Using an External IRB: Quick Guidance

A Tallahassee Memorial HealthCare IRB Guidance Document

TMH IRB may authorize the use of an External IRB for review of certain types of research studies. Note that when an External IRB reviews the study on behalf of TMH, **only the actual IRB review is ceded to that IRB**. The local requirements regarding research will remain the responsibility of TMH. As such, the Principal Investigator and study team will continue to work with the TMH IRB to ensure that investigators and research staff meet the TMH training and COI disclosure requirements, all ancillary reviews are obtained, and the record is updated in Cayuse.

Process of Obtaining Authorization to use an External IRB:

OR Review & TMH IRB 1st Review

- TMH PI receives info from Sponsor and incorporates TMH required language into the consent templates
- TMH PI submits the study in Cayuse for review by the Office of Research, Research Council, Ancillary departments, and TMH IRB
- Office of Research reviews the contract, budget, Subject Injury language, etc.
- Ancillary departments review their divisional responsibilities for feasibility, cost, time and effort commitment (i.e., pharmacy, lab, etc.)
- Research Council reviews the overall operational feasibility of the study (existing investigator commitments and experience, impact on TMH operations, risk to TMH, adequate support staff, etc.)
- TMH IRB conducts review of local context. Once local context requirement have been met, TMH IRB issues stipulations to submit to External IRB
- Cayuse submission is returned to the PI with Stipulations to return upon External IRB review/approval

External IRB Review

- TMH PI submits the application to the External IRB along with the localized study documents that have been reviewed by the TMH IRB
- External IRB reviews and approves the study
- Please contact the TMH IRB if stipulations arise regarding local language, COI disclosures, etc. during your External review

TMH IRB 2nd Review

- TMH PI returns the study to the TMH IRB in Cayuse using the same submission along with External IRB approval letter, stamped informed consent(s), and HIPAA document
- TMH IRB issues Cede Approval letter

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Post Approval Responsibilities of Principal Investigator (and/or study team designee):

1. Once approved as a site by the External IRB, re-submit the study in Cayuse to provide the External IRB approval letter, stamped informed consent(s), HIPAA authorization, expiration date, and External IRB number.
2. Keep a regulatory binder and maintain an active record of all submissions to the External IRB as well as submissions to the TMH IRB.
3. Submit any modifications to the TMH IRB through Cayuse that require local review. Examples of such changes include:
    a. Personnel additions or removals
    b. Changes of Principal Investigator
    c. Changes in Conflicts of Interest
    d. Changes for which there is a specific institutional policy or state law requirement (i.e., review by the COI committee, changes to local Florida law language, etc.)
    e. Changes to the consent form that require amendment to local language (i.e., Subject Injury language, COI language, Subject Cost language, or HIPAA authorization revisions)
4. Submit a Continuing Renewal form
    a. Upload the External IRB approval letter
    b. Upload the most current External IRB stamped Informed Consent
    c. Upload new COI disclosure forms for each member of the study team
5. Promptly report to the TMH IRB any determinations of serious or continuing non-compliance or unanticipated problems that the External IRB made
6. Promptly report to the TMH IRB any notifications of suspension or termination that you receive for the study from the External IRB
7. Promptly report to the TMH IRB any internal Incidents involving increases in risk, those that are serious and related
8. File a Study Closure form in Cayuse when the study has been completed and closed by the External IRB