

When this proposal has been signed, Call _____, Extension _____

**UNIVERSITY OF ROCHESTER PROPOSAL SIGN-OFF FORM
FOR INDUSTRY-SPONSORED CLINICAL TRIALS**

THIS FORM (FRONT AND BACK) SHOULD BE COMPLETED AND SUBMITTED WITH THE STUDY SUMMARY, PROSPECTIVE REIMBURSEMENT ANALYSIS, PARTICIPANT GRID AND TOTAL BUDGET COMPARISON WORKSHEET TO ORPA AFTER ALL NECESSARY SIGNATURES HAVE BEEN OBTAINED.

Principal Investigator (PI) _____ School _____ Dept./Unit _____
Co-PI _____ Study Sponsor _____
Study Title (include protocol number and drug/device name) _____

Proposal Start Date _____ End Date _____
Amount per Patient _____ Estimated Number of Patients _____ Indirect Cost Rate _____

SECTION A -- ADMINISTRATIVE AND POLICY CONSIDERATIONS

- | Yes | No | | Yes | No | |
|--------------------------|--------------------------|---|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | 1. Is this an investigator-initiated study? | <input type="checkbox"/> | <input type="checkbox"/> | 10. Will other individuals be authorized to sign for purchases necessary for the study? If yes, name authorized Individuals: _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | 2. Has a Prospective Reimbursement Analysis been performed? If "No", complete Section C. | <input type="checkbox"/> | <input type="checkbox"/> | 11. Will project require resources of the General Clinical Research Center? If yes, obtain Signature of GCRC Director: _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | 3. Is the University cost sharing or subsidizing costs of the study because the sponsor is not covering all costs? If yes, attach completed copy of Cost Sharing Commitment form. | <input type="checkbox"/> | <input type="checkbox"/> | 12. Will project require services of the Department of Biostatistics? If yes, obtain Signature of Chair, Department of Biostatistics: _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | 4. Are you requesting less than the 30% clinical trial indirect cost rate? | <input type="checkbox"/> | <input type="checkbox"/> | 13. Is the proposed study using space, facilities or resources of Strong Memorial Hospital? If yes, obtain signature of SMH Senior Director for Finance: _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | 5. Does the study require additional/new space or renovation/modification of current space or facilities? | | | If SMH resources other than space are used, please specify: _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | 6. Will there be subcontracts to other institutions? Number? _____ | | | 14. Identify the CLASP-certified individual(s) who will have functional responsibility for oversight of this project, should it be funded. _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | 7. Do you or any of the involved researchers have consulting arrangements, line management or board responsibilities, patents and/or equity holdings with the study sponsor? If yes, please attach a completed UR Conflict Disclosure Form . Do you receive unrestricted funds or gifts from the sponsor that are separate from the study? If yes, please explain: _____ | | | (Signature or initials of this individual recommended) |
| <input type="checkbox"/> | <input type="checkbox"/> | 8. Do you believe that the proposal utilizes or will generate University-owned intellectual property that could be commercialized? | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 9. Are you currently debarred under Section 335a (21 U.S.C.) of the Food, Drug and Cosmetic Act? | | | |

PRINCIPAL INVESTIGATOR'S CERTIFICATION

In signing below the Principal Investigator certifies that the information on the Sign-Off Form is accurate and complete to the best of the Principal Investigator's knowledge and he/she has completed the Blackboard clinical trial training (Course CT-01).
Principal Investigator(s): _____ Date _____

REQUIRED SIGNATURES: (Include chairs and division/unit chiefs if faculty or staff from other university departments or divisions will participate in the study.)

Dept. Chair: _____ Date _____ Division/Unit Chief: _____

Dean: _____ (required if "Yes" has been checked on consideration 2, 3, and 4 above)

ORPA Assignment: _____ Date: _____