Opening a Study

Here is an overview of the steps involved to opening a study:

So you have a new study you just wrote or you have been contacted by an industry sponsor or another institution about participating in their study. What happens next? All you need to do is contact the clinical research coordinator who works on your studies.

Our research staff completes a site survey for industry and some multi-institutional studies.

An agreement (CDA/NDA) between the sponsor and the OSU Technology Commercialization Office (TCO) is negotiated for industry and some multi-institutional studies.

A Clinical Trials Agreement (CTA or contract) between the sponsor and the OSU Office of Sponsored Programs (OSP) is negotiated for industry and some multi-institutional studies. (This can be done concurrently with the Institutional Review Board [IRB] review process.)

Prospective studies are entered into the Research Billing Office system for IHIS uploading and research billing account establishment (as necessary).

Our research staff works with the sponsor/lead site to negotiate a clinical trials budget for industry and some multi-institutional studies. (This can be done concurrently with the IRB review process.)

All cancer studies must be submitted to the Clinical Scientific Review Committee for review and approval prior to IRB submission.

Protocol submission (e.g., application, consents, data capture forms) is prepared and submitted by the research staff and PI to OSU IRB/Western Institutional Review Board (IRB/WIRB). The research staff strives to submit new projects to the IRB within four weeks of receipt of final protocol.

- For WIRB-reviewed protocols (industry-sponsored):
  - · Submission is sent to OSU Office of Responsible Research Practices (ORRP) for entry into the system and brief review of project materials. ORRP provides authorization to submit to WIRB.
  - · WIRB approval and amended documents received.
- For OSU IRB-reviewed protocols:
  - · IRB analyst will screen submission and then forward for review by either the full IRB at a convened meeting or for expedited review by an IRB reviewer.
  - · Modification requests from the reviewers are received approximately one week after meeting/expedited review. Our research staff works with the PI to answer modifications promptly.
  - · Approval received.

IRB/WIRB approval forwarded to OSP for final execution of the contract as necessary.

Our research staff helps schedule any training that is required before opening the protocol to accrual.

The research staff facilitate scheduling the Site Initiation Visit for industry studies and some multi-institutional studies.

Lead clinical research coordinator conducts implementation meeting to ensure that all study team members understand the study and their respective responsibilities.

Protocol is opened to accrual.

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER