



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health
National Institute of Allergy
and Infectious Diseases

DATE: 11/15/2006
TO: Warren Strober, M.D.
PRINCIPAL INVESTIGATOR
FROM: Chair, NIAID-IRB

APPROVAL LETTER

PROTOCOL NUMBER: 89-I-0158
PROTOCOL TITLE: Studies of Immune Regulation in Patients with Common Variable Immunodeficiency and Related Humoral Immunodeficiency Syndromes
MEETING DATE: 9/11/2006
EXPIRATION DATE: 9/14/2007
ADULT RISK/BENEFIT CATEGORY: The research involves more than a minor increase over minimal risk to subjects (45 CFR 46.102(h)(i)). / The research involves the prospect of direct benefit (45 CFR 46.102(h)(i)).
CHILD RISK CATEGORY: Research not involving greater than minimal risk (45 CFR 46.404).
REQUEST: Amendment

Revisions to the Protocol and Consent(s):

- To add to the Minor assent, a statement similar to the Adult Standard consent, that the participant may chose to cease participation at any time. This addition is based on a suggestion made by the IRB at the time of continuing review (June 5, 2006).
- To add a new section to the protocol and create a new consent and assent in order to allow the study team to enter patient data into the USIDNET National Registry database. The Registry is a project of the USIDNET Consortium, a NIH-funded group of investigators working in association with the Immune Deficiency Foundation. The purpose of the Registry is to collect information on individuals with primary immune deficiency diseases.
- Patients eligible for the main study will be eligible for the registry study on a voluntary basis. If they decide to participate, they also have the option to choose whether their data will be sent anonymously or their data will be linked to them through a secure coding system. Only existing data will be entered into the Registry; no additional blood samples or other studies will be obtained for the purpose of entering data into the Registry. Genetic information, if available, will be entered, but patients may decline to have their genetic information entered.

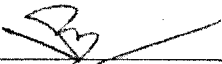
All contingencies, if any, have been met and study activities may proceed. According to Federal Regulation (45CFR46), a continuing review of research shall be conducted at intervals appropriate to the degree of risk, but not less than once per year. The Institutional Review Board (IRB) office recommends submission of continuing review requests 6 weeks prior to the expiration date.

Changes in research activities during the approved IRB period shall not be initiated without prior IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subject. Such amendments must be approved by the IRB prior to implementation.

Additionally, investigators must report to the IRB adverse events in accordance with the procedures outlined in the protocol.

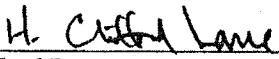
For further guidance, current forms and instructions, please view the IRB web page at <http://intramural.niaid.nih.gov/ocd/IRBweb/>, or call the Human Subject Protections office at (301) 435-9273.

UPDATED CONSENT/ASSENT DISK(S) INCLUDED: YES NO*



V. Koneti Rao, M.D.
Chair, NIAID-IRB

11/16/06
Date



H. Clifford Lane, M.D.
Clinical Director, NIAID

11/16/06
Date

FOR OPS USE ONLY	
Date: <u>11/22/06</u>	Suffix: <u>L</u>
Protocol #: <u>09-I-0158</u>	Specialist: <u>[Signature]</u>

cc: NIAID-IRB

* Consent(s) will be e-mailed to Office of Protocol Services.