



WESTERN INSTITUTIONAL REVIEW BOARD®  
WESTERN INTERNATIONAL REVIEW BOARD®  
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October 20, 2006

R. Michael Blaese, M.D.  
US Immunodeficiency Network  
Suite 308  
40 West Chesapeake Avenue  
Towson, Maryland 21204

Dear Dr. Blaese:

**SUBJECT: APPROVAL OF RESEARCH AND OF WAIVER OF AUTHORIZATION AND  
WAIVER OF CONSENT**

Sponsor: National Institute of Allergy and Infectious Diseases

Sponsor Pr. No.: None

WIRB Pr. No.: 20061385

WIRB Study No.: 1081917

Protocol Title: A Registry of Patients with Primary Immunodeficiency Diseases

On October 16, 2006, Western Institutional Review Board (WIRB) **approved** the research and a request for a waiver of authorization for use and disclosure of protected health information (PHI) for the above-referenced data collection study. This review was conducted at a convened meeting. Please note that this letter is supplemental to the WIRB Certificate of Approval for this study.

WIRB determined that documentation received from you satisfies the three requirements for a waiver of authorization. These requirements are:

1. The use or disclosure of the PHI involves no more than minimal risk to the individuals, based on the following elements:
  - a. An adequate plan to protect identifiers from improper use and disclosure;
  - b. An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research (unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law); and
  - c. Adequate written assurances that the PHI will not be reused or re-disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of PHI would be permitted by HIPAA.
2. The research could not be practicably conducted without access to and use of the PHI;  
and
3. The research could not practicably be conducted without the waiver.

The Board determined that a waiver of authorization for use of the following protected health information is needed:

Abstraction of data from medical records for inclusion into a de-identified registry of patients with primary immunodeficiency diseases.

**WAIVER OF CONSENT**

The Board also determined that documentation received from you satisfies the requirements for waiver of consent according to 45 CFR 46.116(d) for retrospective data collection only.

The Board has **approved** your site to receive the data and **approved** the use of sub-investigators at other sites, if the site does not have an obligation to another IRB. Institutions with their own IRBs are not covered by this approval and must use their designated IRB unless that IRB waives jurisdiction to WIRB.

You may address the Board in person or in writing regarding its action. If you wish to address the Board in person or if you have questions, please contact WIRB Regulatory Analyst, Doreen Packel, M.P.A., C.I.P. at 360-252-2430.

Sincerely,



Theodore D. Schultz, J.D.  
Chairman

TDS:DP:jmb

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cc: Jolene Smith, US Immunodeficiency Network  
Ronald A. Gadde, WIRB Panel One Chair  
Study File; Protocol File