

Principal Investigator Responsibility Memo

Attached is your copy of the approved application for your records. This memo will provide you with important information about research studies that have been approved by the IRB.

APPROVAL PERIOD

In the upper right hand corner of the application is your IRB application number. Please use this number on all correspondence you submit to the IRB. On page 1, in the IRB box, you will find the date of approval, any outstanding conditions of approval, and the approval period of your project. **If you have any outstanding conditions of approval noted by the IRB in the section "Subject to the following conditions," these need to be addressed before the research is initiated.**

Your IRB approval is valid only if you are following approved procedures. All members of the research team need to be informed about the IRB's conditions of approval. The principal investigator is responsible for ensuring that the research team is following approved procedures.

FOSTER CHILDREN/WARDS OF THE STATE

Research involving foster children and/or wards of the state requires additional protections to ensure that their safety and welfare are protected when they are involved in research. Permission for these children must meet all federal regulations and state law pertaining to protections for children who are wards of the state or foster children. Permission for the child to take part in research must be obtained from the child's legally authorized representative as defined by state law.

MODIFICATIONS TO STUDY

Researchers frequently need to make changes in their research project after they have received IRB approval. Any changes to the research activity need to be reviewed and approved by the IRB before implementation. The only exception is when a change is needed to meet the immediate health needs of a research participant.

To request a modification, send **one (1) electronic copy** of a letter to the IRB explaining the changes to be made, including the rationale for the changes and the implications of the changes. Provide **one (1) electronic copy** (if available, hard copy if not) of any materials that need to be revised based on the changes, such as consent and assent forms, recruitment letters or flyers.

Changes to a research project range from minor changes (adding or removing researchers from the project, minor revisions to a study questionnaire or interview) to major changes in the study design (adding a new study population) or acceptability of study risks or benefits (significant new safety information). Minor (minimal risk) changes are reviewed and approved by a Subcommittee of the IRB. All changes approved by the Subcommittee are then reported to the full IRB. Major changes to your approved research project will require full IRB review. Changes which significantly affect the risks or the benefits of the approved research will require full IRB review. Please do not hesitate to consult with the HSPP staff about whether proposed changes would require full IRB review. Contact information is provided in the bottom paragraph of this letter.

REPORTING ADVERSE EVENTS

In addition to changes to the research study, unexpected problems or adverse effects may occur. These need to be reported to the IRB. Please report as soon as possible any adverse events that are unexpected. Unexpected would include any event that was not anticipated, regardless of severity, events which are more serious than expected, or events that occur more frequently than expected. When reporting unexpected adverse events provide the following information: (1) a summary of the event and how it was handled; (2) whether the event is related to the study, (3) the outcome; and (4) whether the event requires changes to the consent form or other information to study participants.

Adverse events that are reasonably expected to occur as a result of the research, which are not of an unexpected frequency or severity, are to be reported to the IRB at the time your study is submitted for renewal. Also, the IRB must be copied on any adverse events reported to the U.S. Food and Drug Administration (FDA), the study sponsor, or other officials, involving research participants enrolled under Children's IRB approval.

RENEWING OR CLOSING YOUR IRB APPROVED RESEARCH

The HSPP staff will send you a reminder to renew your study. This reminder, called a status report, is sent approximately 8-10 weeks before your application is due to expire. It is important that you send your renewals to the IRB in a timely manner. The federal regulations require that all research be reviewed at least once a year and will not allow expired studies to be renewed. If you allow your research study to expire, all research activity must stop. Once expired, if you wish to continue the research, a new IRB application will need to be submitted for IRB review.

It is important to notify the IRB when the study is closed. A study is ready to close when study subjects are no longer being studied or followed as part of the research. If you are in the data analysis stage, you may or may not be ready to close the study. If you still need to retain individual identifiers or links to these identifiers, the study should be renewed. If you may need to contact study subjects to clarify information or you need to review their medical records for research purposes, the study should be renewed.

IRB/HSPP CONTACT INFORMATION

We wish you well in your research project. The HSPP staff is available for consultation and advice and we welcome your calls, drop-ins and e-mails. If we can be of assistance, please contact us.

Mary "Peg" Boyle, Human Subjects Protection Analyst, 206-884-8161, mary.boyle@seattlechildrens.org

Joan Doherty, Human Subjects Protection Analyst, 206-884-5089, joan.doherty@seattlechildrens.org

Tara Polek, Human Subjects Protection Analyst, 206-884-6187, tara.polek@seattlechildrens.org

William Smith, Research Analyst, 206-884-7570, william.smith@seattlechildrens.org

Laura Hill, Program Coordinator, 206-884-4557, laura.hill@seattlechildrens.org

Ranjini Prakash, Program Coordinator, 206-884-2910, ranjini.prakash@seattlechildrens.org

Laurie Bolton, HSPP Director, 206-884-7820, laurie.bolton@seattlechildrens.org

Anne Clancy, HSPP Manager, 206-884-7895, anne.clancy@seattlechildrens.org

Douglas Diekema, IRB Chair, 206-987-4346, douglas.diekema@seattlechildrens.org

***Please note: All submissions should be directed to the IRB via e-mail at irb@seattlechildrens.org**