**REAPPROVED: 06/22/2018**
**EXPIRATION DATE: 06/21/2019**

June 22, 2018

**FROM:** Schulman IRB
**TO:** Tara Caulder, USIDNET
**SUBJECT:** Reapproval
**SPONSOR:** USIDNET
**PROTOCOL NO:** USIDNET
**PROTOCOL TITLE:** A Registry of Patients with Primary Immunodeficiency Disorders

This letter is to inform you that the Board reapproved the referenced protocol for another 12 months.

If the study is expected to last beyond the approval period, you must request and receive re-approval prior to the expiration date noted above. A report to the Board on the status of this study is due prior to the expiration date or at the time the study closes, whichever is earlier. It is recommended that you submit status reports at least 4 weeks prior to your expiration date to avoid any additional fees or lapses in approval. You can find the Study Status Report Form at www.sairb.com. Continue to use the latest Schulman approved informed consent(s).

Approved investigators and sites are required to submit to Schulman for review, and await a response prior to implementing, any amendments or changes in: the protocol; advertisements or recruitment materials ("study-related materials"); investigators (PI and Sub-Is); or sites (primary and additional). Refer to www.sairb.com for comprehensive submission requirements.

Approved investigators and sites are required to notify Schulman of the following reportable events, including, but not limited to: unanticipated problems involving risks to subjects or others; unanticipated adverse device effects; protocol violations that may affect the subjects' rights, safety, or well-being and/or the completeness, accuracy and reliability of the study data; subject death; suspension of enrollment; or termination of the study. Refer to the "Event(s) That Investigators Have to Report to Schulman" guidance document available on the Schulman WebPortal/SiteAccess and at www.sairb.com.

Schulman IRB is in compliance with Part C Division 5 of the Canadian Food and Drug Regulations, the Tri-Council Policy Statement (TCPS), the International Conference on Harmonization Good Clinical Practice Guidelines, the regulations of the United States Food and Drug Administration as described in 21 CFR parts 50 and 56, and the United States Department of Health and Human Services regulations 45 CFR part 46, and the Environmental Protection Agency 40 CFR 26.

**PLEASE REFERENCE IRB # 201209796 ON ALL CORRESPONDENCE FOR THIS STUDY**
*WebPortal/Paperless*