

Children's Hospital Institutional Review Board

Information Sheet

Renewing or Closing a Study

Federal regulations require that studies be reviewed at least annually, though the IRB may choose to require more frequent review. **It is important that study approval not be allowed to lapse; an expired study cannot be renewed.**

Approximately 8-10 weeks before the approval period expires, the principal investigator receives a copy of the status report from the IRB Office. The status report is sent electronically to facilitate completion of the form on the computer. Detailed instructions for completing the status report are included in the mailing.

Study Renewal

If the study is to be renewed, the investigator should complete the status report and return it to the IRB office. This should be done as soon as possible, and no less than four weeks before the approval period expires.

The status report requests information about the progress of the study, which includes:

- A brief, non-technical abstract of the research.
- The number of participants (enrolled, continuing and expected to enroll) in the study at Children's and at all sites.
- The number and types of adverse effects and how they were handled.
- Any problems, complaints, protocol deviations or withdrawals that occurred during the last approval period.
- A brief progress report.
- A summary of recent literature or other new information that is related to risks or benefits associated with the research.
- A summary of changes made to the study during the last period of approval.
- Any proposed changes to the research project
- Sources of funding. All current and pending funding sources that support the research must be listed. If funding sources not previously reported to the IRB are included, one copy of the grant or contract proposal should be submitted with the status report.
- Questions regarding financial conflicts of interest

If accrual for a study is closed but research participants are still being followed as part of the study, the research needs to be renewed. In most cases where activity directly involving research participants is complete but data analysis is ongoing, the study should also be renewed. If you have questions on whether to renew or close a research project, contact the IRB at irb@seattlechildrens.org for advice.

Before submitting a renewal, please refer to the instructions on page 1 for information about the number of copies of the status report and other materials needed for IRB review to proceed.

Once the status report is received, it will be pre-reviewed by the IRB staff to be sure it is complete and ready for IRB review. When ready, the renewal application is assigned to an IRB agenda. Investigators generally do not attend the IRB meeting for a study renewal.

After the renewal application has been reviewed and approved, one copy of the status report is marked "Investigator's Copy" and is sent to the researcher. The number stamped in the upper right corner is the IRB number; and the dates in the IRB Chair signature box identify the new approval period. Keep one copy of the status report in your file along with the application materials that were previously approved by the IRB. You will also receive an IRB approval letter with your Investigator Copy of the Status Report.

Closing a Study

If a study is to be closed, the investigator needs to complete the status report, using it as a final report to the IRB. Please check the appropriate box in section 3 that indicates why the study is being closed. Provide the number of copies of the status report as requested.

Once a study is closed the IRB stores the Master (original signature) copy of the approved application, the closure report and all accompanying materials. These are made available to auditors on request. A copy of the closure report acknowledging the IRB has closed the file is sent to the principal investigator.