ADULT CONSENT - CLINICAL BIOMEDICAL
The Patients' Experience After Stem Cell Transplant

Title of this Research Study
An Expanded Framework to Measure Cognitive Function in Older Adults Undergoing Hematopoietic Cell Transplantation

(Short Title: The Patients' Experience After Stem Cell Transplant)

Invitation
You are invited to take part in this research study. You have a copy of the following, which is meant to help you decide whether or not to take part:

- Informed consent form
- "What Do I need to Know Before Being in a Research Study?"
- "The Rights of Research Subjects"

Why are you being asked to be in this research study?
We are inviting you to participate in this research study because you are:

- Between the ages of 60 and 85
- Have a hematological malignancy
- Considering having a stem cell transplant
- Can read, write, speak, and understand English.

AND none of the following are true for you:

- History of autologous or allogeneic stem cell transplant at anytime in the past
- History of cancer CNS involvement
- History of cranial irradiation or intrathecal chemotherapy. You are still eligible if you had prophylactic intrathecal chemotherapy.
- History of stroke, major or moderate head injury (loss of consciousness >60 minutes or structural brain changes on imaging (if available)), history of brain surgeries, seizure disorder, or demyelinating disorder (ex. multiple sclerosis, etc.)
- Current or past substance use disorder related to alcohol or illicit substances
- Uncorrected vision loss
- Primary psychiatric disorder that required you to stay in the hospital in the last year

If you are pregnant, nursing an infant, or plan to become pregnant during this study, you may not be in this study.

What is the reason for doing this research study?
The purpose of the study is to better understand how stem cell transplant may affect

thinking abilities and whether these changes affect day-to-day activities and quality of life. It is important to us to understand patients experiences so we can provide support in the recovery after a stem cell transplant.

What will be done during this research study?
Once you agree to participate in the research by signing this consent form the following activities will take place:
There are four study visits and each will consist of:
1) assessments of memory and thinking tasks
2) assessments of balance, strength, and endurance. This involves walking, standing, sitting, and squeezing a machine to capture your grip strength.
3) questionnaires about mood, social support, nutrition, quality of life, daily activities, fatigue, physical activity, and symptoms.
4) you will be asked to participate in an interview about your experience of returning to life activities before and after stem cell transplant at 6 and 12 months.
5) at each study visit the study team will collect information from your medical record (or a separate registry you have joined) that relates to your cancer diagnosis, treatment, hospitalizations, complications, medications, lab values, and current health status. Approximately once a year thereafter we will collect information from your medical record about the effects of your treatment, complications and survival.

Study visits take place **before transplant** and **after transplant at 100 days, 6 and 12 months**. If you choose to do the interviews, it may take place during your study visit **before transplant and after transplant at 6 and 12 months.**These visits can be scheduled along with your oncology appointments or at a time that is convenient for you.

To allow enough time for the consent process and filling out required documentation, we ask that you allow 2 hours per visit.

At the first study visit, we will collect a saliva sample. We will look at variation in genes that may have a relationship with one's memory and thinking abilities after cancer treatment. We do not know if such a relationship exists with stem cell transplant. The results will not be linked to your name and will not be shared with anyone. We anticipate that the results will be preliminary and future studies will be needed to validate the results.

If you choose to participate in the interviews, they will be recorded so we can transcribe it to ensure we accurately capture all of the information provided. Within 1-2 weeks after the study visit, you will receive a call from a member of the study

team to discuss your experience with the interview and to make sure we address any questions or concerns.

The recordings and transcription will be stored in a secured file on a server at UNMC. The recordings will be destroyed within 3 months of completing the final study analysis.
After the interview is transcribed and analyzed, you will receive a summary of the interview to review over and make any corrections. A member of the study team may call you to clarify what was discussed in the interview to help better understand your experience returning to life activities.

What are the possible risks of being in this research study?
Some of the activities and surveys might be frustrating or mentally tiring. You will be given opportunities to take breaks and can stop at any time.

During the interview, you may refuse to answer any questions and stop the interview at any time.

There is a risk of falling with strength, balance and endurance assessments. The research team is trained to minimize falling. You may use an assistive device or choose not to complete the assessments if you feel uncomfortable.

There is a risk of loss of the confidentiality of your medical information. We will use identification codes and not your name to identify the information we collect for the study. All data is stored on an encrypted, password protected server or in a locked cabinet in a locked office.

What are the possible benefits to you?
You are not expected to get any benefit from being in this research study.

What are the possible benefits to other people?
We hope that in the future other people may benefit from this study because the results will help identify patients at risk for poor outcomes and help us understand how to best provide education and support for patients and families before and after transplant.

What are the alternatives to being in this research study?
Instead of being in this research study, you can choose not to participate.

What will being in this research study cost you?

You and your insurance company will be responsible for any charges associated with your regularly scheduled appointments with your healthcare team, including geriatrics, oncology, and other departments.

Will you be paid for being in this research study?
You will be paid with a $50 gift-card for each of the visits you complete. You will receive an additional $25 gift cards for participating in interviews before transplant and then at 6 and 12 months.You will receive the gift card at the end of the Research Visit.

Who is paying for this research?
A grant from the National Institute of Health and UNMC is funding this study. The University and the research team are not receiving payments from other agencies, organizations, or companies to conduct this research study.

What should you do if you are injured or have a medical problem during this research study?
Your welfare is the main concern of every member of the research team. If you are injured or have a medical problem or some other kind of problem as a direct result of being in this study, you should immediately contact one of the people listed at the end of this consent form.

How will information about you be protected?
You have rights regarding the protection and privacy of your medical information collected before and during this research. This medical information is called "protected health information" (PHI). PHI used in this study may include your medical record number, address, birth date, medical history, the results of physical exams, blood tests, x-rays as well as the results of other diagnostic medical or research procedures. Only the minimum amount of PHI will be collected for this research. Your research and medical records will be maintained in a secure manner.

Who will have access to information about you?
By signing this consent form, you are allowing the research team to have access to your PHI. The research team includes the investigators listed on this consent form and other personnel involved in this specific study at the Institution.

Your PHI will be used only for the purpose(s) described in the section What is the reason for doing this research study?

You are also allowing the research team to share your PHI, as necessary, with other

people or groups listed below:

- The UNMC Institutional Review Board (IRB)
- Institutional officials designated by the UNMC IRB
- Federal law requires that your information may be shared with these groups:
    - The HHS Office for Human Research Protections (OHRP)
    - National Institutes of Health (NIH)
- The HIPAA Privacy Rule requires the following groups to protect your PHI:
    - Your health insurance company
    - The Fred & Pamela Buffett Cancer Center Scientific Review Committee (SRC)

You are authorizing us to use and disclose your PHI for as long as the research study is being conducted.

You may cancel your authorization for further collection of PHI for use in this research at any time by contacting the principal investigator in writing. However, the PHI which is included in the research data obtained to date may still be used. If you cancel this authorization, you will no longer be able to participate in this research.

How will results of the research be made available to you during and after the study is finished?
In most cases, the results of the research can be made available to you when the study is completed, and all the results are analyzed by the investigator or the sponsor of the research. The information from this study may be published in scientific journals or presented at scientific meetings, but your identity will be kept strictly confidential.

If you want the results of the study, contact the Principal Investigator at the phone number given at the end of this form or by writing to the Principal Investigator at the following address:
Home Instead Center for Successful Aging
Attn: Thuy Koll
730 South 38th Ave
Omaha, NE 68198

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

What will happen if you decide not to be in this research study?
You can decide not to be in this research study. Deciding not to be in this research will not affect your medical care or your relationship with the investigator or the Institution. Your doctor will still take care of you and you will not lose any benefits to which you are entitled.

What will happen if you decide to stop participating once you start?
You can stop participating in this research (withdraw) at any time by contacting the Principal Investigator or any of the research staff. Deciding to withdraw will otherwise not affect your care or your relationship with the investigator or this institution. You will not lose any benefits to which you are entitled. You may be taken off the study if you do not follow instructions of the investigator or the research team, withdraw your consent, do not receive a stem cell transplant, or receive more than one stem cell transplant during the study time period.

Any research data obtained to date may still be used in the research.

Will you be given any important information during the study?
You will be informed promptly if the research team gets any new information during this research study that may affect whether you would want to continue being in the study. If any issues are identified from your questionnaires or assessments, we will work with your transplant team to address the issues.

What should you do if you have any questions about the study?
You have been given a copy of "*What Do I Need to Know Before Being in a Research Study?*" If you have any questions at any time about this study, you should contact the Principal Investigator or any of the study personnel listed on this consent form or any other documents that you have been given.

What are your rights as a research participant?
You have rights as a research subject. These rights have been explained in this consent form and in "The Rights of Research Subjects" that you have been given. If you have any questions concerning your rights, or want to discuss problems, concerns, obtain information or offer input, or make a complaint about the research, you can contact any of the following:

- The investigator or other study personnel
- Institutional Review Board (IRB)
    - Telephone: (402) 559-6463.
    - Email: IRBORA@unmc.edu
    - Mail: UNMC Institutional Review Board, 987830 Nebraska Medical

Center, Omaha, NE 68198-7830

- Research Subject Advocate
  - Telephone: (402) 559-6941
  - Email: unmcrsa@unmc.edu

Documentation of informed consent

You are freely making a decision whether to be in this research study. Signing this form means that:

- You have read and understood this consent form.
- You have had the consent form explained to you.
- You have been given a copy of The Rights of Research Subjects
- You have had your questions answered.
- You have decided to be in the research study.
- If you have any questions during the study, you have been directed to talk to one of the investigators listed below on this consent form.
- You will be given a signed and dated copy of this consent form to keep.

Signature of Subject _____
Date _____

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the subject. In my judgment, the subject possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate.

Signature of Person obtaining consent _____
Date _____

Authorized Study Personnel
Principal
* Koll, Thuy
phone: 402-559-7519
alt #: 402-490-1294
degree: MD

Lead Coordinator
* Free, Marcia (Marcia)
phone: 402-552-7623
alt #: 402-552-7623
degree: RN

What Do I Need To Know Before Being In A Research Study?

You have been invited to be in a **research study**. Research studies are also called "clinical trials" or "protocols." **Research** is an organized plan designed to get new knowledge about a disease or the normal function of the body. The people who are in the research are called **research subjects**. The **investigator** is the person who is running the research study. You will get information from the investigator and the research team, and then you will be asked to give your **consent** to be in the research.

This sheet will help you think of questions to ask the investigator or his/her staff. You should know all these answers before you decide about being in the research.

What is the **purpose** of the research? Why is the investigator doing the research?

What are the **risks** of the research? What bad things could happen?

What are the possible **benefits** of the research? How might this help me?

How is this research different than the care or treatment I would get if I wasn't in the research? Are there other treatments I could get?

Does **everyone** in this research study get the same treatment?

Will being in the research **cost** me anything extra?

Do I have to be in this research study? Will the doctor still take care of me if I say **no**?

Can I **stop** being in the research once I've started? How?

Who will look at my **records**?

How do I reach the investigator if I have more **questions**?

Who do I call if I have questions about being a **research subject**?

Make sure all your questions are answered before you decide whether or not to be in this research.

Academic Research & Services Building 3000 / 987830 Nebraska Medical Center / Omaha NE 68198-7830
402-559-6463 / FAX 402-559-3300 / Email: irbora@unmc.edu / http://www.unmc.edu/irb

THE RIGHTS OF RESEARCH SUBJECTS
AS A RESEARCH SUBJECT YOU HAVE THE RIGHT ...

... to be told everything you need to know about the research before you are asked to decide whether or not to take part in the research study. The research will be explained to you in a way that assures you understand enough to decide whether or not to take part.

... to freely decide whether or not to take part in the research.

... to decide not to be in the research, or to stop participating in the research at any time. This will not affect your medical care or your relationship with the investigator or the Nebraska Medical Center. Your doctor will still take care of you.

... to ask questions about the research at any time. The investigator will answer your questions honestly and completely.

... to know that your safety and welfare will always come first. The investigator will display the highest possible degree of skill and care throughout this research. Any risks or discomforts will be minimized as much as possible.

... to privacy and confidentiality. The investigator will treat information about you carefully, and will respect your privacy.

... to keep all the legal rights you have now. You are not giving up any of your legal rights by taking part in this research study.

... to be treated with dignity and respect at all times

The Institutional Review Board is responsible for assuring that your rights and welfare are protected. If you have any questions about your rights, contact the Institutional Review Board at (402) 559-6463.