When this proposal has been signed, please call _____ **Extension** _____

UR-CTSI PROPOSAL SIGN-OFF FORM

THIS FORM MUST BE COMPLETED AND SUBMITTED TO THE UR-CTSI WITH THE PROPOSAL AFTER ALL NECESSARY SIGNATURES HAVE BEEN OBTAINED. THIS FORM DOES NOT GET SUBMITTED TO ORPA.

Principal Investigator (PI)/Contact PI_____

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

Other Multiple PIs/Co-PIs:_____ Project Sponsor UR-CTSI

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

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

Purpose: ☐ Research ☐ Clinical Research ☐ Training ☐ Fellowship ☐ Equipment ☐ Conference ☐ Public 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		
○	○	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 FAO(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.	Is this an NIH funded multi-site study utilizing the UR's RSRB as the single IRB of record? **If yes, please attach the spreadsheet provided by the RSRB Office**.
○	○	6.	Will research use animals? • **If the animal research is being conducted on the River Campus, are you using controlled Substances** ○ Yes ○ No • **If yes, is there an existing DEA License in place in order to conduct this research?** ○ Yes ○ No
○	○	7.	Will research use radioactive materials or isotopes?
○	○	8.	Will research use human embryonic stem cells?
○	○	9.	Are you requesting less than the maximum F&A costs as allowed by the sponsor's written policy?
○	○	10.	Will there be subcontracts to other institutions? Number? _____
○	○	11.	Is any program income anticipated under this project?
○	○	12.	Do you have consulting arrangements, line management responsibilities, substantial equity holdings with sponsor, subcontractor, or potential vendor?
○	○	13.	Have you submitted an annual conflict of interest disclosure Statement?

Yes	N/A		
○	○	14.	If you have acquired new financial interests since your last disclosure, have you reported these to the institution?

Yes	No		
○	○	15.	For NIH proposals, do all investigators agree to comply with the NIH Public Access Policy? Please see the NIH Policy for details.
○	○	16.	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.
○	○	17.	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?
○	○	18.	Have you engaged in lobbying activities using federal funds to influence any federal employee in connection with this proposal?
○	○	19.	If funded, will other individuals be authorized to sign for purchases necessary for the project? If yes, name authorized individuals:_____
○	○	20.	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.
○	○	21.	Does the project involve international partnerships or activities in foreign countries? Country name: _____
○	○	22.	Will the work involve the transfer of technology and/or materials overseas?
REQUIRED		**23.**	**Identify the CLASP-certified individual(s) who will have functional responsibility for oversight of this project, should it be funded**. _____ **(Name &Signature / 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.*

REQUIRED SIGNATURES (PLEASE SEE PAGE 2 FOR ADDITIONAL SIGNATURES WHICH MAY BE REQUIRED.

Principal Investigator(s): _____ Date:_____

Dept Chair(s): _____Date: _____

OBTAIN FOLLOWING SIGNATURES AS APPLICABLE TO THIS PROPOSAL:

Yes	No		
◯	◯	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): _____
◯	◯	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.
◯	◯	C (a).	Will project require resources of the CRC or CTSI? **If yes, obtain Signature**: _____
◯	◯	C (b).	Is this a Supplement to U of R CTSI? **If yes, obtain CTSI Signature**: _____
◯	◯	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:** _____
◯	◯	E (a).	Will project include recombinant experiments (NIH Guidelines), human pathogens, human blood/tissue/cell lines, (see IBC Webpage).
◯	◯	E (b).	Will project involve CDC or USDA Select Agents or Toxins? Botox®?
◯	◯	E (c).	Will 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)
◯	◯	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):**

If yes to E (a, b, or c), send a copy of this completed signoff form to the IBC Coordinator, Environmental Health & Safety, RC Box 278878.

NIH GUIDELINES/BIOHAZARDS/CARCINOGENS: Projects that use recombinant or synthetic nucleic acid molecules (NIH Guidelines), human pathogens, or human blood/tissue/cell lines (latter only in research labs) require institutional Biosafety Committee approval. Violations of the NIH Guidelines must be reported (reports are public). Projects that use carcinogens require EH&S review (IBC Coordinator/EH&S, x5-3241)

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 resources or staff of the Clinical Research Center should be reviewed by the CTSI. 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:

☐ 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).***

☐ 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).***

☐ 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 Clinical Trial Resources.

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: Clinical Trial Resources.