



Office of Research  
Integrity and Compliance

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Affiliated with  
Northwestern University's  
Feinberg School of Medicine

## ***EXPEDITED APPROVAL NOTICE***

**Ramsay Fuleihan, MD**  
Allergy/Immunology, Box#60

RE: **A Registry of Patients with Primary Immunodeficiency Diseases**

IRB #: **2008-13596**

APPROVED: **August 11, 2008 – Expedited Review**

EXPIRATION OF  
IRB APPROVAL: **August 10, 2009**

**This protocol was approved under the following risk/benefit determination as described in CFR 45 Part 46, Subpart D:**

45 CFR §46.404                      Research not involving greater than minimal risk.

The Institutional Review Board (IRB) reviewed and approved, via expedited procedure as authorized by 45 CFR 46.110 and 21 CFR 56.110, the above-named protocol which will involve human subjects.

**This research was reviewed under expedited review category #5:** “Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).”

***The IRB would like to call your attention to some of your obligations as principal investigator. Prior IRB review and approval is required before any change in the protocol, or in its procedures, may be implemented. A change in the principal investigator or any significant adverse effects or injury to subjects must be reported to the IRB immediately.***

**Please note that if this study is a sponsored study, you may NOT begin work on this study including subject enrollment until your contract/award is fully executed. Please contact Norene McWilliams at (773) 755-6561 or [nmcwilliams@childrensmemorial.org](mailto:nmcwilliams@childrensmemorial.org) for industry sponsored clinical trial contracts.. For non-industry sponsored studies (Federal, subcontracts, foundations, etc) please contact your appropriate OSP delegate.**

Federal regulations require that an IRB conduct continuing review of research not less than once per year, regardless of whether initial approval was via full board or expedited procedures. Please note the expiration date for your current IRB approval and be aware that you must submit a progress report for IRB review prior to the expiration in order to obtain IRB approval for the next approval period. If the current approval expires and you do not obtain approval for another approval period, research on this study, including subject enrollment, must cease until you regain approval. If you have questions about your obligations as principal investigator, please contact the IRB Office at 773-755-6305.

Best wishes for a successful study.

Sincerely,

A handwritten signature in cursive script, appearing to read "Ellen R. Brooks".

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Ellen R. Brooks, PhD, Chair  
Institutional Review Board  
Children's Memorial Research Center