



Children's Hospital Boston

RESEARCH CONSENT FORM

Use Plate or Print:

Protocol Title:

MRN#:

Principal Investigator:

DOB:

Subject's Name:

Gender:

Why is this research study being conducted; What is its purpose?

The purpose of this protocol is to create a registry of patients with primary immunodeficiency diseases (PIDD). This registry will contain clinical and other information that researchers can use to:

- Learn about symptoms and complications seen in a large number of patients with the same disease
- Understand how these relate to specific genetic changes
- Learn the effects of various treatments
- To evaluate quality of life
- To promote collaborative research
- To identify patients with a specific diagnosis for potential participation in multi-institutional clinical trials designed for diagnosis or therapy of their specific disease

Who is conducting this research study, and where is it being conducted?

This research is being conducted by the United States Immunodeficiency Network (USIDNET) a group of investigators funded by the National Institutes of Health (NIH) and receiving administrative services from the Immune Deficiency Foundation (IDF). All medical centers that care for patients with immunodeficiency will be invited to participate. The Principal Investigator from Children's Hospital Boston (CHB) is Dr. Francisco A. Bonilla. We hope to enroll at least several hundred patients from CHB in this registry. We hope to enroll several thousand nationwide.

How are individuals selected for this research study? How many will participate?

Any patient with an established diagnosis of PIDD is eligible for this study. You have been identified through records in the Division of Immunology as an individual with PIDD. We invite you to participate in the registry.

What do I have to do if I am in this research study?

In order for you to participate in this research, all that is required is that you give consent. If you give consent, one or more members of the research team will take information from your medical record and send it to the USIDNET or enter it into the database directly. You will have an opportunity to specify whether or not identifying information will be included, and whether or not you wish to be contacted in the future (see below). Your participation will be considered indefinite, unless you withdraw consent.

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What are the risks of this research study? What could go wrong?

This research does not involve any medical procedures, only collection of information from your medical record. The only risk of participation is a breach of confidentiality. Several means will be used to minimize this risk (see below).

What are the benefits of this research study?

There is unlikely to be direct benefit to you or your child as a result of participation in this research. It is hoped that collecting and studying this information will lead to important knowledge about PIDD and its treatments that will improve diagnosis and care for all patients in the future.

Are there costs associated with this research study? Will I receive any payments?

You will not receive compensation of any kind for your participation in this research.

What will happen with the information obtained as part of this research study? What about confidentiality?

The USIDNET Registry paper and electronic records will be kept in a secure facility maintained by the IDF in Towson, MD. Paper records will be in locked cabinets and accessed only by IDF staff or USIDNET. Electronic records will be stored on password-protected digital media with additional special precautions taken to prevent accidental release over the Internet and unauthorized access by hackers or viruses. Any use of the Registry data by outside investigators will have to be approved by the USIDNET. No investigators will be granted direct access to the Registry. Your identifying information (if you choose to have it included) will only be accessible to authorized Registry users with in the Division of Immunology of CHB and the individuals who operate and maintain the Registry.

What are my rights as a research participant?

Your participation in this research is voluntary. Whether or not you choose to participate will not affect any aspect of your medical care. You may withdraw consent at any time in the future. If you withdraw consent your information will be removed from the Registry and your participation will end.

What information do I need to know about the Health Insurance Portability and Accountability Act (HIPAA)?

During this research, information about your or your child's health will be collected. In general, under federal law, information about patients is private, but there are exceptions and you should know who will have access to this information and might see it.

Researchers may be collecting information about you or your child from medical records. They may also learn things from procedures that are part of the research itself such as tests, office visits, questionnaires and interviews.

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The following people will be able to see this information:

- Medical and research staff at Children's Hospital, including people listed on your informed consent.
- Medical staff that are directly involved in your care that is related to the research or arise from it.
- People, who oversee, advise or conduct research at Children's Hospital, and people who oversee or evaluate research and care, including the Committee on Clinical Investigation, staff working on quality improvement, and other clinicians and administrative staff of Children's Hospital.
- People from agencies and organizations that provide independent accreditation and oversight of research.
- Sponsors or others involved in funding the research.
- Federal agencies that oversee or review research information.
- Government agencies and sponsors.
- If some law or court requires us to share the information, we would have to follow that law or final ruling.

You/your child should be aware that the federal privacy rule does not cover all of these possible uses. This means that once some of the above mentioned users receive your/your child's health information they do not have to follow the same rules. Other laws may or may not protect sharing of private health information. If you have a question about this you may contact the Children's Hospital Privacy Officer at 617-355-5502.

There is no set time for destroying this information and no time limit for its use. Researchers continue to analyze data for many years and it is not possible to know when they will be done.

You/your child do not have to sign this form. If the form is not signed, however, you won't be able to participate in the study. Not signing will not affect your care or your child's care at Children's Hospital in any way now or in the future. Also, there will be no penalty or loss of benefits if you choose not to sign and participate.

You/your child also have the right to withdraw from this study at any time. You have the right to end your permission for Children's Hospital to use or share the protected information about you or your child that was collected as part of the research.

Researchers may also continue to use information already collected to protect the integrity of the study. This means that your withdrawal won't make the whole study useless. Once you remove your permission and you or your child is no longer in the study, no more private health information will be collected. If you wish to withdraw you will need to do so in writing. If you/your child decide to share private information with anyone not involved in the study, the federal law designed to protect privacy may no longer apply to this information.

Although there are some legal limitations, you/your child have the right to get protected information resulting from this research that relates to your treatment or to payments. This information is available

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after the study analysis is done. To request the information, please contact the Hospital's Privacy Officer at 617-355-5502. If you have questions, please be sure to ask for answers.

Research at Children's Hospital: Children's Hospital has recently developed a web-based, interactive educational program for parents called "A Parent's Guide to Medical Research." To find out more about research at Children's Hospital, please visit the program at www.researchchildren.org

Children's Hospital is interested in hearing your comments, answering your questions and responding to any concerns regarding clinical research at Children's Hospital. If you would like further information about the type of clinical research performed at the hospital or have suggestions, questions or concerns regarding clinical research you may send an email to cci@childrens.harvard.edu or call 617 355-7052 between the hours of 8:30 and 5:00.

INVESTIGATOR'S AND/OR ASSOCIATE'S STATEMENT:

I have fully explained to _____ [participant/parent/guardian]

the nature and purpose of the above-described procedures and the risks involved in its performance. I have provided the subject/family with the Privacy Rule if requested. I have answered and will answer all questions to the best of my ability. I will inform the participant of any changes in the procedures or the risks and benefits if any should occur during or after the course of the study. I have given a copy of the consent/authorization form to the subject/family.

Date (MM/DD/YEAR) Signature of **Investigator or Associate**

1. By signing below, the participant agrees to the following (circle one):

I **DO / DO NOT** give consent for the inclusion of any or all of the following identifying information in my registry entry: full name, date of birth, street address, telephone number, email address. If you *do* consent to the inclusion of this information in the Registry, it will only be available to the people who operate and maintain the Registry, and to researchers at CHB. If you *do not* consent to the inclusion of this information, you will be identified in the Registry only by a code known only to researchers at CHB.

2. By signing below, the participant also agrees to the following (circle one):

I **DO / DO NOT** give consent to be contacted through USIDNET in the future if additional information is required that cannot be obtained from the medical record or if an investigator wishes to invite me to participate in any other research for which I may be eligible. If you do not consent, you may still be contacted regarding other research, but not directly through your information in the USIDNET Registry.

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CONSENT/AUTHORIZATION:

I understand that I may use the following contact information to reach the appropriate person/office to address any questions or concerns I may have about this study. I know:

I can call ...	At ...	If I have questions or concerns about ...
Investigator: Francisco A. Bonilla	Phone: 617-355-8594 Pager: 617-355-6369 Immunology on call	<ul style="list-style-type: none"> ▪ General questions about the study. ▪ Research-related injuries or emergencies. ▪ Any research-related concerns or complaints.
Study Contact: Irene Borrás-Coughlin	Phone: 617-355-6127	<ul style="list-style-type: none"> ▪ General questions about the study. ▪ Research-related injuries or emergencies. ▪ Any research-related concerns or complaints.
Office of Clinical Investigations	Phone: 617-355-7052	<ul style="list-style-type: none"> ▪ Rights of a research subject. ▪ Use of protected health information. ▪ Compensation in event of research-related injury ▪ Any research-related concerns or complaints. ▪ If investigator/study contact cannot be reached. ▪ If I want to speak with someone other than the Investigator, Study Contact or research staff

I have been satisfactorily informed of the above-described procedure with its possible risks and benefits. I have been provided with the applicable Privacy Rule provisions under the Health Insurance Portability and Accountability Act. I give permission for my child's participation in this study and for use of the associated protected health information as described above.

I understand that participation in this study is voluntary. If I refuse to permit my child to participate, or choose to withdraw my child from the study at any time, I understand there will be no penalty or loss of benefits to which my child is otherwise entitled, and this decision will not affect present or future care by the doctors or the hospital. I am signing this consent form before my child has participated in any research activities. I have been given a copy of this form.

Date (MM/DD/YEAR) Signature of **Parent or Guardian** Relationship to child

WITNESS SIGNATURE REQUIRED BELOW ONLY IF: (check which one applies)

- the consent document needs to be read to subject or legal representative **or**
- communication impairments limit the subject's ability to clearly express consent **or**
- required by sponsor/CCI.
- other reason: please specify _____

I confirm that the information in this consent form was accurately explained to, and understood by the subject or legally authorized representative, and that informed consent was given freely.

Date (MM/DD/YEAR) Signature of **Witness**