1.10 Scientific and Other Committee Review of Research

1.0 Purpose

The purpose of this policy and procedure is to describe the Organization's requirements for scientific and scholarly merit review, and review by other component committees of the HRPP, of all human subject research protocols (see HRPP policy 1.9 Review of Resources Necessary to Protect Subjects) conducted under the jurisdiction of the UNMC IRB.

2.0 Policy

- 2.1. All human subject research must undergo a substantive scientific and scholarly merit review prior to submission to the IRB.
- 2.2. Human subject research under the jurisdiction and oversight of the UNMC IRB will also be reviewed by other component committees of the HRPP, as appropriate.

3.0 Department, Division, School, College, or Institute 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. 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 Department, Division, School, College, or Institute. 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. If the IRB does not have the appropriate disciplinary expertise for review of the protocol, the Board will utilize a consultant.

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 of the following groups. None of these committees has the authority to approve human subject research to begin that has not yet been approved, 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 Scientific Review Committee (SRC)**:
  - 4.1.1. The Fred & Pamela Buffett Cancer Center 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.
  - 4.1.5. SRC review may precede or follow IRB review depending upon SRC policies.
  - 4.1.6. If SRC review precedes IRB review, the assigned IRB reviewers are notified by the designated IRB Analyst of any concerns expressed by the SRC.
  - 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. If the SRC tables a study, IRB review will be held pending resolution of the SRC concerns. A revised protocol must be provided to the IRB for review.
  - 4.1.9. The ORA will be provided a copy of all SRC reviews, which will be uploaded to the study file in RSS. The SRC is provided a copy of all relevant IRB reviews.
  - 4.1.10. 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 purpose of the Nebraska Medicine P&T Committee review is to ensure safe use, adequate monitoring, accurate dispensing, and control of both investigational and marketed drugs used in research conducted at UNMC/Nebraska Medicine. 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 CHMC. Review of research involving investigational and marketed drugs conducted at CHMC is accomplished by a designated CHMC pharmacist who is a member of IRB-04.
- 4.2.2. P&T Committee review may precede or follow IRB review depending upon the investigator's response to submission deadlines.
- 4.2.3. If the P&T Committee review precedes IRB review, the assigned IRB reviewers are notified by ORA staff of any concerns expressed by the P&T Committee.
- 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 ORA will be provided a copy of all relevant P&T Committee reviews, which will be uploaded to the study file in RSS. The P&T Committee is provided a copy of all relevant IRB reviews.
- 4.2.6. The ORA is responsible for assuring all issues identified by the P&T Committee are resolved. The ORA will not issue final release of a protocol without resolution of all identified issues.
- 4.2.7. If a Request for Change involves a modification in dosing or route of administration of a study drug, P&T Committee must review, as above.

- **4.3. Nebraska Medicine Investigational Device Review Committee (IDRC)**
  - 4.3.1. The IDRC reviews use of investigational devices in research to assure regulatory and operational compliance with Nebraska Medicine policy MI29 and Attachments 1-4. This includes receiving, storing, dispensing, returning or destroying, and billing of such investigational devices.
  - 4.3.2. A designated IRB Analyst will attend all IDRC meetings as the IRB representative.
  - 4.3.3. The ORA will be provided a copy of all IDRC reviews, which will be uploaded to the study file in RSS. The IDRC is provided a copy of all relevant IRB reviews.
  - 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 approval 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 CHMC 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. The IBC is administratively managed through the ORA. An assigned IRB/IBC Analyst attends every IBC meeting.
    - 4.5.3. For research subject to both IRB and IBC review, IBC review may precede or follow IRB review. The ORA will be given a copy of the IBC review.
    - 4.5.4. If IBC review precedes IRB review, the assigned IRB reviewers are notified by ORA staff of any concerns expressed by the IBC.
    - 4.5.5. If IBC review follows IRB review, the ORA staff will refer the protocol for additional review by the full IRB if the IBC required modifications or concerns are more than minor in nature.
    - 4.5.6. 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.
    - 4.5.7. The ORA will be provided a copy of all relevant IBC reviews, which will be uploaded to the study file in RSS. The IBC is provided a copy of all relevant IRB reviews..
- **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. Conflict of Interest Committee (COIC)**: Refer to HRPP policy 1.25 Financial Conflicts of Interest.
- **4.8 Sponsored Programs Administration (SPA) and UNeHealth**: Refer to HRPP policy 1.12 Sponsored Research.
- 4.9. 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)}

Revision #9
Created 21 October 2019 21:45:49 by Autumn M Eberly
Updated 22 December 2023 01:21:15 by Max V. Kuenstling