The Christ Hospital IRB
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Number: 2.07
Effective Date: 11/11/08
Revised Date: 09/22

STANDARD OPERATING PROCEDURE

Notice of Study Closure

POLICY:

Principal Investigators (PIs) are responsible for notifying the IRB whenever an IRB-approved study will be closed, regardless of the reason for closure. Data collection and analysis for the study are not permissible after study closure.

Upon completion of research activities, the investigator must request study closure in Mentor IRB. Until request for study closure is received and acknowledged by the IRB, TCH IRB oversight of the research will remain active, including continuing review of the research as appropriate.

By submitting a study closure request, the researcher confirms that the study is finished and that researchers will have no further interaction with subjects or their data in ways that would require ongoing IRB approval. If a project does not have an expiration date, the PI must email the IRB office to inform IRB staff that the project should be administratively closed.

An investigator should only close a study when the research is permanently closed to the enrollment of new subjects, all participants have completed all research-related interventions or activities, and collection and active analysis of private identifiable information has been completed or if they are leaving TCH. As applicable, the study close-out visit by the sponsor should be completed prior to closure with the IRB.

Once a protocol is permanently closed all research activities must cease, including data analysis (unless the data is de-identified). A protocol that has been closed cannot be reopened. To resume research activities a new protocol must be approved by the IRB. IRB Records will be maintained for at least 3 years after study closure.

DEFINITION:

Study Closure: occurs when research-related interventions or interactions with human subjects have been completed and all data or specimen collection and analysis as described in the IRB-approved research plan have ceased. Study closure is an action taken by the PI and may occur for any of the following reasons:

1. **Completed**: The study has been concluded as described in the protocol.
2. **Premature Closure**: The study has permanently stopped earlier than anticipated by the protocol.
3. **Study is Withdrawn**: A study is stopped prior to the enrollment of the first participant.

PROCEDURE:

Closure by Principal Investigator/Sponsor-Initiated-

A request for study closure must be submitted in Mentor IRB when the project has been completed. If further information is required for review, the IRB will communicate to the Principal Investigator those steps needed to close the study. If premature closure is anticipated (e.g., the study is to be closed earlier than anticipated based on recommendation of the DSMB), the PI should work with the IRB to inform currently enrolled study subjects about the closure and, as appropriate, other research or clinical options that may be available. Additional procedures may need to be established to ensure that the rights and welfare of subjects are protected. The IRB Chair reviews and acknowledges study closure requests. The Chair may recommend the closure request to the convened board for consideration in circumstances such as if there are patient safety concerns. The convened IRB is notified of all closures acknowledged by the Chair at their next convened meeting after review. The IRB Office Staff prepares and send correspondence communication all determinations.

Closure by IRB

The IRB may close projects without a request from the PI in the following circumstances:

1. If it is determined that the PI is no longer affiliated with TCH.
2. In response to unanticipated problems involving risk to subjects or others, serious or continuing non-compliance, findings presented during an IRB review; or problems identified in a monitoring process.
3. If the investigator has not responded to the IRB's requests for revisions and/or clarifications to obtain IRB approval within 3 months (for projects that have not yet received initial IRB approval, continuing review submissions, or amendment submissions that are awaiting response from the investigator).
4. If an approved project expires and the PI does not submit the appropriate documents for continuation of the project.

The IRB Office will prepare and send written notification of all closure circumstances to the PI, the PI's Department Head, and Institutional Official.

REFERENCE:

45 CFR 46.115(b); 21 CFR 56.115(b)