School of Medicine and Dentistry / School of Nursing
URMC Program of Excellence Award
Center for AIDS Research
Request for Applications

APPLICATION DEADLINE: October 21, 2016

With joint funding from the UR School of Nursing (SON) and School of Medicine and Dentistry (SMD) through the auspices of the URMC Program of Excellence in HIV/AIDS, the UR-CFAR announces the following request for applications.

Purpose

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

- To support a broad range of highly innovative research projects and pilot studies addressing key gaps in HIV treatment and prevention, including ones 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),
- To facilitate interdisciplinary and inter-professional collaborations between the UR School of Medicine and Dentistry and School of Nursing, involving biomedical, clinical, epidemiological and social/behavioral sciences

Eligibility

- Each application must include one Co-PI from the School of Nursing and one Co-PI from the School of Medicine and Dentistry
- PIs must have a faculty position within the University of Rochester Medical Center (SMD/SON)

Projects will receive the highest priority if they*:*

- Have strong potential for follow-up NIH funding
- Create new collaborations involving multiple disciplines

Awards

Up to 2 awards will be made for a one-year period with maximum funding per application of **$50,000** in Direct Costs.

Application Instructions

Applications must be submitted to Laura Enders Laura_Enders@urmc.rochester.edu, before or on **October 21, 2016**, no later than 5 PM. 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 PIs, co-investigators and mentors
- ☐ Updated Other Support for PIs 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 $50,000 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 joint School of Medicine and Dentistry / School of Nursing Program of Excellence funds. **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 joint SON/SMD faculty committee and will be assigned a priority score in accordance with these categories**:**

- Significance
- MPIs, 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 3-4 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

Approximately 6 months after a Notice of Award has been issued, the MPIs will be required to present the status of the pilot project work to the CFAR Steering or Mentoring Committee.

Routine reporting is required of the investigators 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 seminar 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
Fall 2016 Pilot Application

1a. TITLE OF PROJECT

2a. CO-PRINCIPAL INVESTIGATOR (SMD)	2b. DEGREE(S)	2c. NEW INVESTIGATOR ☐ No ☐ Yes
2d. POSITION TITLE	2e. DEPARTMENT, MAJOR SUBDIVISION (if applicable)	
2f. TELEPHONE TEL ext: Email:	2g. MENTOR	

2a. CO-PRINCIPAL INVESTIGATOR (SON)	2b. DEGREE(S)	2c. NEW INVESTIGATOR ☐ No ☐ 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 ☐ No ☐ Yes	4b. RESEARCH EXEMPT ☐ No ☐ Yes If yes, exemption #
4c. STATUS OF IRB SUBMISSION/APPROVAL ☐ Approved ☐ Submitted, review pending ☐ Not yet submitted	4d. CLINICAL TRIAL ☐ No ☐ Yes

5a. VERTEBRATE ANIMALS ☐ No ☐ Yes	5b. STATUS OF IACUC SUBMISSION/APPROVAL ☐ Approved ☐ Submitted ☐ Not yet submitted

6a. BIOHAZARD SAFETY Will the project use any materials that would require IBC approval: ☐ No ☐ Yes	6b. HUMAN EMBRYONIC STEM CELL ☐ No ☐ Yes

7a. PROPOSED PROJECT PERIOD	7b. FUNDS REQUESTED	7c. PROPOSED SUBCONTRACT ☐ No ☐ Yes

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 Company_____ UR Financials Cost Center_____

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

Other Multiple PIs/Co-PIs:_____ Project Sponsor_____

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		
☐y	☐n	1.	Does this project contain a clinical research component with clinical procedures? If "Yes", complete Section B (on page 4).
☐y	☐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.
☐y	☐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
☐y	☐n	4.	Will research use human subjects?
☐y	☐n	5.	Will research use animals?
☐y	☐n	6.	Will research use radioactive materials or isotopes?
☐y	☐n	7.	Will research use human embryonic stem cells?
☐y	☐n	8.	Are you requesting less than the maximum F&A costs as allowed by the sponsor's written policy?
☐y	☐n	9.	Will there be subcontracts to other institutions? Number? _____
☐y	☐n	10.	Is any program income anticipated under this project?
☐y	☐n	11.	Do you have consulting arrangements, line management responsibilities, substantial equity holdings with the sponsor, subcontractor, or potential vendor?
☐y	☐n	12.	Have you submitted an annual conflict of interest disclosure statement?

Yes	N/A		
☐y	☐n	13.	If you have acquired new financial interests since your last disclosure, have you reported these to the institution?
Yes	**No**		
☐y	☐n	14.	For NIH proposals, do all investigators agree to comply with the NIH Public Access Policy? Please see the NIH Policy for details.
☐y	☐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.
☐y	☐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?
☐y	☐n	17.	Have you engaged in lobbying activities using federal funds to influence any federal employee in connection with this proposal?
☐y	☐n	18.	If funded, will other individuals be authorized to sign for purchases necessary for the project? If yes, name authorized individuals:_____ _____
☐y	☐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.
☐y	☐n	20.	Does the project involve international partnerships or activities in foreign countries? Country name: _____
☐y	☐n	21.	Will the work involve the transfer of technology and/or materials overseas?
☐y	☐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)

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: _____

Dean: _____ Date: _____

Cost Center Chief: _____ Date:_____

Director of Medical Center 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:

Yes **No**

☐y ☐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): _____

☐y ☐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.

☐y ☐n C. Will project require resources of the CRC? If yes, obtain Signature of CRC Director:

_____

☐y ☐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:

_____

☐y ☐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.

☐y ☐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-Nitrobiphenyl, 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.

☐y ☐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 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.)***

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).