

1.10 Scientific and Other Committee Review of Research

Last Revised: 4/8/2025

1.0 Purpose

The purpose of this policy is to describe the Organization's requirements for scientific and scholarly merit review, and for review by other component committees of the HRPP, of all non-exempt human subject research conducted under the jurisdiction of the UNMC IRB.

2.0 Policy

It is the policy of the Organization that

- 2.1. All human subject research must undergo a substantive scientific and scholarly merit review, either by the Department, Division, School, College, or Institute (collectively, "Unit") prior to submission to the IRB, or by the IRB (or expedited reviewer) if no such process exists within the Unit.
 - 2.2. Human subject research under oversight of the UNMC IRB will also be reviewed by other component committees of the HRPP, as appropriate and as dictated by institutional requirements and policies.
 - 2.3. All non-exempt human subject research conducted at the Organization under the oversight of an external IRB will be reviewed by other component committees of the HRPP as appropriate (as per [HRPP Policy 1.4](#)) before the research will be released.
 - 2.4. All human subject research conducted at external sites where the UNMC IRB is the IRB of record will undergo review by component committees of the relying institution, in accordance with the policies of that institution.
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3.0 Department, Division, School, College, or Institute (collectively, "Unit") Review of Scientific Merit

- 3.1. The PI is responsible for obtaining scientific review of all human subject research prior to submission to the IRB, if a process for such review exists within the Unit. The person or committee responsible for this review will vary depending on the type of research, and the processes and requirements of the PI's Unit. The scientific review

should focus on assuring:

- 3.1.1. The research has a sound scientific design; that is, the research is designed using accepted principles, methods, and practices, the methods are practically feasible, the research has a clear scientific objective, the research has sufficient power to definitively test the objective, and the research offers a plausible data analysis plan.
 - 3.1.2. The research has an acceptable level of scientific/scholarly merit and the knowledge to be gained from the research is sufficiently important.
 - 3.2. The IRB will also evaluate the scientific and scholarly merit of all proposed studies, using the same criteria. If the IRB does not have the appropriate disciplinary expertise for review of the protocol, the Board will utilize a consultant. In its evaluation, the IRB will take into consideration review by the PI's Unit, as well as other external reviews.
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4.0 Reviews by Other Components of the HRPP

Depending upon the nature of the research, proposals may be subject to additional review and approval by one or more components of the HRPP. None of these components has the authority to approve human subject research that has not yet been approved by the IRB, or has been disapproved by the IRB, as per HRPP policy 1.2 (Authority Granted to the IRB by the Organization).

- 4.1. Fred & Pamela Buffett Cancer Center (FPBCC) Scientific Review Committee (SRC)
 - 4.1.1. The FPBCC is a National Cancer Institute (NCI) designated cancer center. As such, a mandatory element of the cancer center is a functioning Scientific Review Committee (SRC).
 - 4.1.2. The SRC reviews the scientific aspects of industry sponsored and investigator-initiated cancer-related research involving human subjects conducted by members of the UNMC faculty and students and members of the Fred & Pamela Buffett Cancer Center.
 - 4.1.3. The SRC is responsible for:
 - 4.1.3.1. Evaluating all new and amended clinical research protocols for scientific merit and to ensure that there are adequate resources available to successfully complete the proposed research.
 - 4.1.3.2. Monitoring accrual to active protocols to ensure that studies meet their accrual goals and to require a reassessment of recruitment strategies and/or accrual goals when necessary.
 - 4.1.3.3. Ensuring that there are no competing studies with overlapping eligibility criteria for a specific disease indication.
 - 4.1.3.4. Establishing each protocol's priority based on NCI guidelines and institutional priorities.
 - 4.1.3.5. Performing annual scientific review of open cancer center protocols, as per SRC policies.
 - 4.1.4. A designated IRB Analyst attends meetings of the SRC as the IRB representative, and a representative of the FPBCC SRC attends the meetings of IRB-01 and IRB-02.
 - 4.1.5. New cancer related human subject research, and changes to approved cancer related protocols, will be reviewed by the SRC as per their policies. This review may occur before or following IRB review.

- 4.1.5.1. All UNMC investigator-initiated cancer related studies must be reviewed and approved by SRC prior to review by the IRB.
- 4.1.6. If SRC review occurs before IRB review, SRC review and approval letters are uploaded to RSS and are available to assigned IRB reviewers.
- 4.1.7. If SRC review follows IRB review, the designated IRB Analyst in consultation with the IRB Executive Chair, or one of the Chairs or Vice-Chairs, will be responsible for assuring that no substantive changes have been made to the protocol or the consent forms by the SRC. If substantive changes have been made, additional review by the convened IRB will be required.
- 4.1.8. The SRC has access to RSS including all relevant IRB reviews.
- 4.1.9. For human subject research subject to SRC review, the ORA will not issue final release of a protocol until it has received notice of approval from the SRC, stating that all scientific requirements for the study have been met.
- 4.2. Pharmacy and Therapeutics Committee (P&T Committee)
 - 4.2.1. The Nebraska Medicine P&T Committee will review new non-exempt human subject research protocols involving any drugs or biologics to assess (1) if the drugs are appropriate in consideration of the proposed protocol and population, (2) if the route of administration is appropriate and will be safely monitored, and (3) the drugs will be administered only by authorized personnel. In addition, upon request of the IRB, the P&T Committee will also review research involving the administration of agents such as vitamins or other chemicals not classified as drugs.

Note: The Nebraska Medicine P&T Committee does not review research conducted at Children's Nebraska (CN). Review of research involving investigational and marketed drugs conducted at CN is accomplished by a designated CN pharmacist who is a member of IRB-04.

- 4.2.2. P&T Committee review may occur before or following IRB review.
- 4.2.3. If P&T Committee review occurs before IRB review, the P&T review and any required modifications are uploaded to RSS and are available to assigned IRB reviewers.
- 4.2.4. If the P&T Committee review follows IRB review, the ORA staff, in consultation with the designated IRB Analyst and the IRB Executive Chair, or one of the Chairs or Vice-Chairs will be responsible for assuring that no substantive changes have been requested by the P & T Committee. If substantive changes have been requested, additional review by the convened IRB will be required.
- 4.2.5. The P&T Committee has access to RSS including all relevant IRB reviews.
- 4.2.6. For human subject research subject to P&T Committee review, the ORA will not issue final release of a protocol until it has received notice of approval from the P&T Committee.
- 4.2.7. If a Protocol Modification involves a change in dosing or route of administration of a study drug, or addition of a new study drug, P&T Committee will review, as above. The IRB will not approve a protocol modification until P&T Committee review is completed.
- 4.3. Nebraska Medicine Investigational Device Review Committee (IDRC)

- 4.3.1. The IDRC reviews use of devices in research conducted within the components of the organization to assure compliance with HRPP policies. This includes receiving, storing, dispensing, returning or destroying investigational devices.
- 4.3.2. The IDRC review and any required modifications are uploaded to RSS and are available to assigned IRB reviewers.
- 4.3.4. For human subject research subject to IDRC review, the ORA will not issue final release of a protocol until it has received notice of release from the IDRC.
- 4.4. Center for Clinical & Translational Research (CCTR)
 - 4.4.1. The CCTR manages the OnCore Clinical Trial Management System (CTMS) and generates the Clinical Study Calendar for clinical trials utilizing CTMS. The study calendar records protocol-specific scheduling of research related procedures/treatments and details how these procedures/treatments will be billed. The Study Calendar is submitted to the IRB thru RSS for clinical trials conducted at NM, UNMC or BMC.
 - 4.4.1.1. Studies conducted at CN may submit a manually prepared billing grid for the same purpose.
 - 4.4.2. CCTR conducts Coverage Analysis (CA), of any study that includes clinical care activities conducted at Nebraska Medicine/UNMC, based on the CTMS Study Calendar. The Coverage Analysis verifies conventional “standard” care vs. research only costs to identify what can or cannot be billed to a third-party payer (either private insurance or Medicare).
 - 4.4.3. The Clinical Study Calendar and CA, if required, are uploaded to RSS and used by the ORA and the IRB in the assessment of financial risk to subjects associated with the research.
- 4.5. UNMC Institutional Biosafety Committee (IBC)
 - 4.5.1. The purpose of the Institutional Biosafety Committee (IBC) is to review research involving recombinant DNA molecules, materials containing recombinant DNA (including gene transfer and some vaccine trials), or research involving biohazardous materials.
 - 4.5.2. A designated IRB Analyst attends meetings of the IBC as the IRB representative.
 - 4.5.3. For research subject to both IRB and IBC review, IBC review may occur before or following IRB review. The ORA will be given a copy of the IBC review.
 - 4.5.4. If IBC review occurs before IRB review, IBC review and approval letters are uploaded to RSS and are available to assigned IRB reviewers.
 - 4.5.5. If IBC review follows IRB review, the designated IRB Analyst in consultation with the IRB Executive Chair, or one of the Chairs or Vice-Chairs, will be responsible for assuring that no substantive changes have been made to the protocol or the consent forms by the IBC. If substantive changes have been made, additional review by the convened IRB will be required.
 - 4.5.6. The IBC has access to RSS including all relevant IRB reviews.
 - 4.5.7. For human subject research subject to IBC review, the ORA will not issue final release of a protocol until it has received notice of approval from the IBC.
- 4.6. Radioactive Drug Research Committee (RDRC) The RDRC is currently registered with the FDA as inactive. However, should a human subject protocol involve research with radioactive drugs, the RDRC would be activated and IRB approval contingent upon RDRC approval.
- 4.7. Export Control

- 4.7.1. The Export Control Office provides guidance and assistance concerning export controls and the permitting, licensing, packaging and shipping of research materials and data when UNMC personnel are conducting or participating in transnational research, as per HRPP policy 1.5 (Requirements for Research Conducted with International Sites).
- 4.7.2. For transnational human subject research, the ORA will not issue final release of a protocol until it has received notice of approval from the Export Control.
 - 4.7.2.1. Research conducted at UNO or by UNO investigators must be reviewed and approved by the Director of Research Compliance (or designee) at UNO.
- 4.8. Conflict of Interest Committee (COIC) Refer to HRPP policy 1.25 Financial Conflicts of Interest.
- 4.9. Sponsored Programs Administration (SPA) and UNeHealth Refer to HRPP policy 1.12 Sponsored Research.
- 4.10. In addition, review by other committees not listed may be required on a permanent or ad hoc basis, for any or all protocols, as dictated by the institution and/or the Institutional Official.

DOCUMENT HISTORY:

? Written: 5/6/2016 (Approved: 5/6/2016) - original author not recorded

? Revised: 2/12/2018 - revision not documented

? Revised: 5/17/2021 - Clarified responsibility for, and process of, scientific review; clarified responsibilities of the P&T Committee, and process of review; simplified description of function and activities of IDRC; clarified responsibilities of the IBC regarding human subject research; updated description of activities of CCTR; added reference to “other committees as directed by institution and/or IO”; clarified responsibilities of ORA vs IRB

? Revised: 8/1/2023 - Corrected typographic errors; changed “administrator” to “analyst” {Approved Rusty McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

? Revised: 3/11/2025 - Specified responsibility for ancillary review of CIRB and SIRB protocols; clarified that scientific review will be undertaken by the investigator’s unit, if such a process exists within the unit; clarified scope and timing of SRC, P&T, IDRC and IBC reviews; added Export Control as ancillary committee of the HRPP, and defined scope and timing; clarified that IRB members have access to reviews by ancillary committees; stylistic changes.

? Revised: 4/8/2025 – clarified scope of IDRC review (section 4.3.1).

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