ORPA Form 114A When this proposal has been signed, Call_____, Extension _____
9-18-12

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

THIS FORM 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 _____Total Budget_____

Amount per Patient_____ Estimated Number of Patients_____ Indirect Cost Rate_____

SECTION A -- ADMINISTRATIVE AND POLICY CONSIDERATIONS

Yes	No		
☐	☐	1.	Is this an investigator-initiated study?
☐	☐	2.	Has a Prospective Reimbursement Analysis been performed? If "No", complete Section D.
☐	☐	3.	Is there a defict or surplus budgeted at >= $20,000 and 20 percent of the budgeted expenses?
☐	☐	4	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 Pre-award THIRD PARTY COST SHARING FORM
☐	☐	5.	Are you requesting less than the 30% clinical trial indirect cost rate?
☐	☐	6.	Will there be subcontracts to other institutions? Number?_____
☐	☐	7.	Does this project involve international partnerships or activities in foreign countries? If yes, provide country name:_____
☐	☐	8.	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?
☐	☐	9.	Do you have consulting arrangements, line management responsibilities, substantial equity holdings with the sponsor, subcontractor or potential vendor?
☐	☐	10.	Have you submitted an annual conflict of interest disclosure statement?

Yes	N/A		
☐	☐	11.	If you have acquired new financial interests since your last disclosure, have you reported these to ther institution?

Yes	No		
☐	☐	12.	Will other individuals be authorized to sign for purchases necessary for the study? If yes, name authorizedIndividuals:_____ _____
☐	☐	13.	Will project require resources of the Clinical Research Center (CRC)? If yes, obtain Signature of CRC Director:_____
☐	☐	14.	Will project require services of the Department of Biostatistics? If yes, obtain Signature of Chair, Department of Biostatistics: _____ _
☐	☐	15.	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: _____ _
		16.	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(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 B (page 2 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 any. The PI also certifies that 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: _____ Date _____

Dean:_____ Date_____
(required if "Yes" has been checked on consideration 3, 4, and 5 above)

ORPA RA:_____ Date:_____

Section B: Additional Signatures Certification

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 any.

Name	**Signature**	**Role on Project** ***(e.g. PI, Res. Assoc.)***

SECTION C -- 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 Research 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?

SECTION D – Reason the Industry-Sponsored Clinical Trial is Exempt from a Prospective Reimbursement Analysis

If Section A Question 2 was answered "No", please check the appropriate box(es) below:

The proposed clinical study has the following characteristics, thus does not have the potential for billings to insurance or to patients:

☐ 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.