

CONTACT US:

333 Longwood Ave.
4th Floor
Boston, MA 02115
Tel: 617-355-7052
Fax: 617-730-0226

Human Subjects Protection Update Children's Hospital, Boston

SEPTEMBER 2009

COMMITTEE ON CLINICAL INVESTIGATION

www.childrenshospital.org/research/irb

Committee on Clinical Investigation

Steven Colan, MD
Chairman

Peter Wolff, MD
Vice Chairman

Susan Kornetsky, MPH
Director

Matt Stafford, CIP
Manager

Elizabeth Carroll, CIP

Robleinsky Dominguez

Anna Mitchell

Ashley Pyszczynski

Irine Breytburg
Technical Support and
Web Development

Quality Improvement Staff (EQuIP)

Eunice Newbert, MPH

Kristin Bowling, MS

Staffing Updates

UPDATE: Pre-Review of New Protocols

UPDATE: Scientific Review

CITI Refresher Course

One Protocol, Multiple Groups: Obtaining Written Consent for Different Study Groups

Electronic IRB Submission Update

Staffing Updates

We are pleased to announce that **Robleinsky Dominguez** has been promoted to IRB Administrator. Robleinsky has worked in our office for over four years as Administrative Associate, handling continuing reviews of protocols and other administrative duties. We know that her experience and skills will make her valuable addition to the IRB administrator staff.

Replacing Robleinsky as Administrative Associate will be **Ashley Pyszczynski**. Ashley has worked in our office as a part-time intern for three years and is already quite familiar with the Office of Clinical Investigations and its operations. Ashley also brings with her some valuable research experience from studies she conducted as an undergraduate at Boston University. Beginning in September, Ashley will take over the handling of continuing reviews and other administrative duties formerly handled by Robleinsky.

As many of you know, our office has been short-staffed since the departure of an IRB Administrator earlier this year. We are now fully-staffed and better poised to serve the research community at Children's Hospital. We wish to thank investigators and research coordinators for their patience during this time of transition.

With the addition of Robleinsky to the IRB Administrator team, we are also updating the list of departments handled by each IRB Administrator. The new breakdown of department assignments is as follows:

Elizabeth Carroll	Robleinsky Dominguez	Anna Mitchell	Matt Stafford
Emergency Medicine	Adolescent Medicine	Dentistry	Cardiac Surgery
Endocrinology	Anesthesia	Developmental Medicine	Cardiology
Infectious Diseases	Immunology	Gastroenterology/ Nutrition	Hematology/ Oncology
Neurology	Medical Critical Care Program (MICU/ICP)	General Pediatrics	Laboratory Medicine
Newborn Medicine	Nephrology	Genetics	Molecular Medicine
Otolaryngology	Nursing	Neurosurgery	Pathology
Psychiatry	Ophthalmology	Research Administration	Physical Therapy
Radiology	Orthopedic Surgery	Respiratory Diseases	Plastic and Oral Surgery
Urology	Surgery		Radiation Therapy

UPDATE: Pre-Review of New Protocols

Last fall the IRB began a new process of administratively pre-reviewing all new protocols before sending them on to the Committee for formal review. Through this process, the IRB staff identifies places in the protocol where incomplete or inconsistent information might prevent the IRB from making the required determinations when approving a protocol. We received feedback from investigators and IRB members alike that the process is helpful. Initially we placed items onto IRB meeting agendas even when the investigators' responses to concerns raised during pre-review had not yet been received. Due to the initial experience with this method and feedback from the Committee, we have decided to only put items before the IRB after all pre-review issues have been addressed and submitted to the IRB office. There can no longer be exceptions. Therefore going forward, a protocol will only be placed on an agenda for review or be sent for expedited review if the CCI office has received the investigator's pre-review responses. Additionally, even if a protocol is ready for review, there is a limit to how many protocols can be reviewed at a given meeting. Therefore, protocols will be added to an agenda on a first-come, first-serve basis based on the date the pre-review concerns were addressed. Please keep this in mind when submitting new protocols.

UPDATE: Scientific Review

Federal regulations for human subjects research require for any approved protocol that an IRB determine that "risks to subjects are minimized...by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk". The Children's Hospital IRB relies upon the departmental review of each protocol to help them make this determination. Because the IRB reviews projects from over 30 departments/divisions and from a diverse group of medical and scientific disciplines, the scientific merit of each protocol is vetted at the department level. A protocol should not be submitted to the committee for review (or for pre-review) until it has been approved by the department's scientific review process. Department-specific requirements for scientific review/approval documentation can be found on the CCI website:

http://www.childrenshospital.org/cfapps/research/data_admin/Site2206/mainpageS2206P19sublevel2.html

In addition review worksheets and evidence of the scientific review process must be submitted with the protocol. In addition the IRB will want to see responses to all the questions raised during scientific review.

CITI Refresher Course

The CCI previously implemented a continuing education requirement for human subjects research training. One way to satisfy the continuing education requirement is by completing the CITI "Refresher" course. We have updated the Refresher course content (and will do so every three years) so that our investigators can re-certify by taking the course without taking the same curriculum. The Refresher course is shorter and less of a time commitment for the learner. If you or someone on your study team has already completed the Basic CITI course previously they need only to take the Refresher, however, the CITI site may direct you to re-take the Basic course. If this happens (if you have already taken the Basic course and the CITI site routes you to it again), simply click "**Main Menu**" and then click "**Add a course or update your learner groups for Children's Hospital of Boston.**" From the resulting page you will be able to change your enrollment to take the Refresher course. Please contact the CCI Office at 617-355-7052 if you have questions.

One Protocol, Multiple Groups: Obtaining Written Consent for Different Study Groups

Many protocols require enrolling multiple groups (i.e. cases/controls, probands/unaffected family members, etc.) in a single protocol. It is not uncommon for the procedures and/or follow-up required for each group to be different. Recent EQuIP reviews have revealed that often a single consent form does not adequately convey the expectations, as the information you need to present often varies based on the subject group. Additionally, it is difficult to format a single signature page to ensure correct and complete written documentation of informed consent, particularly for those protocols that enroll a child AND the child's parent, both as research subjects. The all inclusive language that is often used in consent forms (You/Your Child) can also contribute to confusion about what is expected of the child and what may be expected of the parent (who may also be a research subject).

Considering the issues outlined above, the IRB considers it a best practice to develop separate consent forms for each different group that will be enrolled in a protocol (e.g. child proband, parent of proband, sibling of proband, etc). Please ensure the following has been incorporated into each consent form and/or the consent process.

- The text of the consent forms should be simplified to outline only what is required for that particular group.
- The signature section should be customized to facilitate complete and accurate written consent (e.g. removal of the assent section if the consent form is for unaffected adult subjects, removal of the 'Signature of Adult Participant' header if the consent form is for the proband (who is always under 18), etc.).
- Ensure a separate consent form is obtained for each subject enrolled. A parent/guardian cannot sign a single consent form to enroll multiple children, and a separate consent form should be obtained for both the parent and child, if both are considered research subjects.
- The header of the consent form should contain a subtitle used to clearly document which group the consent form is designed for (e.g. Proband, Unaffected Sibling, etc.).

For protocols that are not yet approved, investigators will be asked to create different, customized, consent forms for each group. Investigators that are currently using a single consent form to enroll subjects in an approved protocol with more than one study group are encouraged to consider revising the consent forms at the time of continuing review. Please contact your IRB administrator if you have any questions/concerns.

Electronic IRB Submission Update

As many of you are aware we are working towards an IRB electronic submission and review process. Over the past year we have made significant process, however there is still additional work to be completed. There is a team of 4 individuals working on this project full time. Many of you have already been contacted to review segments of the development and we will be interacting with others as well move forward and into testing. We expect at least another year of work (some of this will include training). We will keep you posted as we get closer to having a "go live" date.