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[redacted]

SUBJECT CONSENT TO TAKE PART IN A RESEARCH STUDY

Post-Transplant Use of Irradiated Allogeneic Cells - PATIENT

Principal Investigator: [redacted]

This consent form is part of an informed consent process for a research study and it will provide information that will help you to decide whether you wish to volunteer for this research study. It will help you to understand what the study is about and what will happen in the course of the Study.

If you have questions at any time during the research study, you should feel free to ask them and should expect to be given answers that you completely understand.

After all of your questions have been answered, if you still wish to take part in the study, you will be asked to sign this informed consent form.

You are not giving up any of your legal rights by volunteering for this research study or by signing this consent form.

Who is conducting this research study?

[redacted] is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the study. However, there are often other individuals who are part of the research team.

The study doctor (the principal investigator) or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Why is this study being done?

Physicians at [redacted] previously showed that transfusion of immune cells from relatives can sometimes cause the patient's cancer to decrease in size. We are now performing a study to determine if using these same cells (i.e immune cells from relatives) after a transplant can improve the results of the transplant. There are two major things we hope to learn from this study. The first is to determine if administering the immune cells from a closely

related person (parent, child or sibling) after a transplant results in side effects for the patient. The second reason to do the study is to determine if using these cells can help control the patient's cancer.
There will be 2 groups of patients. Both groups will have hematologic malignancies (blood derived cancers such as leukemia, lymphoma, multiple myeloma or related disease):

Group 1 will be composed of patients who have undergone high dose chemotherapy followed by treatment with their own stem cells (***autologous*** stem cell therapy) but remain at high risk for relapse. They will have received high dose chemotherapy to kill cancer cells and then receive their own stem cells to help them recover from the chemotherapy. These patients will then receive experimental immune cells from a relative (the donor) several weeks after they have received their own stem cells. The purpose of administering the donor's immune cells is to determine if they can stimulate the patient's own immune cells to attack the cancer.

Group 2 will be composed of patients who have undergone a transplant using stem cells from a donor (an ***allogeneic*** hematopoietic stem cell transplant) but remain at high risk for relapse (or have already relapsed). Description of the procedure for patients in Group 2 is complicated because participants in the clinical trial in this Group of patients will have 2 donors. The donors are two separate people. The first donor is the standard stem cell donor used in the transplant. They will be referred to as the "standard" donor. It is the cells from the standard donor that result in recovery of blood counts and the development of the immune system of the patient. The second donor (referred to as the "experimental cell donor") will provide the immune cells used in this study. Issues related to the standard stem cell donor are covered in the allogeneic stem cell transplant consent form. This consent form addresses the experimental use of immune cells from the "experimental cell donor" several weeks or longer after the use of the standard stem cell donor. The purpose of using the experimental cell donor cells is to determine if they can stimulate the standard donor's cells to attack the cancer.

Why have you been asked to take part in this study?

You have been asked to participate in the study because you have a hematologic malignancy (a blood cell cancer) that is being treated with stem cell therapy but is at very high risk for either being resistant to the treatment or relapsing after the treatment.

Who may take part in this study? And who may not?

You may participate if you:

- Are 18 years or older
- Have a "high-risk" hematologic malignancy (leukemia, lymphoma, myelodysplasia, multiple myeloma or related disease anticipated to have >80% relapse rate within 2 years after stem cell transplant)
- Are scheduled to undergo high dose chemotherapy with autologous stem cell rescue OR

[redacted] scheduled to (or have previously) undergone an allogeneic hematopoietic stem cell transplant
- Have a relative (child, parent or sibling) who has the appropriate tissue typing (genetic parents and full children will almost always be the appropriate tissue types and ½ of full siblings will have an appropriate tissue type)

You may not participate if you are:

- Pregnant
-

The study doctor and/or research team may also ask you other questions about your medical history in order to make sure you qualify to be in this study.

How long will the study take and how many subjects will participate?

Patients will be enrolled over a 3 year period of time.

A total of 20 subjects will complete the study. There will be 10 patients in each group. There will be an experimental cell donor corresponding to each patient. There may be additional potential experimental cell donors screened if a donor fails the screening.

Each patient will participate in the study for 3 infusions and then be followed up to 3 years.

What will you be asked to do if you take part in this research study?
You will be treated at Rutgers Cancer Institute of New Jersey and receive standard treatment of care for your underlying disease and management of complications of your transplant. The transplant risks associated with the standard therapy are described in the consent forms for the standard transplant procedure (Group 1 – high dose chemotherapy with autologous stem cell rescue; Group 2 – allogeneic hematopoietic stem cell transplantation) that you have read and signed. If you consent to participate in this study you will have additional blood work obtained every 30 days (4 tubes of blood, for select patients only) and treatment with immune cells from a relative as frequently as every 8 weeks for up to 3 treatments.

Group 1 Patients will be treated initially with the experimental immune cells within 42 days after recovery of blood counts following receiving their own stem cells.

Group 2 Patients will be treated initially with experimental immune cells within 120 days after recovery of blood counts following receiving the standard donor's stem cells.

If you have received an allogeneic transplant (from a standard donor) and experience a relapse of the cancer, you may receive experimental immune cells at any time after the standard transplant.

What are the risks and/or discomforts you might experience if you take part in this study?

[redacted]

[redacted]

[redacted] risks and/or discomforts for you being treated with either an autologous or allogeneic transplant are standard and described in the consent forms for these procedures. These standard transplant procedures are very high-risk procedures and they are associated with bleeding, infection and organ (lung, liver, kidney, intestinal, heart, gastrointestinal, neurologic, oral, and other) toxicity.

In addition, an allogeneic transplant is associated with long-term risk of graft-versus-host-disease, which can also lead to long-term organ damage. As described in the consents for these standard procedures these toxicities can be irreversible and result in death. You will sign a separate informed consent form from the Blood and Marrow Transplant Program for this experimental part of your care. The added risks of the experimental cells administered as part of this study include

- The possibility of fevers
- Chills
- Shortness of breath
- Night sweats when the cells are administered
- There is also the potential for excessive activation of the patient's immunity resulting in organ damage manifested as shortness of breath, diarrhea and weakness
- There may also be unexpected adverse effects
- There may also be the discomfort of having blood drawn

For patients who are in **Group 2**, apart from above risks,

- There is also the possibility that administering the experimental donor cells may result in increasing the incidence or severity of organ toxicity associated with graft-versus-host-disease or result in graft rejection. Special tests will be done to minimize the risk of this occurring and the cells are treated to decrease the risk of these outcomes. However if graft-versus-host-disease or graft rejection occurs it can result in low blood counts, infection, bleeding, and organ toxicity. These adverse effects can be severe and result in death.

Are there any benefits for you if you choose to take part in this research study?

The benefit of taking part in this study is that there may be better control of your cancer. However, it is possible that you might receive no direct personal benefit or be harmed from taking part in this study.

What are your alternatives if you don't want to take part in this study?

Your alternative is not to take part in this study. If you do not participate in this study you will receive standard transplant therapy.

[redacted]

[redacted]

How will you know if new information is learned that may affect whether you are willing to stay in this research study?
During the course of the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will there be any cost to you to take part in this study?

There will be no added cost for you to take part in this study. The experimental immune cells will be provided to you at no cost to you. You or your insurance will be charged for standard of care treatment. You are responsible for any copay, deductible or other standard treatment as part of your routine care. The adverse effects related to the experimental therapy are standard complications of the transplant process and will be billed to your insurance company.

How will information about you be kept private or confidential?

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

[redacted] to public view. Only the study doctor and research team will have direct access.

What will happen if you are injured during this study?

Participants in this study will be exposed to certain risks of personal injury associated with standard forms of treatment. In addition, it is possible that during the course of this study, new adverse effects that result in personal injury may be discovered.

The University will make appropriate referrals for medical and/or dental treatment for participants who sustain personal injuries or illnesses as a direct consequence of participation in the research. The participant's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University.

What will happen if you do not wish to take part in the study or if you later decide not to stay in the study?

[redacted]

Title: [redacted]

[redacted] in this study is voluntary. You may choose not to participate or you may change your mind at any time.

If you do not want to enter the study or decide to stop participating, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to [redacted]

Any data that has already been collected cannot be withdrawn because there may not be any identifiers with the data.

At any time, the study doctor can take you out of this study because it would not be in your best interest to stay in it. Your study doctor can stop treatment even if you are willing to stay in the study.

If you decide to withdraw from the study for any reason, you may be asked to return for at least one additional visit for safety reasons.

Who can you call if you have any questions?
If you have any questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the study doctor:

[redacted]

[redacted] as a research participant, you can call:

[redacted]

Human Subject Protection Program
[redacted]

[redacted] **are your rights if you decide to take part in this research study?**
You have the right to ask questions about any part of the study at any time. You should not sign this form unless you have had a chance to ask questions and have been given answers to all of your questions.

[redacted]

[redacted]

PERMISSION (Authorization) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

Information about you and your health is personal and private, so this information generally cannot be used in research without your written permission. The next few paragraphs tell you about how researchers want to use and share your health information in this research study. Your information will only be used as described here or as allowed or required by law. Ask questions if you do not understand any part of the research or the use of your health information. If you sign this consent form, you agree to let the researchers use your information in the research and share it with others as described below.

What is the purpose of the research and how will my information be used?

You are being invited to take part in this research study which is described at the beginning of this form.

The purpose of collecting and using your health information for this study is to help researchers answer the questions that are being asked in the research.

What information about me will be used?

- All information in your medical record
- Hospital discharge summaries
- Radiology records or images (MRI, CT, PET scans)
- Medical history or treatment
- Medications
- Consultations
- Laboratory/diagnostic tests or imaging
- EKG and/or EEG reports
- Pathology reports, specimen(s) or slide(s)
- Emergency Medicine reports

Who may use, share or receive my information?

The research team may use or share your information collected or created for this study with the following people and institutions:

- [redacted]

[redacted]

- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- United States of America's Food and Drug Administration (FDA)

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I be able to review my research record while the research is ongoing?

No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I have to give my permission?

No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this research study. Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.

If I say yes now, can I change my mind and take away my permission later?

Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell him of your decision: Dr. Roger Strair (address provided on first page)

How long will my permission last?

Your permission for the use and sharing of your health information has no set date when your permission will end. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

NOTE SIGNATURE PAGE FOLLOWS IMMEDIATELY

[redacted]

AGREEMENT TO PARTICIPATE

1. Subject consent:

I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered. I agree to take part in this research study.

Subject Name:_____

Subject Signature:_____ Date:_____

2. Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legally authorized representative have been accurately answered.

Investigator/Person Obtaining Consent (printed name):_____

Signature:_____ Date: _____

[redacted]