

UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

INFORMATION ABOUT THIS FORM

You, or your child, may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study. Parents or legal guardians who are giving permission for a child, please note: in the sections that follow the word 'you' refers to 'your child.'

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title:

Genetic Analysis of Psoriasis and Psoriatic Arthritis

1.2 Company or agency sponsoring the study:

The sponsor of this study is the University of Michigan Department of Dermatology. We receive funding from the National Institutes of Health, charitable organizations and private donors.

1.3 Names, degrees, and affiliations of the researchers conducting the study:

James T. Elder, MD, PhD, Department of Dermatology, University of Michigan

Rajan Nair, PhD, Department of Dermatology, University of Michigan

Robert W. Ike, MD, Division of Rheumatology, Dept. of Medicine, University of Michigan

Gonçalo Abecasis, PhD, Department of Biostatistics, University of Michigan

Johann Gudjonsson, MD, PhD, Department of Dermatology, University of Michigan

Trilokraj Tejasvi, MD, Department of Dermatology, University of Michigan

Stefan Stoll, PhD, Department of Dermatology, University of Michigan

Philip Mease, MD, Seattle Rheumatology Associates, Seattle, WA

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

We know from previous studies that genes play an important role in determining who gets psoriasis and/or psoriatic arthritis. The purpose of this study is to understand the genetic basis of psoriasis and psoriatic arthritis. To accomplish this, we are looking for specific gene variants (alleles) that "run in families" with these conditions, or are found more often in cases (people with these conditions) than in controls (healthy people without either of these conditions).

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

Individuals affected with psoriasis and/or psoriatic arthritis (and, in some cases, their family members), and normal volunteers with no personal or family history of psoriasis or psoriatic arthritis.

3.2 How many people (subjects) are expected to take part in this study?

Up to 10,000 in all, with approximately ninety percent of these being enrolled through the University of Michigan.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

- If you have psoriasis a physician or another trained person will make an evaluation of the skin condition.
- If you have psoriatic arthritis you will receive the same evaluation of your skin as would someone who has psoriasis only. In addition, your joints will be evaluated by a physician or another trained person, and you may be asked to undergo an ultrasound examination of certain joints (ultrasound is a painless, non-invasive way of visualizing your joints). We may request your permission to obtain and analyze X-rays of your joints from the University of Michigan Health System, or from other physicians or hospitals. If you have not had these tests, and if they are medically necessary, your doctor may order them. If you are a woman of child-bearing age, it may be necessary to perform a pregnancy test before taking X-rays.
- If you are not able to come to our clinic for evaluation, it is possible to participate remotely by mail. In this case, we will depend on your prior diagnosis, and will ask your permission to contact the physician who diagnosed your condition to confirm diagnosis.
- If you are a normal control, no physical examination is required. You only need to provide a blood sample.
- Whether you have psoriasis only, psoriatic arthritis, or are a normal control, we will collect about 30 milliliters (about one ounce) of blood. If collecting blood samples is difficult due to distance from a clinical lab or other reasons, you can provide saliva samples instead of blood. About 1 teaspoon of saliva will need to be spit into a special collection tube containing a preservative solution and sent to our lab.
- You will be asked to fill out questionnaires and we may also send periodic questionnaires to you in order to update our information of your health status as related to psoriasis.
- No treatment for psoriasis or psoriatic arthritis will be provided as part of this study.
- We may take photographs of areas of your skin for this study. Photographs are an important way for us to document the appearance of your skin. Your photographs will be treated like all the other confidential information used or gathered during this study (see section 9 for details). Your photographs may be used in publications, lectures, newspapers, magazines, and/or television reports. However, neither your name nor other direct identifiers will be linked to your photograph. If photographs are taken of your face, we will make every effort to conceal your identity; either by showing only a very limited area of your face, or by putting black bars over the eyes in the picture. However, in spite of all these preventive measures there is still the possibility that you may be recognizable or that your identity will be revealed. You will not receive any payment or other compensation for the use of your photographs.
- All of the information collected about you will be preserved and made available to others for research. The researchers and officials of the National Institutes of Health will be responsible for deciding how the data will be shared. This information may ultimately have significant therapeutic or commercial value. By agreeing to participate in this study, you consent to such uses. For all research uses of the data, the results of assessments of you (i.e., all of the information collected or monitored and any biological samples including genetic material) will be identified only by a unique participant code that contains no information about your identity. In this form, the data will be entered into a database. The researchers will also make the data available to others to help answer additional research questions in the future. The data will also be submitted to other data repositories maintained, sponsored, or sanctioned by the

National Institutes of Health. Therefore, all of the information collected or monitored and any biological samples including genetic material (i.e., all phenotypic and genomic data) will be used for future research purposes and shared broadly. Your individual-level data will be shared through controlled access and only made available for secondary research after investigators have obtained approval to use the requested data for a particular project. People who request access to the data will have to agree not to try to identify any individuals who have participated in the study. However, there is a small possibility that in the future an unauthorized attempt to identify you or your child as a participant in the study could succeed.

- Genetic information about you will often apply (in one degree or another) to family members. It is not generally the University's policy to provide genetic information about you to your family members. However, certain studies, called "pedigree studies", share such information among family members. For this and related research you may be asked if you are willing to share your genetic information with your family members.
- A portion of the blood or saliva sample you donate will be saved for future studies. This may be in the form of whole blood, cell lines, DNA, and/or serum. Your blood or saliva sample will be stored under a code number that will be connected to your name or other unique identifier. The key to this code will be accessible only to the investigators. In addition to your name, other information about you might be connected to your blood or saliva sample. For instance, information about race, ethnicity, gender, your medical history, and so forth might be available to investigators studying your blood or saliva sample. Such information is important for scientific context and sometimes for public health. It is possible that genetic information might come to be associated with your racial or ethnic group. You will not be notified of any future research, test or analysis that might be performed using your blood or saliva samples. Your blood or saliva samples may be used for research purposes unrelated to this study only if they are first stripped of all personal identifiers ("anonymized" samples). Information about your race, ethnicity, gender, and age may remain attached to such anonymized samples.
- Your identified blood or saliva sample and associated clinical information will not be used in studies other than the one described here without your permission. To indicate your desired level of use, please initial one of the following three options:

_____ I hereby allow my identified blood or saliva sample and clinical information to be used in future studies involving skin and joint disorders.

_____ I do not wish my identified blood or saliva sample and clinical information to be used in studies other than the one described in this consent form, unless I have the new study explained to me and give my specific written permission for their use in it.

_____ I do not wish my identified blood or saliva sample and clinical information to be used in studies other than the one described in this consent form.

4.2 How much of my time will be needed to take part in this study?

Completion of the questionnaires, clinical evaluation and blood or saliva sampling will take from 20 minutes to 2 hours, depending on the evaluation being performed. In rare cases, if we run into difficulties with processing your blood or saliva sample, a second sample may be requested at a later time. Questionnaires that may be mailed to you in the future will take 5-60 minutes. If there is a reason to seek specific information from you in the future for purposes of this study, you may be contacted by the investigators.

4.3 When will my participation in the study be over?

This study is long-term in nature and there is no planned completion date. However, you will not have to do anything after you have been evaluated and have provided your blood or saliva sample, except that we may send you periodic questionnaires to update our information on your health status as mentioned above.

5. INFORMATION ABOUT RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are:

- Collection of blood, which involves a needle stick that can be mildly uncomfortable. The potential risks of blood drawing include blood clotting, a slight chance of fainting, bruising, and infection. These risks will be minimized by maintaining local pressure on the blood drawing site by means of pressure dressing. If you have fainted in the past during a blood draw, inform the doctor and/or researcher beforehand to help minimize associated risks.
- Evaluation of arthritis requires placing pressure on joints, which may be mildly uncomfortable if the joint is inflamed.
- X-rays may be obtained, and this procedure exposes you to small amounts of radiation. The dose of radiation from an x-ray of the lower spine is approximately equal to the amount of radiation one would be exposed to on 90 round trip coast-to-coast airplane flights. However, this is still a very small amount of radiation, equivalent to the exposure from natural sources encountered over 11 months and less than 6% of the lowest radiation dose considered by experts to be harmful. If you are pregnant, X-rays can potentially cause harm to the fetus. Therefore, if the physician determines it to be appropriate, women participants of child-bearing age will be asked to submit to a urine pregnancy test. The cost of this test will be borne by the study.
- The federal Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Under this law:
 - Health insurance companies and group health plans may not request your genetic information that we obtain from this research
 - Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums
 - Employers with 15 or more employees may not use your genetic information that we obtain from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment

GINA does not apply to the following groups, however these groups have policies in place that provide similar protections against discrimination:

- Members of the US Military receiving care through Tricare
- Veterans receiving care through the Veteran's Administration (VA)
- The Indian Health Service
- Federal employees receiving care through the Federal Employees Health Benefits Plans

These are the best-known risks and challenges of genetic research. There might be other risks we do not know about yet. No direct benefits can be promised from your participation, though some people find satisfaction in contributing to scientific knowledge about genetic problems and their medical consequences. It is very important that you talk to your doctor, nurse or genetic counselor if you have questions or concerns about the research study or any of the information in this document.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even when the researchers are careful to avoid them. If you believe that you have been harmed, notify the researchers listed in Section 10 of this form. The doctor who evaluated you will arrange for first aid or emergency care. The cost of this first aid or emergency care may be billed to your insurance company. Additional medical care will be provided if the University or the study doctor determines that they are responsible to provide such treatment. If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

Please note: It is important that you tell the researchers about any injuries, side effects, or other problems that you experience during this study. You may also need to tell your regular doctors.

5.3 If I take part in this study, can I also participate in other studies?

Because this study does not involve any treatments, you will be able to participate in other studies. However, in general, being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. Therefore, in general, you should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. It is possible that the information gathered may ultimately lead to development of better therapies that could be of benefit to future patients.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

In this study, investigators will not tell you what they find out about you, nor will the investigators, your doctor, or the University contact you if a test becomes available to diagnose a condition you might have or later develop. This is unlikely to have a negative impact on your health because both psoriasis and psoriatic arthritis are multifactorial diseases, meaning that multiple genes and the environment determine risk of disease. In this setting, genetic tests are not good predictors of risk. In other words, the presence of a genetic marker does not necessarily mean that a person will develop a disease. Conversely, the absence of a marker does not mean that someone will not get the disease.

There are alternatives to notification by investigators. If you are concerned about a potential genetic malady, and if a test for this malady became available, you and your doctor might choose to test specifically for it. You should discuss this option with your doctor or genetic counselor.

6. OTHER OPTIONS

6.1 If I decide not to take part in this study, what other options do I have?

Your participation in this study is voluntary. The alternative is to not participate, in which case there will be no penalty. You should continue with your present treatment plan. You may also ask the researchers or your doctors about other options you may have.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to

leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information" (below).

If you decide to withdraw from the study, you will be given the following options: (1) You may choose to have your blood or saliva samples destroyed. (2) You may allow us to retain your blood or saliva sample and clinical records without personal identifiers.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

No.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- ✓ The researcher believes that it is not in your best interest to stay in the study.
- ✓ You become ineligible to participate.
- ✓ Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- ✓ You do not follow instructions from the researchers.
- ✓ The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researchers' number listed in section 10.1.

The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers. If you get a bill you think is wrong, call the researchers' number listed in section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Treatment of complications
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

Upon completion of evaluation and blood or saliva collection you will be paid \$20.00. If you are evaluated at the University of Michigan Hospital, we may issue a payment coupon that can be redeemed at the Hospital Cashier's office. If you are participating at any other location, or if you do not want a payment coupon, we will mail you a check as soon as the study documents and blood or saliva sample are received in the Psoriasis Genetics

Laboratory at the University of Michigan. Payments received for participating in research studies are considered income by the Internal Revenue Service.

8.3 Who could profit or financially benefit from the study results?

No person or institution will have direct financial benefit from the outcome of this study. However, the information gathered in this study may be used by the investigators or others in future to develop diagnostic or treatment products that may result in financial gain.

9. CONFIDENTIALITY OF SUBJECT RECORDS

The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my privacy?

The paper documents containing study participant information are kept in locked areas with access to only those who need it for research purposes. Computer records are password protected with access only to authorized individuals. Any web-based forms that you submit are encrypted for security, and the information will *not* be stored on the web site. All individuals at the University of Michigan with access to study participant information have made signed agreements of confidentiality with the University of Michigan Health System. At other participating sites, the collaborating physician(s) will protect your privacy by the standards used to protect the privacy of their own patients. DNA or other biological samples collected from you are identified by coded numbers that do not directly identify you or connect to your medical records. Since this is a genetic study that does not involve any treatment, the evaluation or other information collected in this study will not become part of your medical records. However, any X-ray, ultrasound, or blood test results that were obtained as part of your regular clinical care will remain a part of your medical record, just as they would have been had you not been part of this study.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care.

This may include information about your health and your medical care before, during, and after the study, even if that information wasn't collected as part of this research study. For example:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.).
- All records relating to your psoriasis and/or psoriatic arthritis, the treatment you have received, and your response to the treatment.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results.
- University and government officials may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors, funders, or safety monitors may need the information to make sure that the study is done safely and properly.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.

- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.
- The University of Michigan collaborates with many other organizations, and data are generally shared among them. However, no data shared with other investigators will include your name or other public identifier.
- The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over. Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan Notice of Privacy Practices. This information is also available on the web at <http://www.uofmhealth.org/patient+and+visitor+guide/hipaa>. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you cancel your permission before the end of the study, you will be able to decide what is to be done with your blood or saliva samples, as described in Section 7.1.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: James T. Elder, MD, PhD
Mailing Address: 7412 Medical Science Building I

University of Michigan
1301 E. Catherine St.
Ann Arbor, MI 48109-5675
Telephone: (734) 763-0355

Study Coordinator: Lorela Myftiu or Andrew Libs
Mailing Address: 7421 Medical Science Building I
University of Michigan
1301 E. Catherine St.
Ann Arbor, MI 48109-5675
Telephone: (734) 936-7509

Participating Study site: Dr. Philip Mease, MD
Seattle Rheumatology Associates
601 Broadway, Suite 600
Seattle, WA 98122
Telephone: (206) 386-2000

Study Coordinator: Cathy Loeffler
Research Assistant to Dr. Mease
Seattle Rheumatology Associates
601 Broadway, Suite 600
Seattle, WA 98122
Telephone: (206) 386-2007

You may also express a concern about a study by contacting the Institutional Review Board listed below.

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received a copy of the following document:

- This "Consent to be Part of a Research Study" document. *(Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file.)*

12. SIGNATURES

Research Subject:

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Signature of Subject: _____ Date: _____

Name (Print legal name): _____

Patient ID: _____ Date of Birth: _____

Legal Representative (if applicable):

Signature of Person Legally

Authorized to Give Consent _____ Date: _____

Name (Print legal name): _____ Phone: _____

Address: _____

Check Relationship to Subject:

Parent Spouse Child Sibling Legal Guardian Other: _____

If this consent is for a child who is a ward of the state (for example a foster child), please tell the study team immediately. The researchers may need to contact the IRBMED.

Reason subject is unable to sign for self: _____

Principal Investigator (or Designee):

I have given this research subject (or his/her legally authorized representative, if applicable) information about this study that I believe is accurate and complete. The subject has indicated that he or she understands the nature of the study and the risks and benefits of participating.

Name: _____ Title: _____

Signature: _____ Date of Signature: _____