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 Op (Number/Title): ______________________

Proposed Start Date: __________ End Date: __________ Total Project Budget Requested: __________ Award mechanism (R01, K08, CAREER): __________ Deadline: __________

Proposal Type: ________ New ________ Continuation ________ Supplement ________ Resubmission ________ Renewal ________ Current ledger 5 account (if applicable): __________

F&A (Indirect) Rate: ______________________

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  

1. Does this project contain a clinical trial component? ________ Yes ________ No ________

2. Does this project require additional/new space or renovation/modification of current space or facilities? ________ Yes ________ No ________

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? ________ Yes ________ No ________

- If the cost sharing is Third Party Cost Sharing, attach a re-award THIRD PARTY COST SHARING FORM
- Will research use human subjects? ________ Yes ________ No ________
- Will research use animals? ________ Yes ________ No ________
- Will research use radioactive materials or isotopes? ________ Yes ________ No ________
- Will research use human embryonic stem cells? ________ Yes ________ No ________
- Are you requesting less than the maximum F&A costs allowed by the sponsor’s written policy? ________ Yes ________ No ________
- Are there be subcontracts to other institutions? ________ Yes ________ No ________
- If there is a number? ________

4. Are any program income anticipated under this project? ________ Yes ________ No ________

5. Do you have consulting arrangements, line management responsibilities, substantial equity holdings with the sponsor, subcontractor, or potential vendor? ________ Yes ________ No ________

6. Have you submitted an annual conflict of interest disclosure statement? ________ Yes ________ No ________

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: __________

Dean: ______________________ Date: __________ Space Planning: ______________________ Date: __________

(required for Medical Center if “Yes” has been checked on consideration 2 above)

Project Title: ______________________

Funding Op (Number/Title): ______________________

Proposed Start Date: __________ End Date: __________

Total Project Budget Requested: __________

Award mechanism (R01, K08, CAREER): __________

Proposal Type: ________ New ________ Continuation ________ Supplement ________ Resubmission ________ Renewal ________

F&A (Indirect) Rate: ______________________

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

Project Location: ________ On-Campus ________ Off-Campus ________

If off-campus, location: ______________________

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

Yes  No  

1. Does this project contain a clinical trial component? ________ Yes ________ No ________

2. Does this project require additional/new space or renovation/modification of current space or facilities? ________ Yes ________ No ________

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? ________ Yes ________ No ________

- If the cost sharing is Third Party Cost Sharing, attach a re-award THIRD PARTY COST SHARING FORM
- Will research use human subjects? ________ Yes ________ No ________
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- Will research use radioactive materials or isotopes? ________ Yes ________ No ________
- Will research use human embryonic stem cells? ________ Yes ________ No ________
- Are you requesting less than the maximum F&A costs allowed by the sponsor’s written policy? ________ Yes ________ No ________
- Are there be subcontracts to other institutions? ________ Yes ________ No ________
- If there is a number? ________

4. Are any program income anticipated under this project? ________ Yes ________ No ________

5. Do you have consulting arrangements, line management responsibilities, substantial equity holdings with the sponsor, subcontractor, or potential vendor? ________ Yes ________ No ________

6. Have you submitted an annual conflict of interest disclosure statement? ________ Yes ________ No ________

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: __________

Dean: ______________________ Date: __________ Space Planning: ______________________ Date: __________

(required for Medical Center if “Yes” has been checked on consideration 2 above)

Project Title: ______________________

Funding Op (Number/Title): ______________________

Proposed Start Date: __________ End Date: __________

Total Project Budget Requested: __________

Award mechanism (R01, K08, CAREER): __________

Proposal Type: ________ New ________ Continuation ________ Supplement ________ Resubmission ________ Renewal ________

F&A (Indirect) Rate: ______________________

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

Project Location: ________ On-Campus ________ Off-Campus ________

If off-campus, location: ______________________

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

Yes  No  

1. Does this project contain a clinical trial component? ________ Yes ________ No ________

2. Does this project require additional/new space or renovation/modification of current space or facilities? ________ Yes ________ No ________

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? ________ Yes ________ No ________

- If the cost sharing is Third Party Cost Sharing, attach a re-award THIRD PARTY COST SHARING FORM
- Will research use human subjects? ________ Yes ________ No ________
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- Will research use human embryonic stem cells? ________ Yes ________ No ________
- Are you requesting less than the maximum F&A costs allowed by the sponsor’s written policy? ________ Yes ________ No ________
- Are there be subcontracts to other institutions? ________ Yes ________ No ________
- If there is a number? ________

4. Are any program income anticipated under this project? ________ Yes ________ No ________

5. Do you have consulting arrangements, line management responsibilities, substantial equity holdings with the sponsor, subcontractor, or potential vendor? ________ Yes ________ No ________

6. Have you submitted an annual conflict of interest disclosure statement? ________ Yes ________ No ________

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: __________

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:

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

☐ ☐ 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 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

☐ ☐ 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-Nitrobenzophenone, 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.

☐ ☐ 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):

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<th>Name and Department (printed)</th>
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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 PI’s 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.

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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).*

________________________________________________                        Date: ________________

*Principal Investigator(s) Name(s)*