U-MIC TRANSCRIPT
IRB Oversight for Data and/or Biospecimen Repositories

A research data or tissue bank, or research repository, stores, maintains, and distributes data and/or biospecimens to enable future research. Making data and biospecimens available in repositories, to maximize their utility to the overall research community, is increasingly a priority at both national and institutional levels. Research repositories that hold individually identifiable data or biospecimens are subject to IRB regulation. Per federal guidance, "The IRB should review and approve a protocol specifying the conditions under which data and specimens may be accepted and shared, and ensuring adequate provisions to protect the privacy of subjects and maintain the confidentiality of data."

Repository oversight at Michigan had been tracked in the eResearch Regulatory Management system through the same study application as traditional studies (known as the "HUM" application). However, a new "REP" application is now available to address better the concerns particular to repositories, including information required for IRB oversight and for compliance with University policies on data and physical security and on repository governance.

Newly established repositories should request approval through an REP application for intake, storage, maintenance and distribution of data and/or biospecimens. In some cases, a REP replaces an HUM application; in others, it is an adjunct to one or more HUM "collection applications." There is no requirement at this time for previously approved repositories to transition to from HUM to REP application, but IRB staff will encourage the transition on a case-by-case basis, if it may simplify or clarify oversight.

Researchers obtaining identifiable research data or biospecimens from a repository can indicate a REP as the data or specimen source in a HUM application to the IRB. A single REP application can be expected, over time, to distribute to many different "secondary use" HUMs. The eResearch system allows for "live links" between related HUM and REP applications.

IRBMED and IRB-HSBS host website guidance on repository oversight, including regulatory and policy background information, tips on the REP application, and FAQs. The eResearch Regulatory Management Training webpage includes step-by-step guides on filling out REP applications. REP applications, like HUMs, involve completing a "smartform" pathway and uploading applicable supporting documents.

Contact the IRB with questions about data and biospecimen repositories and the REP application.

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