

RESEARCH SUBJECT INFORMATION AND CONSENT FORM**PROTOCOL**

TITLE: A Registry of Patients with Primary Immune Deficiency Disorders
Version 1.04

SPONSOR: National Institute of Allergy and Infectious Diseases
Bethesda, Maryland
United States

**PRINCIPAL
INVESTIGATOR:**

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STUDY RELATED

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24 HOUR TELEPHONE**AFTER HOURS**

NUMBER: 443-847-4330

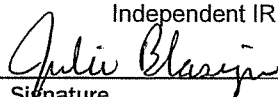
INTRODUCTION:

You are being asked to participate in a research study because you have been diagnosed with a primary immunodeficiency disease. This study will include patients participating in the study at different physicians' offices. This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

In this consent form, "you" always refers to the subject. If you are a parent/legal guardian, please remember that "you" refers to the study subject.

You (or your child/legal dependent) have been invited to be part of a research study. Before you decide (or permit your child/legal dependent) to participate in this research study, you should read this form carefully. This form, called a consent form, explains the study. Please ask as many questions as needed so that you can decide whether you want to participate in this study (or agree

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	9/1/2009
Signature	Date

Initials: _____
Date: _____

to the participation of your child/legal dependent in this study). Please read this form carefully and ask the study doctor or study staff about anything in this form that you have questions about or do not understand. Do not sign this form unless you are satisfied with the answers to your questions.

It is necessary that if you are a parent or legal guardian of a study participant that is not legally permitted to consent to be in a research study on his/her own behalf, then it is necessary that you sign this Informed Consent Form. In addition, if your child/legal dependent is 13 to the age of Legal Consent, the child will be asked to sign the "Assent Signature Section" of this consent form and be given the chance to indicate whether or not he/she wants to participate in this research study.

PURPOSE OF THE REGISTRY:

The purpose of this study is to build a National Registry of people with primary immune deficiency diseases, also known as inherited diseases of the immune system. A "Registry" is a list of clinical and laboratory information from people who have a certain condition in common. Primary immunodeficiency diseases are so rare that doctors and scientists at any single location do not have enough affected patients to understand the entire range of their problems or how to treat them best. By putting information about patients from many places into a single Registry we hope to gain knowledge about the rate of occurrence, causes, natural history, and outcomes of primary immunodeficiencies. There are many individual diseases included in the group of primary immunodeficiencies. The original Registry focused on a few of the more widely known examples including patients with severe combined immunodeficiency (SCID), 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 has been enlarged to also include more than 100 other primary immune deficiency diseases. This is considered a research study because data is being collected about people with primary immunodeficiency diseases

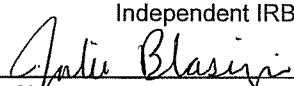
DESCRIPTION OF THE REGISTRY:

The United States Immunodeficiency Network (USIDNET) Consortium, a National Institutes of Health (NIH)-funded group of investigators working in association with the Immune Deficiency Foundation (IDF) to conduct a study in which a patient Registry is being developed. The Immune Deficiency Foundation is the national patient organization dedicated to improving the diagnosis, treatment and quality of life of persons with primary immunodeficiency diseases through advocacy, education, and research. The IDF provides administrative support for USIDNET and developed the initial Registry of patients with Primary Immunodeficiency that has grown to become the current Registry. The National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH) in Bethesda, Maryland, have supported the Registry since its beginning.

A Registry, or list of subjects and information about them, will help physicians understand how many people have each of the primary immunodeficiency diseases. The information collected from many patients will be put together with the goal of improving how doctors diagnose and treat these conditions.

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 may include treatments that have been

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