UNMC Office of Regulatory Affairs Institutional Requirements	Description	Initiated By	Action	Links	Who to Contact with Questions
Collaborative Institutional Training Initiative (CITI)/Good Clinical Practice (GCP) Training	Training in the protection of human subjects is primarily accomplished through completion of this web-based training program. CITI training is required for all investigators and research staff every 3 years if conducting non-exempt research who (a) participate in the process of consent, (b) have contact with subjects, or (c) have access to identifiable private information or identifiable biospecimens. The CITI Training Groups include: - Group 1: Biomedical Research - Group 2: Good Clinical Practice (GCP) - Group 3: Social and Behavioral - Group 4: IRB Members (training no longer active on CITI)	Department	Review CITI/GCP training for research faculty and staff. Ensure training is up to date.	https://citiprogram.org	Office of Regulatory Affairs irbora@unmc.edu
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
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/wp-content/uploads/2020/02/Pathology-Approval-of-Protocols.pdf	Salma Elhag salma.elhag@unmc.edu
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/	ibcora@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

FDA IND/IDE Approval	Investigational New Drug (IND)- A drug permitted by the FDA to be tested in humans but not yet determined to be safe and effective for a particular use in the general population and not yet licensed for marketing. These require an IND application that must be approved before a study is initiated. See IRB policy 6.1 on Research involving Investigational and marketed drugs. An investigational device exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data. All clinical evaluations of investigational devices, unless exempt, must have an approved IDE before the study is initiated. See IRB policy 6.2 on Research involving Investigational and marketed devices	Department	If sponsored trial, ask sponsor for the IND/IDE number. If investigator-initiated trial, work with the FDA to obtain IND/IDE when applicable.	https://www.fda.gov/drugs/types-applications/investigational-new-drug-ind-application https://www.fda.gov/medical-devices/how-study-and-market-your-device/investigational-device-exemption-ide	Sponsor (if a sponsored trial) or FDA
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
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
Conflict of Interest (COI) Management Plan	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

Compensation	Compensation for research subjects may be acceptable if: 1) the possibility of coercion or undue influence is minimized, and 2) the compensation is considered a reasonable incentive either for participation in the research and/or reimbursement for study-related travel and other expenses. See IRB policy 3.8 Research Subject Compensation.	Department	Review study and assess whether or not compensation will be offered.	https://guides.unmc.edu/books/hrpp-policies-and-procedures/page/38-research-subject-compensation	Department contact
Travel Reimbursement Plan	Compensation for research subjects travel and lodging may be reimbursed but must be described in the IRB application. See IRB policy 3.8 Research Subject Compensation.	Department	Review study and assess whether or not travel reimbursement will be offered.	https://guides.unmc.edu/books/hrpp-policies-and-procedures/page/38-research-subject-compensation	Department contact
SSN Clearance	The Social Security Number of a research subject is considered confidential information and should not be used to identify a research subject. In the event that the Social Security Number of a research subject must be accessed to provide payment on a study, a form, Request to Use Social Security Number, must be completed and submitted the Information Security Office which will facilitate approval from the Institutional Review Board. You must follow all policies related to use of SSNs (including UNMC Policy 6085: Social Security Number).	Department	Complete the Request to Use Social Security Number form.	https://wiki.unmc.edu/index.php/Social_Security_Number	Information Security - Deb Bishop or Lisa Bazis debrbishop@nebraskamed.com libazis@nebraskamed.com
Opt-In Recruitment Policy	The Opt-In Recruitment database can be utilized in the recruitment plan for appropriate clinical trials. This database consists of patients who signed the Conditions of Treatment Form indicating their willingness to participate in clinical research. You must obtain permission and complete a short training to use the database. See SOP-51.	Department	Follow SOP-51 to obtain permission and complete training.	https://www.unmc.edu/cctr/resources/crc/sop/CRC-SOP-51-Contacting-Opt-in.pdf	LuAnn Larson llarson@unmc.edu
Subject Recruitment Policy	All clinical research and trials must comply with the recruitment policies outlined in the UNMC IRB-ORA policies and procedures. See IRB policy 3.5 (subject recruitment through advertisements) and 3.6 (subject recruitment through direct invitation).	Department	Review recruitment policies outlined in the UNMC IRB-ORA policies and procedures and acknowledge they will be followed.	https://www.unmc.edu/irb/procedures/procedures/PoliciesProceduresManual.html	IRBORA@unmc.edu
Ethical Access Policy	It is the policy of the organization that obtainment of information about a potential subject, and approach to the potential subject, must occur in a manner that respects the privacy of that person. See IRB policy 3.12 Ethical Access.	Department	Review IRB policy 3.12 Ethical Access and acknowledge it will be followed.	https://guides.unmc.edu/books/hrpp-policies-and-procedures/page/312-ethical-access	IRBORA@unmc.edu
ClinicalTrials.gov (NCT #)	ClinicalTrials.gov is a Web-based resource that provides patients, their family members, health care professionals, researchers, and the public with easy access to information on publicly and privately supported clinical studies on a wide range of diseases and conditions. Information on ClinicalTrials.gov is provided and updated by the sponsor or principal investigator of the clinical study. Studies are registered when they begin and the information on the site is updated throughout the study. Anyone planning to publish must have their study registered.	Department	If sponsored trial, ask sponsor for the NCT number. If investigator-initiated trial, work with Lindsay Hicks to register the trial on ClinicalTrials.gov.	https://www.unmc.edu/irb/procedures/CTdotGov.html	Lindsay Hicks lindsay.hicks@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	Erin Kuhl ekuhl@nebraskamed.com Jeremy Brooke jbrooke@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	Cassie Cruz-Montes ccruz-montes@nebraskamed.com
Contracts and Agreements (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.	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

Subject Injury/International Conference on Harmonization (ICH)	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.	None	UNeHealth or SPA
Executed Reliance Agreement	An agreement between the IRBs of two Organizations engaged in human subject research that documents respective authorities, roles, responsibilities, and communication between an organization providing the ethical review and a participating organization relying on a reviewing IRB.	Department & IRB Administrator	If utilizing a CIRB that UNMC does not have a current reliance agreement with, contact sIRB@unmc.edu for next steps.	https://guides.unmc.edu/books/hrpp-policies-and-procedures/page/14-unmc-irb-ceding-review-to-an-external-irb	Current Reliance Agreements with: NCI, Advarra, WCG/WIRB, StrokeNet For all other IRBs of record contact the department contact and sIRB@unmc.edu