

Utah Psoriasis Initiative

Principal investigator: Kristina P. Callis, M.D., Dept. of Dermatology, University of Utah
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You are being invited to take part in a research study to help researchers better understand psoriasis. Before you decide to enroll in the study, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and ask questions if you don't understand something. Feel free to discuss it with friends and relatives if you wish. Take time to decide whether or not you wish to take part in this research study. This form also contains information about how to contact the people who are conducting the study if you have other questions later. You will be given a copy of this form to keep for your records.

BACKGROUND:

Psoriasis is a chronic skin condition that affects approximately 2.6% of the population. People who get psoriasis have red, scaly patches on their skin, varying from minor skin lesions to an extensive, disfiguring condition affecting nearly the entire body surface. Psoriasis can be a severe disease and may reduce the quality of life of those who are affected. The current treatments are not always effective and can sometimes have serious side effects. It is important to increase our understanding of the disease in order to search for safer, more effective treatments.

Many previous studies have led scientists to believe that psoriasis is in part a genetic disease (a disease that can run in families). Recent advances have made it possible to perform studies to look for the genes that may be involved in this disorder.

The goal of this study is to create a registry of patients with psoriasis. This registry will contain medical and genetic information from willing participants in order to identify genes that cause different levels of risk for psoriasis. If we can identify which genes are responsible for the development of psoriasis, we may then be able to do further studies in the future that help us identify effective psoriasis treatments. We could also study why some drugs work well in certain individuals, but others do not.

The study team is composed of researchers from the University of Utah and DNA Sciences, Inc., (a company that is in the business of identifying genes and what they do). We call this effort the Utah Psoriasis Initiative (UPI).

STUDY PROCEDURE:

What am I being asked to do?

You are being asked to participate in a study that will help us better understand the relationship between psoriasis and genetics in order to develop better psoriasis prevention, screening, diagnosis and treatment methods. Some of the people we are inviting to participate in this study have psoriasis themselves, but others do not. To make the research possible, **you are being asked to do the following:**

1. Provide a blood sample. You will be asked to give a blood sample (two 10-ml tubes and one 5-ml tube, which is equal to about 2 tablespoons). Your blood sample will be sent to DNA Sciences Inc., where the genetic information (DNA) will be analyzed. The analysis will consist of examining how your DNA compares to that of other people, some of who have had psoriasis and some of who do not.

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2. Fill out a brief questionnaire. The questionnaire asks about your medical history, and about the health of your relatives.

3. Allow a skin examination. You will be asked to allow an investigator who is a physician to perform a brief examination of your skin. This will help us to determine if you have psoriasis, where you have psoriasis, and what type of psoriasis you might have.

4. Give permission to link your data to the genealogical records of the Utah Population Database held at the University of Utah. This will allow us to determine if people with psoriasis in Utah are related in any way. This information may be very valuable to us in helping to discover the genetic basis for this disease. The records of the Utah Population Database are held with a very high level of computer security and personal confidentiality.

5. Give permission to link your data with that of your family members. For our research, it is important to know which volunteers are related to which other volunteers. We will construct a genetic family tree and, thus, link records of family members.

How will my DNA sample and my medical history information be connected?

In order for us to identify the genes that are involved in psoriasis risk, we need to be able to compare genetic and medical information about people and their family members. The project staff will store information about your medical and family history in a registry. The registry that contains both medical information and identifying information will be kept in a secure computer not connected to the Internet along with laboratory information about your donated specimens. Only members of our staff who have signed pledges of confidentiality will be able to view both the medical information and the personal information that identifies you at the same time.

Will this information be used in future studies?

Future studies, conducted either by our staff or by others, might be able to use the information collected by this study. Most of these studies could make use of your specimens and information without including any additional information that would identify you (such as your name). These types of studies are called *non-identifying*. As you consider providing a blood or tissue specimen, you have a choice regarding whether you want to be contacted for each non-identifying research study. Some people are curious about the various research projects in which their specimens are used, where others may not want to be bothered to be contacted for each study.

Initial only one of the following options for future studies using your blood specimen:

_____ My blood may be used in future studies without my written consent as long as the researchers do not know my identity. I understand that if a research project wants to use my blood in a way that identifies me, I will be contacted for written permission.

_____ My blood may be used in future studies only if I give written consent again for each study. If I choose this option I will be contacted each time my blood is needed for a study.

It is possible that other studies that could be done with your specimens may need to be connected to medical or health information that can identify you. **If a research project needs to use your**

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specimens in any way that identifies you, you will be contacted for written permission before specimens are released for that research.

How long will I be involved?

We anticipate it will take less than one hour to read the information, sign the forms, fill out a questionnaire, receive a skin examination and provide a blood sample. You may choose at the end of this document if you wish to continue participation in this study on a regular basis. This is optional and if you agree you would be contacted every six months to fill out a short questionnaire and if you choose, come to clinic to receive a skin examination. We anticipate this would require less than 30 minutes each time. We intend to keep your medical and personal information for future studies indefinitely, unless you withdraw from the study.

RISKS:

What are the Risks of Providing a Blood Sample?

Physical Risks: The risks of blood drawing include the possibility of bruising, bleeding, or infection at the site of puncture, and uneasiness associated with needles.

Emotional Risks: Being involved in research that focuses on the inherited aspects of psoriasis can cause you to think more about this issue, which may be stressful and cause you to be anxious, worried or sad. **Participation in this study does not necessarily mean that you or your family members have an inherited reason to develop psoriasis or that you or your family members are at an increased risk for developing psoriasis.**

Social Risks: With any kind of genetic research there are social implications for you to consider. Rarely, genetic information or knowledge that a person has been a part of a genetic research study may cause an employer or insurance carrier to discriminate against that person by denying a job or health insurance. Providing a blood sample for this study will probably not put you at risk for discrimination. We will not release any information about you or your family to your insurance company or employer.

Unforeseen Risks: Participation may also involve risks to participants that are currently unforeseeable.

BENEFITS:

What are the Benefits of Participating in this Study?

We hope future research studies will be of benefit to you, your relatives, and future generations because of the information we are able to learn. Information may become available that may be important to you, your family, or to other people, and you may have an opportunity to learn about this information. It is important to understand that DNA Sciences, Inc. is a for-profit company and hopes to make money by identify genes that have useful medical applications. If they are successful, you will not personally benefit because of your participation in the study.

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CONFIDENTIALITY:

How is my Confidentiality Protected?

All information obtained from this study will be handled in a confidential manner that protects your identity. Information and records are kept in secured files. All participants are assigned a code number. Your blood and tissue sample will also be assigned that code number, and your name will be removed. The list of names and matching code numbers will be stored separately from the other study information and will be available only to the project staff. Rarely, the University's or Company's Institutional Review Board, or a government regulatory agency, might need to see some of the records of this project (such as this consent form), on which you are identified. If we publish the results that we learn from a study, you will not be identified.

PERSON TO CONTACT:

If you have questions or comments about this project, please call the study coordinator, Melissa Weidner at (801)581-6477, the principal investigator: Kristina P. Callis, M.D., (24 hour pager number 339-4235) the co-investigators: Christopher B. Hansen, M.D., and Christopher Carlin, M.D., at (801) 585-7585 or Gerald Krueger, M.D., at (801)581-7837.

INSTITUTIONAL REVIEW BOARD:

If you have questions regarding your rights as a research subject, or if problems arise which you do not feel you can discuss with the Investigator, please contact the University of Utah Institutional Review Board Office at (801) 581-3655.

MEDICAL TREATMENT OR COMPENSATION FOR INJURY:

In the event you sustain injury resulting from your participation in the research project, the University of Utah can provide to you, without charge, emergency and temporary medical treatment not otherwise covered by your own insurance. If you believe that you have sustained an injury as a result of your participation in this research program, please contact the University of Utah Institutional Review Board, phone number (801) 581-3655. By signing this document you are not giving up your right to pursue legal action against any and all parties involved with this research, in accordance with the Utah Governmental Immunity Act, Section 63-30-1:63-30-34 Utah Code Ann. 1953 (as amended).

VOLUNTARY PARTICIPATION:

The choice of whether to have blood drawn and give personal medical information is yours. The alternative is not to participate. If you do not want to participate, there will be no penalty or loss of medical benefits to which you are otherwise entitled. You may choose to withdraw participation at any time. If you do, you can request that all information and blood and tissue samples that you provided to us will be destroyed. However, if some of your samples have already been used in non-identifying studies, we will not be able to retrieve your samples or information derived from them to destroy them.

RIGHT OF INVESTIGATORS TO WITHDRAW SUBJECTS:

Participation in this study may be stopped by the Principal Investigator without your consent. The study may dispose of your samples without your approval.

COSTS TO SUBJECTS:

You do not have to pay for the clinic visit during which the study procedures are performed. You do not have to pay have your blood drawn. However if you arrange to have your blood drawn by someone who is not on the project staff, you may get a bill from a clinic or doctor's office where your blood is drawn. We will reimburse you for the blood draw charge after you provide us with a copy of the bill.

NEW INFORMATION:

The association that we find between genes and psoriasis risk will need to be confirmed by other studies. Because of this, we will not be able to give you genetic results from this study that would be helpful to you or your doctor. However, any significant new findings developed during the course of the research that could affect your willingness to continue participation will be provided to you.

DNA Sciences, Inc., provides a variety of information and services through its Web Site, www.dna.com, which may be of interest to you or your family members. These services include basic information on genetics and disease, chat groups, live discussions with experts in the fields of genetics and medicine, and other opportunities to learn more about recent developments in genetics.

NUMBER OF SUBJECTS

We intend to enroll a total of about 5,000 people in this study.

