



**INDEPENDENT
INVESTIGATIONAL
REVIEW BOARD INC.**

Your Advocate for Clinical Research Participants

DATE: September 16, 2009

Kim Lerner
Chairman

TO: Ramsay Fuleihan, MD
Principal Investigator

Anita McSharry, R.N.
President

FROM: Authorized Signatory *Julie Blasig*
Independent Investigational Review Board, Inc.

SUBJECT: Approval Status Change;
- Informed Consent Form version 9/1/2009
- Progress Report dated 9/4/2009
- Protocol dated August 2009 Ver. 1.04 B

PROTOCOL: (USIDNET) A Registry of Patients with Primary
Immunodeficiency Disorders

The Independent Investigational Review Board, Inc. is an institutional review board structured in compliance with the regulations of the Food and Drug Administration contained in the Code of Federal Regulations (21 CFR 50 and 56, 45 CFR 46, and 40 CFR 26) and is in compliance with the International Conference of Harmonization (ICH) and Good Clinical Practice (GCP) guidelines for IRB/IECs.

Previously at the meeting held on September 1, 2009, the Committee reviewed and unanimously granted "Contingency Approval" for the above noted research study. The "Contingency Approval" was based on the need for protocol revisions, a request for documentation of closure of the study with Western Institutional Review Board and receipt of a progress report.

The Independent Investigational Review Board, Inc. had an opportunity to review the Progress Report indicating the Western Institutional Review Board® closeout date and research status and the revised Protocol which indicated the requested protocol revisions. Based on this information, the study is now considered "Approved". This review was conducted under expedited review procedures.

The Informed Consent Form is unanimously approved. The approved Informed Consent Form is identified as Version 9/1/2009 and stamped, "Approved 9/1/2009". The Informed Consent Form contains all regulatory required consent elements.

Note: It is the responsibility of USIDNET to notify the subjects previously approved under Western Institutional Review Board® of the change in IRB and to provide the appropriate contact information for Independent Investigational Review Board.

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Ramsay Fuleihan, MD
USIDNET

Note: It is the responsibility of the Principal Investigator to be in compliance with all state and local requirements and procedures regarding enrollment of minors.

Note It is the responsibility of the Principal Investigator to collaborate on a regular basis with all Investigators.

As previously noted prior to the end of approval on 8/31/2010, you are required to provide the Independent Investigational Review Board with a written progress report and completed Informed Consent Form for this research and obtain approval for continuing the research. Changes to the protocol or use of non-approved recruitment materials cannot be initiated without IIRB, Inc. review and approval. In the event of any breaches of confidentiality/patient identification, significant deviations from the protocol or problems in the research, written notice to the Independent Investigational Review Board is required.

It is the responsibility of the Principal Investigator to submit all unanticipated problems and serious or continuing non-compliance in a timely manner to the IIRB, Inc. For more information on reporting requirements visit www.iirb.com and the Investigator's Guidebook. Please provide this reporting to the above-noted address so that appropriate follow-up can be initiated.

Thank you for your cooperation.

KL/AMS/jl:kk