THE UNIVERSITY OF CHICAGO
ADULT CONSENT FORM/HEMATOPOIETIC STEM CELL TRANSPLANT
RECIPIENT
The Division of the Biological Sciences-The University of Chicago Medical Center

CONSENT/AUTHORIZATION BY SUBJECT FOR PARTICIPATION IN A
RESEARCH PROTOCOL

Protocol Number: IRB12-1856

Name of Subject: ____________________________

Medical Record Number: _________________________

Study Title: The University of Chicago Transplant Immunology and Immunogenetics Laboratory Research Registry and Specimen Collection Protocol for Biomedical Research

Principal Investigator
Susana Marino MD, PhD, D(ABHI)
Director of Transplant Immunology and Immunogenetics Laboratory
Associate Professor of Pathology
University of Chicago Medical Center
5841 S. Maryland Ave. MC 0006
Chicago, Illinois 60637
(773) 702-1606

Co-Investigators:
(Stem Cell Transplant Program)
Dr. Andrew Artz, MD, MS
Assistant Professor of Medicine
5841 S. Maryland Ave. MC 2115
Chicago, IL 60637
(773) 834-8980

Dr. Hongtao Liu. MD, PhD
Instructor of Medicine
5841 S. Maryland Ave. MC 2115
Chicago, IL 60637
(773) 834-0589

You are being asked to participate in a research study. A member of the research team will explain what is involved in this study and how it will affect you. This consent form describes the study procedures, the risks and benefits of participation, as well as how your confidentiality will be maintained. Please take your time to ask questions and feel comfortable making decision whether to participate or not. This process is called informed consent. If you decide to participate in this study, you will be asked to sign this form.

WHY IS THIS STUDY BEING DONE?
You are being asked to participate in this study because you are a potential stem cell transplant recipient.

The purpose of this study is to collect blood samples for future research. Research with these samples can lead to a better understanding of recipient/donor compatibility and donor selection, as well as to improve recipient survival with this treatment option.

**HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?**

About 100 people will take part in this study at the University of Chicago.

**WHAT IS INVOLVED IN THE STUDY?**

During your scheduled appointment(s), two to three blood samples (about 2-3 tablespoons) will be drawn for clinical testing to assess for donor/recipient compatibility. All samples will be sent to the Transplant Immunology and Immunogenetics Laboratory (TIIL) for analysis. All stem cell transplant donors and recipients considered for transplantation will undergo HLA (human leukocyte antigen) testing. The human leukocyte antigens are genetic fingerprints that help the body distinguish between its own cells and what is foreign and is a necessary blood test to assess for donor/recipient compatibility or match. The results of your testing will be given to you by a member of the transplant team.

There may be some leftover blood from your samples after analysis has been completed that would otherwise be thrown away. We would like your permission to collect, store, and use all leftover blood samples for future research purposes. Along with your routine blood collection to assess for recipient/donor compatibility, we ask you to donate two additional blood samples (about 2-3 tablespoons) before the transplant and after the transplant for research purposes.

Along with HLA testing (genetic testing), we will perform other genetic tests in the future on your samples. Genes are the material that is passed from parents to children that determines the make-up of the body. The results of future genetic testing will not be shared with you. In addition your samples will be used to set up functional assays for detecting the best recipient/donor match in a laboratory setting. The doctors directing the research will receive the results of these tests and will use this information for the purpose of the research study.

Your samples collected for this study will be used for approved research at the University of Chicago. Your samples may be shared with outside institutions for collaborative research. However, your samples will not contain any information that can identify you. Your samples will not be sold.

Research using pre-transplant samples for research along with the corresponding medical information and recipient questionnaires is an important way to understand transplant recipient/donor matching along with problems that may be noted after transplantation.
The doctors directing this study will collect information about you for the purpose of the research. The following information will be collected from your medical record now and for the next 10 years: name, date of birth, race, ethnicity, gender, medical record number, vital signs (blood pressure, pulse, respirations), height, weight, educational status, state/country currently living in, country of birth, countries lived in, admitting diagnosis, clinical presentation (signs & symptoms), sensitizing events (transfusions, pregnancies, previous transplants), physicians names, surgical and biopsy procedures (previous transplants, specimen and related hematology/pathology reports, results of tissue samples from other institutions, occupational exposure(s), allergies, smoking history, history of recreational drugs, alcohol history, diet, medications, past medical history, family medical history, information regarding the transplant recipient including HLA testing, radiographic imaging results, hospitalizations at outside institutions and course of treatment, clinical outcomes, and medical outcomes from an illness.

HOW LONG WILL I BE IN THE STUDY?

Your participation in this study will consist of two pre-transplant and two post-transplant visits, but in some instances, the physician evaluating you as a transplant recipient may require additional blood samples for clinical testing obtained at a future visit. Left over specimens may be used for research purposes. Your blood samples will be stored and used indefinitely.

WHAT ARE THE RISKS OF THE STUDY?

The risks of participating in this study may be a minor discomfort to you from the needle puncture to obtain a blood sample. Associated risks with drawing blood include: inflammation, swelling, infection (rare), bleeding from the site of puncture. Special care by the doctor, trained/certified phlebotomist (an individual specially trained in drawing blood) or nurse collecting the sample will be taken to avoid any complications. The risk to you is the potential breach of privacy or disclosure of your medical information. The likelihood that an unauthorized individual could identify you is extremely small. However, complete confidentiality cannot be 100% guaranteed.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there will not be a direct medical benefit to you. We hope the information learned from studies utilizing your samples will benefit other individuals undergoing stem cell transplantation in the future.

WHAT OTHER OPTIONS ARE THERE?

You may choose not to participate. The decision of whether or not you wish to participate in this study will not affect your care at the University of Chicago Medical Center.

WHAT ARE THE COSTS?
Clinical services provided during a research study are either research-related or related to usual medical care. Research-related services are done to complete the research and the costs are not the responsibility of you or your insurance.

The costs that are considered research-related for this study include the following: the collection of blood samples, the processing and storage, testing and analysis of these research samples. Dr. Susana Marino will be responsible for these costs. You and your insurance carrier will not be responsible for any cost related to the research only cost.

Usual medical care costs include any and all services that are considered medically necessary for your disease. The cost of this usual, ongoing medical care will be the responsibility of you or your insurance, and may include deductibles and co-payments. Similarly, this care will be subject to all the same requirements and restrictions of your insurance. The standard of care services includes clinic visits, examinations, the collection of standard blood samples, processing, testing and analysis of these standard samples.

If you suffer an unanticipated injury as a direct result of this research and require emergency medical treatment, the University of Chicago Medical Center will provide such treatment at the University of Chicago Medical Center at no cost to you. You must notify Dr. Susana Marino as promptly as possible after your injury in order to receive this care. An injury is “unanticipated” if it is not one of the known effects of a study drug, medical device or procedure, and is not the result of your disease or condition. The costs of any non-emergency care for such an injury will be billed to you or your insurance in the ordinary manner. If you think that you have suffered a research related injury, you must let Dr. Susana Marino know right away.

WILL I BE PAID FOR MY PARTICIPATION?

You will not be paid for participation in this study. Your samples may be used for the development of diagnostic methods, new therapies, medicines, treatments for diseases, and material or other development, which may be patented or otherwise have commercial value. However, there are no plans to compensate you in the event commercial development using your blood takes place.

WHAT ABOUT CONFIDENTIALITY?

Study records that identify you will be kept confidential. Your samples will be coded and labeled with a randomized barcode number. Research related information will be available to immediate research personnel. Research information about you will be stored in a locked office in a password protected database and will not be entered into any University of Chicago records. The data collected in this study will be used for the purpose described in the form. By signing this form, you are allowing the research team access to your medical records, which include Protected Health Information. Protected Health Information (PHI) consists of any health information that is collected about you, which could include your medical history and new information collected as a result of
this study. The research team includes the individuals listed on this consent form and other personnel involved in this study at the University of Chicago.

It is possible in the future for your sample(s) to be used for collaborative research with outside institutions. If your sample(s) will be used for collaborative research outside the University of Chicago, your sample will be de-identified. No personal information or identifying information about you will be shared outside the University of Chicago.

Your records may be reviewed by federal agencies whose responsibility is to protect human subjects in research including the Food and Drug Administration (FDA) and Office of Human Research Protections (OHRP). In addition, representatives of the University of Chicago, including the Institutional Review Board, a committee that oversees the research at the University of Chicago, may also view the records of the research. If your research record is reviewed by any of these groups, they may also need to review your entire medical record.

If health information is shared outside the University of Chicago, the same laws that the University of Chicago must obey may not protect your health information.

The results from clinical testing will become part of your medical record. During your participation in this study, you will have access to your medical record. The doctors listed on the first page of this form are not required to release to you research information that is not part of your medical record.

The consent form will be kept by the research team for at least six years. Study results will be kept in your research file and be used by the research team indefinitely. At the time of study completion, either the research information not already in your medical record will be destroyed or information identifying you will be removed from study results. Any research information in your medical record will be kept indefinitely.

Data from this study may be used in medical publications or presentations. Your name and other identifying information will be removed before this data is used. If we wish to use identifying information in publications, we will ask for your approval at that time.

The Genetic Information Nondiscrimination Act (GINA) is a federal law that may help protect you from health insurance or employment discrimination based on genetic information. GINA is a federal law that will protect you in the following ways:

- Health insurance companies and group plans may not request genetic information from this research;
- Health insurance companies and group plans may not use your genetic information when making decisions regarding your eligibility or premiums;
- Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment.
GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. If you choose not to participate in this study, your care at the University of Chicago/University of Chicago Medical Center will not be affected. You may choose not to participate at any time during the study. Leaving the study will not affect your care at the University of Chicago/University of Chicago Medical Center.

If you choose to no longer be in the study and you do not want any of your future health information to be used, you must inform Dr. Susana Marino or Dr. Andrew Artz in writing at the address on the first page.

You will be given a signed copy of this document. This consent form document does not have an expiration date.

WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

You have talked to ________________________________________________________ about this study and you had the opportunity to ask questions concerning any and all aspects of the research. If you have further questions about the study, you may call Dr. Susana Marino at (773)702-1606.

If you have any questions concerning your rights in this research study you may contact the Institutional Review Board, which is concerned with the protection of subjects in research projects. You may reach the Committee office between 8:30 am and 5:00 pm, Monday through Friday, by calling (773) 702-6505 or by writing: Institutional Review Board, University of Chicago, McGiffert Hall, 2nd Floor, 5751 S. Woodlawn Avenue, Chicago, Illinois 60637.

CONSENT

SUBJECT

The research project and the procedures associated with it have been explained to me.

I have agreed to participate in this study. My participation is voluntary and I do not have to sign this form if I do not want to part of this research study.

Signature of Subject:_______________________________________________________

Date:___________________ Time:__________________________AM/PM (circle)
PERSON OBTAINING CONSENT

I have explained to____________________________________________________the
nature and purpose of the study and the risks involved. I have answered and will answer
all questions to the best of my ability. I will give a signed copy of the consent form to the
subject.

Signature of Person Obtaining Consent:________________________________________

Date: _____________________________ Time:__________________ AM/PM (Circle)

INVESTIGATOR/PHYSICIAN

Signature of Investigator/Physician:___________________________________________

Date:______________________ Time: ________________________ AM/PM (Circle)