

When this proposal has been signed, please call _____ Extension _____
UNIVERSITY OF ROCHESTER PROPOSAL SIGN-OFF FORM
THIS FORM MUST BE COMPLETED AND SUBMITTED WITH THE PROPOSAL TO ORPA
AFTER ALL NECESSARY SIGNATURES HAVE BEEN OBTAINED.

Principal Investigator (PI)/Contact _____ School/College _____ Dept/Unit _____
 Please check if this is a Multiple PI project (as defined by NIH)
 Other Multiple PIs/Co-PIs _____ Project Sponsor _____
 Project Title _____
 Funding Opportunity (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 ledger 5 account (if applicable): _____
 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		Yes	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	1. Does this project contain a clinical trial component? If "Yes", complete Section B (on page 4).	<input type="checkbox"/>	<input type="checkbox"/>	13. Have you acquired new financial interests since your last disclosure, have you reported these to the institution?
<input type="checkbox"/>	<input type="checkbox"/>	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.	<input type="checkbox"/>	<input type="checkbox"/>	14. For NIH proposals, do all investigators agree to comply with the NIH Public Access Policy? Please see the NIH Policy for details.
<input type="checkbox"/>	<input type="checkbox"/>	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 account(s) _____ -If the cost sharing is Third Party Cost Sharing , attach a re-award THIRD PARTY COST SHARING FORM	<input type="checkbox"/>	<input type="checkbox"/>	15. Is this an Individual NRSA (F-awards) Fellowship? If yes, complete the Individual Fellow and Faculty Mentor Certification for NIH F-awards Certification http://www.rochester.edu/ORPA/Forms/
<input type="checkbox"/>	<input type="checkbox"/>	4. Will research use human subjects?	<input type="checkbox"/>	<input type="checkbox"/>	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?
<input type="checkbox"/>	<input type="checkbox"/>	5. Will research use animals?	<input type="checkbox"/>	<input type="checkbox"/>	17. Have you engaged in lobbying activities using federal funds to influence any federal employee in connection with this proposal?
<input type="checkbox"/>	<input type="checkbox"/>	6. Will research use radioactive materials or isotopes?	<input type="checkbox"/>	<input type="checkbox"/>	18. If funded, will other individuals be authorized to sign for purchases necessary for the project? If yes, name authorized individuals: _____
<input type="checkbox"/>	<input type="checkbox"/>	7. Will research use human embryonic stem cells?	<input type="checkbox"/>	<input type="checkbox"/>	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.
<input type="checkbox"/>	<input type="checkbox"/>	8. Are you requesting less than the maximum F&A costs allowed by the sponsor's written policy?	<input type="checkbox"/>	<input type="checkbox"/>	20. Does the project involve international partnerships or activities in foreign countries? Country name: _____
<input type="checkbox"/>	<input type="checkbox"/>	9. Will there be subcontracts to other institutions? Number? _____	<input type="checkbox"/>	<input type="checkbox"/>	21. Will the work involve the transfer of technology and/or materials overseas?
<input type="checkbox"/>	<input type="checkbox"/>	10. Any program income anticipated under this project?	<input type="checkbox"/>	<input type="checkbox"/>	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)
<input type="checkbox"/>	<input type="checkbox"/>	11. Do you have consulting arrangements, line management responsibilities, substantial equity holdings with the sponsor, subcontractor, or potential vendor?			
<input type="checkbox"/>	<input type="checkbox"/>	12. Have you submitted an annual conflict of interest disclosure statement?			

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).** 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 SIGNATURE PLEASE SEE REVERSE FOR ADDITIONAL SIGNATURES WHICH MAY BE REQUIRED

Dept Chair: _____ Date: _____ Division/Unit Chief: _____ Date: _____
 Director of Medical Center
 Dean: _____ Date: _____ Space Planning: _____ Date: _____
 (required for Medical Center if "Yes" has been checked on consideration 2 above)

OBTAIN FOLLOWING SIGNATURES AS APPLICABLE TO THIS PROPOSAL:

- | | | | |
|--------------------------|--------------------------|--------|---|
| Yes | <input type="checkbox"/> | 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): _____ |
| No | <input type="checkbox"/> | 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. |
| <input type="checkbox"/> | <input type="checkbox"/> | C. | Will project require resources of the CRC? If yes, obtain Signature of CRC Director: _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | 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: _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | 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 web page at http://www.safety.rochester.edu/homepages/ibchome.html |
| <input type="checkbox"/> | <input type="checkbox"/> | 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. |
| <input type="checkbox"/> | <input type="checkbox"/> | 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): |

Name and Department (printed)

Signature

Name and Department (printed)

Signature

Name and Department (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

If Question 1 in the **ADMINISTRATIVE AND POLICY CONSIDERATIONS** section was answered “Yes”, please check one of the appropriate box(es) below:

- A Prospective Reimbursement Analysis was completed because the trial includes clinical procedures.

The proposed clinical study has the following characteristic (check one box), does not have the potential for billings to insurance or to patients, thus is exempt from the requirement to complete a Prospective Reimbursement Analysis:

- The study does not involve human subjects.
- The study involves a retrospective chart review.
- The study involves completion of a survey/questionnaire.
- Specimens to be used in the research are to be obtained by/released to study staff for non-therapeutic analysis.
- The study is observational in nature—all items/services are dictated by clinical care and are not specified in the protocol.
- The sponsor has indicated it will pay for all of the items/services required for the study.

PRINCIPAL INVESTIGATORS' CERTIFICATION

In signing below the Principal Investigator(s) certify that he/she has completed the Blackboard clinical trial training (Course CT-01).

Principal Investigator(s) Name(s)

Date: _____