



# Human Subjects Protection Update Special Communication

AUGUST 27, 2008

COMMITTEE ON CLINICAL INVESTIGATION

## Committee on Clinical Investigation Staff

**Steven Colan, MD,  
Chairman**

**Peter Wolff, MD  
Vice Chairman**

**Susan Kornetsky,  
Director**

**Irine Breytburg,  
ISD**

**Robleincsky  
Dominguez**

**Anna Mitchell**

**Anne Sarco**

**Elizabeth Carroll**

**Matthew Stafford**

## Quality Improvement Staff

**Eunice Newbert**

**Kristin Bowling**

### **CONTACT US:**

**333 Longwood Ave.  
4th Floor  
Boston, MA 02115**

**Tel: 617-355-7052  
Fax: 617-730-0226**

## **Administrative Staff Changes for Office of Clinical Investigation**

We would like to welcome Elizabeth Carroll to the staff of the Committee on Clinical Investigation. Elizabeth comes to us from Children's National Medical Center where she worked their as an IRB coordinator. Elizabeth has been hired as an additional IRB analyst and increases the staff we have available to support the clinical research community. We have adjusted the departmental assignments accordingly. To determine the analyst assigned to your department/division, please refer to the following chart. We do our best not to switch departments and analyst how future changes may be necessary as we continually monitor our volume.

<b>Elizabeth Carroll</b>	<b>Anne Sarco</b>	<b>Anna Mitchell</b>	<b>Matt Stafford</b>
Emergency Med.	Adolescent Med.	Anesthesia	Cardiac Surgery
Infectious Diseases	Dentistry	Gastroenterology	Cardiology
Nephrology	Developmental Med.	Genetics	Lab. Medicine
Newborn Med.	Endocrinology	Immunology	Orthopedic Surgery
Otolaryngology	General Medicine	Neurosurgery	Pathology
Radiology	General Pediatrics	Ophthalmology	Physical Therapy
Urology	Hematology/ Oncology	Pulmonary	Surgery
	Neurology	Research Admin.	Other Departments
	Nursing		
	Psychiatry		

## **Additional Changes Underway:**

### **Pre –review of all applications by an IRB administrator**

During the upcoming months the clinical investigation administrative office will implement a new PRE-REVIEW process. All protocol applications, continuing reviews and amendments will be pre-reviewed by an IRB analyst when it is submitted to the office. The analyst will send the investigator questions and suggest modifications and revisions. The investigator will need to respond to the pre-review prior to the protocol being placed on the agenda or being sent to the chairperson for administrative/expedited review. The goal is to reduce review time once it reaches the committee/chair for review. We will advise you with further details and a plan for implementation in the upcoming months.

### **Paperless IRB Submission and Review Process**

Over the summer, the CCI office began the process of planning for an electronic paperless IRB submission and review process. The vendor chosen has experience in many other university and hospital IRB settings and is the same vendor working on the CHERP grants system. The first part of the planning/development phase is

currently underway. At the present time there is no estimate as to when the system will be available. We want to inform you that this is a future goal and advise you we will need many volunteers from the research community for the testing phase. Anyone interested in volunteering for the testing phase may contact Susan Kornetsky via email. We will need both PIs and coordinators.