Institutional Review Board

Introduction

The UNMC Institutional Review Board (IRB) reviews all human subject protocols conducted by anyone on the premises of UNMC, Nebraska Medicine, Children's Hospital & Medical Center, Nebraska Medicine - Bellevue, and the University of Nebraska at Omaha (UNO) or conducted by UNMC or UNO faculty or students for adequate human subjects protection. The IRB serves as a resource for questions regarding clinical research and human subject protections at UNMC. IRB review and approval is **required** before human study protocols can be initiated.

- **Exempt, expedited, or full board.** Human research studies are classified as either exempt, expedited, or full board. There are several types of research considered exempt, such as quality improvement and health outcomes data where results are shown in aggregate without individual identifiers. Exempt and expedited research is discussed further on the IRB website.
- **Adult versus pediatric protocols.** Separate IRB boards review and approve adult and pediatric protocols. The adult IRBs meet on the first and third Thursday of the month (with the exception of January and July when the board meets only on the third Thursday). The UNMC-Children's Hospital & Medical Center Joint Pediatric IRB meets on the fourth Tuesday of the month. Deadlines and meeting dates for IRB meetings can be found on the IRB website.

If research involves both adult and pediatric populations, the IRB Office assesses which IRB will review the study based on the majority population and other considerations. Nevertheless, all IRB applications, adult as well as pediatric, will be submitted electronically using the online RSS-Research Support System. For questions, contact the IRB staff.

Studies classified as exempt or expedited are reviewed either by IRB Staff or IRB members outside of a convened meeting.

Key Contacts

The **Office of Regulatory Affairs (ORA)** can answer questions and assist with the IRB submission process.

402-559-6463
irbora@unmc.edu

Submission and Approval

All research involving human subjects conducted on site at UNMC, Nebraska Medicine, Children's Hospital & Medical Center, Nebraska Medicine - Bellevue or UNO, or conducted by their employees or representatives at other sites, must receive approval by a designated IRB before the research may commence. Human subject research includes all research conducted with a human subject as defined as "a living individual about whom an investigator (whether professional or student) obtains: 1) data through intervention or interaction with the individual or 2) identifiable private information."

Research involving data or human biological materials (HBM) with subject identifiers also requires IRB application and approval. A complete listing of included and exempt research can be found in the UNMC Human Research Protection Program (HRPP) Policies and Procedures Manual, Policy #2.6.

Not all work on human specimens constitutes Human Subject Research. The NIH rules can be complex, and useful information can be found on the NIH website.

There may be exemptions to requirements for human subject research rules, but the investigator cannot make that final determination, which must be made by the IRB. Contact the IRB staff for guidance whether your project requires IRB review and approval. HRPP Policies and Procedures, Policy #2.6.

Submitting an Application

All IRB applications are submitted online using the Research Support System (RSS). Use your UNMC NetID or Nebraska Medical Center email username and password. If you are unsure of which IRB application to complete, please contact the IRB Office.

The application requires an initial review and approval of scholarly merit and resource use by an authorized department member, such as the chairperson, an authorized delegate, or appointed review committee of the PI's department or division, prior to submission.

Instructions are in the IRB's Procedures webpage.

The IRB charges a fee for review of full board or expedited industry sponsored studies. The Commercial Fee Form can be downloaded from the IRB website.

Additional Committee Reviews

Depending upon the nature of the research, proposals may be subject to additional review and approval by one or more of the following groups before obtaining IRB approval:

- **Fred & Pamela Buffett Cancer Center Scientific Review Committee (SRC):** The SRC must review and approve all cancer-related research involving human subjects conducted by members of the UNMC faculty, trainees, and members of the Fred & Pamela Buffett Cancer Center.
- **Pharmacy and Therapeutics Committee (P&T):** The P&T committee ensures the safety, accurate dispensing, and control of both investigational and marketed drugs. Upon request of the IRB, the P&T also reviews research involving the administration of agents such as vitamins or other chemicals not classified as drugs. If your protocol requires administration of any medication to human subjects, you must check the P&T box in the IRB electronic application.
- **Radioactive Drug Research Committee (RDRC):** The RDRC reviews human subject protocols involving research with radioactive drugs.
- **Conflict of Interest (COI) Committee:** When an IRB application is submitted and the PI indicates that he/she or other Responsible Personnel on the application have a financial interest, the IRB must review the financial interest and a COI management plan must be developed. If the financial interest is:
  - *Not Significant*, the COI management plan must be reviewed and approved by the IRB Executive Chair before IRB final approval.
  - *Significant Financial Interest*, the COI management plan must be reviewed and approved by expedited review or the full IRB before the protocol qualifies for final approval.
- **Sponsored Programs Administration (SPAdmin)/UNeHealth** reviews all grants and contracts funding human subjects research, including the study protocol, IRB application, consent documents.

Final IRB approval will not be given until SPAdmin or UNeHealth has a fully executed contract (for industry-sponsored research) and all other reviews and the institutional requirements have been met.

Additional Documents to Submit

The following documents, as applicable, should be submitted with the IRB application:

- Planned subject recruitment material which must be approved and stamped

- Pharmacy and Therapeutics (P&T) Committee Investigational Drug Study Registry and/or Marketed Drug Form
- Performance site approval for all non-UNMC, NEMed, UNO and Children's Hospital & Medical Center sites
- Copy of all questionnaires, surveys, assessment tools, and other relevant materials
- Detailed protocol
- Investigator's brochure
- Grant Application
- IRB Review Fee Form for all commercially sponsored research projects
- UNMC Disclosure of Potential Conflict of Interest Form for the Principal Investigator as well as any responsible personnel if a financial interest has been declared in the IRB Application for that individual(s)
- Clinical Trial Master Matrix/Billing grid. This document identifies protocol scheduled procedures and source of payment for each of the procedures. This research billing "matrix/grid" must be submitted for any study that includes clinical care conducted at NEMed/NMB/UNMC/UNMC-Physicians clinics or facilities irrespective of funding.
  - **Where can I find information regarding the Research Matrix/Billing grid?** See the SPAdmin Clinical Billing website.
  - **Who do I contact to help develop my billing "matrix"?** The Senior Research Billing Analyst will assist with completion of the matrix/billing grid as well as review it prior to IRB submission, including Coverage Analysis if indicated. Investigators/Coordinators who have questions or would like assistance with matrix completion may contact 402-559-7421 or see the SPAdmin Clinical Billing contact page.

Research Involving Children or Adolescents

UNMC and Children's Hospital & Medical Center have a Joint Pediatric IRB. Deadlines and meeting dates for the Pediatric IRB can be found on the IRB website.

Biomedical and Behavioral-Social Science studies have an adult and pediatric application. All other applications types are the same for adult and pediatric study populations. If you are unsure of which application to complete, please contact the IRB Office.

Assistance Preparing the Application

The UNMC IRB in the Office of the Vice Chancellor for Research is available to assist investigators from initial submission to study completion. If you have any questions regarding the IRB application, contact the IRB office.

The Clinical Research Center (CRC) has research personnel who can prepare your clinical trial IRB application and all forms required for submission on a fee-for-service basis. See the CRC website for information about this service.

The Pediatric Research Office (PRO) staff can prepare your clinical trial IRB application and all forms required for submission for Pediatric Studies at UNMC and Children's Hospital & Medical Center. The PRO charges a fee for this service. For more information, please see the PRO website .

Compliance and Regulatory Requirements for Human Subject Research

The Compliance Office and Officer answer questions related to research compliance. A listing of compliance areas and responsible officers is available on the academic affairs compliance website.

Managing risks associated with potential conflicts of interest begins with establishing a culture of transparency. UNMC utilizes a Web-based system called **COI-SMART** to assist in the disclosure process. COI-SMART identifies potential conflicts of interest, documents them, and when necessary, establishes plans to manage the risk.

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