# 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 the institutional review board (IRB) for the purpose of monitoring the safety and progress of the trial. Your personal information will not be shared without your explicit consent.

## Procedures Involved

Patients in this trial will be assigned to one of two treatment arms. The procedures involved in each arm are as follows:

- Arm A (High Dose Treosulfan): Patients will receive high dose treosulfan intravenously (IV) over 120 minutes on days -6 to -4 and fludarabine IV over 60 minutes on days -6 to -2. Patients will then undergo total-body irradiation on day -1 and allogeneic hematopoietic stem cell transplantation on day 0. Patients will receive cyclophosphamide IV on days 3-4 and will be administered cyclosporine, mycophenolate sodium or mycophenolate mofetil, and filgrastim as outlined in the trial protocol.
- Arm B (Low Dose Treosulfan): Patients will receive low dose treosulfan IV over 120 minutes on days -6 to -4 and fludarabine IV over 60 minutes on days -6 to -2. Patients will then undergo total-body irradiation and allogeneic hematopoietic stem cell transplantation, and receive cyclophosphamide, cyclosporine, mycophenolate sodium or mycophenolate mofetil, and filgrastim as in Arm A.

After completion of the transplant, patients will be followed up at 28, 56, 84, 365, and 730 days.

## 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 or loss of benefits.
- The right to ask questions and receive answers about the trial.
- The right to receive information about new findings that may affect your willingness to continue participating in the trial.

## Contact Information

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

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## Ethical Guidelines

This trial adheres to the following ethical guidelines:

1. **Respect for Persons**: Participants will be treated with dignity and their decisions will be respected. Individuals with limited ability to make decisions will receive fair protection, and informed consent will be obtained from all participants.
2. **Beneficence**: The study will do no harm and will