

Children's Hospital Institutional Review Board Information Sheet Modifications

When a study is approved by the IRB, the IRB assigns an approval period. Investigators may request modifications (changes) to the study during that period, within limitations. **Approval of a modification does not alter the date of the study's approval period. Renewal notices are sent based on the approval period previously assigned.**

Changes to the study may not be implemented until approved by the IRB.

Modifications represent changes in the protocol. The degree and significance of the changes affect whether the modification receives full or expedited review by the IRB. The majority of modifications received by the IRB receive expedited review. However, a modification that proposes substantial changes to the study design or aims, study procedures, the assessment of risk and benefit, or previous determinations or requirements by the IRB, will require full IRB review.

Modification procedures

The investigator submits an electronic copy of the following:

- A [modification request form](#) to the IRB describing the change and the rationale.
- Any approach materials or documents given to participants that are affected by the modification, such as consent and assent forms, approach letters, telephone scripts or questionnaires.

Once the request is received, the IRB has the following options:

- The IRB Chair may approve the modification request as it has been submitted.
- The IRB Chair may request additional information from the investigator.
- The IRB Chair may appoint an ad hoc subcommittee to review the modification.
- The IRB Chair may refer the modification to the full board for consideration.

When the modification is approved, a copy of the approval is sent to the investigator.

Please contact an IRB Coordinator with questions about modifying an approved study. You may reach the IRB Coordinators by email at irb@seattlechildrens.org or by telephone. Find the contact information for the IRB Coordinators on the IRB web site http://irb.seattlechildrens.org/contact.asp#irb_coordinator