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Masonic Cancer Center, University of Minnesota

SCREENING CONSENT

Phase I/II Study of Human Chorionic Gonadotropin and Epidermal Growth Factor Supplementation (Pregnyl®) to Support Tolerance and Repair As Adjunct Therapy in High-Risk or Refractory Acute Graft-Versus-Host Disease

High-risk aGVHD – ARM 1

Principal Investigator:
Shernan G. Holtan, MD
Division of Hematology, Oncology and Transplantation

For questions about research appointments, the research study, research results, or other concerns, contact the study team at:

Lead Investigator: Dr. Shernan Holtan
Phone Number: (612) 301-1095
Email Address: sgholtan@umn.edu

The study will be conducted at 2 cancer research centers around the United States; however the University of Minnesota is the lead institution and Shernan Holtan, MD from Hematology, Oncology and Transplantation is the principal investigator (the physician in charge) of this research study. Up to 88 patients will be treated on this study nationally: 78 at the University of Minnesota and 10 at Rush University in Chicago, IL.

You are invited to participate in this research study because you have acute Graft-Versus-Host Disease (GVHD), a complication of your recent hematopoietic cell transplant. To be considered for this study you must be between the ages of 0 and 76 years and have acute GVHD which, because of its severity, is at a high-risk of not being controlled by the usual therapy alone.

You may be eligible for a therapy for GVHD that involves using a drug called Pregnyl, also known as hormone human chorionic gonadotropin (HCG). Pregnyl is approved by

the United States Food and Drug Administration (FDA) to treat infertility in women by stimulating ovulation as well as to treat testicle development issues in males. Its use in acute GVHD is considered investigational.

However, before doing a full evaluation, we are requesting permission to do some pre-testing on a blood sample to see if you have a specific biomarker in your blood. A biomarker is a measureable substance in your body that is a sign or a predictor of whether or not you have a disease, or how a disease may react to therapy. The biomarker we are looking for in this case, amphiregulin, is a protein that can be used to define your risk for GVHD.

You are asked to read this form before you agree to the pre-screening process. If you have any questions, we will make sure they are answered before you agree.

If you agree by signing this consent form, a blood sample will be collected.

The pre-screening blood sample will be tested as follows:

Your blood will be tested for the **amphiregulin biomarker**.

The biomarker will help determine whether or not you may be eligible for this study and/or which part of the study treatment may be the most beneficial.

Risks

You will have slightly less than 1 tablespoon of blood collected. The risks of having **blood drawn** include pain, bruising and/or redness where the blood is drawn from your arm. Rarely this place where the needle is stuck in becomes infected (red, warm, swelling). Some people feel faint (like they may pass out) when having blood drawn, but this can be avoided by looking away.

Benefits

There will be no benefit to you for the pre-screening. You will not be paid.

Costs

The costs of this lab test is paid for by the study.

Research Related Injury

In the event that this research activity results in an injury, treatment is available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company. If you think you have suffered a research related injury, let someone associated with the study know right away.

Confidentiality

The records of this study will be kept private. Information gained from this study will be used for research and educational purposes. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical record for research, quality assurance, and data analysis include:

- Departments at the University of Minnesota with appropriate regulatory oversight
- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people

To this extent, confidentiality is not absolute.

A description of this clinical trial will be available at http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Use Of Identifiable Health Information

Your PHI created or received for the purposes of this study is protected under the federal regulation known as HIPAA. Refer to the attached HIPAA authorization for details concerning the use of this information.

Right To Say No

The decision to have your blood pre-screened is completely up to you. If you do not want to be considered for this study, you have the right to say no.

Contacts and Questions

Information for contacting the study Principal Investigator is provided on the 1st page of this document.

This research has been reviewed and approved by an Institutional Review Board (IRB) within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 or go to www.irb.umn.edu/report.html. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

FEEDBACK

After the study, you may be asked to complete a survey about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey after the study is over, but you would like to share feedback, please contact the study team or the Human Research Protection Program (HRPP). See the "Contacts and Questions" section of this form for study team and HRPP contact information.

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Statement of Consent

I have read it or it has been read to me. I have had my questions answered. I agree to have blood collected and tested as a pre-screening for a study on GVHD treatment.

_____ _____

Signature of subject /legally authorized representative Date

_____

Printed Name of subject/legally authorized representative

_____ _____

Signature of the researcher obtaining consent Date

_____

Printed Name of the researcher obtaining consent

WITNESS STATEMENT:

The participant was unable to read or sign this consent form because of the following reason:

☐ The participant is unable to read the information
☐ The participant is visually impaired
☐ The participant is non-English speaking
☐ The participant is physically unable to sign the consent form. Please describe:

_____

☐ Other (please specify):

_____

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For the Consent of Non-English Speaking Participants when an Interpreter is Used:
As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

_____ _____
Signature of Interpreter Date

_____
Printed Name of Interpreter

OR:

Statement from a Non-Interpreter:
As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

_____ _____
Signature of Individual Date

_____
Printed Name of Individual