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Human Subjects Protection Update Children’s Hospital, Boston

SEPTEMBER 2011

COMMITTEE ON CLINICAL INVESTIGATION

www.childrenshospital.org/research/irb

Committee on Clinical
Investigation Staff

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Matt Stafford, Manager

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Anna Mitchell

Ashley Pyszczynski

Quality Improvement
Staff (EQulP)

Eunice Newbert, MPH

Staffing Updates

Change to the CCI
Telephone System

CHERP Helpful Hints

Note re: Specific
Letter Wording

Staffing Updates

We are pleased to announce that **Ashley Pyszczynski** has been promoted to IRB Administrator and will be responsible for several departments. Please note that some assignments will change once she is fully trained. We will keep you updated on any future changes. Ashley will continue to handle all the continuing reviews in addition to her departmental responsibilities. **Congratulations Ashley!**

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

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

Our Phones Have Changed

In an effort to respond to your inquiries more efficiently we have changed the phone structure in our office. When you call our general office number (57052) you will be presented with a menu and asked to connect directly with the IRB administrator assigned to your department. The following are our direct phone lines below so you may call us directly without having to listen to the entire message.

Elizabeth Carroll	x8-4022
Robleinscky Dominguez	x5-5935
Susan Kornetsky	x5-7053
Anna Mitchell	x5-3296
Ashley Pyszczynski	x5-3297
Matt Stafford	x5-4965

CHERP Helpful Hints:

Based on the inquiries received and the problems that investigators encounter in CHERP we would like to offer you the following tips and advice. Please review them carefully in an effort to avoid common mistakes and problems that may hold up submitting and processing your protocols and related activities

New Protocol Submissions

- Once you have responded to all sticky notes or made other requested changes, please "Submit Response" as indicated on the left hand side of the protocol workspace. Until a response is submitted, the protocol will remain in your inbox and you will continue to receive reminder emails. Please note that this process is similar for sticky notes in amendments and continuing reviews.

Amendment Submissions

- In CHERP, only revised tracked documents should be uploaded; it is not necessary to also upload a "clean" version. The tracked changes are accepted once the amendment is approved, so that only clean documentation remains post-IRB approval.
- When revising documents that have been uploaded to CHERP, please "Upload Revision" instead of deleting the old documents and adding the new documents so that a history is created of previously IRB approved documents.
- Once your protocol has been converted to CHERP and you wish to modify the consent forms, please go to the Documents tab in the protocol workspace. The "Draft Consents" are the most recently IRB approved consent forms that can be modified with track changes. Please keep the document name of the consent the same to ensure that once the amendment is approved, only the most recently IRB approved consent is visible in the consent library.

Staff Amendment Submissions

- Please contact CHERP support (ext. 43267) for new CHB employees and all non-CHB employees that need to be added to the CHERP system. Training documentation for these employees should be forwarded to your respective IRB administrator.
- CITI training documentation for CHB employees is uploaded biweekly to CHERP, provided that the CHB employee enters their CHB ID on the CITI website. It is therefore unnecessary to forward CITI training documentation for CHB employees to the CCI office.

Continuing Review Submissions

- Continuing review submissions are reviewed once they are submitted. We recommend submitting continuing renewals two IRB meetings prior to expiration (approximately 5 weeks prior to expiration). Please see our website at http://www.childrenshospital.org/cfapps/research/data_admin/Site2206/mainpageS2206P8.html for the IRB meeting dates.

Note re: Specific Letter Wording

It has come to our attention that some Sponsors may require specific wording in the approval documentation, i.e. specific document names and version dates. This request needs to be provided to the IRB office with the initial new protocol or amendment submission along with an exact list of the requested wording to ensure that the required wording is included in the approval documentation.