IRB Authorization Agreement – OPTIMIZE

1. **Name of Institution Providing IRB Review**: National Marrow Donor Program® (NMDP)

 **IRB Registration #**: IRB00001253 **Federalwide Assurance (FWA) #**: FWA00000441

1. **Name of Signatory Institution Relying on the NMDP IRB**:

 **Signatory Institution’s OHRP Federalwide Assurance (FWA) #**: FWA

1. **A Signatory Institution’s “Component Institution” is defined by the NMDP IRB as meeting all of the following criteria:**
	1. the Component Institution operates under a different name from the Signatory Institution, but the Signatory Institution has legal authority for the Component Institution;
	2. the FWA number for the Component Institution is the same as the Signatory Institution;
	3. the local context considerations of the Component Institution are the same as the Signatory Institution;
	4. the boilerplate language and institutional requirements of the Component Institution are the same as the Signatory Institution; and
	5. the conduct of research at the Component Institution is monitored by the same office as the Signatory Institution.

 **List the Signatory Institution’s Component Institution(s) by name:**

1.

1. **A Signatory Institution’s “Affiliate Institution” has a different FWA # from the Signatory Institution, and is defined by the NMDP IRB as meeting all of the following criteria:**
2. the local context considerations of the Affiliate Institution are the same as the Signatory Institution;
3. the boilerplate language and institutional requirements of the Affiliate Institution are the same as the Signatory Institution; and
4. the conduct of research at the Affiliate Institution is monitored by the same office as the Signatory Institution.

 **List the Signatory Institution’s Affiliate Institution(s) by name, and include the FWA#:**

1.

The Officials signing below agree that       may rely on the NMDP IRB for review and continuing oversight of its human subject research described below:

**This agreement is limited to the following specific protocol:**

CIBMTR CRO Services OPTIMIZE: *A Phase II Study of Reduced Dose Post Transplantation Cyclophosphamide as GvHD Prophylaxis in Adult Patients with Hematologic Malignancies Receiving HLA-Mismatched Unrelated Donor Peripheral Blood Stem Cell Transplantation* (NMDP IRB-2023-0464)

The review and continuing oversight performed by the NMDP IRB will meet the human subjects protection requirements of       OHRP-approved FWA. The IRB at the National Marrow Donor Program® will follow written procedures for reporting its findings and actions to appropriate officials at      . Relevant minutes of NMDP IRB meetings will be available upon request. Supporting documents will be made available on the study-specific website or by the central study-level protocol team/data coordinating center.       remains responsible for ensuring compliance with the NMDP IRB’s determinations and with the terms of its OHRP-approved Assurance. The division of responsibilities between the NMDP IRB and       are detailed in Attachment 1. This agreement does not preclude the relying institution or its researchers from taking part in research not covered by this agreement. This document must be kept on file at both institutions and provided to OHRP upon request.

**Signature of Signatory Official at National Marrow Donor Program®:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_

Brian Lindberg, J.D., Chief Legal & Policy Officer/General Counsel

**Signature of Signatory Official at**      **:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_

**Print Full Name**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Institutional Title:**

**Contact Information for NMDP IRB:**

Meggan McCann, MPH

Director, Strategic Programs

IRB Administrator

763-406-5776

mmccann@nmdp.org

**Contact Information for Signatory Institution:**

Name:

Title:

Phone:

Email:

Attachment 1

**Division of Responsibilities Between NMDP IRB and the Relying Institution**

**The responsibilities of the NMDP IRB are to:**

1. Maintain an NMDP IRB membership that satisfies the requirements of 45 CFR 46 and 21 CFR 56.
2. Conduct review of research according to all applicable regulations and laws for OPTIMIZE.This includes initial review, continuing review, review of modifications to previously approved research, as well as review of any other study-specific documents.
3. Conduct review of local context considerations as outlined in the required forms submitted by the Relying Institution and the investigator. (Refer to Appendix A for a list of the required forms.)
4. When necessary, suspend or terminate approval of all or part of the research study at the Relying Institution that is not being conducted in accordance with the IRB’s requirements, or that has been associated with unexpected serious harm to participants. Report such suspensions or terminations to NMDP Signatory Official, OHRP, FDA, or any other applicable agency according to NMDP policies and procedures.
5. Conduct review of potential unanticipated problems involving risks to subjects or others and/or potential serious or continuing noncompliance when the Relying Institution or other entity reports an incident, experience, outcome or potential noncompliance.
6. Report any determinations of unanticipated problems involving risks to subjects or others and determinations of serious or continuing noncompliance that occurred at the Relying Institution to NMDP Signatory Official, OHRP, FDA, or any other applicable agency according to NMDP policies and procedures. Prior to sending the report to any federal agency, a draft report will be forwarded to the Relying Institution for review and comment. In no case will such opportunity for review and comment interfere with timely submission of required reports. Although NMDP will consider any comments submitted, the final content of the report is up to the discretion of the NMDP.
7. Prompt notification to Relying Institution of its findings and actions with respect to any unanticipated problems involving risks to subjects or others, subject injuries, or subject complaints which are related to or may affect subjects participating in research at Relying Institution. Additionally, NMDP IRB will ensure prompt notification to Relying Institution of any finding of serious or continuing noncompliance on, or any suspension or termination of IRB approval for, that portion of a study taking place at Relying Institution.
8. Review any researcher or research staff financial conflict of interest (FCOI) management plan(s) submitted by the Relying Institution and decide whether the management plan(s) as written is sufficient to allow the research to continue at the Relying Institution.
9. Provide the NMDP IRB Notices of Action and any other pertinent study documents to the central study-level protocol team/data coordinating center for distribution to the Relying Institution.
10. Provide institution-specific documents related to the NMDP IRB review by email to research staff and institutional designees.
11. Upon request, provide NMDP IRB Standard Operating Procedures and IRB membership roster to the Relying Institution.

**The responsibilities of the Relying Institution are to:**

1. Researchers must comply with the determinations and requirements of the NMDP IRB. The Relying Institution is responsible for ensuring compliance with the NMDP IRB’s requirements at the research site.
2. Comply with NMDP IRB policies and procedures.
3. Complete and submit the forms that provide local context issues relevant to the institution and the research protocol. (Refer to Appendix A for a list of the required forms.)
4. Research may be further reviewed and approved or disapproved by officials of the Relying Institution, but they may not approve the research if it has not been approved by the NMDP IRB.
5. The Relying Institution and the researchers acknowledge and agree to cooperate with the NMDP IRB for all reviews, record keeping and reporting. All information reasonably requested by the NMDP IRB will be provided in a timely manner.
6. The Relying Institution and its researchers acknowledge that they are primarily responsible for safeguarding the rights and welfare of each research participant, and that the participant’s rights and welfare must take precedence over the goals and requirements of the research.
7. Oversee the conduct of the study at their institution. This includes but is not limited to:
	1. Monitoring protocol compliance;
	2. Maintaining compliance with state, local, or institutional requirements related to the protection of human subjects;
	3. Initiating changes in the research only after NMDP IRB review and approval, except where necessary to eliminate apparent immediate hazards to the participants.
	4. Enrolling individuals in the research only after NMDP IRB review and approval.
	5. Obtaining, documenting, and maintaining records of consent for each participant or each participant’s legally authorized representative as stipulated by the NMDP IRB.
	6. Providing a mechanism to receive and address concerns/complaints from local study participants and others about the conduct of the research;
	7. Notifying the NMDP IRB of any study-specific incidence, experience or outcome that rises to the level of an unanticipated problem involving risks to subjects or others and/or potential serious or continuing noncompliance. At the time the incident, experience or outcome is reported to the NMDP IRB, the Relying Institution must also provide a plan to manage it.
8. Manage organizational conflicts of interest related to the study.
9. Obtain disclosures of and manage financial conflicts of interest (FCOI) of researchers and research staff at the Relying Institution. Provide conflict of interest management plans to the NMDP IRB.
10. Ensure initial and ongoing qualifications of researchers and research staff at the Relying Institution, including complying with the human research subject protection education and continuing education requirements of the Relying Institution.
11. Ensure compliance with applicable Health Insurance Portability and Accountability Act (HIPAA) privacy regulations. This includes making determinations as required by and in compliance with the HIPAA Privacy Rule for use and disclosure of protected health information (PHI) for the research, including waivers of, or alterations of authorizations.
12. Conduct other ancillary reviews required by the protocol or by the Relying Institution (e.g., scientific review, biosafety, radiation safety, etc.)
13. Incorporate institutional boilerplate language into the NMDP IRB-approved template consent form to create the consent form to use for a specific study:
	1. The institution must use the NMDP IRB-approved consent form template.
	2. Institutional boilerplate language must be approved by the NMDP IRB.
	3. No language changes may be made to the consent form with the exception of NMDP IRB-approved boilerplate language.
	4. The institution must submit the institutional consent form to the central study-level protocol team/data coordinating center for review prior to implementing the consent form.
	5. The institution must obtain NMDP IRB approval of changes to the boilerplate language prior to implementation.
	6. The institution must obtain NMDP IRB approval of translations of the consent form prior to implementation.

APPENDIX A

The following forms, which provide local context issues relevant to the institution and the research protocol, must be submitted to the NMDP IRB.

1. **Single IRB Signatory Institution Enrollment and Local Context Form**
	* The Signatory Institution must complete and submit this form to the NMDP IRB at the time that the Institution wishes to enroll in the NMDP sIRB.
	* Information in this form must be updated annually.
2. **NMDP sIRB Study-Specific Local Context Worksheet**
	* The Principal Investigator or Study Coordinator at the study site must complete and submit this form (signed by the Principal Investigator) to the NMDP IRB at the time that the Principal Investigator wishes to participate in a study where the NMDP IRB will serve as the site’s IRB of record for the study.
	* This form must be submitted for each study.
	* Any updates to information in this form must be submitted to the NMDP IRB as soon as the changes occur.