

**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 AND BUDGET 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 _____

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"/> | 9. 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. 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"/> | 3. Are you requesting less than the 25% clinical trial indirect cost rate? | <input type="checkbox"/> | <input type="checkbox"/> | 10. Will project require resources of the General Clinical Research Center? If yes, obtain Signature of GCRC Director: _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | 4. Does the study require additional/new space or renovation/modification of current space or facilities? | | | _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | 5. Will there be subcontracts to other institutions? Number? _____ | <input type="checkbox"/> | <input type="checkbox"/> | 11. Will project require services of the Department of Biostatistics? If yes, obtain Signature of Chair, Department of Biostatistics: _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | 6. 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: _____ | <input type="checkbox"/> | <input type="checkbox"/> | 12. Is the proposed study using space, facilities or resources of Strong Memorial Hospital? If yes, obtain signature of SMH Senior Director for Finance: _____ |
| | | | | | _____ |
| | | | | | If SMH resources other than space are used, please specify: _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | 7. Do you believe that the proposal utilizes or will generate University-owned intellectual property that could be commercialized? | | | _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | 8. Are you currently debarred under Section 335a (21 U.S.C.) of the Food, Drug and Cosmetic Act? | | | 13. 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 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.

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)

Research Profile for Industry-Sponsored Clinical Trials

In order to evaluate and document the proposed industry-sponsored clinical trial's relationship to the stated missions of the Medical Center, the University requires that all Principal Investigators complete this Research Profile. It is not necessary to answer "yes" to every question in order to demonstrate that the study contributes to our exempt purposes. It will be the responsibility of the Chair or Unit Chief to review the Profile; any questions concerning the nature of a study must be discussed with the Dean.

Yes No

 Has the PI or other University-designated individual had input or involvement in the study design and/or been designated manager of data coordination activities?

 Is the study a systematic investigation aimed at the discovery, interpretation or verification of facts? If yes, please describe briefly or attach summary of the scientific intent of the study: _____

 Is the project furthering an educational purpose? If yes, please indicate how residents, fellows, or students are involved in the study: _____

 Is there therapeutic intent (i.e., potential of some benefit) to improve the research subjects' condition?

 Is the study concerned with new application of products or drugs in order to improve the ability to treat various diseases and conditions?

 Does the project qualify as scientific research involving testing to validate a scientific hypothesis, rather than routine testing to determine if the item meets certain specifications?