NMDP[SM] Single IRB

Who are we?

The NMDP Institutional Review Board (IRB) was established to protect the rights and welfare of human subjects recruited to participate in research activities under the backing of NMDP. The members of the NMDP IRB are a diverse group of distinguished healthcare professionals, donor advocates, and patient advocates with expertise in bone marrow transplantation and hematology/oncology. NMDP is fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

What do we do?

The primary focus of the NMDP IRB human subjects review is research involving cell therapies, including the protection of both donors and recipients of hematopoietic cell transplants (HCT) participating in research. The NMDP IRB serves as the IRB of record for all studies managed by Center for International Blood and Marrow Transplant Research (CIBMTR) CRO Services, meaning the NMDP IRB reviews all study-level submissions. For sites participating in studies managed by CIBMTR CRO Services, the NMDP IRB serves as the central IRB for non-federally funded research or as the single IRB (sIRB) for federally-funded research. The NMDP IRB also serves as the single IRB for the NIH-funded Blood and Marrow Transplant Clinical Trials Network (BMT CTN).

Why use the NMDP single IRB?

Sites participating in BMT CTN or federally-funded CIBMTR CRO Services research are required to rely on the NMDP single IRB. Other multi-site studies may also benefit from relying on the NMDP IRB due to its expertise in HCT research. Using the NMDP sIRB streamlines the IRB review process and reduces the work burden at sites. Sites are not responsible for IRB submissions of continuing reviews or protocol amendments, as study-wide submissions to the NMDP IRB are prepared by the central protocol team.

How does my site get started?

Check out our helpful resources below for how to obtain NMDP IRB approval for your site using our online system called IRBManager.

Getting Started

Step	Details
Obtain Access to IRBManager	• Visit https://nmdp.my.irbmanager.com • **New users:** Register by clicking the **Click here to register** link. • **Existing users:** Your username is your email address. Need to reset your password? Click the **Forgot Password** link. • **More information:** See section 2 of the IRBManager User Guide.
Complete one-time institutional enrollment in the NMDP sIRB	• Must be completed once by an institutional representative (typically someone from the local institution's IRB office) prior to opening the first study at your site • Submit the NMDP ***Single IRB Signatory Institution Enrollment and Local Context*** xForm from your dashboard in IRBManager • Unsure if your institution is enrolled? Email IRBstaff@nmdp.org to find out. • **More information:** See section 4 of the NMDP Single IRB Manual
Obtain an IRB Authorization Agreement (IAA) for the specific study	• IAAs can be downloaded here. • The IAA must be signed by an institutional official, typically a representative of the local institution's IRB office. • If the study falls under a master IAA (e.g. master IAA for BMT CTN studies) that has already been executed, this step is not necessary • **More information:** See section 4 of the NMDP Single IRB Manual
Create your study-site specific consent forms	• Use the current NMDP IRB-approved template study consent form provided by the protocol team. • Turn track changes on and insert your institution's required boilerplate consent language, as applicable, that is on file with the NMDP single IRB. • Do **not** embed HIPAA authorization language in the consent form. • Send your redlined version of the consent form to the central study-level protocol team for pre-approval. • **More information:** See section 5 of the NMDP Single IRB Manual

Complete study-site submission in IRBManager	• Submit the ***NMDP sIRB Study-Specific Local Context Worksheet*** xForm from your dashboard in IRBManager.
	  ○ *Need someone else to have access to the form? Click the **Collaborators** link at the top of the form.*
	• Attach the following to the xForm and submit:
	  ○ Documentation of the site PI's training in human research protections (not GCP)
	  ○ Redlined versions of consent forms approved by the central study-level protocol team.
	  ○ Documentation of the central study-level protocol team's approval of consent forms.
	  ○ IRB Authorization Agreement (IAA) for the specific study.
	  ○ If applicable, any locally-developed recruitment or participant-facing consent material.
	• Site PI signs off on xForm – PI receives an email from IRBManager with a link to the xForm to review, sign off, and submit. Form is then pre-reviewed by NMDP IRB staff
	• To check on the status of your xForm, go to ***xForms*** on your dashboard. Click the link to see the stage it's in.
	• **More information:** See section 5 of the NMDP Single IRB Manual

Maintenance

Task	Details
Annual Worksheet Review	• Annually, local signatory institutions must review the ***Single IRB Signatory Institution Enrollment and Local Context Form*** to verify the form reflects the current policies and procedures for the institution. • **More information:** See section 5 of the NMDP Single IRB Manual
Continuing Reviews	• No action needed from sites! • The central study-level protocol team obtains approval and distributes to sites. • **More information:** See section 5 of the NMDP Single IRB Manual

Protocol Amendments	• The central study-level protocol team obtains approval and distributes to sites.
	• If there is a consent amendment, complete the following:
	  ○ With tracked changes on, make the amendment revisions to the previously-approved institutional consent form.
	  ○ Send your redlined version of the consent form to the central study-level protocol team for pre-approval.
	  ○ After pre-approval, submit ***IRB Request for Study Amendment*** xForm in IRBManager. Attach 1) the redlined version of the consent form, and 2) documentation of the central study-level protocol team's approval.
	• **More information:** See section 5 of the NMDP Single IRB Manual

Reportable Events	• The following events must be promptly reported to the NMDP IRB:
	  ○ Potential unanticipated problems
	  ○ Potential serious or continuing noncompliance
	  ○ Major protocol exceptions, including eligibility exceptions.
	  NOTE: Major protocol exceptions must be approved by the NMDP IRB prior to implementation.
	• Decision charts are available for deciding if potential unanticipated problems or potential serious or continuing noncompliance should be reported.
	• **More information:** See section 7 of the NMDP Single IRB Manual

Site Personnel Changes	• Principal Investigator:
	  ○ Submit ***Revised NMDP sIRB Study-Specific Local Context Worksheet*** xForm, accessible under the specific study
	  ○ Attach documentation of new PI's training in human research protections (not GCP)
	  ○ Attach redlined consent document(s) showing change in PI
	• To update study-site personnel responsible for IRB submissions, a current study-site contact submits the ***Add/Remove Study-Site Contacts*** xForm in IRBManager.
	• **More information:** See section 5 of the NMDP Single IRB Manual

Other Institutional Changes and Submissions	Other institutional documents or changes that must be submitted to the NMDP IRB by the signatory institutional primary contact include: • Institutional boilerplate language • Institutional short forms in each language • Signatory institution primary contact or signatory official

	• Changes to information in the ***Single IRB Signatory Institution Enrollment and Local Context Form*** **More information:** See section 5 of the NMDP Single IRB Manual
Other Study-Specific Changes and Submissions	Other study-specific documents or changes that must be submitted to the NMDP IRB by the study-site contacts or site PI include: • Waivers of consent and/or assent • Changes to information in the ***NMDP sIRB Study-Specific Local Context Worksheet*** (e.g., changes in enrollment population, COI, site's recruitment process, etc.) **More information:** See section 5 of the NMDP Single IRB Manual

Helpful Links & Resources

IRB Policies and Procedures (link)
Relying on NMDP IRB Webpage (link)
Manual for Local Institutions Using the NMDP as a Single IRB (link)
IRBManager: (link)
IRBManager User Guide for Researchers and Research Staff (link)
IRBManager FAQs (link)

Which xForm do I use?

For initial site approval on a study, use the *NMDP sIRB Study-Specific Local Context Worksheet*.
After initial site approval on a study has been received, click into the study under My Studies on your dashboard, click Start xForm on the left, then choose the appropriate xForm. Read the description of an xForm to determine which one to use.

Still need help?

For questions or assistance, contact IRBStaff@nmdp.org.