UNIVERSITY OF WASHINGTON
CONSENT FORM
Loeys-Dietz Pregnancy Study

Researchers:

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Researchers' statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study 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 OF THE STUDY

The primary purpose of this study is to learn about pregnancy in women with Loeys-Dietz Syndrome (LDS). So far it is known that mutations in 4 different genes (regions in the DNA that encode for protein in the body) can cause LDS. These genes include TGFBR1, TGFBR2, TGFB2, and SMAD3. Individuals with this disorder have mutations or changes in their DNA that result in faulty make-up of blood vessels and other connective tissues. Connective tissue is the framework or scaffolding of the body that includes bone, skin, joints and blood vessels. Complications in women with connective tissue disorders have been reported during and after pregnancy and include aortic dissection, uterine and artery rupture, severe bleeding, and death. At this time, there are no official recommendations for pregnancy and LDS; no guidelines for management, counseling, or route of delivery. We hope to better characterize pregnancy complications associated with LDS and help develop recommendations through our work.

We are also requesting your permission to be contacted in the future when additional clinical information is needed or when we are recruiting for new research studies about your disorder.

STUDY PROCEDURES

When we receive a signed consent form, you will be contacted by phone by one of the researchers to review your family history and your medical history. This will include a review of all pregnancies and previous diagnostic testing. Once we determine which records we would like to review (including any visits to the hospital, clinic visits, radiology studies, and any surgical records), we will send a medical record release form to you for your signature. During the interview with you, we may ask questions about the age and health concerns of your children, particularly if pertinent to delivery complications. You may refuse to answer any questions asked of you during the phone interview. The interview may take between 30 minutes to 1 hour to complete.

In review of your family history, it is possible that we will identify relatives who have LDS and have been pregnant. They might be interested in participating in the study. This could include your children or a parent. We are also interested in collecting clinical information about deceased relatives who had LDS. We will ask you to assist us in offering enrollment to your living relatives by arranging for them to contact us. We may also ask the Legally Authorized Relative (LAR) of one of your deceased relatives to give us permission to review the records of your deceased relative.

RISKS, STRESS, OR DISCOMFORT

We do not anticipate any physical injury or discomfort to the individuals participating in the study. You may experience fear, anxiety, worry or depression, as a result of the questions asked about your medical history. If you feel that you have been harmed in anyway through your participation in this study you should contact the LDS Pregnancy Research Team at 1-800-288-7362.

BENEFITS OF THE STUDY

You will not directly benefit from this study. We hope that this study will help us provide better care and counseling for patients with LDS who wish to become pregnant and it is possible that this will better inform you or your family members.

OTHER INFORMATION

Taking part in this study is voluntary. You can stop at any time. You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. The medical information gathered by this study is confidential, meaning that it will not become part of your medical records or reported to anyone unless you direct us to do so.

The study records will be stored in a computer database in the Dept. of Pathology at the University of Washington by a study number that cannot be tracked to your name without referring to a separate list (database) that contains the study number and names. The medical information about you entered into the database will be compared with other subjects in the study. The results of this comparison will be published in a medical journal. We may want to

use the study information to compare with a larger group of subjects with the same diagnosis at some time in the future. Therefore, the link between the study data and your identity will remain indefinitely.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm. We are required to release your name and other identifying information to the appropriate officials if we find or suspect child abuse, elder abuse, or intent to harm yourself or others.

If you have any questions about the study or the consent form, please contact Dru Leistritz or Melanie Pepin two of the study investigators at 206-543-5464 toll free:1-888-288-7362 and she will try to find the answer for you. (email: dru2@u.washington.edu, mpepin@u.washington.edu Note: Please remember that we cannot guarantee the confidentiality of e-mail communication)

Printed name of study staff obtaining consent Signature Date

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 about the research, I can ask one of the researchers 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.

Printed name of subject Signature of subject Date

When subject is not able to provide informed consent

Printed name of representative Signature of representative Date

Relationship of representative to subject

Contact Information:
Name: _____
Address: _____

City, State _____
Zip _____

Phone: _____
E-mail: _____

I am willing to be contacted about future research studies into LDS. At that time, my participation will be voluntary.

☐ Yes
☐ No

Copies to: Researcher
Subject