

**The University of Texas Southwestern Medical Center
Children's Medical Center of Dallas, Parkland Health & Hospital
System Retina Foundation of the Southwest, Texas Scottish
Rite Hospital for Children The University of Texas Southwestern
Moncrief Cancer Center**

**Authorization for Use and Disclosure of
Health Information for Research Purposes**

NAME OF RESEARCH PARTICIPANT: _____

Note: If you are a parent or guardian of a minor and have been asked to read and sign this form, the "you" in this document refers to the minor.

What is the purpose of this form?

This authorization describes how information about you and your health will be used and shared by the researcher(s) when you participate in the research study: Immunologic and genetic profiles in subsets of patients with morphea ("Research Project"). Health information is considered "protected health information" when it may directly identify you as an individual. By signing this form you are agreeing to permit the researches and other others (described in detail below) to have access to and share this information. If you have questions, please ask a member of the research team.

Who will be able to use or share my health information?

may use or share your health information with Heidi Jacobe, MD and his or her staff at UT Southwestern Medical Center ("Researchers") for the purpose of this research study.

Will my protected health information be shared with someone other than the Researchers?

Yes, the Researchers may share your health information with others who may be working with the Researchers on the Research Project ("Recipients") for purposes directly related to the conduct of this research study or as required by law. These other people or entities include:

- The University of Texas Southwestern Medical Center, Children's Medical Center, Texas Scottish Rite Hospital for Children, Parkland Heath and Hospital System, Veteran's Affairs Medical Center and The University of Texas Medical Center at Houston. These are other research facilities that are working with UT Southwestern on the Research Project.
- The UT Southwestern Institutional Review Board (IRB). This is a group of people who are responsible for assuring that the rights of participants in research are respected. Members and staff of the IRB at UT Southwestern may review the records of your participation in this research. A representative of the IRB may contact you for information about your experience with this research. If you do not want to answer their questions, you may refuse to do so.
- Representatives of the Food and Drug Administration (FDA). The FDA may oversee the Research Project to confirm compliance with laws and regulations. The FDA may photocopy your health information to verify information submitted to the FDA by the Sponsor.



- Representatives of domestic and foreign governmental and regulatory agencies may be granted direct access to your health information for oversight, compliance activities, and determination of approval for new medicines, devices, or procedures.

How will my health information be protected?

Whenever possible your health information will be kept confidential as required by law. Federal privacy laws may not apply to other institutions, companies or agencies collaborating with UT Southwestern on this research project. UT Southwestern cannot guarantee the confidentiality of your health information after it has been shared with the Recipients.

Why is my personal contact information being used?

Your personal contact information is important for the UT Southwestern Medical Center research team to contact you during the study. However, your personal contact information will not be released without your permission.

What health information will be collected, used and shared (disclosed)?

The Researchers will collect: Complete medical history including current medications, family history, medical records of previous skin examinations, ultrasound examination of you morphea, biopsy of morphea and unaffected skin, photographs, blood markers and questionnaires regarding you r quality of life.

Will my health information be used in a research report?

Yes, the research team may fill out a research report. (This is sometimes called “a case report”.) The research report will not include your name, address, or telephone or social security number. The research report may include your date of birth, initials, dates you received medical care and a tracking code. The research report will also include information the research team collects for the study.

Will my health information be used for other purposes?

Yes, the Researchers and Recipients may use your health information to create research data that does not identify you. Research data that does not identify you may be used and shared by the Researchers and Recipients in a publication about the results of the Research Project or for other research purposes not related to the Research Project.

Do I have to sign this authorization?

No, this authorization is voluntary. Your health care providers will continue to provide you with health care services even if you choose not to sign this authorization. However, if you choose not to sign this authorization, you cannot take part in this Research Project.

How long will my permission last?

This authorization has no expiration date. You may cancel this authorization at any time. If you decide to cancel this authorization, you will no longer be able to take part in the Research Project. The Researchers may still use and share the health information that they have already collected before you canceled the authorization. To cancel this authorization, you must make this request in writing to: Heidi Jacobe, MD. 5323 Harry Hines Blvd. Dallas, Texas 75390-9069.

Will I receive a copy of this authorization?

Yes, a copy of this authorization will be provided to you.



Signatures:

By signing this document you are permitting UT Southwestern Medical Center to use and disclose health information about you for research purposes as described above.

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Signature of Research Participant

_____ Date

For Legal Representatives of Research Participants (if applicable):

Printed Name of Legal Representative: _____

Relationship to Research Participant: _____

I certify that I have the legal authority under applicable law to make this Authorization on behalf of the Research Participant identified above. The basis for this legal authority is:

(e.g. parent, legal guardian, person with legal power of attorney, etc.)

Signature of Legal Representative

_____ Date

