Gift of Life Institute
Transplant Pregnancy Registry International
Informed Consent Document

Sponsor / Study Title:	**Gift of Life Institute / "National Transplantation Pregnancy Registry"**
Principal Investigator: (Study Doctor)	**Michael Moritz, M.D.**
Telephone:	**877-955-6877** **215-557-8090 (24 Hours)**
Address:	**Transplant Foundation** **401 N. 3rd Street** **Philadelphia, PA 19123**

Purpose of the study:
The TPR registers female transplant recipients who have had post-transplant pregnancies or who are currently pregnant, and male transplant recipients who have fathered pregnancies post-transplant, as well as those who conceived or fathered pregnancies while taking commonly-used transplant medications for other indications. The purpose is to study the outcomes of all post-transplant pregnancies and the potential effects of immunosuppressant drugs, other medications and other health factors on pregnancy outcomes. The TPR allows information to be collected from a larger number of participants and across a larger geographic area than would be available at a single transplant center.

Participation in the study:
To date over 3,000 patients have participated in the TPR. The study has no fixed endpoint. You will be asked to complete the initial questionnaire, speak to a study coordinator periodically by phone, and sign a consent form to release medical records for the study. You may not benefit from participating in this research directly, but we hope that what we learn from the study will be helpful to future patients or society in general. You will not receive payment for your participation in this study, and there is no cost to you to participate. Anything learned during this study that may affect your health or willingness to continue to participate in the study will be told to you.

Potential risks or discomforts:
There is a very small risk of a breach of privacy or confidentiality. Many safeguards are used to minimize this risk, and your confidential health information will only be accessible to study personnel and will be maintained in a secure facility. The information obtained from this study may be published in scientific and medical journals or presented at scientific and medical

meetings, but you will not be personally identified in these publications and presentations. Your participation in the TPR is completely voluntary.

If at any time you are uncomfortable continuing your participation, you may withdraw your consent. If you choose to remove yourself from the study, the collection of health information will be stopped, but information that has already been collected may still be used. Refusing to participate in this study or withdrawing consent from continued participation will NOT affect your ability to receive medical care.

Protection of privacy and confidentiality:
Information such as your name, address, social security number and any mental or health records or test results is considered "confidential health information." The investigators and coordinators for the TPR as well as other study-related staff at Gift of Life Institute may have access to your confidential health information. Your de-identified confidential health information may also be shared with the funding sponsors of the study, including Astellas Pharma US Inc., Pfizer Inc., Bristol-Meyers Squibb Company, or with the Food and Drug Administration (FDA) for the purpose of regulatory compliance, or with any other person or agency required by law.

Financial disclosure:
The funding sponsors of the TPR are paying Gift of Life Institute to conduct this research.

Whom to Contact about this study:
During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The Investigator's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the Investigator at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00008001.

Statement of Consent:

I have read this form and its contents were explained to me. I agree to be in this research study for the purposes listed above. All of my questions were answered to my satisfaction. I am not giving up any of my legal rights by signing this form.

_____ _____/_____/_____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____/_____/_____
Signature of Surrogate Date

_____
Printed Name of Surrogate

_____ _____/_____/_____
Signature of Witness to Surrogate Date

_____
Printed Name of Witness to Surrogate

_____ _____/_____/_____
Signature of Interviewer Date

_____
Printed Name of Interviewer