UNMC Office of Regulatory Affairs Institutional Requirements	Description	Initiated By	Action	Links	Who to Contact with Questions
Committee Reviews					
Scientific Review Committee (SRC) Approval	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	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. Clinical trials which utilize any medication must have the protocol reviewed by the Medical Staff Pharmacy and Therapeutics Committee (P&T Committee). P&T review will occur following submission of the IRB application. Drug registry forms for all medications must be uploaded into RSS along with all required documents.	Regulatory Coordinator	Complete the P&T Drug Registry Form and upload 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	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)	The IDRC will review any study that has a device or equipment that is: •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 The IDRC will also review studies that: •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 Grace Videtich with the protocol and associated documents for IDRC review.	None	Grace Videtich grvidetich@nebraskamed.com
Conflict of Interest (COI) Committee	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	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/	Salma Elhag salma.elhag@unmc.edu
Radiation Safety Approval	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 Mark Theis or Frank Rutar with the protocol and associated documents for review.	https://www.unmc.edu/ehs/radiation-safety/index.html	Mark Theis mtheis@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)	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	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	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
Contracts and Agreements including Subject Injury/International Conference on Harmonization (ICH) (clinical trial agreements, data use agreements, data transfer agreements, material transfer agreements)	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	More information coming soon	Department		https://info.unmc.edu/it/services/it-project-intake-process/index.html https://info.unmc.edu/it/services/it-project-intake-process/documents/it-assessement-process-overview.pdf	Nicole Becker Ashok Mudgupali