Purpose

This guide has been drafted by the Saint Francis Hospital and Medical Center Research Development Office to use as a reference while completing the Trinity Health Of New England IRB’s Reapproval/Closure Form located in the electronic IRB system (iRIS).

Policy

Trinity Health Of New England IRB requires that all Investigators provide a progress report and, if reapproval is desired, a formal reapproval request. The progress report is due six weeks prior to the expiration date. Requests for renewal for sponsored pharmaceutical/device research protocols must be submitted eight weeks prior to the anniversary date with completed Financial Disclosure Forms. Investigators are required to provide a progress report whether patients were entered in the study or not. Investigators should also provide an abstract/summary form. In order to provide the IRB with sufficient information to determine whether the research protocol continues to fulfill the criteria for approval Investigators are required to submit:

1. Protocol Progress Report/Request for Reapproval/Closure Form and any attachments included as part of the report
2. Current consent form / HIPAA Authorization
3. An Abstract/Summary form which includes a recent literature search (conducted within 30 days of submitting Progress Report) and its impact on the study

Failure of an Investigator to provide a progress report will result in the expiration of the protocol. Investigators will be notified by the IRB in writing that all research activities must stop, including (but not limited to) new enrollment, screening, study visits, medical record review, data analysis, presentations and publications. The letter will also indicate that the Investigators have 30 days to submit the material or the study will be closed. In order to continue research after the closure, Investigators will have to submit an initial application and go through the review process.

The IRB Program Coordinator will meet with Investigators following closures of protocols to ensure that research activities stopped when IRB approval expired. In instances of a closure of a protocol when an investigator leaves the Institution and does not officially close a protocol/arrange for transition to another appropriate trained investigator within the Institution, a follow up audit will be conducted when feasible. If the IRB (or chair) finds that there is an overriding safety concern or ethical issues making it in the best interest of the participant to continue in the study, the IRB may permit research activities to continue for the brief time required to complete the continuing review process. Failure to provide progress reports may also result in loss of the privilege to use IRB services in the future.

Link to the Trinity Health Of New England IRB Policy

Steps and Procedures

1. Log on to iRIS (electronic IRB system)

   iRIS is not compatible with Safari or Excel

   - iRIS website: https://stfrancis.imedris.net
   - If you don’t know your user ID, please contact the Trinity Health Of New England IRB:
     Telephone: (860) 714-4068 or Kathy Alexander (Kathryne.Alexander@TrinityHealthOfNE.Org)

2. Access the Reapproval/Closure Forms by any of the methods indicated below:

   OR

   Click note pad to open study

3. Add a new form
4. Confirm study information:

5. Identify study status and funding:

For funded studies - attach Financial Disclosure Forms under section 2.3

Note: The Conflict of Interest System is a separate system in iRIS; therefore a copy of each completed Financial Disclosure Forms needs to be attached to the IRB Application and/or Reapproval Form. Only attach copies of the Financial Disclosure Form which indicate that the electronic signature has been applied.
6. For ongoing studies answer the following questions:

Remember to attach required documents

7. Additional Information requested for all studies:
8. Complete the Abstract/Summary:

Copy the Lay Summary from section 1 the initial submission packet

9. Abstract/Summary continued:

For questions 5.5 – 5.13 provide a brief summary or write N/A for not applicable.
10. Abstract/Summary continued:

11. Notify PI to Signoff:

Note: The Library staff at Saint Francis Hospital and Medical is a great resource. Please contact them if you need assistance with a literature search (library@stfranciscare.org)
Literature Search Example:


It is helpful to include the Abstract of each article. Change format to Abstract.

Enter custom date range (IRB requests relevant publications within the last year).

Note: To save your PubMed literature search: right click the mouse and select save as.
To print your PubMed literature search: right click the mouse and select print.