1.3 UNMC IRB Serving as the Single IRB for Multisite Research

Last Revised: 4/21/2025

1.0 Purpose

The purpose of this policy is to describe the Organization’s requirements for the UNMC IRB to serve as the Single IRB (SIRB) for multisite research.

2.0 Policy

It is the policy of the Organization that:

- 2.1. The UNMC IRB may serve as the SIRB for multisite research as permitted or required by HHS regulations at 45 CFR 46.114 and FDA regulations at 21 CFR 56.114.
  - 2.1.1. The UNMC IRB may serve as the IRB of record in accordance with the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research (NOT-OD-16-094).
- 2.2. The Assistant Vice-Chancellor for Regulatory Affairs and/or Director or Assistant Director of the Office of Regulatory Affairs (ORA) have authority to determine whether or not to allow the UNMC IRB to serve as the Single IRB for multisite research.
  - 2.2.1. For all non-exempt research, the Organization requires execution of a Reliance Agreement.
  - 2.2.2. For exempt research, the Organization does not normally require execution of a Reliance Agreement.
- 2.3. Research conducted at external organizations where UNMC is the IRB of record must comply with HRPP policies of the relying institution, except as specified in this policy and/or in the Reliance agreement.

3.0 Definitions

- 3.1. Cede Review: The Organization has agreed to transfer IRB review and oversight authority for specified research to another institution’s IRB (reviewing IRB).
- 3.2. Local Context: Unique legal requirements, cultural or religious values, or other site-specific variables that exist at a site where subjects are enrolled in research.

- 3.3. Reliance Agreement (also known as an Authorization Agreement): An agreement between two Organizations engaged in human subject research that documents respective authorities, roles, and responsibilities of the organizations.
- 3.4. Relying Institution: A participating Institution that cedes IRB review to the IRB of record (reviewing IRB) designated under a Reliance Agreement.
- 3.5. Site Principal Investigator (Site PI) is the lead investigator at each institution participating in multisite research responsible for the conduct of the research at the participating institution.
- 3.6. Lead Principal Investigator (Lead PI) is the study-wide Principal Investigator with ultimate responsibility for the conduct and integrity of multisite research.
- 3.7 Reviewing IRB: The IRB which is responsible for conducting IRB review and approval of cooperative human subject research, and for ongoing oversight of such research, as described in 45 CFR 46.109.
- 3.8. Office of Regulatory Affairs (ORA): The UNMC office responsible for the support of the IRBs and the day-to-day operations of the HRPP.

4.0. UNMC IRB, Relying Institution, and Lead PI Responsibilities

- 4.1. It is the responsibility of the UNMC IRB (as reviewing IRB) to:
  - 4.1.1. Conduct review of the research in full accordance with applicable federal and state regulations, and all relevant HRPP policies (including, but not limited to, initial review, continuing review, review of amendments, noncompliance, unanticipated problems involving risk to subject or others, deviations, adverse events, study holds, suspensions, and terminations).
    - 4.1.1.1. Review any COI management plans from the relying institution to assure the plan is adequate in consideration of the nature of the conflict. The UNMC IRB as reviewing IRB may apply additional restrictions and/or limitations but may not be less restrictive than those required by the relying institution.
  - 4.1.2. Obtain any additional approvals from DHHS when the research involves pregnant women, fetuses, and neonates; or children; or prisoners (as applicable per DHHS and FDA regulations).
  - 4.1.3. Determine if the relying organization(s) apply their FWA to some or all of the research and ensuring the IRB review is consistent with the requirements of the Relying Institutions FWA (as applicable per DHHS and FDA regulations).
  - 4.1.4. Make determinations required by HIPAA Privacy Rule (45 CFR Parts 160 and 164) when the relying IRB does not accept the responsibility to make those determinations.
  - 4.1.5. Should termination of a reliance agreement occur, ensure that it is clear who will have the responsibility of continued oversight of study activities until closure or transfer of the study.
  - 4.1.4. Report all determinations of serious or continuing noncompliance, unanticipated problems involving risk to the subject or others, and suspensions or terminations to the Relying Institution, Institutional Officials and Federal Agencies.
  - 4.1.5. Report to the Relying Institution:
    - 4.1.5.1. Any unanticipated problems involving risk to the subject or others associated with subjects enrolled at the institution.
    - 4.1.5.2. Any serious or continuing noncompliance.

        - 4.1.5.3. Any serious complaints which impact the rights and welfare of research subjects.
        - 4.1.5.4. The results of any audits conducted, or reports filed, by FDA or OHRP.
        - 4.1.5.5. Any FDA Form 483 or warning letter pertaining to the study or IRB review.
        - 4.1.5.6. Any other communication from FDA or other governmental agency citing improper or inadequate research practices.
    - 4.1.6. Notify the Investigator and the Relying Institution (when applicable) of the IRB's determinations.
    - 4.1.7. Provide the Relying Institution's investigators and research staff with the Point of Contact (POC) to obtain answers to questions, express concerns, and convey suggestions regarding the IRB.
    - 4.1.8. Upon written request, provide Relying Institutions with access to relevant records related to IRB review (including, but not limited to minutes, approved protocols, consent forms, and other records that document the IRB's determinations to the Relying Institution).
    - 4.1.9. Ensure HRPP policies are readily accessible to Relying Institutions through the IRB website and that there is a mechanism for communicating updates to the policies.
    - 4.1.10. Maintain all research records for at least seven years after completion of the research and make available for inspection or copying by the HHS Office of Human Research Protection (OHRP) and/or FDA upon request in accordance with federal regulations.
    - 4.1.11. Ensure compliance with UNMC's OHRP-approved FWA.
- 4.2. It is the responsibility of the Relying Institution to:
    - 4.2.1. Advise the UNMC IRB of any applicable state or local laws which govern research conducted at the site, or any circumstances related to the conduct of research at the relying site which must be taken into account when the UNMC IRB conducts the review.
    - 4.2.2. Complete all additional reviews required by the relying Institution, including but not limited to biosafety review, radiation safety review, recombinant DNA research review, human stem cell research review and conflict of interest, and advise the UNMC IRB of any requirements resulting from the additional Institutional reviews.
    - 4.2.3. Ensure that all investigators participating in the research are qualified by education, training, experience and licensure (as applicable) to conduct the research in accordance with all applicable regulations and relying institution HRPP policies.
        - 4.2.3.1. Notify the UNMC IRB of the termination, suspension, or modification of any clinical privileges of the relying institution's Medical Staff who are participating in the studies under the oversight of the UNMC IRB..
    - 4.2.4. Advise the UNMC IRB of any allegations of noncompliance. The UNMC IRB, in conjunction with the participating site IRB, will determine how best to handle the allegation in consideration of the need to maintain due process and protect the whistleblower.
    - 4.2.5. Advise the UNMC IRB of any complaint directly from subjects or others. The relying institution will be primarily responsible for the resolution of the complaint as necessary.
    - 4.2.6. Advise the UNMC IRB within three business days of any contact by the FDA, HHS, or any other persons or entities regarding any of the research under the oversight of the UNMC IRB.

- 4.2.7. Notify the UNMC IRB within three business days in the event that the FDA or other governmental agency issues the relying Institution any “Notice of Inspectional Observations”, “Warning Letters”, or other communications citing improper or inadequate research practices with respect to research under the oversight of the UNMC IRB.
- 4.2.8. Ensure that all investigators participating in the research understand their responsibilities under applicable federal regulations (45 CFR 46 including subparts as applicable, 21 CFR 50, 56, 312, 812, and HIPAA Privacy Rule), state laws, institutional policies, and the protocol.
- 4.2.9. Ensure investigators at the participating site comply with relevant UNMC HRPP policies (including but not limited to reporting adverse events, deviations, and noncompliance) except when adherence to local institutional policy is required by law, regulation, or specific agreement between UNMC IRB and the participating site.
  - 4.2.9.1. In the absence of a specific relying site policy, the site will comply with the relevant UNMC HRPP policy.
- 4.2.10. Ensure that all research personnel involved in the process of consent or assent are properly trained and are fully aware of their responsibilities relative to the obtainment of informed consent/assent according to institutional policies, applicable federal regulations, and state law.
- 4.2.11. Maintain a copy of the signed informed consent document in accordance with relying institution policies, applicable HHS and FDA regulations, and ICH-GCP.
- 4.2.12. Maintain all research records in accordance with relying institution policies, applicable HHS and FDA regulations, ICH-GCP and HIPAA Privacy Rule as appropriate.
- 4.2.13. Ensure compliance with its OHRP approved FWA (if applicable).
- 4.2.13. Permit the UNMC IRB, or its authorized representatives, the FDA, and OHRP to the extent permitted by law, to conduct the following:
  - 4.2.13.1. Examine and inspect the Relying Institution facilities used for the performance of the studies, including storage and use of any investigational products.
  - 4.2.13.2. Observe the conduct of the studies.
  - 4.2.13.3. Inspect and copy all documents relating to the studies, including research records, patient medical records, informed consent documents, Investigational Product logs, and other study specific data.
  - 4.2.13.4. Interview, as necessary, all necessary personnel involved in patient care for the studies.

- 4.3. It is the responsibility of the Lead (study-wide) PI to:
  - 4.3.1. Serve as the primary contact with the UNMC IRB. The Lead PI assumes primary responsibility for notifying the relying sites of all UNMC IRB actions.
  - 4.3.2. Promptly respond to requests for information from Site PIs and/or study teams at relying institutions or the Relying Institution IRBs.
  - 4.3.3. Ensure the Site PIs have access to the UNMC HRPP policies.
  - 4.3.5. Provide participating sites with the IRB approved versions of all study documents.
  - 4.3.6. Promptly report to all Site PI’s any unanticipated problems involving risks to subjects or others, research related subject injuries, or significant subject complaints that are related to or may affect subject’s willingness to continue participation in the study.
  - 4.3.7. Notify Site PIs of all UNMC determinations and communications, including initial review, continuing review, Requests for Change, and reportable events.

- 4.3.8. Ensure Site PIs submit the participating site (pSite) Continuing Review Application.
- 4.3.9. Notify the Site PI of any lapse in IRB approval of their site and any applicable corrective action plans.
- 4.3.10. Provide access, upon request, to all study records by audit by any Relying Institution, the UNMC IRB, and other regulatory or monitoring entities.
- 4.3.11. Other PI responsibilities are defined in HRPP policy 1.26 (PI Qualifications and Responsibilities).

DOCUMENT HISTORY:

? Undocumented activity: 4/4/2016

? Undocumented activity: 3/27/2018

? Revised: 10/21/2021 - Major revisions in format; content revised to be consistent responsibilities described in HRPP 1.4, Notification: not documented

? Revised: 8/25/2023 - Added additional responsibility for UNMC HRPP regarding review of relying institution COI management plan (section 4.1.1.1).

? Revised: 11/13/2024 – clarified which UNMC HRPP policies must be complied with by participating sites (section 5.7); corrected typographic errors; stylistic changes.

? Revised 4/21/2025 - Clarified that the Assistant Vice-Chancellor for Regulatory Affairs and/or Director or Assistant Director of the Office of Regulatory Affairs (ORA) have authority to determine whether or not to allow the UNMC IRB to serve as the Single IRB for multisite research (section 2.2); added definition of ORA (section 3.8); clarified that UNMC IRB is responsible for making determinations required by HIPAA Privacy Rule when the relying IRB does not accept the responsibility to make those determinations (section 4.1.4); clarified that, should termination of a reliance agreement occur, UNMC IRB will ensure that it is clear who will have the responsibility of continued oversight of study activities until closure or transfer of the study (section 4.1.5); clarified that the Relying Institution will be responsible to ensure that all investigators participating in the research are qualified by education, training, experience and licensure (as applicable) to conduct the research in accordance with all applicable regulations and relying institution HRPP policies (section 4.2.3); clarified that the Relying Institution is responsible to ensure investigators at the participating site comply with relevant UNMC HRPP policies except when adherence to local institutional policy is required by law, regulation, or specific agreement between UNMC IRB and the participating site (section 4.2.9); deleted description of processes more suited for SOPs; stylistic changes.

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