# 3/31/16 - Revised
# Center for AIDS Research
# 2016 Request for Applications
# CFAR / CTU (ACTG / HVTN) Collaborative Pilot Award

**APPLICATION DEADLINE: April 8, 2016 by 5 PM EST**

Due to changes, this RFA has been extended. The new deadline is April 8, 2016. **Additionally, a Letter of Intent with a one page concept sheet or a discussion regarding the application topic with CFAR / CTU faculty (Dr. Keefer and/or Dr. Schifitto) is required by March 4, 2016.**

## Goals

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

- To support highly innovative translational 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 the UR HIV/AIDS Clinical Trials Unit (CTU; consisting of clinical research sites for the **AIDS Clinical Trials Group** [ACTG] and **HIV Vaccine Trials Network** [HVTN]) and members of the UR CFAR.

Applications may be targeted to either HIV therapeutics research (ACTG), HIV prevention research (HVTN), or both, and are also expected to address both goals listed above.

## Background

***The CFAR/ACTG/HVTN Collaborative Pilot Award program is new for 2016, and offers $50k in funds for one year,*** with the goal of building new collaborations between the UR's CFAR and its CTU investigator teams (ACTG and/or HVTN) - while also supporting innovative science that is likely to lead to high-impact discoveries and follow-on funding.

## Scientific Areas of Interest

This RFA is intended to support pilot awards that address scientific areas of interest. These include:

- The ACTG areas of scientific research focus listed below. Further information can be found at actgnetwork.org/committees/scientific:
    - End-Organ Disease/Inflammation Transformative Science Group
    - Hepatitis Transformative Science Group
    - HIV Reservoirs and Viral Eradication Transformative Science Group
    - Tuberculosis Transformative Science Group
    - Women's Health Inter-Network Scientific Committee
    - Neurology Collaborative Science Group
- The HVTN conducts phase I through III clinical trials of HIV vaccine candidates, in populations both at low-risk and high-risk for HIV infection. The HVTN website hvtn.org has further information regarding the HIV Vaccine Trials Network areas of interest and scientific disciplines:
    - Vaccinology
    - Immunology
    - Statistics and Computational Biology
    - Behavioral Science

  HVTN applications are encouraged to focus on:
    - Novel proposals within the scope of the HVTN research agenda using existing HVTN-procured clinical, laboratory, behavioral data, and/or samples (i.e. serum, PBMC).
    - Novel prospective approaches to engage hard-to-reach communities at high-risk for HIV acquisition for preventive HIV vaccine research.

**We strongly encourage potential applicants to discuss planned research studies with ACTG leadership and HVTN leadership well in advance of submitting a proposal or concept sheet (Dr. Mike Keefer and/or Dr. Giovanni Schifitto). This can be particularly helpful to potential applicants in the early stages of brainstorming and conceptualizing a proposal, as the leadership has substantial familiarity with the HVTN and ACTG studies and types of data and samples that may be available.**

## Eligibility

- For this pilot, PI's are expected to focus on research questions of interest to the ACTG and/or HVTN (see above) and collaborate with members of the UR ACTG and/or UR HVTN.
- Any UR faculty member is eligible to be the PI on this proposals (i.e., Professors, Associate Professors, Assistant Professors, Research Associate Professors, Research Assistant Professors, Instructors)
- **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*:*

- Align with ACTG or HVTN research priorities.
- Are highly innovative (including high-risk/high-reward proposals) and have the potential to lead to major advances in the field.
- Have strong potential for follow up funding by national, state or private agencies
- Are interdisciplinary and create new collaborations between the CFAR and the CTU

## Awards

One award will be made for a one-year period with maximum funding of **$50,000** in Direct Costs. *If sufficient high quality proposals are received, a second award may also be funded.*

## Application Instructions

Applications must be submitted to Laura Enders, Laura_Enders@urmc.rochester.edu, before or on **April 8th, by 5 PM EST.** Applicants are encouraged to submit electronically as an attachment in pdf format.

## Application Requirements:

- ☐ **Letter of Intent with a one page concept sheet or discussion regarding the application topic with CFAR / CTU faculty (Dr. Keefer and/or Dr. Schifitto) is required by COB March 4, 2016**
- ☐ CFAR Proposal sign-off form
- ☐ Draft Cost Sharing form signed by department (fully 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 PIs 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 $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 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 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 – Michael Keefer
CFAR Administrator – Laura Enders
CTU Leadership: - Michael Keefer

CFAR Office
P: 585-273-2939
F: 585-473-9573
http://www.urmc.rochester.edu/cfar/

**ACTG contacts**

**End-Organ Disease/Inflammation**
Giovanni Schifitto, MD, MS
University of Rochester Medical Center
School of Medicine and Dentistry
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**Hepatitis**
Andrew Talal, MD, MPH
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School of Medicine and Biomedical Sciences
Department of Medicine
ahtalal@buffalo.edu
P: 716-888-4738

**HIV Reservoirs and Viral Eradication**
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**Tuberculosis**
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**Women's Health**
Mike Keefer, MD
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School of Medicine and Dentistry
Department of Medicine, Infectious Diseases
Michael_Keefer@URMC.rochester.edu
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**Neurology**
***Giovanni Schifitto, MD, MS**
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**HVTN Contacts**

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P: 585-275-6632

***Please contact Dr. Mike Keefer and/or Dr. Giovanni Schifitto to meet the pre-application requirement to discuss the application topic in lieu of a one-page concept sheet**.

# UR CFAR
## Grant Application

| 1a. TITLE OF PROJECT |
|---|
| |

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

| 3. ADDITIONAL INVESTIGATORS (if applicable) | |
|---|---|
| NAME | DEPARTMENT, MAJOR SUBDIVISION (if applicable) |
| | |
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| 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<br>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 040 UR Financials Cost Center CC 12193-000 (DCFAR)

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

Other Multiple PIs/Co-PIs: _____ Project Sponsor CFAR

Project Title _____

Funding Op (Number/Title) _____ Award mechanism (R01, K08, CAREER) _____

Proposed Start Date _____ End Date _____ Total Project Budget Requested _____ Deadline _____

Proposal Type: ☐ New ☐ Continuation ☐ Supplement ☐ Resubmission ☐ Renewal Current UR Financials FAO (if applicable): GR _____

F&A (Indirect) Rate _____ Award Type: ☐ Grant ☐ Contract ☐ Subcontract/subaward

Purpose: ☐ Research ☐ Clinical Research ☐ Training ☐ Fellowship ☐ Service ☐ Other

Project Location: ☐ On-Campus ☐ Off-Campus If off-campus, location _____

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

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

| Yes | No | | |
|---|---|---|---|
| ☐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.)*** |
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## SECTION B: Prospective Reimbursement Analysis (PRA) (Note 1)

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

☐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).