Y ☐ N ☐

1. Does this project contain a clinical research component with clinical procedures?
   - If “Yes”, complete Section B (on page 4).

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.

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 FAQ(s)

   - If the cost sharing is Third Party Cost Sharing, attach a Pre-award THIRD PARTY COST SHARING FORM

4. Will research use human subjects?

5. Will research use animals?

6. Will research use radioactive materials or isotopes?

7. Will research use human embryonic stem cells?

8. Are you requesting less than the maximum F&A costs as allowed by the sponsor’s written policy?

9. Will there be subcontracts to other institutions?
   - Number ______

10. Is any program income anticipated under this project?

11. Do you have consulting arrangements, line management responsibilities, substantial equity holdings with the sponsor, subcontractor, or potential vendor?

12. Have you submitted an annual conflict of interest disclosure statement?

Yes ☐ No ☐ N/A ☐

13. If you have acquired new financial interests since your last disclosure, have you reported these to the institution?

14. For NIH proposals, do all investigators agree to comply with the NIH Public Access Policy? Please see the NIH Policy for details.

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.

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?

17. Have you engaged in lobbying activities using federal funds to influence any federal employee in connection with this proposal?

18. If funded, will other individuals be authorized to sign for purchases necessary for the project? If yes, name authorized individuals:

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.

20. Does the project involve international partnerships or activities in foreign countries? Country name: _________

21. Will the work involve the transfer of technology and/or materials overseas?

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)

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: __________

Dean: __________________________ Date: __________ Director of Medical Center __________________________ 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: __________
OBTAI N FOLLOWING SIGNATURES AS APPLICABLE TO THIS PROPOSAL:

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Faculty Dept. Name (printed)  Signature

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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 PI’s’ signature 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). 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.

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.

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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)._ 

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**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:

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**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](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](http://www.rochester.edu/ORPA/Clinical_Trial_Resources/index.html)).