

UNMC Office of Regulatory Affairs Institutional Requirements	Domain	Description	Initiated By	Action	Links	Who to Contact with Questions
Committee Reviews						
Scientific Review Committee (SRC) Approval	Fred & Pamela Buffett Cancer Center	A functioning Scientific Review Committee (SRC) is a mandatory element of a National Cancer Institute (NCI) designated clinical cancer center. The SRC oversees the scientific aspects of cancer-related research involving human subjects. The application form must be completed and review can occur simultaneous with IRB review, with the exception of investigator-initiated trials which require SRC approval prior to submission to the IRB.	Regulatory Coordinator	Complete and submit SRC application in OnCore.	https://unmc.edu/cancercenter/clinical/prms https://www.unmc.edu/cctr/clinical-trials/ctms-training/training-resources/	PRMS Office prmsoffice@unmc.edu
Pharmacy & Therapeutics (P&T) Approval	Nebraska Medicine	<p>The Nebraska Medical Center Investigational Drug Service provides custom pharmaceutical services for the clinical and translational researcher. The Investigational Drug Service Pharmacist is available to address questions or concerns regarding pharmaceutical and investigational agents used in clinical trials.</p> <p>Clinical trials which utilize any medication must have the protocol reviewed by the Medical Staff Pharmacy and Therapeutics Committee (P&T). P&T review will occur following submission of the IRB application. A copy of the Study Intake form must be uploaded into RSS along with all required documents.</p>	Regulatory Coordinator	Upload a copy of the Study Intake form in RSS.	https://www.unmc.edu/cctr/resources/pharmacy/index.html https://www.unmc.edu/irb/procedures/forms/miscellaneous.html	Investigational Pharmacy InvestigationalPharmacy@nebraskamed.com
Institutional Biosafety Committee (IBC) Approval	Vice Chancellor for Research Office	The IBC has been charged by Federal law with the planning and implementation of the campus Biosafety Program with a purpose to ensure the health and safety of all personnel working with biohazardous agents. The IBC makes certain that research conducted at the institution is in compliance with the NIH Guidelines for Research Involving Recombinant DNA Molecules and the Select Agent Rule, drafts campus biosafety policies and procedures, and reviews individual research proposals for biosafety concerns.	Regulatory Coordinator	Complete the IBC application within RSS.	https://www.unmc.edu/ibc/	Office of Regulatory Affairs irbora@unmc.edu
Investigational Device Review Committee (IDRC)	Nebraska Medicine	<p>The IDRC will review any study that has a device or equipment that is:</p> <ul style="list-style-type: none"> - experimental - FDA approved/released; but, is being used "off-Label" - commercially available to the general public for purposes not medically related - an application that is being used in research in a manner outside the use for which it was designed and/or marketed <p>The IDRC will also review studies that:</p> <ul style="list-style-type: none"> - utilize experimental software to facilitate use of a device/equipment or to collect data - utilizes an In-Vitro device (IVD), even if it is used at a central lab - receive approved devices or equipment that is not currently stocked or used at NM - expect to utilize hospital stock as the investigational item - require the hospital to purchase devices, equipment, and/or supplies to facilitate the research - result in cost to install or renovate hospital spaces to store or use the device/equipment - provide devices at no cost for use on a study and does not expect the device/equipment to be returned (i.e. Patient/Hospital gets to keep the device for use post study) 	Department	Email protocol and associated documents for IDRC review to the IDRC mailbox (devices@nebraskamed.com).	None	Grace Videtich grvidetich@nebraskamed.com IDRC mailbox devices@nebraskamed.com
Conflict of Interest (COI) Committee	UNMC Business & Finance	Potential conflicts of interest arise in a variety of circumstances in the academic health sciences center environment when an individual's private financial interests either conflict with or create the appearance of conflicting with UNMC's public interests. This policy applies to potential conflict of interest arising in any UNMC activity, including but not limited to research, teaching, patient care, outreach to underserved populations and the associated business activities in support of them. Covered Persons shall disclose all financial interests related to their University of Nebraska responsibilities so that an analysis of potential conflict of interest may be conducted. When a conflict of interest is identified, the conflict will either be managed or eliminated to reduce the appearance of bias and maintain responsible stewardship of public resources.	Department/ Contracting	Email Sara Ward to notify her of the individual(s) with the potential conflict of interest. Include the following information: - Name of individual with potential conflict - Title of the study - Sponsor - Project ID number (if known - UNeHealth/SPA can provide this number) - IRB number (if known) - PI	https://www.unmc.edu/academicaffairs/compliance/areas/conflict.html	Sara Ward sara.ward@unmc.edu

Institutional Sign-Off						
Pathology Approval	Department of Pathology	The Department of Pathology and Microbiology is committed to furthering the research of all UNMC investigators and assisting faculty in accessing the material they need. Pathology approval is required for clinical research and trials utilizing tissue for research purposes.	Department	Request pathology approval in the OnCore Registry module.	https://www.unmc.edu/cctr/resources/pathology.html https://www.unmc.edu/cctr/clinical-trials/ctms-training/videos/	Kurt Fisher kfisher@unmc.edu Shania McClure smcclure@unmc.edu
Radiation Safety Approval	Department of Radiology/Radiation Safety	Radiation Safety is responsible for the management of radioactive material and the use of radiation at UNMC and Nebraska Medicine in accordance with the Nuclear Regulatory Commission (NRC) and Nebraska Department of Health and Human Services regulatory requirements.	Department	Email Carrie Carson or Frank Rutar with the protocol and associated documents for review.	https://www.unmc.edu/ehs/radiation-safety/index.html	Carrie Carson carrie.carson@unmc.edu Frank Rutar frutar@unmc.edu
Export Control (Research with international components, collaborations with Non US-entities, physical exports, department of defense or NSRI funding, publication or participation restrictions, or proprietary research)	Vice Chancellor for Research Office	Export controls are federal laws and regulations that govern shipments and other transfers of commodities, technologies, services, and money to foreign countries. Export controls also regulate disclosures of sensitive information, including some research data, to non-U.S. persons. The regulations consider all of these transactions to be exports, even if all parties involved are in the United States. In some cases, UNMC may need to obtain authorization from a federal agency, usually in the form of an export license, before personnel can participate in certain export transactions. The Export Control Office provides resources and other support to UNMC personnel engaging in export-controlled activities.	Department/PI	Complete international project questionnaire: https://redcap.link/985all2p	https://www.unmc.edu/academicaffairs/compliance/areas/export-control/index.html	exportcontrol@unmc.edu
Coverage Analysis	Clinical Research Center	The coverage analysis is a systematic process that evaluates the financial risk of clinical research studies. It 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). The process also compares the billing grid, informed consent, and budget to ensure the documents align.	CRC Clinical Trials Analyst	Submission of study to studyintake@unmc.edu will place study in the queue for review.	https://www.unmc.edu/spa/clinical-trials/billing/index.html	Jeremy Brooke jbrooke@nebraskamed.com Heather Kloppenborg hkloppenborg@nebraskamed.com Lisa Hughes-Potter lhughes-potter@nebraskamed.com
Billing Grid/Matrix	Clinical Research Center	The billing grid/matrix is a tool that is used to record protocol specific scheduling of research-related procedures/treatments and details on how these procedures/treatments will be billed.	Clinical Trials Analyst/Research Biller	Submission of study to studyintake@unmc.edu will place study in the queue for review.	https://www.unmc.edu/spa/clinical-trials/billing/index.html	Veronica Hernandez vehernandez@nebraskamed.com Nikki Johnson nikkjohnson@nebraskamed.com
Contracts and Agreements including Subject Injury/International Conference on Harmonization (ICH) (clinical trial agreements, data use agreements, data transfer agreements, material transfer agreements)	Vice Chancellor for Research Office - Sponsored Programs Administration UNeHealth	UNeHealth is the contracting and fiscal arm for industry-funded clinical trials on behalf of University of Nebraska Medical Center. SPAdmin negotiates many other types of agreements as a service to faculty investigators, including clinical trial agreements, business associate agreements, cooperative group agreements, consulting agreements, data use agreements, etc. A material transfer agreement is required when transferring drug for patient-oriented research or human samples or biologic material for research purposes. Subject injury and ICH language included in the contract is sent to the IRB by either UNeHealth or SPA to ensure there is consistency between the contract language and the informed consent form.	Contracting	Submission of study to studyintake@unmc.edu will place study in the queue for review.	https://www.unmc.edu/spa/clinical-trials/unehealth/index.html https://www.unmc.edu/spa/contracts/other/index.html	UNeHealth - Amanda Leingang or Amy Carson amanda.leingang@unmc.edu acarson@unmc.edu SPA spadmin@unmc.edu Material Transfer Agreements - Jeff Andersen jeff.andersen@unmc.edu
IT Assessment	Nebraska Medicine	The IT Assessment Process is designed to review all third-party vendors' services, software, and hardware intended for use at UNMC and NM before implementation. The goal is to reduce software duplication, ensure proper software licensing, and assess and mitigate risks to the enterprise. The Solutions Assessment Committee meets every Friday to review all requests, with research being just a small part of their agenda. Once approved, an email will be sent stating the request is "closed complete," indicating approval. This approval can then be uploaded into RSS.	Department	Complete the form and submit. If you have questions contact Lisa Treat.	IT Project Intake - Nebraska Medicine Portal	Nicole Becker nbecker@nebraskamed.com Lisa Treat ltreat@unmc.edu