

Reliance on National Marrow Donor Program (NMDP) Central Institutional Review Board (CIRB)
(Updated 10/12/2022)

This guidance reviews the process for use of the NMDP CIRB for IRB review and oversight of research involving University of Massachusetts-Worcester (UMass) investigators. UMass maintains an Agreement with the NMDP CIRB which sets forth understandings, authority, and responsibilities of both institutions.

The University of Massachusetts-Worcester, in an effort to create a framework that will facilitate the review of multi-site research, has entered into an agreement with the NMDP CIRB whereby UMass may rely upon the NMDP CIRB for IRB review and approval of all research studies sponsored by the Blood and Marrow Transplant Clinical Trials Network (BMT CTN).

Although UMass may rely upon the NMDP CIRB for review of certain research projects, the Institution is still responsible for the conduct of that research. Therefore, while not responsible for IRB approval of ceded studies, the UMass Chan IRB must be aware of and approve of the submission being sent to the NMDP CIRB through an administrative pre-review. The NMDP CIRB will not review any UMass Chan study prior to UMass Chan IRB administrative pre-review.

In order for the UMass IRB to be able to extend this agreement to include a specific BMT CTN research study, all of the following conditions must apply:

The research is not phase 1 or first-in-human.
A waiver (partial or full) of HIPAA Research Authorization is not required.

If you wish to rely on the NMDP CIRB and your study meets the criteria above, follow the approval process outlined below.

Research studies that do not meet the criteria above, including phase I or first-in-human trials, will be considered by the UMass Chan IRB on a case-by-case basis.

To initiate a request, email IRBreliance@umassmed.edu with a copy of the protocol, master consent, name of the UMass Chan PI, a description of how UMass Chan will be involved, and the name of the reviewing IRB. In addition, requests should include

- A description of the investigational product, including how it is administered and its risks
- Proposed staffing and their experience with clinical research and Phase I trials
- The setting in which research procedures will occur
- Safety measures, including the plan for coordinating care for subjects in the absence of a 24-hour inpatient clinical trials unit. For example, explain which service subjects would be admitted to and how care will be coordinated and communicated between the clinical team and the study team.

Approval Process

In IRB Manager: Instructions for completing the worksheets about local context can be found on the NMDP website at <https://network.bethematchclinical.org/research/institutional-review-board/> Click on [Study Site Forms](#) and reference the "IRBManager for Researchers and Staff" guide.

- Confirm that the Annual Principal Investigator Worksheet about Local Context is Approved by the NMDP CIRB.

- Identify the Study: Check the NMDP Website and confirm that the study to be opened is listed: <https://network.bethematchclinical.org/research/research-protocols/>
- Complete the Study-Specific Worksheet About Local Context: This should be completed by the lead researcher (or designee) via IRB Manager (<https://nmdp.my.irbmanager.com>)

In RMS eIRB:

- Initiate a multi-site relying study and select *NATIONAL MARROW DONOR PROGRAM* as the external IRB.
- Verify that all study staff have completed CITI human subjects training, conflict of interest training, and if a clinical trial, GCP training.
- Upload the following Study-Wide Documents
 - NMDP Master Protocol
 - Investigator brochure (if applicable)
 - NMDP CIRB approved consent form template
 - Most current NMDP CIRB approval letter for study
- Upload the following Local Study Documents
 - Annual Principal Investigator Worksheet About Local Context
 - Study-Specific Worksheet about Local Context
 - Subject Consent Form(s): Subject injury language must be taken from the current UMass Chan approved template for unfunded research found at [https://umassmed.sharepoint.com/sites/RMS/IRB/SitePages/Library-\(SOPs,-Forms,Templates,-Etc\).aspx](https://umassmed.sharepoint.com/sites/RMS/IRB/SitePages/Library-(SOPs,-Forms,Templates,-Etc).aspx) **NOTE:** No revisions to the NMDP-approved consent form are allowed except adding the NMDP approved cover sheet and replacing NMDP consent form language with the NMDP-approved UMass Chan specific language, where applicable.
 - UMass Chan [HIPAA Research Authorization Form](#) unless using a compound consent and authorization
 - UMass Chan specific recruitment materials
 - Any other required UMass Chan approvals, which must be obtained before submitting to the NMDP CIRB, e.g.,
 - [IBC](#) registration or an explanation in the pSite form as to why IBC registration is not required
 - RSC approval or a copy of the [Questions for PI](#) documenting why RSC approval is not required
 - [COI](#) approval and mitigation plan
- The UMass Chan IRB does not need a copy of every study document approved by the NMDP CIRB.

Once all required documents have been uploaded into RMS eIRB, the PI has submitted the study, and the submission is in Pre-Review (and is no longer in Pre-Submission), the UMass Chan IRB will conduct an administrative review which includes the following activities:

- Confirming that the PI is not restricted as per the [Investigator’s Manual](#)
- Reviewing the list of active study staff for current CITI human subjects research training
- Reviewing the uploaded documents to assure that the study meets the conditions of the reliance agreement and local requirements
- Notifying the study team of any issues, including required changes to the consent form, through Pre-Review Clarifications Requested in eIRB

Once the NMDP CIRB has approved the study, the study team uploads the NMDP CIRB approval letter and the final approved site-specific documents to Local Study Documents in RMS eIRB. The PI then submits the response.


Once the UMass Chan IRB verifies that the approved documents match the ones that were cleared for submission, it will acknowledge receipt.

PI POST-CIRB APPROVAL RESPONSIBILITIES:


Once NMDP CIRB approval is granted, the NMDP CIRB will maintain oversight of the study. Therefore, subsequent submissions (e.g., amendments, continuing reviews, reportable events) go directly to the NMDP CIRB for review. However, the annual continuing review and other items listed below must also be submitted to UMass Chan IRB through RMS eIRB.

Information to Also Submit to UMass Chan IRB	RMS eIRB Function
All changes in study staff, including changes in PI	Create Site Modification
Proposed changes to research injury compensation language or conflict of interest declarations	Create Site Modification
Unanticipated problems involving risks to subjects or others, reports of serious and/or continuing non-compliance, or IRB suspension or termination through RMS eIRB – when the information involves a UMass Chan subject or investigator	Report New Information
Notification of reapproval plus current site-specific materials, study-wide protocol, and IB if not already in RMS	Create Site Modification to upload current site-specific materials (e.g., consents)
	Update Study Materials to upload IRB reapproval letter and current study-wide protocol and IB
Closure of the study or UMass Chan as a site	Update Study Materials to upload closure letter

GENERAL TIPS

	<ul style="list-style-type: none"> • Make sure you are working from the most recent instructions and from IRB approved templates. • Read through the instructions in full before starting and prepare your materials offline. • Make sure all study staff have completed the required human subjects, GCP, and COI CITI trainings. • Make sure all ancillary reviews are complete.
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ADMINISTRATIVE REVIEW AND CONSENT FORM TIPS

	<ul style="list-style-type: none"> • Follow the UMass Chan CIRB approved cover sheet and replace CIRB consent form language with the CIRB-approved UMass Chan specific language, where applicable • All research happens under the auspices of the Medical School. <ul style="list-style-type: none"> ○ Ensure that the informed consent conveys that UMass Chan Medical is conducting the research. When research at UMass Chan happens in a clinical setting, subjects may be seen at, e.g., UMass Memorial Medical Center. ○ When the consent or authorization discusses disclosure of protected health information, it must cite as applicable UMass Memorial Medical Center or UMass Memorial Health as the covered entities that hold the protected health information. ○ If the UMass Memorial logo appears, the UMass Chan logo must also be present. • When a HIPAA authorization is necessary, the consent must include a complete HIPAA authorization, or the study team can add a UMass Chan stand-alone HIPAA authorization. See HRP-330 – WORKSHEET – HIPAA Authorization to evaluate whether a consent is a compound consent and authorization. • A HIPAA authorization must permit disclosure to UMass Chan and UMMH. The following UMass Chan boilerplate is suggested when the consent does not have similar language. <ul style="list-style-type: none"> ○ <i>The UMass Chan Medical School and UMass Memorial Health, including their Institutional Review Board (IRB) and research, billing, and compliance offices</i>
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For IRB Office Use Only

Document Version History:

Date	Status
02/10/2022	Initial Post
07/13/2022	Minor revisions
10/11/2022	Revised to update study/site closure process