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Reliance on Northeast ALS (NEALS) Network Central Institutional Review Board (CIRB)

(Updated 04/24/2026)

This guidance reviews the process for use of the NEALS CIRB for IRB review and oversight of research involving University of Massachusetts-Worcester (UMass) investigators. UMass maintains an Agreement with the NEALS 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 NEALS CIRB whereby UMass may rely upon the NEALS CIRB for IRB review and approval of select NEALS research studies.

Although UMass Chan may rely upon the NEALS CIRB for review of specific research projects, the Institution is still responsible for the conduct of that research. Therefore, the UMass Chan IRB must be aware of and approve of the submission being sent to the NEALS CIRB through an administrative review. The NEALS CIRB will not review any UMass Chan study without written clearance from the UMass Chan IRB.

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

- The research is not phase 1 or first-in-human.

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 **to use NEALS CIRB for a study that DOES NOT meet the criteria in the table above**, email IRBreliance@umassmed.edu with a copy of the protocol, master consent, name of the UMass Chan PI, and 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.

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To initiate a request to use NEALS CIRB for a study that DOES meet the criteria above, follow the approval process outlined below:

Approval Process

In RMS eIRB:

- Initiate a multi-site relying study and select *MASS GENERAL BRIGHAM INCORPORATED* 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
    - CIRB approved master protocol
    - Investigator brochure (if applicable)
    - CIRB approved master consent and/or assent templates
    - Most current CIRB approval letter for study
- Upload the following Local Study Documents
    - Red-line copies of site-specific materials based on the CIRB-approved templates (e.g., draft consent form for use at UMass Chan)
    - UMass Chan HIPAA Authorization Stand Alone Form unless using a compound consent and authorization
    - Completed UMass Chan HRP-508 pSite Supplement and Communication Plan or comparable NEALS CIRB document
    - Any NEALS CIRB documents that require local HRPP/IRB review
    - Any other required UMass Chan approvals, which must be obtained before submitting to the NEALS CIRB, e.g.,
        - Institutional Biosafety Committee IBC registration or an explanation in the pSite form as to why IBC registration is not required
        - Radiation Safety Committee approval or a copy of the *Questions for PI* documenting why RSC approval is not required
        - Gene and Cell Therapy Advisory Committee approval
        - Conflict of Interest Committee COI approval and mitigation plan
- **The UMass Chan IRB does NOT need a copy of every study document approved by the NEALS CIRB** (e.g. study measurement documents, master recruitment materials, etc.).

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 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
- Sending a written determination to the study team (via Add Comment) indicating that the application may be submitted to the NEALS CIRB

Once the administrative review is complete, the study team submits the corresponding application to the NEALS CIRB.

Once the NEALS CIRB has approved the study, the study team uploads the NEALS 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 NEALS CIRB approval is granted, the NEALS CIRB will maintain oversight of the study. Therefore, subsequent submissions (e.g., amendments, continuing reviews, reportable events) go directly to the NEALS CIRB for review. However, the annual continuing review and other items listed below must also be submitted to the 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

Information to Also Submit to UMass Chan IRB	RMS eIRB Function
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 study/site reapproval letter(s) 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

- 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.
- See eIRB Course 4: Multi-Site Relying Study Submission Process.

Administrative Review and Consent Form Tips

- **Use the UMass Chan research injury language from the UMass Chan HRP-502 Consent Document and HIPAA Authorization template.**
    - The UMass Chan boilerplate is consistent with the clinical trial agreement and the requirements of the Contracting Guide. The Contracting Guide is shared early in the contract process with the sponsor. The guide includes a Subject Injury Coverage Statement that outlines prohibited language. Study teams should only

submit for administrative review redline consents that use the UMass Chan research injury language.

- If the CTA does not include research injury coverage, you may be able to use the existing language in the consent template or the UMass Chan boilerplate for unfunded research.

- If the consent includes references to the European Economic Area's General Data Protection Regulation (GDPR), obtain administrative review from privacyandcompliance@umassmed.edu before submitting the draft in RMS eIRB. If you see references to data controllers or local data protection authorities in Europe, the consent likely requires review by Privacy and Compliance.
- All research happens under the auspices of the Medical School.
    - Ensure that the informed consent conveys that UMass Chan Medical School 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.
- Remove any language in which subjects give up rights or ownership of samples or information collected about them.
    - The clinical trial agreement provides the sponsor a right of use, not ownership.
    - The consent can inform subjects that they will have no rights related to discoveries made as part of the research and that they will not share in any profits.
- Ensure that the consent does not overpromise coverage of possible related expenses. The following UMass Chan boilerplate is suggested for clinical research consents when the consent does not have similar language.
    - *You or your insurance will not have to pay for tests and procedures that are done for research purposes only. However, you or your insurance will be billed for all routine medical and diagnostic costs that are part of the standard of care for treating your condition. This may include the cost of tests, procedures, or medicines to manage any side effects. You will be responsible for any deductibles, co-payments, or co-insurance payments that your coverage normally requires.*

  - *Drug name or agent will be provided to you at no cost; however, you or your insurance may be billed for the administration of this drug or agent.*

- Do not overpromise confidentiality.
  - There are many groups at UMass Chan and UMMH that will necessarily have appropriate access to identifiable information about subjects, including through OnCore and EPIC.
  - The consent may not permit subjects to opt out of the study doctor notifying a subject's regular doctors about the subject's participation in the research. Due to safety concerns, UMass Chan does not permit these opt-outs. Study teams may remove or revise these opt-outs.
- When a HIPAA authorization is necessary, the consent must include a complete HIPAA authorization, or the study team can add a UMass Chan HIPAA Authorization Stand Alone Form. 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.
  - *The UMass Chan Medical School and UMass Memorial Health, including their Institutional Review Board (IRB) and research, billing, and compliance offices*
- Consents must provide a 24-hour contact number for studies that are greater than minimal risk
- If the research includes pregnancy testing of minors, add the corresponding language from the UMass Chan consent template:
  - *If you could get pregnant, you will have pregnancy testing as part of this study. Only you will be told the results. If you are a minor and are found to be pregnant, we will talk to you about getting appropriate healthcare and the support of an adult. A positive pregnancy test means that you cannot be in this study. Because you will be asked to leave the study, your parents may find out that you are pregnant. If you are uncomfortable with pregnancy testing, then you should not be in this study.*

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For IRB Office Use Only

Document Version History:

Document Version Date	Revisions Made
02/10/2022	Initial Post
04/06/2022	Modified to add Example of Multi-site Relying Study in eIRB – what to enter into UMass Chan RMS eIRB when starting a study that involves SMART IRB (including Advarra), NEALS IRB, Strokenet IRB, or Other IRB
07/13/2022	Minor revisions
03/29/2023	Revised to clarify how to get started, added Gene Therapy Committee, and updated links
04/23/2026	Updated document to ensure compliance with accessibility standards (ADA WCAG)