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Masonic Cancer Center, University of Minnesota
Blood and Marrow Transplantation Program

CONSENT TO PARTICIPATE IN RESEARCH

Hematopoietic Stem Cell Transplant for Dyskeratosis Congenita or Severe Aplastic Anemia: Standard of Care Considerations

Principal Investigator: Christen Ebens, MD, MPH

You have either Dyskeratosis Congenita (DC) or Severe Aplastic Anemia (SAA) that is causing bone marrow failure. A hematopoietic stem cell transplant using donor stem cells is planned. The proposed transplant is considered standard of care meaning it is not investigational or experimental. With this form you are being asked to allow the use of routine clinical information collected as part of a transplant to be used to answer research questions.

This form is called a consent form. The intent of this form is to let you know the purpose of this data collection, what type of routine data will be collected, and the possible risks and benefits of sharing your information with researchers at the University Of Minnesota. If you wish to take part in this study, you will be asked to sign this consent form.

This study is being conducted at the Masonic Cancer Center of the University of Minnesota. Christen Ebens, MD, MPH is the principal investigator (the physician in charge) of this study.

Introduction

Only ten or so stem cell transplants for DC or SAA are performed each year at the University Of Minnesota in comparison to transplants for malignancies (cancer). For this reason, in order to learn more about the outcomes of such transplants, you are asked to allow routine clinical data to be collected and maintained in OnCore, the Masonic Cancer Center's (MCC) clinical database. In addition, you are asked to give permission to allow for the review and analysis of specific transplant related endpoints routinely collected by the University Of Minnesota Blood and Bone Marrow Transplantation (BMT) Database.

Although not part of this consent process, the description of the transplant procedure is attached to the end of this document. Your doctor may alter this plan based on your individual disease and medical needs.

Study Purpose

The primary purpose of this study is to record outcomes and patient characteristics in the Masonic Cancer Center and BMT databases for patients undergoing a transplant for the treatment of Dyskeratosis Congenita (DC) or Severe Aplastic Anemia (SAA). The data will be analyzed for transplant "milestones" such as time to blood count recovery (engraftment) and how patients are doing at 3 months and 6 months after the transplant.

Study Procedures

Participation in this study will not alter your treatment or medical care. All information for this study will be collected from your medical records. There are no additional blood draws or procedures that are part of this study; this study only allows members of the University of Minnesota BMT Team to collect and analyze routine studies that will be performed as standard of care for your transplant.

Risks of Study Participation

The only risk to agreeing to this data collection study is a small risk of loss of confidentiality. Your name and other direct identifiers will be stored in both the Cancer Center's database and the BMT database. Both databases reside on the University Of Minnesota computer server and are restricted in their access. No information directly identifying you will be presented or published by this study.

Benefits of Study Participation

There will be no direct benefit to you for agreeing to the collection, storage and analysis of routine clinical data. It is hoped the information learned from this study will benefit other patients with graft failure in the future.

Alternatives to Study Participation

As this study is only asking to collect, store and analyze routine clinical data, you may choose to not participate in this study without affecting your treatment.

Study Costs

There will be no cost to you for the storing and analysis of the clinical information related to your transplant collected by this study.

Costs associated with treatment and care will be billed to you and/or your health insurance/health plan in the usual way.

You will receive no payment or compensation for taking part in this study.

Confidentiality

The records of this study will be kept private. Information will be kept in study case report forms and the databases previously described. 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 records for research, quality assurance, and data analysis include:

- The University of Minnesota Institutional Review Board (IRB), a group of people who review the research study to protect your rights
- The University of Minnesota Masonic Cancer Center and/or their designee

To this extent, confidentiality is not absolute.

A description of this clinical trial is available on 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.

Protected Health Information (PHI)

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.

Voluntary Participation and Length of Study Participation

Taking part in this study is your choice. You may choose either to take part or not to take part in the study.

If you decide to take part in this study, data will be collected as long as you are followed by the University Of Minnesota for your transplant. However you may stop the data collection at any time by contacting a member of the medical staff at the University Of Minnesota.

No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get medical care from this institution.

Contacts and Questions

The physicians involved in your care are available to answer any questions you may have concerning this study at any time. The study's principal investigator, Dr. Christen Ebens may be reached at (612) 626-8094.

This research has been reviewed and approved by an 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 https://research.umn.edu/units/hrpp/research-participants/questions-concerns. 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.

If you choose to participate, you will be given a signed copy of this form to keep for your records.

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Signature

I have read this consent form or it has been read to me. I have had my questions answered. I agree to take part in this data collection study.

_____ _____
Signature of subject Date

_____
Printed Name of subject

_____ _____
Signature of the person obtaining consent Date

_____
Printed name of the person obtaining consent

☐Check if this section is not applicable (no Legally Authorized Representative used)

My signature documents my permission for the named participant to take part in this research.

_____
Printed Name of Participant

_____ _____
Signature of Legally Authorized Representative Date

_____
Printed Name of Legally Authorized Representative

_____
Authority of Subject's Legally Authorized Representative or Relationship to Subject

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Witness Signature (if applicable)
The parent/guardian was unable to read or sign this consent form because of the following reason:

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

_____

- ☐ Other (please specify):_____

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 parent/guardian, I represent that the English version of the consent form was presented orally to the parent/guardian in the parent/guardian's own language, and that the parent/guardian 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 parent/guardian, I represent that the English version of the consent form was presented orally to the parent/guardian in the parent/guardian's own language, and that the parent/guardian was given the opportunity to ask questions.

_____ _____
Signature of Individual Date

_____
Printed Name of Individual

Please refer to the next few pages for a description of the transplant and the possible risks associated with the procedure.

Check applicable disease document used:
☐ Dyskeratosis Congenita (DC)

☐ Severe Aplastic Anemia (SAA)