BAYLOR SCOTT & WHITE RESEARCH INSTITUTE

Baylor University Medical Center, Baylor Scott & White All Saints Medical Center

Sammons Outpatient Cancer Center, Simmons Transplant Institute

Liver Consultants of Texas Clinic

CONSENT FORM AND PRIVACY AUTHORIZATION

PROJECT TITLE: Transplant Biorepository Protocol

PRINCIPAL INVESTIGATOR (“PI”): Dr. Giuliano Testa

TELEPHONE NUMBER: 214-820-2050

**Key Information**

**1. WHY HAVE I BEEN ASKED TO TAKE PART IN THIS STUDY?**

You are being asked to take part in this research study because you previously underwent a transplant or will be having a transplant surgery at Baylor University Medical Center and/or Baylor Scott & White All Saints Medical Center.

**2. WHY IS THIS STUDY BEING DONE AND HOW LONG WILL IT LAST?**

The purpose of this study is to improve diagnosis and care of transplant patients. We hope to more about the human body, diseases, and potentially improve people’s health in the future.

If you are donating an organ, we think you will be in this study for one day. If you are receiving an organ transplant you will be in this study for the rest of your life or the life of the organ.

**3. WHAT WILL I BE ASKED TO DO IN THIS STUDY?**

If you decide to take part in this study, you will be asked to provide your blood and/or tissue samples. We will also collection information about your medical care before, during, and after your surgery.

**4. WHY MIGHT I WANT TO TAKE PART IN THIS STUDY?**

There is no direct benefit to you for participating in this study. Other people in the future may benefit from your participation in the study.

**5. WHY MIGHT I NOT WANT TO TAKE PART IN THIS STUDY?**

It may hurt when you are having your blood drawn. There is also a chance that you will have a bruise at the place where the needle is stuck into your arm. There is also a slight chance that the place where the needle is stuck will become infected.

**6. WHAT OTHER OPTIONS ARE THERE?**

Your other option is to not be in this study. Being in this study is voluntary and you do not have to participate.

**7. HOW WILL TAKING PART IN THE STUDY AFFECT ME FINANCIALLY?**

There is no additional cost to you if you take part in this study.

**Detailed Information**

**How Many People Will Take Part In This Study?**

About 19,600 participants will take part in this study at Baylor University Medical Center and/or Baylor Scott & White All Saints Medical Center.

**What Will I be Asked To Do?**

You will be asked to allow the researcher to collect blood or tissues samples from you at specific time points before, during or after your transplant surgery. If you are a kidney donor or recipient or liver donor or recipient, then these blood or tissue samples will only be collected when regular standard of care testing is being performed. However, if you are a uterus recipient or donor and for some reason the research blood sample could not be obtained at the time of your standard of care draw, these blood samples maybe drawn by a separate blood draw if you allow. The specific time points are listed below based on the type of your organ transplant.

Collection of samples will occur as follow:

*If you are a liver donor*: The collection of blood will occur at hospital admission. Volume of blood collected (6 tablespoons or 90 cc)

*If you are a liver recipient*: The collection of blood will occur at hospital admission (8 tablespoons or 120 cc), at the occurrence of Acute Rejection (8 tablespoons or 120 cc), and at annual Follow-Up visit (8 tablespoons or 120 cc),

*If you are a kidney donor:* The collection of blood will occur at hospital admission (about 6 tablespoons or 900 cc)

*If you are a kidney recipient*: The collection of blood will occur at hospital admission (8 tablespoons or 120 cc), at the occurrence of Acute Rejection (8 tablespoons or 120 cc), and at annual Follow-Up visit (8 tablespoons or 120 cc),

*If you are a uterus donor:* The collection of blood will occur at hospital admission for your uterus donation surgery (about 8 tablespoons or 120 cc). During your donation surgery, you will also be asked to allow the researcher to collect 1-2 small additional pieces of tissue samples (the size of a tip of a pencil) from your cervix and/or lymph nodes along with the collection of vaginal fluid with a swab.

*If you are a uterus recipient:*

The collection of blood will be about 8 tablespoons (or 110-120 cc) and will occur as follows:

* At hospital admission for your surgery
* From discharge to Week 4: Every other week visits
* From Week 4 to Pregnancy: Every 4 weeks visits
* From pregnancy to Delivery: Every 4 weeks visits (or more frequently, as needed)
* From discharge to the 2nd Pregnancy or Explant: Every 4 weeks visits
* From explant to Discharge: Daily visits
* Post explant Follow Up: Week 1, Month 1, Month 3, Month 6, Month 12 and Month 24

The collection of 1-2 small additional pieces of tissue samples (the size of a tip of a pencil) from your cervix and or lymph nodes will occur at the following visits if the study doctor feels that it is necessary

* From day of Transplant (Day 0) to Discharge: Once between Day 3 to Day 7
* From discharge to Week 4: Every other week visits
* From week 4 to pregnancy: Every 4 weeks visits
* From pregnancy to delivery: Every 4 weeks visits (or more frequently, as needed)
* Day of Delivery
* From discharge to the 2nd Pregnancy or Explant: Every 4 weeks visits

The collection of 1-2 small additional pieces of tissue samples (the size of a tip of a pencil) from your endometrium will occur at the following visits if the study doctor feels that it is necessary:

* From week 4 to Pregnancy: Every 4 weeks visits
* From discharge to Pregnancy or Explant: Every 4 weeks visits

You will be asked to allow the researcher to collect vaginal fluid with a swab on the day of transplant and placenta tissue on the day of delivery.

The specimen will be stored in a repository at Baylor University Medical Center. The specimens may be shared with investigators outside this study. If we complete our research and no longer need to keep the specimens, we will destroy them. The specimens may be used for genetic testing and to develop new medical products. Neither you nor your doctor will receive research information or test results from the research. Research information and test results will not be placed in your medical record or used in your medical care. There are no plans to pay you for this or other products should this occur.

You will be asked to allow the researcher to review your medical records and copy the information from these records into his/her research charts for this project. This information will be reviewed by the researcher and his/her staff to answer the specific question as outlined above.

**How Long Will I Be In The Study?**

If you are donating an organ, we think you will be in this study for one day. If you are receiving an organ transplant you will be in this study for the rest of your life or the life of the organ.

You can stop taking part in this study at any time. If you decide to stop taking part in the study and want your information removed, you should let the researcher or his/her staff know.

**What Are The Risks of this Study?**

There is a small risk people other than researchers could link your specimen with you. In that case, someone outside the study could learn about your risk for certain diseases. We will protect your confidentiality by removing your name, address, and date of birth from specimens you provided. Instead, we will use numerical codes in your specimens.

**Risks Related to Blood Draw:** It may hurt when you are having your blood drawn. There is also a chance that you will have a bruise at the place where the needle is stuck into your arm. There is also a slight chance that the place where the needle is stuck will become infected.

There are some additional risks if you are uterus recipient. These risks are related to the Cervical and Endometrial Biopsy procedure as follows:

**Risks Related to Cervical Biopsy:** You may bleed after taking a cervical biopsy. There is also a chance that you will have pelvic infection.

**Risks Related to Endometrial Biopsy:** You may bleed after taking an endometrial biopsy. There is a rare chance of pelvic infection and puncture of the uterine wall with the biopsy device.

**What If I am Injured While Taking Part in This Sub-Study?**

The people doing this research project will do everything they can to make sure you do not get hurt during the project. If you do get hurt, you should tell the researcher or his/her staff and they will help you to get necessary medical care. You or your insurance company may need to pay for the medical care. Baylor Scott and White Health, Baylor Scott and White Research Institute, Baylor University Medical Center, and Baylor All Saints in Fort Worth, have not set funds aside to pay you money if you are hurt. You have not given up any of your legal rights by signing this form.

**What About Confidentiality?**

You have a right to privacy. This means that all the information about you from this study will only be shown to the people working on this study. The results of this study may be published in a scientific book or journal. If this is done, your name will not be used. All information about you from this research project will be kept in a locked office or other locked area. Information that is kept on computers will be kept safe from access by people who should not see it.

The privacy law requires that Baylor Scott & White Research Institute (“BSWRI”) and your doctors and other health care providers and facilities that have provided services to you, which could include physicians that work for the Scott & White Clinic, Health Texas Provider Network or Texas Oncology, P.A., Baylor University Medical Center, Baylor Scott & White All Saints Medical Center (BSWASMC), Scott & White Medical Center – Temple and other health care providers depending on where you have received care (collectively, “Your Health Care Providers”) get your permission before giving any of your health information to other people. There are people who need to review your information to make sure this study is done correctly. These people may look at or copy your information while they are doing this review. When you sign this form, you give permission to BSWRI and Your Health Care Providers to give other people information about your health as needed for the research project. These groups include people who work for BSWRI (including the Institutional Review Boards), Baylor Scott and White Health, the US Food and Drug Administration, the Office for Human Research Protections and the Association for the Accreditation of Human Research Protection Programs. Even though we usually remove your name from the information, the people who get this information may be able to figure out who you are. The kinds of health information that might be given to these people include results from lab tests or other tests like x-rays. This information might also include notes and other information in your medical records. We may ask for these notes and other information in your medical records from Your Health Care Providers. This means that the records of your care and information about you maintained by Your Health Care Providers may be given to the people mentioned above and, by signing this form, you are agreeing that Your Health Care Providers may release this information to these people.

* This also might be information about diseases like Human Immunodeficiency Virus (“HIV”) or Acquired Immune Deficiency Syndrome (“AIDS”).
* This could also be information about drug or alcohol abuse.

You do not have to give this permission and it is all right to refuse to sign this form. Your doctor will still treat you and your insurance company will still pay your medical bills (according to their policy) even if you do not give your permission for BSWRI and Your Health Care Providers to release this information. However, since it is important for the people listed above to have access to your information, if you do not sign this form, you cannot be in this study.

If you give permission to BSWRI and Your Health Care Providers to give other people information about your health and the other people are not part of the group that must obey the privacy law, your health information will no longer be protected by the privacy law. However, we will take all reasonable measures to protect your information from being misused.

If you change your mind and later want to withdraw your permission, you may do so. You must notify BSWRI in writing at 3434 Live Oak St., Dallas, TX 75204. Please be sure to tell us the name of this study and the PI for this study for which you are withdrawing your permission. BSWRI will provide your withdrawal notice to Your Health Care Providers promptly after BSWRI receives your withdrawal notice. While not required, you should also talk to your PI and Your Health Care Providers and make sure they are aware you are withdrawing your permission. If you withdraw your permission, it will not apply to information that was given to others by BSWRI before you withdrew or to information given to others by Your Health Care Providers before Your Health Care Providers receive your notice withdrawing your permission. If you withdraw your permission, you will no longer be able to take part in this study.

You may not be allowed to look at your health information during this study. However, at a later time, you will be able to look at this information. This later time will be sometime after this study is completed. Unless permission is withdrawn, this permission will not expire at the end of this study.

**Additional Financial Information**

There are no costs to you for being in this study and you will not be paid for being in this study.

**What are My Rights As a Subject?**

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. If you agree to take part and then decide against it, you can withdraw for any reason.

Deciding not to be in the study, or leaving the study early, will not result in any penalty or loss of benefits that you would otherwise receive.

We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study.

**Whom Do I Call If I have Questions or Problems?**

If you have concerns, complaints or questions about the study or have a research-related injury, contact the Giuliano Testa, MD at 214-820-2050.

For concerns, complaints or questions about your rights as a research subject or if you simply wish to speak with someone who is not a part of the research staff, contact the IRB Office at 214-820-2687.

**Statement of Person Obtaining Consent:**

I have explained to the purpose of this study, the procedures required and the possible risks and benefits to the best of my ability. They have been encouraged to ask questions related to taking part in this study. I gave a copy of this consent to the subject.

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Signature of Person Obtaining Consent Date Time

**Confirmation of Consent by Research Subject:**

You are making a decision about being in this research study. You will be asked to give your written consent if you want to be in this study. Giving consent is like giving permission. You should not give your permission to be in this study until you have read and understood all the pages in this form. If you cannot read, then someone can read the form to you. Make sure that all your questions about this study have been answered before you sign this form. When you sign this form, you are giving your permission to be in the study. By signing this form, you have not given up any of your legal rights or released anyone from liability for negligence.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ has explained to me the purpose of this study, the study procedures that I will have, and the possible risks and discomforts that may happen. I have read (or have been read) this consent form. I have been given a chance to ask questions about the research study and the procedures involved. I believe that I have enough information to make my decision. I have also been told my other options. To the best of my knowledge, I am not in any other medical research. Therefore, I consent to take part as a subject in this study and authorize the activities described in this consent. I also acknowledge that I have received a copy of this consent form.

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Signature of Subject Date Time