National Marrow Donor Program® Institutional Review Board

**NMDP Single IRB**

**study-specific local context worksheet**

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

**Protocol Identification**

1. Sponsor Protocol ID Number:
2. Protocol Title:

**Primary Contacts**

1. Name of Signatory Institution:
2. Principal Investigator information
	1. Name (include full name and highest degree earned):
	2. Institution:
	3. Phone number:
	4. Email address:
3. Study Coordinator at site
	1. Name:
	2. Institution:
	3. Phone number:
	4. Email address:

**Research Staff**

1. How many sub-investigators do you have supporting you in conducting this study?
2. How many research nurses/CRAs do you have supporting you in conducting this study?
3. Have you or any of your research staff reported a financial conflict of interest related to this study that resulted in a management plan?

[ ] No

[ ] Yes: Attach the institutionally-approved management plan.

**Principal Investigator Resources**

1. How many actively accruing research studies, for which you are the PI, do you have open, including NMDP IRB-approved studies and those not reviewed by the NMDP IRB?
	1. List NMDP IRB-approved studies by Protocol ID Number (or state “none” if there aren’t any).
2. How many study subjects are currently receiving study intervention for studies for which you are the PI?

**Subject Recruitment and Selection**

1. Describe how potential study subjects will be identified and recruited to this study at your site.
2. Identify the recruitment materials you will use for this study.

[ ] Sponsor-supplied materials

[ ] Locally-developed recruitment materials (Reminder: Study-specific material requires NMDP IRB approval)

[ ] Other: Please describe:

1. What subject population(s) will you be enrolling on this protocol? (check all that apply)

[ ] Adults

[ ] Minors

1. Check all vulnerable populations from which you intend to enroll on this study.

[ ] Children

[ ] Pregnant women

[ ] Economically disadvantaged

[ ] Educationally disabled

[ ] Physically disabled

[ ] Other: Please describe:

1. For each vulnerable population checked, indicate safeguards.

[ ] Children

[ ] Youth Information Sheets

[ ] Assent

[ ] Extra monitoring

[ ] Researchers credentialed in pediatrics

[ ] Other health professionals with pediatrics experience

[ ] Other: Please describe:

[ ] Pregnant women\*\*

[ ] Inclusion is scientifically appropriate based on preclinical studies

[ ] Information is provided pertaining to how study intervention could impact the woman and the fetus

[ ] Other: Please describe:

[ ] Economically disadvantaged

[ ] Cost burden is fully explained

[ ] No financial incentives are provided

[ ] Social services are available to assist study subject

[ ] Other: Please describe:

[ ] Educationally disabled

[ ] Verbal explanation of the research is provided in lay language

[ ] Extra time is available to answer questions

[ ] At the potential study subject’s request, family members/significant others can participate in informed consent process

[ ] Caregiver to assist with medications and identifying adverse events

[ ] Translations are available, if needed

[ ] Other: Please describe:

[ ] Physically disabled

[ ] Treatment facility is accessible

[ ] Assistance is available, as needed

[ ] Witness to consent is available, as needed

[ ] Other: Please describe:

[ ] Other: Describe all safeguards you use for Other vulnerable populations.

**\*\*Additional Confirmation When Investigator Intends to Enroll Pregnant Women [45 CFR 46.204(h),(i),(j)]**

Confirm the following statements by choosing “True”.

1. No inducements will be offered to terminate a pregnancy.

[ ] True

[ ] False

1. Research team will have no part in decisions related to the timing, method, or procedures used to terminate the pregnancy.

[ ] True

[ ] False

1. Research team will have no part in determining the viability of a neonate.

[ ] True

[ ] False

**Compensation to Study Subjects**

1. Describe any compensation/incentives provided to the study subjects. This includes compensation as a part of the study in addition to compensation/incentives provided by the Signatory Institution or others to study subjects at your institution, for example: parking validation, cafeteria voucher, other.

**Informed Consent Process**

Answer the following questions regarding the process used to introduce this study to a potential study subject and obtain their informed consent.

1. Where does the consent discussion take place?
2. Who is authorized to obtain consent?
3. How long does the potential study subject have to review the consent document before a response is required, including time to take the consent document home?
4. Who is available to answer questions?
5. How is the potential study participant’s understanding of consent assessed?

**Using a Legally Authorized Representative (LAR)**

1. Do you plan on enrolling study subjects on this study through an LAR?

[ ] No

[ ] Yes

1. Provide a description of how you assess a potential study subject’s ability to provide consent on this study.

**Measures to Protect Confidentiality**

Confidentiality is defined as the study subject’s understanding of, and agreement to, the ways identifiable information pertaining to them will be stored and shared. Identifiable information can be printed, electronic, or visual (such as photographs).

1. Check all measures that will be used to maintain the confidentiality of identifiable information for this study.

[ ] Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study.

[ ] Computer-based files will be available to study personnel through the use of access privileges and passwords.

[ ] Prior to obtaining access to identifiable information, study personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information.

[ ] Whenever feasible, identifiers will be removed from study-related information.

[ ] Other: Please describe:

**Measures to Protect Privacy**

Privacy is defined as the study subject’s ability to control how other people see, touch, or obtain information about them. Violations of privacy can involve circumstances such as being seen without clothing or partially clothed, being photographed without consent, being asked personal questions in a public setting, etc.

1. Check all measures that will be used to maintain the study subject’s privacy for this study.

[ ] Use of drapes or other barriers to vision for subjects who are required to disrobe.

[ ] Consent is obtained prior to collecting photographs involving study participants.

[ ] Sensitive information is collected and used with respect to maintaining privacy.

[ ] Individuals are not identified publicly without their consent.

[ ] Other: Please describe:

**Pharmacy Information**

1. Will the drugs/agents used in the study be managed by a pharmacist?

[ ] N/A: This study does not involve drugs/agents. *(Skip to Q31)*

[ ] No: If the drugs/agents will not be managed by a pharmacist, provide the name and title of the responsible person for the drugs/agents at each practice/location where research will be conducted.

[ ] Yes: If a pharmacist will be managing the drugs/agents used in the study, provide the name and title of the pharmacist at each practice location where research will be conducted.

1. How is the pharmacist or responsible person provided with a copy of the protocol at each practice location?

**Emergency Resources**

1. Check all resources available at the site to treat emergencies resulting from study-related procedures.

[ ] ACLS trained personnel and crash cart

[ ] BCLS trained personnel

[ ] Emergency response team within facility

[ ] Emergency drugs and supplies to stabilize study subject until emergency personnel arrive

[ ] Staff available to call 911

[ ] Other: Please describe:

**Endorsement by the Relying Institution**

1. Does your institution’s IRB office require you to submit a request to rely on an external IRB?

[ ] No

[ ] Yes *(Answer Q32.1)*

32.1 Does your IRB office issue an “Endorsement Letter” or similar documentation stating that your request was granted?

[ ] No

[ ] Yes: Submit that documentation to the NMDP single IRB with this form.

**Confirmation of Intent to Comply:**

I, as Principal Investigator at this site, confirm that:

* I will comply with the Federal regulations pertaining to human research protections as well as applicable Federal, state, and local laws.
* I will comply with NMDP IRB and Network Group/sponsor directives and requirements pertaining to this study.
* I oversee all sub-investigators and research staff assisting with this study at this site and am responsible for their compliance with the same.
* All sub-investigators and research staff assisting with this study at this site are appropriately qualified and trained, including being in compliance with the human research subject protection education and continuing education requirements of my institution.
* All ancillary reviews and other requirements of my institution will be completed prior to beginning any study-related activities.

I understand that this study may not be opened at my institution, and no study-related activities may begin, until I receive both an approval confirmation from the NMDP IRB and a notice of site activation from the Network Group/sponsor.

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Signature of Principal Investigator Date

**Submission Checklist**

**The following items must be submitted with this Study-Specific Local Context Worksheet:**

 [ ]  Redlined (tracked-changes) version of consent/assent forms with institutional contact information and boilerplate language (if applicable) inserted. *NOTE: The site-specific consent form for this study should be approved by the Protocol/Study Coordinator prior to submitting it to the NMDP IRB.*

 [ ]  Copy of the email documenting the Protocol/Study Coordinator’s approval of your institutional consent/assent form(s).

 [ ]  Documentation of Principal Investigator training in protection of human subjects

 [ ]  If applicable, “endorsement letter” or similar documentation stating that relying institution granted reliance on the NMDP IRB for this study.

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