

GCO # 04-0524

PART I: RESEARCH PARTICIPANT INFORMATION SHEET

TITLE OF PROJECT:

Building a Registry of Patients with Primary Immune Deficiency

A. PURPOSE OF THE STUDY:

You (your child or your ward) are being asked to participate in a research study. The purpose of this study is to build a National Registry of subjects with one of a group of primary immune deficiency diseases. A "Registry" is a list of basic information about people who have a certain disease or condition in common. These immune deficiency diseases are thought to be rare and include: leukocyte adhesion deficiency, x-linked agammaglobulinemia, common variable immune deficiency, Di George syndrome, Hyper IgM syndrome, Wiskott Aldrich syndrome and chronic granulomatous disease. We would like to contribute data on a number of subjects with this relatively rare diseases to this National Data Base. The information will be age, sex, race or ethnic group, immunologic lab tests that were used to diagnose the condition, and what complications may have occurred since the condition started, lung disease, blood changes, etc. The goal is to discover basic outcome data, ethnic, racial characteristics, kind of complications, etc. You will not be contacted by anyone. If a new study about you (or your child's) immune defect comes up, your doctor will be notified, who can then share this with you to find out if you are interested in participating or not.

As the data collection expands, other primary immune deficiency diseases may be added.

You (your child or your ward) qualify for participation in this study because you (your child or your ward) have been found to have one of these primary immune deficiency diseases. We are asking your permission to submit your (or your child or ward's) immunologic studies and basic clinical information to this National Data Base, without revealing your personal identifiers such as name, date of birth, social security number or address, etc.

B. DESCRIPTION OF THE RESEARCH:

By building a National Registry of patients, we are trying to understand how many people have these selected primary immune deficiency diseases and how we might better diagnose and treat these conditions. We will submit your initials, sex and year of birth to the Registry so that your identification will not be revealed.

Subject/Surrogate Initials _____

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Doctors or scientists who are studying these illnesses will be able to have access to this information, if they request the information in writing; outlining the nature of the study, and obtain permission from the scientific steering committee of the Registry. Even then, only anonymous data can be shared and your personal identity will never be revealed to these doctors or scientists. In some circumstances, a new test or treatment will be developed and doctors or scientists will be able to request from the Registry, the name of doctors who treat patients with certain immune defects. If this request is approved by the Steering Committee of the Registry, your doctor may be notified that the test or treatment is available. After this, your own doctor, would be able to let you know of this development, and you will have a chance to decide if you are interested or not. However, your doctor will not reveal your name or any personal identifiers unless this is your wish.

Since the data collection will be very large and pooled with that of numbers of other subjects, it will not be practical or possible to later remove your clinical or laboratory information from the Registry.

We estimate that the part of the study from Mount Sinai will include up to 500 subjects.

C. COSTS/REIMBURSEMENTS:

There are no costs for you (your child or ward) to be involved in this study.

D. POTENTIAL RISKS AND DISCOMFORTS:

There are no major risks for you (your child or your ward) in participating in this study. While we will not reveal your name or other personal identifiers, it is remotely possible that another person at the data center of the Registry who receive the basic data could make a guess about your name from your initials and year of birth. However your initials will not be made known to anyone who sees the data as these will be removed at the time of data entry. You will be given a coded number which will not identify you to anyone else.

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E. POTENTIAL BENEFITS:

There may be no direct benefit to you (your child or your ward) from participating in this study.

You (your child or your ward's) participation may help doctors better understand your (your child or your ward's) medical conditions, and may lead to better treatments. Participating in the study may also advance medical knowledge in general, so others may benefit.

F. ALTERNATIVES TO PARTICIPATION:

The alternative is not to participate.

G. CONFIDENTIALITY:

Your identity as a participant in this research study will be kept confidential in any publication of the results of this study. The information obtained during this research (Research Record) will be kept confidential to the extent permitted by law. However, this Research Record and your personal Medical Record (if any and if relevant to the study) may be reviewed by government agencies (such as the Food and Drug Administration or the Department of Health and Human Services), the agency or company sponsoring this research, individuals who are involved in, or authorized to monitor or audit, the research, or the Institutional Review Board (the committee that oversees all research in humans at Mount Sinai School of Medicine) if required by applicable laws or regulations.

H. COMPENSATION/TREATMENT:

If you (your child or your ward) believe that you have suffered an injury related to this research as a participant in this study, you (your child or your ward) should contact Dr. Charlotte Cunningham-Rundles at telephone number (212) 659-9268

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I. VOLUNTARY PARTICIPATION:

Participation in this study up until the time that your own specific data has been entered into the Registry. After this it will be pooled with the data of many other subjects. It will not be possible to later remove your own data from the Registry. If you decide after you have signed this consent, and the data has not been sent to the Registry, you may withdraw. If you (your child or your ward) decide not to participate, this will not affect your or (your child or your ward) ability to receive medical care at Mount Sinai or to receive any benefits to which you or (your child or your ward) are otherwise entitled.

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

A signed copy of this consent form will be given to you.

J. TERMINATION OF PARTICIPATION :

You (your child or your ward) may discontinue participation in the study at any time without penalty or loss of benefits to which you (your child or your ward) are otherwise entitled.

You (your child or your ward) also accept that the physician, local institution, or sponsor may withdraw you (your child or your ward) from the study or cancel the study at any time without your (your child or your ward's) consent.

You may discontinue participation in the study at any time without penalty or loss of benefits to which you are otherwise entitled.

K. CONTACT PERSON(S):

If you (your child or your ward) have any questions, at any time, about this research, or want to discuss any possible study-related injuries please contact Dr. Charlotte Cunningham-Rundles at telephone number (212) 659-9268 . If you (your child or your ward) still have questions you may discuss them with a member of the Institutional Review Board (the committee which oversees research at Mount Sinai School of Medicine) at telephone number (212) 659-8980.

Subject/Surrogate Initials _____

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L. DISCLOSURE OF FINANCIAL INTERESTS:

None

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AUTHORIZATION TO PARTICIPATE IN RESEARCH

The participant/surrogate and the investigator/delegate must each SIGN, DATE and TIME this two page authorization form.

Research Subject's Name (printed): _____

1. I hereby volunteer to participate in a research program under the supervision of Dr. Charlotte Cunningham-Rundles and her associates at Mount Sinai School of Medicine.

2. I acknowledge that I have read, or had explained to me in a language I understand, the attached consent document and that _____ has explained to me the nature and purpose of these studies. This explanation included a description of the parts of the study that are experimental, the possible discomforts, symptoms, side effects and risks that I might reasonably expect, and the possible complications, if any, that I might reasonably experience from both known and unknown causes as a result of my participation in these studies. I have had the opportunity to ask questions I had about the study and all of the questions I asked were answered to my satisfaction.

3. I understand that I am free to withdraw this authorization and to discontinue my participation in these studies any time. The consequences and risks, if any, of withdrawing from the study while it is ongoing have been explained to me. I understand that such withdrawal will not affect my ability to receive medical care to which I might otherwise be entitled.

4. I confirm that I have read, or had read to me, this entire authorization and that all blanks or statements that require completion were in fact, properly completed before I signed this authorization.

Research Subject/Surrogate: _____
Signature

Name: _____
Print Name

Relationship: _____
If signed by surrogate

Date: _____ Time: _____

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