

INSTITUTE: National Institute of Allergy and Infectious Diseases

STUDY NUMBER: 89-I-0158

PRINCIPAL INVESTIGATOR: Warren Strober, M.D.

STUDY TITLE: Studies of Immune Regulation in Patients with Common Variable Immunodeficiency and Related Humoral Immunodeficiency Syndromes

Continuing Review Approved by the IRB on 6/5/06

Amendment Approved by the IRB on 9/11/06 (L)

Date Posted to Web: 11/23/06

Patient Registry Consent Form

• INTRODUCTION

We invite you to take part in a research study at the National Institutes of Health (NIH).

First, we want you to know that:

Taking part in NIH research is entirely voluntary.

You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled. However, to receive care at the NIH, you must be taking part in a study or be under evaluation for study participation.

You may receive no benefit from taking part. The research may give us knowledge that may help people in the future.

Second, some people have personal, religious or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). If you have such beliefs, please discuss them with your NIH doctors or research team before you agree to the study.

Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone at NIH, or with family, friends or your personal physician or other health professional.

• PURPOSE OF THIS RESEARCH STUDY

You (your child or your ward) are being asked to participate in a research study. The purpose of this study is collect information on individuals with primary immune deficiency diseases. This collection of information is called a "Registry". The Registry already contains information about people with: severe combined immunodeficiency (SCID), leukocyte adhesion deficiency (LAD), X-linked agammaglobulinemia (XLA), common variable immune deficiency (CVID), DiGeorge syndrome (DGS), hyper IgM syndrome (HIGM), Wiskott Aldrich syndrome (WAS), and chronic granulomatous disease (CGD). The Registry will also include other primary immune deficiency diseases. The Registry is important because each of these diseases is rare. The Registry helps research because more information is available.

MEDICAL RECORD**CONTINUATION SHEET for either:**

NIH 2514-1, Consent to Participate in A Clinical Research Study

NIH 2514-2, Minor Patient's Assent to Participate In A Clinical Research Study

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The Registry includes information on age, sex, race or ethnic group, and lab tests that were used to diagnose and monitor the condition. The Registry also includes treatments used for your condition and medical problems you may have had. This information will help investigators learn how to better diagnose and treat these diseases. It will also help investigators and others learn about the problems some patients have.

You (your child or your ward) qualify for inclusion in this registry because you (your child or your ward) have been found to have one of these primary immune deficiency diseases. We are asking permission to submit your (or your child or ward's) immunologic studies and basic clinical information to this Registry.

The Registry is a project of the U.S. Immunodeficiency Network (USIDNET) Consortium, a NIH-funded group of investigators working in association with the Immune Deficiency Foundation.

- **DESCRIPTION OF THE REGISTRY**

A Registry of patient information may help us understand how many people have each disease. The information may improve how we diagnose and treat these conditions.

If you agree, your information will be added to the Registry. The Registry information would include specific medical information on your condition, your sex, race, year of birth, State where you were born, State where you live, your doctor's name, and your doctor's address.

Under OPTION ONE, your identity will not be revealed. Your doctor may update your information to include changes in your condition or treatment.

Under OPTION TWO, your name, full date of birth and mailing and/or e-mail address will be kept in a separate database. Your specific medical information will be assigned a code number when it is included in the Registry. Your personal identification information will be kept in a separate location. The only link to the Registry will be the code number. Your doctor may update your information to include changes in your condition or treatment as well as changes in your name or contact information. You will be told about research that uses Registry information. Registry workers may ask you for additional information for the Registry. They may also send you information about other research projects.

Doctors or scientists who want to use Registry information have to make a written request. The request must be approved by the USIDNET steering committee. No personal identity information will be shared. Your identity will never be revealed to these doctors or scientists.

The USIDNET steering committee may permit information about new tests, treatments, or research projects to be sent to your doctor. Your doctor will be able to share this information with you.

Under OPTION ONE, it will not be possible to remove your information from the Registry. The Registry workers will not be able to determine which information is yours. There is information from more than 1500 individuals with primary immunodeficiency diseases in the Registry.

Under OPTION TWO, you can remove your information from the Registry. You can remove either your identifying information or all your information. If you decide to stop being part of the Registry, you should contact your doctor or Dr.

PATIENT IDENTIFICATION**CONTINUATION SHEET for either:**

NIH-2514-1 (10-84)

NIH-2514-2 (10-84)

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Michael Blase of the Immune Deficiency Foundation at telephone number (800) 296-4433. Please be aware that it will not be possible to remove your information that has already been incorporated into medical publication.

- **GENETIC INFORMATION**

Genetic tests can help tell researchers about how health or illness is passed on to you by your parents or from you to your children. You may have had some blood drawn for genetic testing at another facility or at the NIH. We will not draw extra blood for the registry. We are asking your permission to enter the results of this testing into the Registry. You can participate in the Registry even if you choose not to have your genetic information entered.

- **POTENTIAL RISKS AND DISCOMFORTS**

We will not reveal your identity to the doctors or scientists using the Registry database, but it is possible that someone could figure out who you are. Under **OPTION TWO**, your identity will be kept separately from the Registry information. It is possible that your identity could be revealed even if it is held separately. If USIDNET learns that your identity has been revealed, you will be told.

- **POTENTIAL BENEFITS**

There are no direct benefits to you (your child or your ward) from being part of the Registry.

Participation may help doctors to better understand these medical conditions, and may lead to better treatments. Information in the Registry may also advance medical knowledge in general, so others may benefit.

- **ALTERNATIVES TO PARTICIPATION**

The alternative is not to be part of the Registry.

- **VOLUNTARY PARTICIPATION**

It is your decision to be part of this study or not. You will receive the same care and treatment whether you decide to be part of this study or not.

If you change your mind after you sign this consent, every effort will be made to remove your information from the Registry. If your information has not been supplied to the Registry, your information will not be submitted. **Under OPTION ONE** it will not be possible to remove your information from the Registry after submission. **Under OPTION TWO** your information can be removed from the Registry. Your identifying information will also be removed.

Any new information that develops during this collection of data, which might affect your decision to participate, will be given to you immediately.

The identity of individuals who are part of the Registry will not be made public in publications based on Registry information.

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- **TERMINATION OF PARTICIPATION**

You (your child or your ward) may decide to stop being part of the Registry at any time. There will be no penalty or loss of benefits from this decision.

- **REGISTRY COORDINATOR INFORMATION**

If you (your child or your ward) have any additional questions about this registry, please contact Dr. Michael Blaese of the Immune Deficiency Foundation at telephone number (800) 296-4433. If you (your child or your ward) still have questions, you can also contact a member of the Office of Human Research Protections (the committee that oversees this type of research) at telephone number (866) 447-4777.

- **MAKING YOUR CHOICE**

The choice to participate in the Registry is up to you. You may still get care or join other studies at NIH, no matter what you decide.

Please read each statement below and think about your choice. Then mark an "X" in the box of your choice.

1. I do not wish to participate in the Registry. []
2. I agree to participate in the USIDNET Registry under the supervision of the Steering Committee of the USIDNET Consortium. []
3. I have read this consent form, and/or had it explained to me in language I understand. The explanation included a description of the risks of participating. I have been able to ask all of my questions about the Registry. All the questions I asked were answered.

I wish to participate following the conditions outlined for:

OPTION ONE [] in which no record of my personal identity is kept by USIDNET

OPTION TWO [] in which my identity will be kept in a separate location by USIDNET and will be linked to my Registry information by an assigned code number.

4. I wish to participate, but I do not want genetic information entered into the Registry []

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OTHER PERTINENT INFORMATION

1. Confidentiality. When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

The Federal Privacy Act protects the confidentiality of your NIH medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or other authorized people.

2. Policy Regarding Research-Related Injuries. The Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the National Institutes of Health, the Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

3. Payments. The amount of payment to research volunteers is guided by the National Institutes of Health policies. In general, patients are not paid for taking part in research studies at the National Institutes of Health.

4. Problems or Questions. If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Warren Strober, M.D.; Building 10, CRC Room 5-3952. Telephone: 301-496-6810 or 301-496-9663. Other researchers you may call are: Ivan Fuss, M.D.; Peter Mannon, M.D.; Ashish Jain, M.D.; and Susie P. Dill, R.N.

You may also call the Clinical Center Patient Representative at 301-496-2626.

5. Consent Document. Please keep a copy of this document in case you want to read it again.

COMPLETE APPROPRIATE ITEM(S) BELOW:			
<p>A. Adult Patient's Consent I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study.</p> <p>_____ Signature of Adult Patient/Legal Representative</p> <p>_____ Date</p>	<p>B. Parent's Permission for Minor Patient. I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby give permission for my child to take part in this study. (Attach NIH 2514-2, Minor's Assent, if applicable.)</p> <p>_____ Signature of Parent(s)/Guardian</p> <p>_____ Date</p>		
<p>C. Child's Verbal Assent (If Applicable) The information in the above consent was described to my child and my child agrees to participate in the study.</p> <p>_____ Signature of Parent(s)/Guardian</p> <p>_____ Date</p>			
<p>THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE FROM SEPTEMBER 14, 2006 THROUGH SEPTEMBER 14, 2007.</p>			
<p>_____ Signature of Investigator</p>	<p>_____ Date</p>	<p>_____ Signature of Witness</p>	<p>_____ Date</p>

PATIENT IDENTIFICATION

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY (Continuation Sheet)

• Adult Patient or • Parent, for Minor Patient

NIH-2514-1 (5-98)

P.A.: 09-25-0099

FAX TO: (301) 480-3126

File in Section 4: Protocol Consent