U-MIC TRANSCRIPT
Document Finalization at Scheduled Continuing Review

The IRB must review all supporting documents—such as recruitment materials and informed consent documents—as part of both initial study review and any scheduled continuing reviews that take place while the documents are in use or will be in use in the future. Once a study's subject recruitment period has permanently ended, the IRB no longer needs to review and approve recruitment materials during scheduled continuing review; likewise, once researchers have concluded all subject interaction and intervention, the study's informed consent documents are no longer subject to IRB review at scheduled continuing review.

When enrollment is ongoing, and the answer to the eResearch SCR application's section 1.1—"characterize the ongoing study activity"—is "Renewal—Study Activity Continues" and the answer to section 1.1.1—"has subject enrollment concluded"—is no, the IRB must review the recruitment materials uploaded to section 8-2.8 as part of the scheduled continuing review process. After review, the IRB will finalize the materials by updating their approval and expiration dates.

If subject enrollment has permanently ended, IRB staff will modify the titles of uploaded recruitment documents by adding "X-DO NOT USE_," this way indicating that the materials are no longer in use and subject to review.

When subject interaction or intervention is planned or ongoing, and the answer to eResearch section 1.1, regarding ongoing study activity, is "Renewal—Study Activity Continues" and the answer to section 1.1.1—"has subject enrollment concluded"—is no, the IRB must review the informed consent materials uploaded to section 10-1.1 as part of the scheduled continuing review process. After review, the IRB will finalize the materials by updating their approval and expiration dates.

If ongoing or future study activities are limited to follow-up, IRB staff will modify the titles of uploaded recruitment documents by adding "X-DO NOT USE_," this way indicating that these materials are no longer in use and subject to review.

Note that if the University of Michigan is in a multisite trial coordinated by another site, the UM IRB does not need to review recruitment or consent materials once they are no longer in use at UM. On the other hand, when the University of Michigan is the coordinating center for a multisite trial, the UM IRB may need to review and finalize supporting documents even after they are no longer in use at UM, depending on U-M's role as a coordinating center.

Contact the IRB for more information about IRB review of study-related documents.

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