

1.4 UNMC Ceding Review to an External Central IRB

1.0 Purpose

The purpose of this policy and procedure is to describe the Organization's requirements for the UNMC IRB to cede review to an external IRB.

2.0 Policy

- 2.1. It is the policy of the Organization that all non-exempt research under the authority of the UNMC IRB and conducted, supported, or otherwise subject to regulation by any Federal department or agency which has adopted the Common Rule will rely on upon approval by a single IRB for that portion of the research that is conducted in the United States, in accordance with 45 CFR 46.114, unless excluded from this requirement under 45 CFR 46.114(b)(2).
- 2.2. It is the policy of the Organization that all NIH-funded research will rely on upon approval by a single IRB, in accordance with the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research (NOT-OD-16-094), unless excluded from this requirement under NIH policy (NOT-OD-18-003).
- 2.3. It is the policy of the Organization that selected independent commercial IRBs may serve as the IRB of record as permitted by HHS regulations at 45 CFR 46.114 and FDA regulations at 21 CFR 56.114 for new commercially sponsored clinical trials, with the exceptions specified under Section 2.5 below.
- 2.4. It is the policy of the Organization that the National Cancer Institutes (NCI) Central IRBs (CIRBs) may serve as the IRB of record for pediatric and adult research sponsored by the National Cancer Institute (NCI) National Clinical Trials Network (NCTN) as

permitted by HHS regulations at 45 CFR 46.114 and FDA regulations at 21 CFR 56.114.

- 2.5. It is the policy of the Organization that other external IRBs may serve as the IRB of record as permitted by HHS regulations at 45 CFR 46.114 and FDA regulations at 21 CFR 56.114 on a case-by-case basis, with the exceptions specified under Section 2.6 below, provided the following conditions are met:
 - 2.5.1. For research which constitutes greater than minimal risk, the external IRB is part of an accredited HRPP or has completed the OHRP QA Self-Assessment Tool
 - 2.5.2. For research which constitutes no more than minimal risk, the external IRB reviews the research appropriately, in compliance with all federal, state, and local regulations, and the review criteria utilized by the external IRB are in compliance with the Organization's ethical standards and with applicable laws and regulations, and with the specific approval of the IO, in consultation with the IRB Executive Chair as appropriate.
 - 2.5.3. The external Institution has a valid FWA, and the external IRB is registered with OHRP and FDA (as applicable).
- 2.6. It is the policy of the Organization that, unless use of a single IRB subject is required by 45 CFR 46.114, or required by NIH policy, the use of an external IRB is not permitted for:
 - 2.6.1. Clinical trials initiated by a UNMC investigator.
 - 2.6.2. Use of a Humanitarian Use Device (HUD) subject to 21 CFR 814.124(a).
 - 2.6.3. Emergency research subject to FDA regulations at 21 CFR 50.24.
 - 2.6.4. Research that involves the use of vaccines developed or manipulated at UNMC.
 - 2.6.5. Research involving gene transfer.
 - 2.6.6. Emergency use of a test article subject to FDA regulations at 21 CFR 56.102(d) and 21 CFR 56.104(c).
 - 2.6.7. Research involving prisoners as subjects.
 - 2.6.8. Research involving fetal tissue or HESCs, or their derivatives.
- 2.7. It is the policy of the Organization that the IO, in consultation with the IRB Executive Chair as appropriate, has the sole authority to determine whether or not to allow the UNMC IRB to cede review of research described in 2.5 to an external IRB.
- 2.8. It is the policy of the Organization that the IO, in consultation with the IRB Executive Chair as appropriate, has the sole authority to allow exceptions to the exclusions in 2.6 above.
- 2.9. It is the policy of the Organization that it will accept the review and approval of an external IRB for human subject research exempt under 45 CFR 46.104; however, the Organization will not require the execution of a Reliance Agreement.
- 2.10. It is the policy of the Organization that there must be an executed Reliance Agreement between UNMC and the external IRB's institution or the commercial IRB, prior to utilization of the external or commercial IRB, for all non-exempt research.
- 2.11. It is the policy of the Organization that all Organizational review requirements must be completed, and the Reliance Agreement be fully executed before the research will be released to the external or commercial IRB, for all non-exempt research; however the IO and Executive Chair have the authority to allow exceptions to this policy.
- 2.12. It is the policy of the Organization that the research may not commence until approval has been granted by the external IRB.
- 2.13. It is the policy of the Organization that research conducted under the purview of an external IRB will be subject to all relevant policies of the external (reviewing) IRB, and investigators of the Organization must comply with those policies, except as specified in addendum 2.

- 2.14. It is the policy of the Organization that investigators must comply with Organization policies as described in Addendum 2.
 - 2.15. It is the policy of the Organization that all research conducted under an external IRB is subject to post approval monitoring per HRPP policy 1.21 (Post-Approval Monitoring of Research).
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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 or external IRB)
 - 3.2. Reliance Agreement (also known as an Authorization Agreement): An agreement between two Organizations engaged in human subject research that documents respective authorities, roles, responsibilities, and communication between an organization between the reviewing and relying IRBs.
 - 3.3. Relying Institution: A participating Institution that cedes IRB review to the IRB of record (reviewing IRB) designated under a Reliance Agreement.
 - 3.4. Reviewing IRB (or External IRB): The IRB which is responsible for conducting IRB review and approval as described in 45 CFR 46.109 for cooperative human subject research. For the purpose of this policy, reviewing IRB and external IRB are the same.
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4.0 External IRB, UNMC IRB, and PI Responsibilities

- 4.1. It is the responsibility of the external 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 policies of the external IRB (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).
 - 4.1.2. 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. 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.

- 4.1.4. Report to the UNMC IRB:
 - 4.1.4.1. Any unanticipated problems involving risk to the subject or others associated with subjects enrolled at the institution.
 - 4.1.4.2. Any serious or continuing noncompliance.
 - 4.1.4.3. Any serious complaints which impact the rights and welfare of research subjects.
 - 4.1.4.4. The results of any external audits conducted by FDA, OHRP, sponsors, and CROs.
 - 4.1.4.5. Any reports filed with the FDA or OHRP.
 - 4.1.4.6. Any FDA Form 483 or warning letter pertaining to the study or IRB review.
 - 4.1.4.7. Any other communication from FDA or other governmental agency citing improper or inadequate research practices.
- 4.1.5. Notify the Investigator and the Institution (when applicable) of the IRB's determinations.
- 4.1.6. Provide a Point of Contact (POC) and contact information for UNMC researchers and research staff to obtain answers to questions, express concerns, and convey suggestions regarding the use of the external IRB.
- 4.1.7. Upon written request, provide UNMC 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).
- 4.2. It is the responsibility of the UNMC IRB and HRPP (on behalf of the relying institution) to:
 - 4.2.1. Advise the external IRB of any applicable state or local laws governing research conducted at this Organization.
 - 4.2.2. Advise the external IRB of completion of all additional reviews required by the 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 of any requirements resulting from the additional Institutional reviews.
 - 4.2.3. Advise the external IRB of any circumstances when the review must take into account additional regulatory requirements or local HRPP requirements.
 - 4.2.4. Ensure that all investigators participating in the research are members of the Institution's medical staff in good standing and are credentialed and privileged to perform the procedures outlined in the studies.
 - 4.2.4.1. Notify the external IRB of the termination, suspension, or modification of any clinical privileges of the Organization's Medical Staff who are participating in the studies authorized by the external IRB.
 - 4.2.5. Advise the external IRB of any allegations of noncompliance which are received by the ORA and which are found to be serious or continuing, or which represent an unanticipated problem involving risk. The external IRB, in conjunction with the ORA, will determine how best to handle the allegation in consideration of the need to maintain due process and protect the whistleblower.
 - 4.2.6. Advise the external IRB of any complaint directly from subjects or others. The Research Subject Advocate Office will assist in the resolution of the complaint as necessary.
 - 4.2.7. Advise the external IRB of any contact by the FDA, HHS, or any other persons or entities regarding the research within three business days of contact.
 - 4.2.8. Notify the external 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 the research specified above.

- 4.2.9. Ensure that UNMC applies its FWA to all research and ensure that the IRB review is consistent with the requirements of the UNMC’s FWA.
- 4.2.10. Ensure that, should termination of a reliance agreement occur, it is clear who will have the responsibility of continued oversight of study activities until closure or transfer of the study.
- 4.2.11. 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.
- 4.2.12. 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.
- 4.2.13. Notify the reviewing IRB when local policies that impact IRB review are updated.
- 4.3. It is the responsibility of the UNMC PI to:
 - 4.3.1. Complete all requirements for submission of request to utilize the CIRB to the ORA.
 - 4.3.2. Complete all requirements for submission to the external IRB.
 - 4.3.3. Comply with all relevant UNMC HRPP policies, such as, but not limited to, those related to compensation, advertisement, ethical access, short form consent, process and documentation of consent.
 - 4.3.4. Comply with all determinations and requirements of the external IRB.
 - 4.3.5. Comply with the external IRB’s requirements for initial and continuing review, record keeping, and reporting in a timely manner.
 - 4.3.6. Promptly report the following to the external IRB (in accordance with their policies):
 - 4.3.6.1. Any proposed changes to the research.
 - 4.3.6.2. Conflict of interest (COI) management plans (in accordance with HRPP policy 1.25 Financial Conflicts of Interest). The UNMC PI and research staff must comply with all determinations.

Note: The external IRB may impose additional safeguards; however, the external IRB may not be less stringent than what is required by the UNMC COI management plan.

- 4.3.6.3. Incidents of noncompliance. Copies of all reports to the federal government (e.g., OHRP, FDA, federal sponsor or funding agency) must also be provided to the ORA.
- 4.3.6.4. Protocol deviations.
- 4.3.6.5. Any complaints from subjects or others. The UNMC Research Subject Advocate Office will assist in the resolution of the complaint as necessary.

- 4.3.6.6. Data Safety Monitoring Reports
 - 4.3.6.7. Internal adverse events and other events which qualify as an unanticipated problem involving risk to the subject.
 - 4.3.7. Promptly report to the UNMC IRB
 - 4.3.7.1. Any new or modified conflicts of interest of responsible personnel (per HRPP policy 1.25 Financial Conflicts of Interest), and any new or modified management plans.
 - 4.3.7.2. Additional requirements by the external IRB to the UNMC COI management plan.
 - 4.3.7.3. Incidents of non-compliance
 - 4.3.7.4. Copies of all reports to OHRP and/or FDA.
 - 4.3.7.5. Reports of internal adverse events
 - 4.3.7.6. Changes in study personnel
 - 4.3.8. Ensure all investigators and research staff have the appropriate qualifications and expertise to conduct the research.
 - 4.3.9. Ensure that all research personnel understand their responsibility in enrolling participants in the research; including obtainment, documentation, and maintenance of records of consent for each subject/LAR.
 - 4.3.10. Conduct monitoring in addition to, or in cooperation with, the external IRB and the ORA.
 - 4.3.11. Notify the ORA when a study is completed
 - 4.4. There may be additional external IRB, UNMC IRB, and PI, responsibilities dictated by the IRB Reliance Agreement. The fully executed IRB Reliance Agreement must be maintained as documentation verifying the responsibilities of each organization to ensure compliance with the requirements of the Common Rule.
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5.0 Procedures

- 5.1. For all non-exempt human subject research, the PI must submit the Central IRB Application (CIRB) through RSS. The application must be accompanied by the following documents:
 - 5.1.1. Full protocol
 - 5.1.2. Sponsor's template consent forms and/or information sheets

Note: It is recommended that the PI contact the ORA to determine if the proposed research will qualify for external IRB review prior to submission of the application. Acceptance of the application by the ORA does not

signify that review will be ceded.

- 5.2. The IRB Administrator must determine that the request to utilize an external IRB satisfies the requirements of Section 2 above. The administrator, in consultation with the Executive Chair, as appropriate, will then present to the IO the request to allow the UNMC IRB to cede IRB review to the external IRB.
- 5.3. If the IO approves the request, the UNMC IRB Administrator will review the Central IRB Application to determine that:
 - 5.3.1. The research satisfies UNMC requirements including, but not limited to:
 - 5.3.1.1. HRPP policies as described in addendum 2.
 - 5.3.1.2. Review and approval by other components of the HRPP (including, as appropriate, Conflict of Interest Committee, Fred & Pamela Buffett Cancer Center Scientific Review Committee, Pharmacy & Therapeutics Committee, Investigational Device Review Committee, Pathology, IT Security if SSNs maintained)
 - 5.3.1.3. Contract review by Sponsored Programs Administration or UNeHealth
 - 5.3.1.4. Coverage analysis and matrix/study calendar
 - 5.3.2. Appropriate agreements are in place, including, but not limited to:
 - 5.3.2.1. Executed sponsored agreement
 - 5.3.2.2. Data Use, Data Transfer and/or Material Transfer Agreements
 - 5.3.2.3. IRB Reliance Agreement between UNMC IRB and external IRB
 - 5.3.3. The UNMC IRB Administrator will issue a conditional acceptance letter to the investigator, with conditions based on Organizational requirements.
 - 5.3.4. The following items are available to investigators and may be provided to the external IRB:
 - 5.3.4.1. UNMC Consent Form letterhead (use recommended but not required).
 - 5.3.4.2. The UNMC required consent form language (addendum 1 to this policy).
 - 5.3.4.3. Any COI management plan including any requirements for disclosure in the informed consent form.
 - 5.3.4.4. Additional information related to local context issues, including state, local or institutional regulations or policies that may impact IRB review.
 - 5.3.5. Once all Organizational requirements have been met (as specified in HRPP policy 2.2 Section 8.0: Full IRB Review and HRPP policy 2.3 Section 13.0: Expedited Review) and the IRB Reliance Agreement is fully executed, the IRB Administrator will provide the PI with an acceptance letter granting acceptance of IRB oversight by the external IRB.
 - 5.3.6. The study may not be initiated until the acceptance letter has been provided to the PI.

Note: Once it has been determined that an external IRB will serve as the IRB of record for any given study, all communications from the PI and other study personnel regarding IRB review of the study or its status must be with the external IRB, except as specified in Sections 4.3.7 above. UNMC IRB staff do not have the authority to respond to questions or concerns on behalf of the external IRB.

Note: The external IRB policies and procedures for stamping (or not stamping) consent forms with the approval dates take precedence. The UNMC IRB will not review or provide an approval stamp on any consent forms or information sheets approved by an external IRB.

- 5.4. For research exempt under 45 CFR 46.104, a copy of the protocol and application submitted to, and approved by the external IRB (or HRPP) will be accepted by the ORA in lieu of the Central IRB Application.
 - 5.4.1. The IRB administrator will review submitted materials as described in HRPP Policy 2.6 Exempt Research.
 - 5.4.2. If acceptable, the protocol will be designated ET and will otherwise be handled as an EX protocol.
- 5.5. The ORA, the IRB and the IO retain the authority to suspend research conducted within the organization which has been ceded to an external IRB, if the ORA, IRB or IO believes such action is necessary to protect the rights and welfare of human subjects of the research. The suspension will be promptly reported to the external IRB.

Addendum 1: UNMC Required Consent Form Language

Title: As the IRB of record allows, the consent Form should appear on UNMC/ Nebraska Medicine letterhead for easy identification as a research consent form. The UNMC IRB number should appear in the consent.

Contraception/Pregnancy Language for FDA regulated research: Insert appropriate contraception language based on FDA Pregnancy and Lactation Labeling Rule and/or FDA Use-In-Pregnancy category, as per HRPP Policy 3.9 Contraception Requirements.

Category A and Some Category B Drugs (do not require contraception) It is possible that the medicines used in this study could injure a fetus if you or your partner becomes pregnant while taking them. You have already been told what is known about this possibility, and you are encouraged to ask further questions. Category B, C and D Drugs It is possible that the medicines used in this study could injure a fetus if you or your partner becomes pregnant while taking them. You have already been told what is known about this possibility, and you are encouraged to ask further questions.

You may want to discuss this with others before you agree to take part in this study. If you wish, we will arrange for a doctor, nurse, or counselor who is not part of this study to discuss the potential risks and benefits with you and anyone else you want to have present.

Because of the potential risks, you or your partner must not become pregnant while participating in this study. Women must have a negative pregnancy test before entering the study (and before each treatment as appropriate).

If you are sexually active and can get pregnant, or can get your partner pregnant, you must use ONE (or TWO) appropriate method of birth control every time you have sex, or you must not have sex.

You can get additional information about methods to avoid pregnancy by calling the UNMC Research Subject Advocate's Office at (402) 559-6941.

You or your partner will need to continue to avoid pregnancy for X months after finishing the research.

Should you or your partner become pregnant while on this study, you should immediately notify the study personnel. The investigator will assist you in finding appropriate medical care. The investigator also may ask to be allowed to continue getting information about your pregnancy. You can refuse to provide this information.

Category X drugs: Since studies of the drug in humans, or investigational or post-marketing data, have demonstrated fetal risk, contraception is required and the language must be at least as protective as Category D language above. Often the sponsor and/or FDA require inclusion of specific language relating to fetal risk, monitoring for pregnancy and prevention of pregnancy in the consent form. The language cannot be modified.

The consent form should indicate how frequently pregnancy testing will be performed, how often subjects will be informed of results, and whether subjects will be removed from the study if they become pregnant. If the study involves minors, the consent form must disclose that the results of the pregnancy testing will be shared with the parents. For more information, please see UNMC [HRPP policy 3.10](#) Pregnancy Testing.

Costs to Subject (required for all clinical trials): You will have to pay any insurance deductibles and co-payments. If you want to speak with someone about your insurance, just tell us.

Payment:

If SSN is required for payment, then use the following standard statement:

In order to pay you, you will have to provide your social security number. You can choose not to provide this and still participate in the research but we will be unable to pay you.

If this study has a tissue bank include this standard statement:

We do not plan to pay you if any new drugs or products are made using the sample(s) you donated. It is our policy that all donated samples belong to the organization.

Subject Injury Language for greater than minimal risk research Add the following to consent form
subject injury language: Your health and safety is our main concern. If you are injured or have a medical problem because of this study call someone listed at the end of this consent form. You can get emergency medical treatment at Nebraska Medicine. You can also go to your doctor, the nearest emergency room or call 9-1-1.

{Insert the commercial sponsor language}

We have no plans to pay for your treatment or give you any other money or compensation. Signing this does not mean you have given up any of your legal rights. HIPAA Language:

We also will get medical information about you (like medical record number, medical history, or the results of physical exams, blood tests, x-rays or other medical or research procedures). We call this protected health information" or PHI. PHI is protected by a law called the HIPAA Privacy Rule. We will collect the smallest amount of PHI that we can. We will keep your PHI as confidential as possible.

By signing this consent form, you are letting us (the researchers listed on this consent form and other people involved in this research at the Organization) have access to your PHI. Your PHI will be used only for the purposes described in the section "What is the reason for doing this research study?"

You can change your mind and tell us to stop collecting your PHI for use in this research at any time by writing to the principal investigator. We can still use the PHI we have already collected. If you tell us to stop collecting your PHI, you will have to stop being in this research.

We may share your PHI with other groups listed below:

The UNMC Institutional Review Board (IRB) Institutional officials designated by the UNMC IRB The HHS Office for Human Research Protections (OHRP)

We may share your PHI with other groups listed below. The HIPAA Privacy Rule requires these groups to protect your PHI.

The Food and Drug Administration (FDA) {if study involves FDA regulated drug, device, or biologic}
National Institutes of Health (NIH) {if study is funded by the NIH}

Researchers at insert the name of the institution(s) involved in the study if this is a multi-institution study where PHI will be shared with other researchers

Your health insurance company {if the Institution expects third party payers to pay for clinical procedures performed during the course of the research}

The Fred & Pamela Buffett Cancer Center Scientific Review Committee (SRC) {if the research involves patients with cancer}

We may share your PHI with other groups listed below. These groups are NOT required by HIPAA to protect your PHI. If we share your PHI with these other groups they may share it with others who also do not have to protect it under HIPAA:

{insert name of sponsor}, which sponsors this research and may pay the Organization to do this research

{insert name of CRO} which has been hired by the sponsor to help run the research

The Data and Safety Monitoring Committee (DSMC)

{name of NCI National Cooperative Group}

The National Cancer Institute's (NCI) Clinical Trial Reporting Program

NOTE: Choose one of the statements that appropriately represents your study:

You are letting us use and share your PHI for as long as the research is going on.

Or:

You are letting us use and share your PHI for as long as the sponsor needs so it can get approval from the FDA.

Or:

There is currently no plan to end this study. You are letting us use and share your PHI for as long as we want.

Information related to subject rights should include the UNMC IRB and Research Subject Advocate Contact information

What are your rights as a research participant?

You have rights as a research subject. These rights have been explained in this consent form and in The Rights of Research Subjects that you have been given. If you have any questions concerning your rights, or want to discuss problems, concerns, obtain information or offer input, or make a complaint about the research, you can contact any of the following:

The investigator or other study personnel

Institutional Review Board (IRB) Telephone: (402) 559-6463. Email: IRBORA@unmc.edu

Mail: UNMC Institutional Review Board, 987830 Nebraska Medical Center, Omaha, NE 68198-7830 Research Subject Advocate Telephone: (402) 559-6941 Email: unmcrsa@unmc.edu

Addendum 2: UNMC HRPP Policies to be followed by institution investigators

Process of informed consent, including remote consent and electronic signature, documentation of consent and use of Short Form; per HRPP policies 5.1 (Obtaining Informed Consent From Research Subjects), 5.3 (Use of a Remote Consent Process), and 5.5 (Use of the Short Form Consent Document)

Research Data Privacy, Confidentiality, use of PHI, and Data Safety Monitoring; per HRPP policies 3.2 (Data and Safety Monitoring), 3.3 (Privacy Interests and Confidentiality of Research Data), and 3.4 (Use of Protected Health Information in Research).

Subject Identification and Recruitment, including Ethical Access; per HRPP policies 3.5 (Subject Recruitment through Advertisements), 3.6 (Subject Recruitment through Direct Invitation), 3.7 (Finder's Fees and Recruitment Bonuses), and 3.12 (Ethical Access).

Subject payment; per HRPP policy 3.8 (Research Subject Compensation).

Pregnancy testing, pregnant partner, and contraception; per HRPP policies 3.9 (Contraception Requirements) and 3.10 (Pregnancy Testing).

Investigator and research staff training; per HRPP policy 1.23 (HRPP Training Requirements and Opportunities for Research Personnel).

Research involving subjects with impaired decision-making capacity; per HRPP policy 4.6 (IRB Review of Research Involving Subjects with Impaired Decision-Making Capacity).

DOCUMENT HISTORY:

? Written: not documented (Approved: not documented)

? Revised: 5/30/2017 - revision not documented

? Revised: 2/28/2018 - revision not documented

? Revised: 10/21/2021 - Added organizational policy to comply with Common Rule and NIH requirements regarding use of a single IRB; deleted redundant policy statements; clarified requirements for accreditation of reviewing IRB; modified types of research not eligible for use of

external IRB; moved list of UNMC policies that must be followed to addendum 2; clarified responsibilities of external IRB, UNMC IRB and investigators; clarified ORA and IRB procedures; clarified required documents to be submitted by PI; other minor reorganization of policy; added Addendum 1 and 2. Notification: not documented

? Revised: 12/8/2022 - modified addendum 1 to correct inconsistencies with Consent Form template (Subject Injury, HIPAA, and Participant Rights sections) {Approved Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

? Revised: 8/25/2023 – Added responsibility for UNMC HRPP regarding notification of reviewing IRB when local policies that impact IRB review are updated (section 4.2.11). {Approved Rusty McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

? Revised 1/22/2024 - added UNMC IRB and HRPP responsibility to ensure that UNMC applies its FWA to all research and ensure that the IRB review is consistent with the requirements of the UNMC's FWA (section 4.2.9) and ensure that, should termination of a reliance agreement occur, it is clear who will have the responsibility of continued oversight of study activities until closure or transfer of the study (section 4.2.10). {Approved Rusty McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

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