

Investigation into the Immunologic and Molecular Basis of Primary Immune Deficiencies and Immune Regulatory Disorders

What is the purpose of this study?

The purpose of this research study is to help the doctors learn more about disorders of the immune system. The research doctors of the Cancer and Blood Diseases Institute at Cincinnati Children's Hospital Medical Center would like to collect blood / tissue samples from patients with a diagnosis or suspected diagnosis of an immune disorder, control subjects and healthy family members. These samples may then be used for ongoing study of the human immune system. Research using these samples may help the doctors learn more about immunologic diseases and develop better treatments for these diseases. The research doctors and team will also need to look at and store your medical information in a secure database to help them do their studies. The blood or tissue that is collected and stored may also be used to help identify the genetic source of the disease. If you are participating as a control subject or a healthy family member, you will be helping further the research aimed at treating immune disorders.

Who will be included?

You are being asked to take part in this research study because you have been diagnosed with a disorder of the immune system or because you are suspected of having such a disorder. You may also have been asked to participate because you are a family member of someone that has been diagnosed with an immune system disorder (family member), or as a healthy independent volunteer.

What samples / information do we need?

Biological samples will be collected from study participants. These samples include peripheral blood, bone marrow, skin tissue, buccal and nasal epithelia cells, cord blood and tumor cells (if applicable). Your personal and medical information will also be collected.

What is involved?

If you take part in this study, you will have the following tests and procedures; as determined by your doctor. In general, your doctor may:

- ask you to provide one or more types of biological specimen(s)
- request permission to maintain your personal and medical information linked to the biologic specimen in a secure database
- establish an immortalized cell line using part of your biological specimen
- request your permission to conduct genetic studies
- allow samples obtained under this consent to be sent to institutions outside of CCHMC to investigators with IRB approved research protocols. Any samples and / or data sent to a researcher outside of Cincinnati Children's will be de-identified.

What will be done with the samples?

The biological specimens that you provide will be used in an ongoing study of the human immune system. This study will take a variety of approaches to investigating immune disorders. Some methods will seek to understand how the immune system works and to better describe immune deficiencies and immune regulatory disorders. Other approaches will focus on how the parts of the immune system communicate with each other. Researchers may seek to identify the genetic basis of some immune disorders. Your biological samples may be included in just one or perhaps many of these research methods.

Collection and Storage of Personal and Medical Information:

The Clinical Management and Research Support Core within the [Division of Hematology/Oncology](#) will protect your records so that items that may identify you such as your name or date of birth, will be kept private. Your information will be kept in a secure database that is password protected. Only the Principal Investigator and co-investigators of this study and their designees will have access to this database. Information identifying you will not be made available to other investigators, the public, nor will it be published. You will not be identified in any publication resulting from any research using this data or these samples.

What are the benefits?

If you agree to take part in this research study, there will not be a direct medical benefit for you. The information learned from this research study may benefit other patients with an immune disorder in the future.

Will I get all the facts about the study?

If you are interested in participating in this study, you will meet with a study coordinator who will explain all of the details of the study. The study coordinator will review the consent form and will be sure that all questions are answered. The consent form describes all the procedures, risks, benefits and who to contact with questions or concerns. Study procedures will not begin until the consent has been signed by the patient (if over 18 years) or the parent / guardian of the patient.

What are the risks?

A detailed list of possible risks will be provided to those patients interested in knowing more about the study.

Who should I contact for more information?

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