Welcome!

Thank you for your interest in the National Registry for Ichthyosis and Related Disorders. The National Institutes of Health has funded the Registry with the goal of supporting studies aimed at determining the cause of these disorders and how to treat them more effectively. Our mission is to identify people in the United States with the skin ailments referred to as the ichthyoses and other related disorders, and encourage them to participate in the Registry. Because of the large number of people involved, individuals with ichthyosis vulgaris are excluded from enrollment.

The Registry is set up as a database listing individuals who are affected with these disorders. We try to collect as much information as we can about your skin ailment and how it has affected you. The Registry offers a well-characterized group of individuals with specific diagnoses for study by skin biologists, pharmacologists, and others. We also share information about research projects with those who have enrolled in the Registry and expressed an interest in finding out about studies. You are not obligated to participate in any research studies at all, and may withdraw from the Registry at any time.

How Do You Enroll In The Registry?

You enroll through your local Dermatologist. There are some forms to fill out, and a phone interview with the Registry coordinator to complete your enrollment. That's about it! The steps you need to take are:

1. We ask you to sign the Consent/Assent Forms, and return one set to the Registry (Please sign the Assent Form as well if the person enrolling is under the age of 18). You can do this at your Dermatologist's office or at home. We are happy to answer any questions you have before you give us your signed consent. The other set of consent forms is for your own records.

2. Your Dermatologist needs to fill out a short Physician's Form describing your diagnosis and how your disorder affects you, and send it to the Registry.

3. When we receive a Consent/Assent and/or a completed Physician Form, we will contact you and discuss the Phone Interview. We provide a Patient Enrollment Form for you and your family to fill out at home. When you have completed the form as best as you can, you do not send the form in. Instead, you call the Registry and tell us when it would be convenient for you to be interviewed on the phone, and use the completed form as a reference during the interview. As a subject, you may refuse to answer any questions you wish. All this information is entered into a database.

Research Projects

The existence and goals of the Registry are being advertised to skin scientists in the U.S. Investigators who want to review the database or contact interested people with specific diagnoses will submit a brief proposal that will detail the types of people they are interested in for their particular study. After receiving approval from the Registry Advisory Committee, the appropriate people are identified through the database. We will mail letters to everyone in the database that stated they were interested in hearing about research projects, and that meet the general criteria for the investigator's study. The letters will identify the study as being approved by the Registry, and will invite those individuals to contact the investigator to participate in the proposed study. In this way, you will have the option of participating in each appropriate study while your privacy is protected.
Confidentiality

Your confidentiality is assured. The database is secured. You will be assigned a patient code and data are stored by code for confidentiality. Access to the database and modification of data are by password and are limited to approved Registry personnel. Identifying information of enrollees is given to no one by the Registry. If you desire, you may enroll in the Registry anonymously. This means that the information about your skin disorder is entered into the Registry, but without name, address or other identifying data. Anonymous participation in the Registry will mean you will not be able to actively participate in any of the research studies, but the information may be useful for studies about how your disorder has affected you and others like you. Any time you wish to withdraw from the Registry, all identifying data pertaining to you will be purged from the computer files.

Dermatologists

If you do not currently see a Dermatologist, the Registry can provide a list of “regional experts” along with local practitioners as needed. If necessary, we have arranged for the Regional Support Network Consultant Physicians of F.I.R.S.T. to see affected individuals, and can refer you to the nearest center. Funding for the Registry does not include funds for physician visits or travel expenses, but the regional consultant physicians have agreed to keep the costs at a minimum.

A BIOPSY IS NOT REQUIRED to enroll in the Registry. We do ask your dermatologist for a copy of any biopsy slide(s), as well as any pertinent reports from tests that help clarify your diagnosis. Some of the specific diagnoses we include in the Registry can only be confirmed using the results of a specific blood test or skin biopsy, and any diagnosis is more accurate and better understood if we obtain all of the information we possibly can.

Thank you for your help. The Registry Coordinator, Geoff Hamill, is happy to talk with you about any issues or questions you may have at any point in your association with us. Please feel free to call at anytime.

Yours truly,

Philip Fleckman, MD
Associate Professor of Medicine (Dermatology)
Principle Investigator, National Registry for Ichthyosis and Related Disorders

Geoffrey Hamill, RN
Research Nurse II
Registry Coordinator, National Registry for Ichthyosis and Related Disorders
RESEARCHER'S STATEMENT
We are asking you to participate in a research registry. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the registry or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called informed consent. We will give you a copy of this form for your records.

PURPOSE AND BENEFITS
The National Institute of Arthritis, Musculoskeletal and Skin Disease (NIAMS) is sponsoring a Registry for Ichthyosis and Related Disorders. The NIAMS is part of the National Institutes of Health (NIH), and supports research for basic and clinical studies of the skin in normal and disease states.

The purpose of the Registry is to aid in searching for basic defects, improving methods of diagnosis, and developing effective methods in treatment and prevention of these disorders.

Participation in this Registry will not directly benefit you/your child. However, your/your child's disorder is uncommon and little information is available about the incidence, prevalence, or even in some cases specific criteria for diagnosis. Accumulation of larger numbers of affected individuals will allow investigators to define the disorders more accurately and to search more effectively for basic defects, improve methods of diagnosis, and develop effective methods of treatment and/or prevention of the afflictions.

PROCEDURES
You or your child participate by giving information to the Registry. This requires that you/your child see a Dermatologist (a skin doctor), who has special training in skin diseases, and fill out two forms with the help of your doctor and the Registry Coordinator.

In some cases you/your child may be asked to travel to a "regional expert" who is particularly experienced in diagnosing and treating these disorders. This usually happens when the local Dermatologist cannot determine what your problem is, or when there is no one in your town who is able to make a specific diagnosis. Because this is necessary to make a diagnosis of the specific disorder and is therefore a normal part of medical care, the NIAMS cannot pay for your doctor visit or for your travel expenses.

After you/your child have signed this consent form your physician will fill out a short Physician's Form containing information about your/your child's skin problem. This will take less than five minutes. The Physician's Form and this consent form will then be returned to the Registry. You will also be given a Patient Enrollment Form. The Registry Research Nurse will be in contact with you to arrange a convenient time to discuss the questions on the Patient Enrollment Form. It would be helpful if you looked over the questions in the Patient Enrollment Form before you discuss them at length with the Registry Nurse. If you are puzzled by some of the questions and need help in answering them do not worry, the Registry Nurse will help you.

Once the Physician's Form and this consent form are received, the Registry Coordinator will be in contact with you to discuss the questions on the Patient Enrollment Form. This will information will be gathered by phone at no expense to you (the Registry Coordinator will call you) and will take place at a mutually convenient time. It will take approximately 60 minutes to answer the questions. The most personal and sensitive questions to be asked relate to where on your body the skin is affected and how your skin trouble affects your life. Your may refuse to answer any question.

If you/your child wish, you may also take part in research studies that try to understand the cause of your skin disorder or find ways to treat it. Even if you are not interested in participating in research studies, by answering the questions on the Physician's Form and the Patient Enrollment Form, your participation in the Registry will make valuable information available to researchers interested in learning more about your disorder and others like it. All information in the Registry will remain anonymous.

INTEREST IN PARTICIPATING IN STUDIES
Your willingness to provide this information to the Registry is appreciated by the NIAMS, Dermatologists who care for individuals with disorders of keratinization, and researchers who study individuals with disorders of keratinization in order to understand the disorders and to make more accurate diagnoses and design more effective means of treatment. Thank you!

Some of the information in the Registry may be used for epidemiologic studies. This information will remain anonymous - you/your child will not be identified in any way. Another purpose of the Registry is to act as a database of individuals with specific, accurately diagnosed disorders who are interested in participating in research studies. You do NOT have to participate in research studies in order to be enrolled in the Registry. If you are interested in participating in studies, the Registry will contact you by mail when appropriate studies arise. In all cases, research proposals will be reviewed by members of the Advisory Committee of the Registry. The Advisory Committee is composed of Dermatologists and scientists who study the ichthyoses and related disorders and of lay
persons who have friends or family members affected with or who themselves have such disorders. All research proposals must also be approved by a Human Investigation Committee that has been certified by the NIH. If you are interested in learning about such investigations, the Registry will inform you BY MAIL when appropriate studies arise. You may contact the investigator directly if you wish to learn more. Under no circumstances will your name, address, phone number, or any other personal identifying information be given directly to investigators by the Registry.

**RISKS, STRESS, OR DISCOMFORT**

Minor invasion of privacy is involved in providing the information on the forms. By agreeing to enroll in the Registry, you are giving permission for your/your child’s doctor or medical professional to release dermatologic records, biopsy tissue and/or slides, blood samples and/or reports to the Registry for diagnostic purposes. You will be asked to provide address and phone numbers for the Registry's use in contacting you. Initially the Registry Coordinator will contact you to complete information for the database. Subsequently, you will be mailed information about approved studies of investigators who are seeking individuals with your/your child's particular problem. An annual mailing from the Registry with return, postage-free mailings for you will be used to maintain contact. If you agree, we will be looking at your records for the entire time that the Registry is functioning after you authorize us to do so. The first 90 days will be covered by your signed authorization. To avoid having to ask you to sign a new form every 90 days, after the first 90 days we will be able to look at your records under a Confidentiality Agreement with the record-holder. You do not have to sign this consent/assent form giving us authorization to access your medical records. However, if you do not sign this consent/assent form then you/your child cannot be enrolled in the Registry.

**OTHER INFORMATION**

You/your child's identity will remain confidential. Although the Registry will have your name and identifying information, you will remain anonymous and only Registry employees will have access to the information in your file. This means that if this information is published or presented to scientific meetings, no names or other identifying information will be used. Your/your child's social security number is requested as a definitive means of identification. You do not have to give this information if you do not wish to.

During this study, we will need to look at your medical records submitted by your/your child’s enrolling physician and other health care providers you have designated as having helped you/your child care for your/your child’s skin in the past. We will look at the records to find out the nature of your skin disease and any other health conditions that may be related, as submitted by you/your child during the interview or by your/your child’s enrolling physician on the Physician’s Enrollment Form. We need this information to clarify/confirm the diagnosis of your/your child’s skin disease. Your signature on this form allows us to access these records indefinitely. Only the information submitted to us in the Physician’s Enrollment Form, results of tests done elsewhere to characterize your/your child’s skin disease, and the information obtained during your/your child’s enrollment interview will be accessed.

Participation in the Registry is completely voluntary. Your doctor will continue to treat and help you regardless of whether you participate. You/your child have/has the right not to participate or withdraw from this Registry at any time without penalty or loss of benefits to which you are otherwise entitled. You'll be kept informed of any significant findings that arise as a result of this Registry. If at any time you/your child decide to withdraw from the Registry, all demographic data pertaining to you/your child will be purged from the computer files.

At the end of the period for which the Registry is funded, all information will be turned over to the NIAMS. All demographic data will be purged from the computer files before the information is turned over to the NIAMS. Should alternative support be identified and the database remain at the University of Washington, the measures described above for confidentiality will remain in effect.

Thank you for your help and for your efforts in obtaining this information. We hope that the expense you have incurred and time you have given to make the Registry a success will result in useful, new information about the basic defects, improved methods of diagnosis, and/or effective methods in treatment and prevention of these disorders.

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**SUBJECT'S STATEMENT:**

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later on about the research I can ask one of the investigators listed above. If I have questions about my rights as a research subject I can call the Human Subjects Division at (206) 543-0098. I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

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**Typed or printed name of investigator**  
**Signature of investigator**  
**Date**

**Typed or printed name of subject**  
**Signature of subject**  
**Date**

**Typed or printed name of subject’s parent/legal guardian**  
**Signature of parent/legal guardian**  
**Date**

Contact phone #: (____) _____-_____. Hm/Wk Address:
Keep one signed copy for your files, and return one signed copy for the Researcher’s files.

Return form to: National Registry for Ichthyosis and Related Disorders
University of Washington - Dermatology, Box 356524

Toll-free Phone #: 1-800-595-1265
Seattle, WA  98195-6524
UNIVERSITY OF WASHINGTON
National Registry for Ichthyosis and Related Disorders

ASSENT FORM (To be completed if Enrollee is a minor) (Revised 4/14/2003)

Principal Investigator: Philip Fleckman, MD, Professor - Dept. of Medicine (Dermatology)  Telephone: (206) 543-5290

RESEARCHER'S STATEMENT

WHY WE WANT TO DO THIS AND HOW IT MAY HELP YOU
We want to make a list of all the kids and grownups in the country who have a skin problem like yours. With this list we hope to learn what causes these problems and how to make them better. Helping us do this will probably not help you get better right away. It may be helpful later on.

WHAT WE WANT TO DO
You and your Mom or Dad or Guardian can help by giving information to us. You will have to see your skin doctor and may even have to see a special skin doctor who is particularly interested in your problem. The skin doctor will help you and your Mom or Dad or Guardian by telling us about your skin problem. We will then call your Mom or Dad or Guardian to get more information. We will ask a lot of questions. You do not have to answer all of them.

The answers to your questions will help us understand your problem better. If you want to be part of special studies that researchers who are interested in your problem are doing, we will tell you about the studies as they occur. You do not have to be part of these studies in order to answer the questions for us.

HOW THIS MIGHT HURT YOU
If you help us, we will know your name, phone number, address, and what your skin problem is. Some people do not like to give this information out.

OTHER THINGS
We will not give anyone your name, address, or phone number, or tell anyone what your problem is. You do not have to help us in this way if you do not want to. We will still like you and take care of you if you do not help. You do not have to answer all the questions we ask. You may choose what you want to tell us. We will tell you and your Mom and Dad, or someone special to you if we learn anything important from this information. We will answer any questions you have now or later. If you decide later on that you do not want us to have this information, we will remove your name, address, and phone number from the Registry.

SUBJECT'S STATEMENT
The doctors told me what they want to do and what to expect. I was told I don’t have to participate unless I want to. The doctors answered my questions. If I have any other questions I can call the doctors and ask them or have my parent/guardian call them anytime. I choose to volunteer for this project.

Keep one signed copy for your files, and return one signed copy for the Researcher’s files.

Return form to: National Registry for Ichthyosis and Related Disorders
University of Washington - Dermatology, Box 356524 Seattle, WA 98195-6524

Toll-free Phone #: 1-800-595-1265