University of Pittsburgh

School of Medicine
Thomas E. Starzl Transplantation Institute

Biomedical Science Tower, 15th Floor
200 Lothrop Street
Pittsburgh, Pennsylvania 15213-2582
412-624-6700
Fax: 412-624-6666
www.sti.upmc.edu

Name: _____
Please Print

CONSENT TO ACT AS A SUBJECT IN A RESEARCH STUDY

TITLE: International Solid Organ Transplantation Tolerance (ISOrTT) Registry

PRINCIPAL INVESTIGATOR: George Mazariegos, M.D.
Associate Professor of Surgery
Director, Pediatric Transplantation
Children's Hospital of Pittsburgh
3705 Fifth Avenue
Suite 7950
Pittsburgh, PA 15213
412-692-6110

CO INVESTIGATORS:
Ron Shapiro, MD
Kareem Abu-Elmagd, MD, PhD
James Wallis Marsh, MD
7 South UPMC Montefiore
412-647-5800

Fadi Lakkis, MD
Angus Thomson, PhD
Adriana Zeevi, PhD
Beth Elinoff, RN, MPH, CCRC
E1540 BST
412-624-6611

Rakesh Sindhi, MD
Steve Webber, MD
Children's Hospital
412-692-6110

Source of Support
Starzl Transplantation Institute (STI) Research Funds

Why is this research being done?
After organ transplantation, a concern is rejection (the body attacks the organ) of the transplanted organ. Immunosuppression (using medicines to stop the body's immune system from attacking the transplanted organ) is used to prevent rejection. Yet, there are people who have working organ transplants and do not take any medicine for immunosuppression. These people are considered "tolerant". It is important to try to figure out why some people can be off immunosuppression and not reject their organ. One of the first steps in answering the many questions about tolerance is to identify people who are tolerant. Information about tolerant people will be put into an international database. This database will let researchers study possible associations between the information gathered and tolerance. The database will also help us identify people who might benefit from current and future research studies looking at tolerance.

Who is being asked to take part in this research study?
People one year of age and older who have had an abdominal solid organ (liver, kidney or intestine) are being asked to participate. You are being asked to take part in this research study because you have a working, solid organ transplant and have not taken medicine for immunosuppression for at least 12 months. Up to 10,000 people from all over the world will be asked to participate.

What procedures will be performed for research purposes?
If you/your child agree to participate in this research study, you will be asked to sign this consent form. Clinical information about your/your child's care before, during and after your transplant will be entered in to a web-based international registry. Every year, the investigators will update this information. The information entered into the web-based registry will not have your/your child's name, address, social security number or hospital ID number. Your information will be given a code number and your/your child's personal identity will be stripped from the information. Only the investigators listed on the first page of this consent form will have access to the code.

What are the possible risks, side effects, and discomforts of this research study?
There are no risks of physical injury associated with your participation in this registry. Participation in this registry does involve the possible risk that information about your health might become known to individuals outside of the Starzl Transplantation Institute. The risk of breach of confidentiality is rare (occurs in less than 1% or less than 1 out of 100 people) and could affect your/your child's ability to be insured, employed, or influence plans for children or have a negative impact on family relationships, and/or result in paternity suits or stigmatization.

We will attempt to preserve your/your child's medical record confidentiality by assigning a special research code number to your medical record information stored in the registry, and by removing personal identifiers (for example, your/your child's name, social security number, medical record number) from information stored about you/your child in the registry. Information linking the research code number to your/your child's name and other personal identifiers will be stored in a separate secure location.

What are possible benefits from taking part in this study?
It is unlikely that you/your child will receive any direct benefit as a result of your participation in this registry.

However, medical record information contained within the registry will be used for research studies directed at improving our knowledge and treatment of organ transplantation and this knowledge may benefit patients who have an organ transplant in the future.

Will my/my child's insurance provider or I/my child be charged for the costs of any procedures performed as part of this research study?
There will be no charges billed to you/your child or your/your child's insurance provider for participating in this registry.

Will I/ my child be paid if I take part in this research study?

No, you/your child will not receive any payment for participating in this registry.

Who will know about my/my child's participation in this research study?
This research study will involve the recording of current and/or future identifiable medical information. The information that will be recorded will be limited to information concerning your/your child's transplant.

All information related to your/your child's involvement in this research study will be stored in a locked file cabinet or in the secure web-based database. Your/your child's identity on these records will be indicated by a case number rather than by your/your child's name, and the information linking these case numbers with your/your child's identity will be kept separate from the research records. You/your child will not be identified by name in any publication of the research results unless you sign a separate consent form giving your/your child's permission (release).

In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information (which may include your/your child's identifiable medical record information) related to your/your child's participation in this research study:

> Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information (which may include your identifiable medical record information) for the purpose of monitoring the appropriate conduct of this research study.

In unusual cases, the investigators may be required to release identifiable information (which may include your/your child's identifiable medical information) related to your/your child's participation in this research study in response to an order from a court of law. If the investigators learn that you/your child or someone with whom you/your child are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

For how long will my/my child's medical record information continue to be placed in the Research Registry and for how long will this information be used for research purposes?
Your/your child's medical record information will be updated in the registry every year until 1) you/your child are no longer living; or 2) you withdraw your permission for participation in the Research Registry. Your medical record information contained within this registry will be used for research purposes for an indefinite period of time.

Is my/my child's participation in the Research Registry voluntary?
Your/your child's participation in this registry, to include the use of your/your child's medical record information for the research purposes described above, is completely voluntary. Whether or not you provide your permission for participation in this registry will have no affect on your/your child's current or future medical care at the University of Pittsburgh Medical Center, affiliated health care provider, or your/your child's current or future relationship with a health care insurance provider. Whether or not you provide your permission for participation in this registry will have no affect on your/your child's current or future relationship with the University of Pittsburgh.

May I withdraw, at a future date, my consent for participation in this Research Registry?
You may withdraw, at any time, your consent for participation in this registry, to include the additional collection of your/your child's medical record information and its further use for the research purposes described above. However, any research use of your/your child's medical record information prior to the date that you formally withdraw your permission will not be destroyed.

To formally withdraw your permission for participation in this registry you should provide a written and dated notice of this decision to the principal investigator of the Research Registry at the address listed on the first page of this consent form.
****

Voluntary Consent
The above information has been explained to me and all of my questions have been answered. I understand that any future questions I have about this research will be answered by the investigator(s) listed on the first page of this consent document at the telephone numbers given. I also understand that I may always request that my questions be answered by a physician involved in this research study. Any questions I have about rights as a research subject will be answered by the Human Subject Protection Advocate, IRB Office, University of Pittsburgh (1-866-212-2668). By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

By signing this form, I agree to participate in this study.

_____ _____
Participant/Subject Signature Date

Adults (18 years of age or older) determined to be cognitively impaired due to temporary reasons as listed below and thus, unable to provide direct consent

_____
Participant's Name (Print)

The above-named individual is unable to provide direct consent for study participation because _____

_____

Therefore, by signing this form, I give my consent for his/her participation in this research study.

_____ _____
Representative's Name (Print) Representative's Relationship to Participant

_____ _____
Representative's Signature Date

For children under the age of 18:

_____
Participant's (child's) name (print)

I understand that, as a minor (age less than 18 years), the above-named child is not permitted to participate in this research study without my consent. Therefore, by signing this form, I give my consent for his/her participation in this research study.

_____ _____
Parent's or Guardian's name (Print) Relationship to participant (child)

_____ _____
Parent's or Guardian's signature Date

ASSENT:
I certify that I have carefully explained the purpose and nature of this research study to the child subject in age appropriate language. He/she has had an opportunity to discuss it with me in detail. I have answered all his/her questions and he/she has provided affirmative agreement (i.e. assent) to participate in this study.

_____ _____
Investigator's Signature Date

_____
Investigator's Printed Name

For children able to sign their name:
This research has been explained to me, and I agree to participate.

_____ _____
Signature of Child-Subject Date

_____
Printed Name of Child-Subject

CONSENT FOR CONTINUED RESEARCH PARTICIPATION: (For Proxy Consent OR Minors Who Have Turned 18)

I understand that I am currently participating in a research study. I further understand that consent for my participation in this study was initially obtained from my authorized representative as a result of my inability to provide direct consent at the time that this

initial consent was requested. I have now recovered to the point where it is felt that I am able to provide direct consent for continued participation in this research study.

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the continuation of this study and that such future questions will be answered by the researchers listed on the first page of this form. I also understand that any questions I have about my rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668).

By signing below, I agree to continue my participation in this research study. A copy of this consent form will be given to me.

_____ _____

Participant's Signature Date

Certification of Informed Consent

I certify that I have explained the nature and purpose of this research study to the above-named individual, and I have discussed the potential benefits and possible risks of study participation. Any questions the individual has about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____	_____
Printed Name of Person Obtaining Consent	Role in Research Study
_____	_____
Signature of Person Obtaining Consent	Date/Time