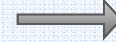


Central IRB at University of Michigan Workflow Independent/Commercial IRB

Project is identified as a candidate for ceding oversight to a central non U-M IRB. (*multi-site, industry-sponsored, phases III and IV clinical trials*)

No



Follow standard workflow for studies conducted at U-M.

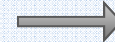
Yes



Study team confirms project is a multi-site study being conducted under the oversight of a central IRB listed below where U-M is being added as a performance site.

- Western IRB
- Chesapeake IRB
- Schulman Associates IRB
- Quorum Review
- NCI CIRB

No



Contact U-M IRB to evaluate the potential for development of a new Central IRB relationship.

Yes



Study Team creates a Clinical Trial Routing Form (CTRF) in the electronic proposal management system (eRPM). To ensure proper routing respond in the following manner:

- Question 5.1.3 - Answer **Yes**
- Question 5.1.4 - Choose the Central IRB you intend to use. *In the event the IRB of choice isn't listed, do **not** choose Other - contact the U-M IRB.*
- Study Team completes the Proposal Approval Form (PAF) in the eRPM



Study Team completes the "Requesting review by a non-UM IRB" (ceding application) in eResearch regulatory management (eResearch). When completing, be sure to include the protocol, consent template, recruitment materials, and **documentation of most recent central IRB approval** as provided to the Study Team by the sponsor or CRO. Team is also required to insert U-M local context language (provided by U-M IRB) into the template consent.



The eResearch ceding application is reviewed by applicable U-M ancillary committees (e.g., PRC, COI, IDS, RDRC/SHUR, CRAO) according to their procedures.



The eResearch ceding application is reviewed by the U-M IRB for final determination of ceding oversight of the project to a Central IRB. If the application is accepted, an acknowledgement letter ceding oversight is issued for the project.



Upon acknowledgement of ceding application by the U-M IRB and completion of all submission requirements of the Central IRB, the Central IRB is now the IRB of record for this protocol. Study teams remain responsible for ensuring all U-M requirements are maintained.