Informed Consent Document

Description and Purpose of the Trial

This clinical trial, identified as NCT04195633, is a phase II study titled "Hematopoietic Stem Cell Transplantation From Haploidentical Donors in Patients With Hematological Malignancies Using a Treosulfan-Based Preparative Regimen." The purpose of this trial is to evaluate the effectiveness and safety of a donor stem cell transplant, treosulfan, fludarabine, and total-body irradiation in treating patients with blood cancers (hematological malignancies).

Potential Risks and Benefits

Risks

The potential risks associated with this trial include:

- General risks: These may include discomfort, pain, or infection at the injection or catheter site, as well as the potential for allergic reactions to the medications used in the trial.
- Side effects: Common side effects of the medications used in this trial may include nausea, vomiting, diarrhea, fatigue, hair loss, and increased risk of infection.
- Drug risks: The medications used in this trial, including treosulfan, fludarabine, and cyclophosphamide, may have additional risks, such as liver or kidney damage, decreased blood cell counts, and an increased risk of secondary cancers.

Benefits

The potential benefits of participating in this trial include:

- Improved treatment outcomes for patients with hematological malignancies.
- Contribution to the advancement of medical knowledge and the development of new treatments for blood cancers.

Sharing of Medical Information

Your medical information will be kept confidential and will only be shared with the research team, regulatory agencies, and other authorized individuals. Your information will be coded and will not include your name or other identifying information.

Procedures Involved

The procedures involved in this trial include:

- Administration of high or low dose treosulfan, fludarabine, and cyclophosphamide via intravenous infusion.
- Total-body irradiation.
- Allogeneic hematopoietic stem cell transplantation.
- Administration of cyclosporine, mycophenolate sodium or mycophenolate mofetil, and filgrastim.
- Regular follow-up visits and assessments.

Rights of Participants

As a participant in this trial, you have the following rights:

- The right to be treated with respect and dignity.
- The right to withdraw from the trial at any time without penalty.
- The right to be informed about any new information that may affect your decision to participate in the trial.
- The right to ask questions and receive answers about the trial.
- The right to privacy and confidentiality.

Contact Information

If you have any questions or concerns about this trial, please contact:

- Filippo Milano, Principal Investigator
- Phone: 206.667.5925
- Email: fmilano@fredhutch.org

Ethical Guidelines

This trial adheres to the following ethical guidelines:

1. **Respect for Persons**: Participants will be treated with dignity and their decisions respected. Informed consent will be obtained, and

participants will be provided with sufficient information to make an informed decision.
2. **Beneficence**: The study will do no harm and maximize possible benefits while minimizing possible harms. The risks and benefits will be clearly communicated to participants.
3. **Justice**: The benefits and burdens of research will be distributed fairly. The selection of participants will be equitable, and the trial will not exploit vulnerable populations.
4. **Confidentiality**: Participants' privacy will be protected, and their data will be kept confidential.
5. **Informed Consent**: A clear explanation of the study, its purpose, procedures, risks, benefits, and the rights of participants will be provided, ensuring they understand and voluntarily agree to participate.

Signature and Date

I have read this consent form or had it read to me. I have discussed it with the study doctor, and my questions have been answered. I will be given a signed and dated copy of this form. I agree to take part in the main study.

Patient's signature: _____

Date: _____\