

Memorandum of Understanding for Industry Initiated and Sponsored Clinical Trials

The purpose of this agreement is the establishment of a mutually beneficial arrangement for the administration of an industry initiated and sponsored clinical trial. The specific elements of the agreement, and the budgetary requirements that the Center for Women's Health Research has established for clinical trials reflect our past experience with a wide variety of trials and sponsors. We have formalized the process in order to protect both parties (CWHR and PI/Division), and affirm that if the trial adheres to this process it should generate income, or at minimum be revenue neutral. At the end of the study, any "profit" or surplus of funds, not including start-up funds, will be divided equally (50/50) between CWHR and the PI's division. The PI's division is responsible for any financial loss after execution of the contract. Please initial or check the boxes below to indicate your understanding and acceptance of each item, and sign at the bottom.

- CWHR will be the administrator of the trial, and as such will provide assistance with the following:
 - Budget creation, negotiation with sponsor, and ongoing management
 - Study personnel recruitment
 - IRB preparation and submission
 - Submissions to and follow-up with Office of Clinical Trials (OCT)
 - Ongoing oversight of recruitment and enrollment, with reports provided monthly to PI and Division Director
 - Reports to PI and Division Director at 3 and 6 month points for assessment of viability

- PI will be responsible for hiring the study manager and any other study personnel, and they will be employed through PI's home department (unless personnel are shared with another study and are employed through the home department for that study).

- After execution of the contract, the PI's division will be responsible for covering study costs incurred by a delay in start time (often referred to as bridge funding), including time for CWHR administrative personnel.

- CWHR will examine study recruitment and enrollment monthly using reports completed by the study manager (Appendix IV), and will provide feedback to the study manager, PI and Division Director regarding financial viability of the study.

- CWHR reserves the right to discontinue our participation in any given study after 6 months if the enrollment data suggest that the study will not be financially self-sustaining (via capitated payments from sponsor for recruitment/enrollment/completion) beyond the period of time covered by start-up funds. If the PI chooses to continue the study beyond this point, s/he and/or the PI's home department agree to take financial responsibility for any losses incurred, including CWHR administrative costs if we continue to be the funds administrator.

- CWHR will split the study profit 50/25/25 with 50% to CWHR, 25% to the PI's Division Director and 25% to the PI at study close.

- CWHR will operate under the Center's F&A Sharing Policy at study close.

Principal Investigator

Date

Division Director

Date

CWHR Administrator

Date