# U-MIC TRANSCRIPT
# Central IRBs

A central IRB is a single institutional review board that provides regulatory and ethical review services for multiple sites participating in a research project. A central IRB may be independent (sometimes called commercial) or institutional. The University of Michigan has Master Services Agreements with the following independent IRBs:

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

Examples of institutional IRBs include university or hospital IRBs.

Ceding is established through an IRB agreement that delineates responsibilities between the entities. Ceding only transfers IRB oversight; all other regulatory oversight and workflows remain at the University of Michigan. To cede oversight of research, the UM IRB must agree to relinquish certain responsibilities, and the central IRB must agree to assume those responsibilities. This may be accomplished via:

- an IRB Authorization Agreement (with institutional IRBs that hold FWAs) or
- a Master Services Agreement (with independent IRBs)

Independent IRBs charge a fee, which is usually paid by the research sponsor. The billing process varies depending on the Master Services Agreement with the central IRB. Institutional IRBs typically charge fees only for industry-sponsored research.

The study team requests the use of a central IRB by creating a Clinical Trial Routing Form (CTRF) in eResearch Proposal Management (eRPM) and indicating which central IRB will be used when completing the PAF application. In eResearch Regulatory Management (eRRM), the study team completes the "Requesting Review by a Non-UM IRB" application, also called the ceding application. This application is reviewed by the ancillary committees, and reviewed and acknowledged by the applicable UM IRB.

The project must remain active in the eResearch system, undergoing annual Scheduled Continuing Review in order to record key data elements about the conduct of the study at UM such as enrollment numbers. Amendments must be submitted for changes to the UM study team members or if a project change may impact any ancillary committee's review or the decision to cede the project to the external IRB. An AE/ORIO must be submitted for any

- related serious adverse event that occurs in UM subjects
- unanticipated problem that occurs in UM subjects
- serious and/or continuing non-compliance determination regarding the UM site

- or hold or suspension of the project

In addition, when the project is completed, it should be terminated in eResearch to assure appropriate regulatory close-out.

Contact IRBMED for more information about central IRBs.

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