Follow standard workflow for studies conducted at U-M.

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

Study 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)

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

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

Yes

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.