TN Department of Health

Office of Informatics and Analytics

IRB Frequently Asked Questions

1. How do I know if I need an IRB?
    a. If your project meets the definition of Human subject or Research then an IRB review is required. These definitions may be reviewed at OHRP SITE HERE
2. Where and how do I begin to make an IRB submission? *This should link to the SOP*
3. May I start my research before the IRB review and decision is complete?
    a. No activities may be initiated prior to the IRB review and decision. A decision letter will be available following the review.
4. How long will it take to complete the IRB review?
    a. When a complete IRB has been received and all initial questions have been answered, the submission will be referred to the appropriate IRB member(s) for review. The convened IRB meets monthly; however, the length of time may vary based upon the number of times it is returned for corrections prior to being sent for a member review.
5. What is the IRB review process?
    a. Once submitted the IRB staff reviews and returns for additional questions/clarifications or additional documents. When these are received, the Data Stewards reviews the requested data and provides a recommendation or they do not recommend the data be used in the project. The Data Steward may have additional clarifications or questions, if so; the submission will be returned for responses. Once these steps are completed, the submission will either be sent to a member(s) for subcommittee review or placed on the agenda for full committee review. Once a member receives the submission, they have two (2) weeks to complete their review.
6. How long will my IRB approval last?
    a. IRB approval is for a 12-month period from the original approval. You will be required to submit a continuing review at least 30 days prior to the expiration date. If the continuation is approved another 12-month approval is granted.

7. What if my study changes after my approval?
    a. To make changes to your study, including adding procedures, research personnel, or documentation, log into iMedRIS and submit the “Amendments” form. This form will give you an opportunity to modify your original application and submit new documentation to the IRB for review and approval. These changes may not be implemented prior to the approval of the amendment.
8. What training is required by the IRB?
    a. All study staff are require to have CITI training. A basic course in biomedical research, social/behavioral research, or research with records of lab specimens only must be completed with a score of 80% or above on each module. A report identifying the completed modules must be submitted. https://about.citiprogram.org/en/homepage/