

CONSENT TO PARTICIPATE

Long-Term Followup of Daughters of Kidney Transplant Patients

Background: There is little information on the long-term health and pregnancy outcome of women whose mothers were kidney transplant patients. Immunosuppressive medications are continued during the transplant patient's pregnancy because they are necessary to prevent rejection of the kidney. The baby is also exposed to these medications as they cross the placenta. The majority of these babies have been healthy at birth and through early childhood. There have been no long-term studies on the children of kidney transplant patients, and many are themselves now of reproductive age. We are conducting a survey of the adult daughters of kidney transplant patients. The **Purpose** of the study is to document that these women have remained healthy and that no unrecognized disorders or reproductive problems are occurring.

Study Procedure: If you are willing to participate in the study, please return the signed Consent form and the filled out Questionnaire Data Form. You will then be contacted to make sure all information is complete and to answer any questions you might have. We estimate that the questionnaire and interview will take 15-20 minutes of your time, and you are free to omit any question you do not want to answer.

Risks: There is no risk to your health other than the possibility of emotional stress. All questions will be answered in order to minimize any worries you might have. The risk of loss of privacy is slight since all information is confidential and will not be given to anyone else.

Benefits: The primary potential benefit to you is reassurance that exposure to the anti-rejection medications before birth was not harmful (if this is confirmed). Should any unanticipated disorders, fertility, or pregnancy problems be discovered, you will be informed and counseled appropriately. The results of this survey will also be valuable to future transplant patients and their physicians for counseling before attempting pregnancy.

Alternative Procedures: You have the alternative of not participating.

Confidentiality: Your participation in this study will be kept confidential. We will keep all research records that identify you private to the extent allowed by law. Information about your health and pregnancies is available only to the investigators and study coordinator. However, representatives from the University of Utah research board may inspect and /or copy the records that identify you. Results of the study may be published; however, your name and other identifying information will be kept private. All records are filed securely in locked file cabinets in the office of the study coordinator and will be destroyed at completion of the study.

Person to Contact: If you have any questions concerning this study, you may contact Dr. James R.

Scott or Sheryl Martin at (801) 583- 6000.

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 Institutional Review Board Office at (801) 581-3655.

University's Liability Statement: If you are injured from being in this study, the University of Utah can give you medical care. This medical care will be given to you immediately for emergency problems. The University will not charge you for this medical care, but we will bill your insurance company if you have insurance. If you sign this document you are not giving up your right to take legal action against the University or other companies involved with this research. The University of Utah is a part of the government. If you are injured in this study, and want to sue the University or the doctors, nurses, students, or other people who work for the University, special laws may apply. The Utah Governmental Immunity Act is a law that controls when a person needs to bring a claim against the government and limits the amount of money a person may recover. See Section 63-30-1 through 63-30-38 of the Utah Code.

Voluntary Participation: Participation in this study is voluntary. Declining to participate will involve no penalty or change in your medical care. You may discontinue participation in this study at any time and still receive the same standard of care you would normally expect.

Unforeseeable Risks: Since no treatment is involved, it is doubtful that there are any unforeseeable risks to your health by participating in this survey.

Right of Investigator to withdraw subject: If you do not meet the study requirements, the investigator may withdraw you without your consent.

Costs to subjects: There are no costs to the participants that result from this research, and there is no compensation.

Number of subjects: The goal of this research project is to survey 100-150 adult daughters of mothers who received a kidney transplant at the University of Utah or other transplant centers.

New information: New findings may develop during the course of the research. You may obtain the results by contacting Sheryl Martin, Research Coordinator at Ph. (801) 583-6000.

Authorization: Signing this document means you allow us, the researchers in this study, and others working with us to use information about your health for this research study. You can choose whether or not you will participate in this research study. However, in order to participate you have to sign this consent form. The information we will use is: name, address, telephone number, obstetrics and medical history, current and past medications or therapies.

Others who will have access to your information for this research project are the University of Utah’s Institutional Review Board (the committee that oversees research studying people) and authorized members of the University’s workforce who need the information to perform their duties (for example: to provide treatment or to ensure integrity of the research).

In conducting this study, we may share your information with groups outside the University of Utah Health Sciences Center. If the kidney transplant was performed at another University hospital, similar authorized physicians or individuals may be involved. Other hospitals and medical centers we are working with to identify transplant mothers and daughters are: University of Colorado, University of Florida, University of Pittsburgh, University of Minnesota, University of Iowa and University of Pittsburgh. Information disclosed to groups outside the University of Utah Health Sciences Center, Primary Children’s Medical Center, Shriners’ Hospital may no longer be covered by the federal privacy protections.

You may revoke this authorization. **This must be done in writing.** You must either give your revocation in person to the Principal Investigator or the Principal Investigator’s staff, or mail it to James R. Scott, MD, 423 Wakara Way, Suite 201, Salt Lake City, Utah 84108. However, if you mail it, your signature must be notarized. If you revoke this authorization, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research. You have a right to information used to make decisions about your health care. However, your information from this study will not be available during the study; it will be available after the study is finished. This authorization does not have an expiration date.

CONSENT:

I confirm that I have read and understand this consent and authorization document and have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. I will be given a signed copy of the consent and authorization form to keep.

I agree to participate in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.

Participant’s Name (daughter)

Participant’s Signature (daughter)

Date

Participant's Name (mother)

Participant's Signature (mother)

Date

Name of Person Obtaining Authorization and Consent

Signature of Person Obtaining Authorization and Consent

Date