National Marrow Donor Program® Institutional Review Board

**NMDP Single IRB**

**Signatory Institution local context worksheet**

[ ]  Initial Submission: Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ ]  Revised Submission: Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signatory Institution Information**

1. Name of Signatory Institution:
2. Local Context Representative or person completing this form
	1. Name:
	2. Role/Title:
	3. Phone number:
	4. Email address:
3. Check all applicable Network Group memberships for the Signatory Institution

[ ] BMT CTN Core Clinical Center

[ ] BMT CTN Core Consortium

[ ] BMT CTN Affiliate Center

[ ] RCI BMT

1. Does your institution use different but equivalent protections for research **not** covered by DHHS regulations, or does your institution use the same policies and procedures for all research?

[ ] Different but equivalent protections for research not covered by DHHS regulations

[ ] Same policies and procedures for all research

1. Is your organization accredited by AAHRPP?

[ ] Yes

[ ] No, but our human research protection program **is** accredited by *(name of accrediting company)*:

[ ] No, our human research protection program is not accredited.

**For answers to the questions below, please do not just attach your SOPs or provide links to your SOPs. Although you are welcome to submit your SOPs, we require brief answers on this form that are sufficient to understand the local context for your institution.**

**State and Local Law**

1. What is your state law and corresponding institutional policy regarding legally authorized representatives including who may serve as a legally authorized representative?
2. What is the age of majority in your state?
3. What are the other state or local laws that govern the conduct of research at your institution?

**Research Oversight**

1. Identify the office and person at your institution responsible for the oversight of the conduct of research. (This person cannot be a Principal Investigator who will open studies with the NMDP Single IRB.)
	1. Office name:
	2. Responsible person:
	3. Phone number:
	4. Email address:
	5. Describe how this person(s) ensures the safe and appropriate performance of the research at the Signatory Institution and at all Component and Affiliate Institutions, including:
		1. Ensuring the initial and ongoing qualifications of investigators and research staff, specifically:
			1. Maintaining investigators’ curriculum vitaes (CVs):
			2. Maintaining investigators’ current medical licensures:
			3. Verifying the investigators’ and research staff’s current training in human research protections prior to allowing to cede to an external IRB:
			4. Confirming that the investigator is in good standing and authorized to conduct research at your institution prior to allowing to cede to an external IRB:
		2. Verifying the research site has adequate resources (including space, equipment, and personnel) for conducting a study prior to allowing to cede to an external IRB:
		3. Overseeing the conduct of the research:
		4. Monitoring protocol compliance:
		5. Maintaining compliance with state, local, or institutional requirements related to the protection of human subjects:
		6. Providing a mechanism to receive and address concerns from local study participants and others about the conduct of the research:
2. Identify the office and person at your institution responsible for identifying, managing, and reporting to the NMDP IRB potential unanticipated problems involving risks to subjects or others and/or serious or continuing noncompliance.
	1. Office name:
	2. Responsible person:
	3. Phone number:
	4. Email address:
	5. Describe in detail how this person(s) identifies and manages potential unanticipated problems and/or serious or continuing noncompliance.

**Financial Conflicts of Interest**

1. Describe how the Signatory Institution gathers and evaluates Principal Investigator and research staff financial conflicts of interest for studies on the NMDP Single IRB menu, specifically, how are potential conflicts of interest identified and managed prior to allowing to cede to an external IRB?

**Ancillary Reviews**

1. Are there any ancillary reviews required at your institution prior to activating research protocols?

[ ] No

[ ] Yes: List all required ancillary reviews:

**Institutional Policies Pertaining to the Informed Consent Document and Process for NMDP IRB-Approved Studies**

1. How is the informed consent process conducted with non-English speaking potential study participants?
2. For what languages are translations routinely required for every study?
	1. For required translations, what process is currently used to translate the informed consent document?
3. Does your institution allow the use of a Short Form with non-English speaking potential study participants?

[ ] No

[ ] Yes:

1. If Yes, indicate which institution’s Short Form must be used.

[ ] Local institution participating in the research (i.e., your institution)

[ ] Institution where designated IRB is located (i.e., NMDP IRB)

[ ] Either institution’s Short Form may be used.

1. If Yes, describe your institution’s policy regarding the number of times the Short Form may be used per language before the full consent form must be translated into that language.
2. Who provides consent? (Check all that apply.)

[ ] Potential study participant

[ ] Parent for potential pediatric study participant

[ ] Legally Authorized Representative

[ ] Other: Please explain:

1. Describe your institution’s policy regarding assent by children or impaired adults.
2. Describe your institutional policies and guidelines that govern the informed consent document.
3. Provide the boilerplate language that is added to the NMDP IRB-approved informed consent document. This is standard language required by the institution that is inserted into the existing NMDP IRB-approved informed consent document, such as, birth control language, coverage of research injury, required phone numbers for the study doctor, and a person unaffiliated with the study who can answer general clinical trial questions, etc. Please attach a separate document in Word format that only includes this boilerplate language. Do not just attach your institution’s template consent form.
4. Provide any other institutional requirements for informed consent documents, if applicable. (If applicable, an attachment in Word format can be attached to this form.)

**Community Descriptors**

1. Does the community have a positive attitude toward the conduct of research?

[ ] Yes

[ ] No: Please explain:

1. Is there anything else the NMDP IRB should know about the anticipated study participant population at the Signatory Institution?

[ ] No

[ ] Yes: Please explain:

**Additional Information**

1. Is there anything else the NMDP IRB should know about the Signatory Institution’s local context?

[ ] No

[ ] Yes: Please explain:

**Email this form to** **NMDPSIRB@nmdp.org****. Questions? Email** **NMDPSIRB@nmdp.org****.**