Quick Guide: Protocol Amendment Form

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 Protocol Amendment Form located in the electronic IRB system (iRIS).

Policy

Trinity Health Of New England IRB requires all Investigators to request, in writing, IRB approval of protocol changes prior to their implementation by submitting a Protocol Amendment Form and when indicated, an amended consent form. Investigators are required to submit electronically in iRIS:

1. Protocol Amendment Form
2. Consent Form, if amended (one clean copy & one copy with changes highlighted)
3. Amended document (one clean copy & one copy with changes highlighted) or new proposed document
4. Supporting documentation (such as revised protocol and investigator’s brochure – one copy with changes flagged or highlighted)

Protocol Amendments are reviewed in the same manner as initial reviews and the determination of eligibility for expedited and full board review apply. The IRB will consider the review criteria checklist for protocol amendments. A revision may not be disapproved by expedited review. The IRB chair or primary reviewer may recommend that the revisions be reviewed by the full board. Minor changes are reviewed and approved by expedited review by the Chairman of the IRB or a designated primary reviewer, and the applicable regulation justifying the approval is documented in writing on the Amendment form and in the minutes of the IRB meeting. Examples of minor changes that are eligible for expedited approval include, but are not limited to:

1. Administrative or informational changes
2. Additions or deletions of investigators or study coordinators
3. Corrections of grammatical or typographical errors
4. Changes leading to clarification of a protocol
5. Minimum changes in numbers of enrolled participants
6. Changes recommended by members of the IRB at an adjourned meeting during which the Chair or the IRB has been designated to approve the changes by the expedited mechanism
7. Changes secondary to drug dispensation, software upgrades
8. Changes in the consent form to incorporate Health Insurance Portability and Accountability Act (HIPAA) language
9. Revisions that include changes to the protocol that may impact research participants, but that do not affect the risks to participants
10. Advertisements for recruiting study subjects (include final print copy, audio and/or video and transcript)

Significant changes in a protocol that involve increased risk to participants undergo full IRB review and voting at a convened meeting. Enrollment may continue and the currently approved protocol must be followed until notification by the IRB that the changes have been approved.

Any changes that incorporate unanticipated added risks due to adverse events, including but not limited to informed consent documents, will be reviewed by the full board. Investigators must not use informed consent forms that do not include all known risks and side effects. Therefore, new enrollment must be suspended pending full IRB review.

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of additional risk and approval of revised consent documents. In cases where enrollment has been suspended pending IRB review and the timing of entry of a subject into a protocol is an issue, an emergency meeting of the IRB will be called. IRB approval is required prior to implementation of any change. However, investigators are permitted to take measures in order to eliminate apparent immediate hazards to the subjects without prior IRB approval. The investigator must report the incident to the IRB within five (5) working days (see section entitled “Investigator Reporting Requirements” in the IRB Policies).

**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](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](mailto:Kathryne.Alexander@TrinityHealthOfNE.Org))

2. **Access the Protocol Amendment Form by the following method:**

   ![Protocol Amendment Form Image]

   **Click the notepad to open study**
3. Click add a new form:

4. Complete Amendment Information:

**Note:** When completing an Amendment to add new study staff contact the IRB to confirm:
1) New staff have completed the required CITI training
2) New staff have an established iRIS account

Attach two versions of all revised documents
1) A clean copy for the IRB to stamp
2) A track changes copy highlighting the changes

In the text box- provide a detailed explanation of the amendment and justification or rationale for the amendment (do not use acronyms).
Note: Answer all questions and enter N/A in the text boxes for any items which are not applicable to your study.

5. Click Save Form:

6. Notify PI to Signoff: