POLICY:

A study may be closed by the researcher/sponsor, or by the IRB. Procedures have been established to assure proper study closure.

Study closure is defined by TCH IRB when:
1. All subjects have completed final visits and follow up.
2. The sponsor or its representative has indicated closure at the research site.
3. If the study was conducted under a Federal Wide Assurance, all data analysis at the site is completed.

Upon completion of research activities, the investigator must submit a Study Closure Report to the IRB. (See Section 3.0, part 3.5 of IRB Reference Manual for more information regarding Study Closures.) If the investigator fails to notify the IRB of study closure, then he/she will continue to be responsible for completing the Continuing Review Reports. IRB study files will be maintained for a 3-year period after study closure.

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.

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

PROCEDURE:

I. Closure by the Investigator/Sponsor

1. Investigator/Sponsor-initiated Termination or Suspension of a Research Protocol – IRB Notification

Termination or suspension of an IRB-approved research protocol by the principal investigator and/or sponsor of the research study shall be reported promptly (i.e., within 1 day of the receipt of the sponsor termination/suspension notice) to the IRB office if the termination/suspension is based on a change in the risk-to-benefit ratio of study participation (e.g., serious adverse events, non-effectiveness of the research intervention). Termination/suspension of a research study for other (e.g., administrative) reasons shall be reported to the IRB office within 10 working days of receipt of the
termination/suspension notice. IRB notification shall include reference to the current IRB approval number and a letter that addresses:

a. The reason for study termination or suspension (e.g., subject accrual complete and data analyzed; demonstrated absence of benefit based on interim data analysis; serious adverse event).

b. The number of subjects currently enrolled in the study at The Christ Hospital and the status (e.g., currently undergoing research intervention and monitoring; completed intervention follow-up monitoring only; completed study) of each of these enrolled subjects.

c. A description of the procedures that will be used to notify subjects currently participating in the study of the study termination/suspension; and the procedures that will be undertaken to ensure their orderly and safe withdrawal from the study and their follow-up care, if applicable.

d. A description of the procedures that will be used to notify subjects who previously participated in the study of the study termination/suspension, if felt to be important to their rights or welfare.

2. For terminated research protocols, a Study Closure Report/Final Report Form or a Closure Letter shall be submitted to the IRB office within 10 working days of notification of closure by the sponsor. This report will be reviewed by TCH IRB staff and IRB Chair or designee and will be presented at the next IRB meeting for their review, consideration, discussion and acknowledgement. The IRB does not routinely send confirmation of receipt of study closure to the research site.

This Final Report shall address, at a minimum:

a. The final number of subjects enrolled in the study at The Christ Hospital.

b. A summary of outcomes and conclusions to include:
   -- statement of the extent to which the specific aims of the protocol were addressed
   -- impact of the study on the relevant scientific/medical issues under investigation
      (e.g., a description of new knowledge, findings, or information bearing on the risks or benefits to human research subjects).

3. For research protocols suspended due to serious adverse events, IRB approval is required to reinitiate the research study. The written request for study re-initiation shall address:

a. The outcome of investigations on the causality of the serious adverse event(s).

b. The frequency of occurrence of the serious adverse event at TCH IRB or external sites, if applicable.

c. Modifications of the protocol and consent form to address the serious adverse event.

II. Closure by the IRB:

SOP 2.07 Study Closure
4. TCH IRB has the authority to terminate or suspend its approval of a research protocol that is not being conducted in accordance with regulatory or IRB requirements or that is associated with serious harm to human research subjects. The IRB Chairman is authorized to suspend or terminate research on an urgent basis. Suspensions and terminations by someone other than the convened IRB are reported to and reviewed by the convened IRB. The IRB Chairman sends written notification reports stating the reasons for the IRB’s action to suspended or terminated research within 30 days to:
   - TCH Institutional Official and Appropriate Hospital Department Head
   - Principal Investigator
   - OHRP, when the research is covered by DHHS regulations
   - Other federal agencies when the research is overseen by those agencies, and they require reporting separate from that to OHRP.
   - FDA, when the research is FDA-regulated

III. File Retention:

Research files are retained for three years after completion of the research [CFR 56.115(b)].

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<th>Date Revised</th>
<th>Reason For Change</th>
<th>Revised By</th>
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<tr>
<td>4/30/15</td>
<td>added that when a study is closed it can not be reopened. A new protocol must be submitted to the IRB</td>
<td>Becky</td>
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