# 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, <u>Laura\_Enders@urmc.rochester.edu</u>, before or on <u>October 22nd</u>, by 5 PM EST. Applicants are encouraged to submit electronically as an attachment in pdf format.

Аp	pplication 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
П	Plans for Future Funding (limited to 1 page):
_	<ul> <li>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.</li> </ul>
	Data Analysis Plan (half-page limit):
	<ul> <li>Provide a brief data analysis plan and identify if bioinformatics support is needed for data collection and management.</li> </ul>
	Mentoring Plan (applies only to CoPIs who are Assistant Professors or Research Assistant Professors):
	<ul> <li>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</li> </ul>
	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.
	<ul> <li>Unless exceptional circumstances, funds may not be used to support faculty salary but the budget must identify the proposed effort.</li> </ul>
	<ul> <li>Funds may not be used for travel to professional meetings or equipment.</li> </ul>
	<ul> <li>Funds may be used to support research supplies and expenses, travel to collect data and other non- faculty salary.</li> </ul>
	- 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			
2d. POSITION TITLE		2e. DEPARTMENT, MAJOR SUBDIVISION (if applicable				
2f. TELEPHONE  TEL ext: Email:		2g. MENTOR				
3. ADDITIONAL INVESTIGATORS (if applica		MA IOD OURDINGOOM				
NAME	DEPARTMENT,	MAJOR SUBDIVISION	(п аррисавіе)			
	•					
4a. HUMAN SUBJECTS RESEARCH  No Yes	b. RESEARCH EXEI	MPT s If yes, exemption #				
4c. STATUS OF IRB SUBMISSION/APPROV	_	t yet submitted	4d. CLINICAL TRIAL			
5a. VERTEBRATE ANIMALS 5	5b. STATUS OF IACU	JC SUBMISSION/APPR	OVAL Not yet submitted			
6a. BIOHAZARD SAFETY  Will the project use any materials that wou	ıld require IBC approv	/al: No Yes	6b. HUMAN EMBRYONIC STEM CELL  No Yes			
7a. PROPOSED PROJECT PERIOD	7b. FUNDS REQUE	ESTED	7c. PROPOSED SUBCONTRACT			

## **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.

Drin	oinal Invoc	etigator (PI)/Contact PI	UF	R Finan	cials	UR Financials Cost Center
Plea	ase check i er Multiple				Project Sponsor	
Proj	ject Title					
Fun	ding Op (N	lumber/Title)				Award mechanism (R01, K08, CAREER)
		t Date End DateTotal Proje				
					val	Current UR Financials FAO (if applicable): GR
F&A	(Indirect)	Rate Award Type:			Co	ontract Subcontract/subaward
Pur	pose:	Research Clinical Research Training		•		Service
Proj	ject Locatio	on:   On-Campus   Off-Campus   If off-cam	pus, location	ı		
	ADMIN	ISTRATIVE AND POLICY CONSIDERATIONS (MUST B	SE COMPLE	TED B	Y PI)	- Please explain "yes" responses on additional sheets
	N	IOTE: All Co-Investigators, and other named investig	ators, MUS	T comp	lete	Section A ("Additional Signatures Certification")
Yes	No		Yes		13	. If you have acquired new financial interests since your last
⊒у	□n 1.		Шу	···	13.	disclosure, have you reported these to the institution?
		component with clinical procedures?  If "Yes", complete Section B (on page 4).	<b>Yes</b> □y		1/	. For NIH proposals, do all investigators agree to comply with the
<b>□</b> у	□n 2.	Does this project require additional/new space or	_			NIH Public Access Policy? Please see the NIH Policy for details
		renovation/modification of current space or facilities? Check all that apply:	□у	□n	15.	Is this an Individual NRSA (F-awards) Fellowship? If yes, complete the Individual Fellow and Faculty Mentor Certification
		Equipment/Utility support Additional, New or				for NIH F-awards Certification Individual Fellow and Faculty
		Renovated Space If yes, include an explanation on amount of space needed, cost and source of funds.	□у	Πn	16	Mentor Certification for NIH F-awards.  Are you currently debarred or suspended from doing business
<b>□</b> у	□n 3.	Does this proposal involve cost sharing or matching	Шу		10.	with the federal government or excluded from Medicare or other
		funds? If yes, complete below: -Total Amount of cost sharing				federal/state health care programs, or are you currently in default on any federal student loans?
		-Type of cost being sharedPlanned cost share UR Financials FAO(s)	□у	□n	17.	Have you engaged in lobbying activities using federal funds to influence any federal employee in connection with this
⊐y	□n 4.	-If the cost sharing is <b>Third Party Cost Sharing</b> , attach Pre-award THIRD PARTY COST SHARING FORM Will research use human subjects?	а Пу	□n	18.	proposal?  If funded, will other individuals be authorized to sign for purchases necessary for the project? If yes, name authorized individuals:
⊒y X	□n 5. □n 6.	Will research use animals? Will research use radioactive materials or isotopes?	□у	П.	10	. Is this proposal a collaborative inter-school/college program with
∃y ∃y ∃y	□n 7.	Will research use human embryonic stem cells?	Шу	U''	19.	sharing of indirect cost recovery? If yes, attach completed copy
□y	□n 8.	Are you requesting less than the maximum F&A costs as allowed by the sponsor's written policy?	□у	Πn	20	of Sharing of Indirect Cost Recovery form.  Does the project involve international partnerships or activities
<b>□</b> у	□n 9.	Will there be subcontracts to other institutions?	Шу	···	20.	in foreign countries? Country name:
⊒y	□n 10	Number? Is any program income anticipated under this project?	□y	□n	21.	Will the work involve the transfer of technology and/or
∃y		Do you have consulting arrangements, line	Пи	п.,	22	materials overseas?  Identify the CLASP-certified individual(s) who will have
		management responsibilities, substantial equity holdings with the sponsor, subcontractor, or potential vendor?	□у	ш <u></u>	22.	functional responsibility for oversight of this project, should it be funded.
⊐y	□n12.	Have you submitted an annual conflict of interest disclosure statement?				(Signature or initials of this individual recommended)
		PRINCIPAL INVES	TICATORS	, CEDT	IEIC	ATION
m si m	nust also in upplementa nade in the	elow the Principal Investigator(s) (Pls) certify that the abounclude signatures of all investigators in Section A (pa	ve is accurate ge 3 of this lidition, the Pally to crimina	e and o form). I(s) und al, civil,	omp The dersta or a	olete to the best of the PIs' knowledge. This certification be PI certifies the proposal (including any subsequent and that any false, fictitious, or fraudulent statements or claims dministrative penalties. The PI(s) agrees to accept
Prin	icipal Inves	etigator(s):				Date:
		REQUIRED SIGNATURES: (PLEASE SEE REVER	RSE FOR AL	DITIO	NAL	SIGNATURES WHICH MAY BE REQUIRED)
Dep	ot Chair:	Date:	Cost Center	Chief:		Date:
			Director of M	ledical	Cent	ter
nea	III	Date:	Space Plann (required for		ıl Ce	Date: enter if "Yes" has been checked on consideration 2 above)
Г	Form Rev	, 01/01/15 For O	RPA use or	nlv:		

Date:

ORPA RA:

#### **OBTAIN FOLLOWING SIGNATURES AS APPLICABLE TO THIS PROPOSAL:** Yes No □n A. Is proposed project using space or facilities of Strong Memorial Hospital? If yes, obtain Signature of SMH Senior Director for Finance Пν (x5-3033 - Room 1-2412): Will project require resources of the University Vivarium? If yes, please list the animal species □y □n B. 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. $\square$ у □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: Пν ☐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. Пν ☐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. $\square$ v □n F. Will faculty or staff from other University departments, divisions, or units participate in this project or will resources of another department.

#### **DESCRIPTION OF PROPOSAL SIGN-OFF RESPONSIBILITIES**

unit or office (see below) be used? If yes, obtain signature of Participating Department Chair(s), Dean(s), or Director(s):

Signature

Signature

Signature

**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)** 

Faculty and Dept. Name (printed)

Faculty and Dept. Name (printed)

Faculty and Dept. Name (printed)

# 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. Pl, Res. Assoc.)

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## SECTION B: Prospective Reimbursement Analysis (PRA) (Note 1)

	If Question 1 in the <b>ADMINISTRATIVE AND POLICY CONSIDERATIONS</b> 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).						
	□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 <u>not</u> a clinical trial (i.e. there is <u>not</u> 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 Investig	Date:					
	Timolpal mivoolig	ator(o) realino(o)					
<u>NOTE 1</u> :	defines a Prospect	tochester Clinical Research Standard Operating Procedures Regarding Financial Oversight and Billing Compliance ive Reimbursement Analysis as "the process of determining and documenting what procedures, items and tests in a ard of care or strictly related to research. This information is then used to determine the appropriate payer of such I).					
NOTE 2:	Medicare and Med accessible in the C	e is a questionnaire that assists with the determination whether a clinical trial is a "Qualifying trial" as per Centers for icaid Services guidelines. The PRA Template is a worksheet within the UR's Budgeting Workbook for clinical trials, linical Trial Resources Share Point site (that is accessible through the link on this web page er.edu/ORPA/Clinical_Trial_Resources/index.html).					
<u>NOTE 3</u> :	visit in a clinical res UR's internally pre Total Budget comp Resources Share F	d/Billing Plan is an EXCEL worksheet on which is documented the proper payer for each clinical procedure for each search study plan. A Total Budget comparison worksheet allows comparison of the sponsor's financial offer to the pared budget and indicates whether a potential deficit or surplus exists. The Participant Grid/Billing Plan and the varison are worksheets within the UR's Budgeting Workbook for clinical trials, accessible in the Clinical Trial Property of the propert					

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