



# Children's Hospital Boston

Clinical Investigation Office  
333 Longwood Avenue, 4<sup>th</sup> floor  
phone 617-355-7052 | fax 617-730-0226

**To:** Francisco A. Bonilla, MD

**From:** Anna Mitchell, IRB Administrator  
Committee on Clinical Investigation

**Date:** August 12, 2008

**Re:** **NOTICE OF EXPEDITED APPROVAL**  
**IRB Approval Date: 08/01/2008**  
**IRB Activation/Release Date: 08/11/2008**  
**IRB Expiration Date: 07/31/2009**

**Protocol Number:** X08-08-0385

**Protocol Title:** A REGISTRY OF PATIENTS WITH PRIMARY IMMUNODEFICIENCY DISEASES

---

The Committee on Clinical Investigation has approved the above referenced protocol through expedited review procedures. We are now able to release this approval to you since you have adequately responded to the Committee's questions and concerns.

Risks were determined to be minimal with no potential for direct benefit.

The Committee has determined that only one parent/guardian is required to provide permission for their child to participate in this study.

Assent is required from those subjects capable of understanding the research and its ramifications. If you determine a particular child is not capable of providing assent, you will need to provide justification on the informed consent after the parental signatures.

The staff changes adding Lisa Stutius, MD, Erin Janssen, MD and Andrew Shulman, MD have been approved as part of this final approval.

## **Expired training:**

The following person(s) were **removed** from this protocol because they have not yet satisfied the continuing education requirement for human subjects training.

- Dale Umetsu, MD – Training was last completed 3/8/05, continuing education training is now required.
- Janet Sue Chou, MD – Completed CITI Non-Interventional training 10/3/06 but is now intervening and obtaining consent which would require full Biomedical training through CITI.
- Michael Pistiner, MD – Training was last completed 7/13/05, continuing education training is now required.

The above-listed person(s) should not be involved with this protocol in any way until they have satisfied the required continuing education requirement for human subjects training and you have submitted an amendment to our office to add them back onto the protocol. As of September 1, 2006, all principal investigators and research staff listed on all human subject protocols are required to complete continuing education in human subject protection, every three years. For information on the continuing education requirement and instructions for fulfilling it, please see [http://www.childrenshospital.org/cfapps/research/data\\_admin/Site2206/Documents/Continuing\\_education\\_training.doc](http://www.childrenshospital.org/cfapps/research/data_admin/Site2206/Documents/Continuing_education_training.doc)

The approved consent form is available on-line through the CHB Informed Consent Library. To obtain the consent form, please go to <http://chbcfapps/research/consents>. The ICLibrary should be accessed each time you need a consent form to ensure that the current version of the consent is always used. Do not store the consent forms on your computer or make copies for future use. Note that the activation/expiration date on the consent form can only be changed or modified by the staff of the Clinical Investigation Office. Please also note that subjects cannot be enrolled in a study if the consent form has expired. A copy of the signed consent should be kept in your files. It is our understanding that consent forms will be stored in the research record. The subject/family must also be given a signed copy.

The occurrence of unanticipated problems should promptly be reported to this office. Any revisions, amendments, or changes to the protocol require prior Committee approval. The Committee has asked this office to notify investigators that clinical investigation protocol files are subject to audits at some future time.

cc: Raif Geha, MD  
Irene Borrás-Coughlin