Site Information Sheet

This document provides a detailed overview of the University of Nebraska Medical Center's clinical research site. It includes up-to-date information on site personnel, facilities, processes, policies and procedures.

Please note: *Per site standard operating procedure, this Site Information Sheet is provided in lieu of completing Sponsor/CRO feasibility surveys and questionnaires. Patient population-specific questions will be addressed, as needed.*

General Site Information

The University of Nebraska Medical Center (UNMC) is Nebraska's only public academic health sciences center, serving not only the local communities in the Omaha-metro area, but participating in outreach programs throughout the entire state. In addition, UNMC serves many communities in the surrounding six-state area. UNMC is accredited by the Higher Learning Commission (HLC) and has been continuously accredited since 1913.

Located in mid-town Omaha, UNMC and its clinical enterprise partner, Nebraska Medicine (NM), share the mission to lead the world in transforming lives to create a healthy future for all individuals and communities through premier educational programs, innovative research and extraordinary patient care.

Nebraska Medicine and UNMC have a shared zip code system using 98XXXX at the beginning of the address. The last 4 digits are an internal zip codes to get to specific people within a department/area not necessarily a physical location.

IMPORTANT ADDRESSES	
Clinical Sites	
Main Campus	
University of Nebraska Medical Center (UNMC) ***Research & Education Partner***	University of Nebraska Medical Center 42nd & Emile Street Omaha, NE 68198
Nebraska Medicine (NM) ***Hospital Partner***	Nebraska Medicine 4350 Dewey Avenue Omaha, NE 68105
Additional Locations	
Clinical Research Unit (CRU)- University Tower (Main Campus) 981230 Nebraska Medical Center Omaha, NE 68198-1230 (402) 559-7685	An outpatient clinical research facility with skilled research nurses and laboratory staff, which can also assist with inpatient protocols. The CRC includes 3,300 square feet of outpatient care space, including five exam rooms, two procedure rooms, phlebotomy/intake space, and a processing laboratory. Resources and services are available to all UNMC/Nebraska Medicine affiliated researchers.
Clinical Research Unit (CRU)- Global Center for Health Security 3925 Dewey Ave Omaha, NE 68198-5550 (402)-836-9400	An outpatient clinical research facility that is equipped with negative pressure exam rooms, a pharmacy, a laboratory and separate "hot" (negative pressure rooms) and "cold" zones. This facility's infrastructure is used to serve in clinical trials and due to the pandemic, the need for such a space became apparent when needing to safely work with participants who are infected but do not require admitted hospital care.
Dermatology Clinic	
Lauritzen Outpatient Center (LOC) 4014 Leavenworth Street, 3rd floor Omaha, NE 68105 (402)-552-7928	The Department of Dermatology specializes in the diagnosis and management of all diseases of the skin, hair, nails and mucous membranes. Through UNMC's partnerships with Nebraska Medicine, Children's Hospital & Medical Center (CHMC) of Omaha, and the VA Nebraska-Western Iowa Health Care System (VA-NWIHCS), we provide comprehensive care in general

Village Pointe Health Center 17405 Burke Street Omaha, NE 68118 Entrance J	dermatology, pediatric dermatology, dermatologic surgery, rheumatologic and autoimmune skin diseases, complex and rare conditions of the skin, skin cancer, varicose veins and laser and cosmetic dermatology. Our faculty are highly involved in education, research and outreach/service activities.
Diabetes, Endocrinology, & Metabolism (DEM) Clinics	
Diabetes Center at Specialty Services Pavilion (main campus) 4350 Emile St. Omaha, NE 68105 (402) 559-8700 **Diabetes and Endocrinology at Bellevue** 2510 Bellevue Medical Center Drive, Suite 250 Bellevue, NE 68123 (402) 559-8700	The Diabetes Center at Nebraska Medicine combines clinical care, counseling, education and research to find better ways to prevent and treat diabetes. The Center provides services related to both Type 1 and Type 2 diabetes, as well as a full range of endocrinology services.
Gastrointestinal (GI) Clinic	
Gastroenterology/Hepatology Clinic (Main Campus) 982000 Nebraska Medical Center Omaha, NE 68198-2000 Phone: (402) 559-4015	An outpatient clinic that is focused on the diagnosis and treatment of gastrointestinal and liver diseases. Areas of special expertise include hepatitis, cirrhosis, inflammatory bowel disease, pancreatic disease, cancer of the upper and lower GI tract and motility disorders. This clinic also supports a world-renowned liver and small bowel transplant program.
Heart and Vascular Clinics	
Heart and Vascular Center at Durham Outpatient Center (main campus) 4400 Emile St Omaha, NE 68105 Phone: (402) 559-8888 **Heart and Vascular Center at Oakview Health Center** 2727 S 144th St, Suite 100	The cardiovascular services program brings together experienced specialists from cardiology, interventional radiology, vascular surgery, neurosurgery, and cardiothoracic surgery. Vascular services include outpatient clinics with a full array of advanced medical equipment and state-of-the-art angiography suites. The non-invasive vascular laboratories provide a full range of studies including carotid, venous and arterial exam, angiography,

Omaha, NE 68144 (402) 596-4444 **Heart and Vascular Center at Bellevue** 2510 Bellevue Medical Center Dr., Suite 250 Bellevue, NE 68123 (402) 559-8888	intravascular ultrasonography and transcranial doppler. The center includes a hybrid operating room that provides the technology of a catheterization lab and interventional radiology suite and allows our doctors to also perform open surgery.
Neurological Sciences Clinics	
Neurological Sciences Clinical Research Center 4242 Farnam St., Suite 363 Omaha, NE 68131 **Neurological Sciences Center at Clarkson Doctors Building North** 4242 Farnam St., Suite 650 Omaha, NE 68131 (402) 559-8600 **Neurological Sciences Center at Clarkson Doctors Building South** 4239 Farnam St., 1st Floor Suite 105 Omaha, NE 68131 (402) 559-8600	The specialty clinics, located in both Clarkson Doctors Buildings North and South, offer the newest medications and treatments available for comprehensive, multidisciplinary care of ALS, Epilepsy, Huntington's Disease, movement disorders, stroke, Parkinson's Disease, dystonia and spasticity, memory disorders, and MS. These clinics provide the most advanced and specialized care available.
Oncology Clinics	
Fred & Pamela Buffett Cancer Center (main campus) 505 S. 45th Street Omaha, NE 68106 (402) 559-5600 **Village Pointe Cancer Center (VP)** 111 North 175 Street Omaha, NE 68118 (402) 559-5600 **Bellevue Medical Center (BMC)** 2500 Bellevue Medical Center Drive Bellevue, NE 68123 (402) 763-3000	The Fred & Pamela Buffet Cancer Center, located at the UNMC/NM Main campus location, includes 53 clinic rooms and 26 private infusion rooms. All standard hospital equipment is available to assess patient health (scale, stadiometer, blood pressure cuff, etc.). Satellite sites (VP and BMC) are located within 12 miles of the main campus and offer many of the same services as the main campus location (clinics, diagnostic center, imaging, treatment center).
Ophthalmology Clinic	

Truhlsen Eye Institute **Carl Camras Center for Innovative Clinical Trials in Ophthalmology** 3902 Leavenworth Omaha, NE 68198 (402) 559-1853	Outpatient eye clinic with research facility staffed with skilled, certified ophthalmic technicians, optometrists, and ophthalmologists, which can perform eye exams for research studies being conducted across campus. The Camras Center includes 4 exam rooms equipped with slit lamp, tonometers, direct and indirect ophthalmoscopes, Snellen and ETDRS vision charts, in addition to full service diagnostic equipment including OCT, Fundus camera and visual field machines.
Pulmonary Clinic	
Cardiopulmonary Rehabilitation Clinic at Clarkson Doctors Building South 4239 Farnam St, Suite 534 Omaha, NE 68131 (402) 552-2936	The Pulmonary Rehabilitation program is an outpatient service at NM. This program is designed to meet the needs of patients who have chronic respiratory problems. Each customized program is based upon the specific lung problem or disease.
Transplant Clinic	
Multi-Organ Transplant Center (main Campus) 4315 Nebraska Medical Center Omaha, NE 68105 (402) 559-5000	An outpatient multidisciplinary clinic specializing in pediatric and adult services, including surgical repairs, advance surgeries, solid organ evaluation, transplantation and post-op care. Multidisciplinary staff includes physicians, surgeons, nurses, medical assistants, pharmacists, financial counselors, dieticians, social workers, hepatologists, nephrologists, gastroenterologists, oncologist, psychologists, psychiatrists, child life and development, occupational and feeding therapists.
Local Laboratories (as will be listed in Box 4 of the 1572)	
Nebraska Medical Center Clinical Laboratory 983135 Nebraska Medical Center Omaha, NE 68198-3135 CLIA ID: 28D0453728 CAP: 1974901 Clinical Research Unit- University Tower (processing lab only) 981230 Nebraska Medical Center Omaha, NE 68198-1230 CLIA Waiver ID: 28D0896348 **Clinical Research Unit- Global Center for Health Security (processing Lab only)**	Village Pointe Laboratory 111 North 175th Street Suite 20114 Omaha, NE 68118 CLIA ID: 28D1088086 CAP: 7216313 Bellevue Medical Center Laboratory 2500 Bellevue Medical Center Drive Bellevue, NE 68123 CLIA ID: 28D2002078 CAP: 7224872

3925 Dewey Ave Omaha, NE 68198-5550 **Note:** *We will not list or provide documentation for external laboratories (i.e. labs closer to the patient's home) that may occasionally be used for a limited number of standard of care tests. Please refer to the FDA Guidance listed below.*[1]

Shipping Address for Laboratory Kits	Address will be provided at study start-up, once study staff has been assigned.

Long-term storage (on-site)
UNMC General Supply 601 South Saddle Creek Road Omaha, NE 68106

Start-up Process Overview

Each department manages the early evaluation process for all new clinical trials, as outlined below.

Early Evaluation

- Initial study inquiry – At a minimum, a protocol synopsis will be required for physicians to determine initial study interest. If a physician is interested in a potential study, a full protocol will be requested for the clinical team to review.
- Confidentiality Disclosure Agreement (CDA) execution - if required, to receive full study protocol
- Department approval
  - All new studies must be reviewed by the Disease-Focused Teams (DFTs).
  - All trials must be endorsed by the appropriate DFT
  - DFTs consist of relevant clinical research staff which include, but are not limited to, physicians, nurses, and project coordinators
  - In order for the DFT to review, a full protocol must be provided in advance of the meeting.
- Internal Feasibility/Approval (occurs in parallel with other processes) and includes an objective review of:
  - Does the PI have the time required?
  - Is there an available coordinator with time available?
  - Does the institution have the patient population determined by a records review?
  - Are all of the needed tests and equipment required available?
- Site Qualification/Site Selection - if applicable
  - Our standard practice is to only allow on-site qualification visits (SQVs, PSVs, etc.) for sponsors/CROs that have not visited the site within the previous 12 months.

- Whenever possible, qualification visits are encouraged to be done virtually.
- Ancillary department approvals (pathology, pharmacy, radiology, biological production, etc.)
- Study documents requested
  - Regulatory packet (current study protocol, Investigator's Brochure, pharmacy and laboratory manuals, consent forms and patient-facing documents, FDA form 1572, financial disclosure forms)
  - Editable contract template
  - Budget template

Start-up Process

- Once a study has been approved by the Department and all required study documents have been received, the study will be sent through a centralized study intake process for start-up activities (i.e. coverage analysis, budget, contract, regulatory, etc.).
  - Required documents include:
    - Clinical Trial Protocol
    - Informed Consent Template
    - Budget Template
    - Contract Template
- Once staff is assigned, contact information will be provided to the sponsor/CRO.
- All start-up processes can run in parallel (budget/contract negotiation, regulatory submissions).

Regulatory Submissions

Local IRB	University of Nebraska Medical Center Institutional Review Board 987830 Nebraska Medical Center Omaha, NE 68198 (402) 559-6463 irbora@unmc.edu https://unmc.edu/irb General Information • UNMC IRB FWA#: FWA00002939 • The UNMC IRB operates in compliance with 21CFR50, 56; 45CFR46, the ICH-GCP Guidelines, and is registered with OHRP/FDA. Statements regarding compliance for each can be found on their website. https://unmc.edu/irb • The UNMC Adult IRB meets twice per month (1st & 3rd Thursdays), with the exception of January and July, in which the IRB only holds one meeting (3rd Thursday) • The UNMC Joint Pediatric IRB meets one per month (4th Tuesday) • Submission deadlines are 2 weeks prior to meeting dates. Review letters are typically issued within 10 business days from the meeting date. •

Central IRB	The local IRB has approved select central IRBs for use. If the sponsor utilizes a central IRB of record, the regulatory coordinator can provide more detail and guidance as to whether local or central IRB will be used for submission. If it is determined by the site that a central IRB will be used, an abbreviated application must *first* be submitted to the UNMC (local) IRB. All institutional requirements must be met ***prior*** to the UNMC IRB allowing oversite by a central IRB. Institutional requirements may include: ○ Scientific Review Committee (SRC) ○ Pharmacy & Therapeutics Committee (P&T) ○ Institutional Biosafety Committee (IBC) ○ Investigational Device Review Committee (IDRC) ○ Conflict of Interest Committee (COI) ○ Pathology Review ○ Radiation Safety Review ○ Export Control ○ Coverage Analysis ○ Billing Grid/Matrix ○ Contracts & Agreements ○ IT Assessment For more information see HRPP Policy & Procedure 1.4 UNMC Ceding Review to an External Central IRB.
Regulatory Documents & Binder Management (include eReg info here)	• The regulatory coordinator will provide, to the sponsor, the completed essential regulatory documents during the study start-up process. (e.g. 1572, financial disclosures, etc.) • Only essential regulatory documents (as defined by federal guidelines and regulations) will be completed by the site. Any other sponsor/CRO forms or worksheets requesting information that has already been provided by this Site Information Sheet will not be completed by the site. Representatives from the sponsor/CRO may extract this information for their internal forms, as needed. • All of the site's investigators' CVs and medical licenses are stored electronically. CVs are updated every 2 years. The site will not complete abbreviated "one-page" CVs or profiles. • All of the site's investigators and research staff have completed CITI Human Subjects' Research Training and Good Clinical Practice (GCP) Training.

	Certificates are stored electronically, and copies are available upon request. Training is renewed every 3 years.
	Review Committees (submitted in parallel with local IRB submissions)
Scientific Review Committee (SRC)	A functioning Scientific Review Committee (SRC) is a mandatory element of a National Cancer Institute-designated clinical cancer center. The SRC oversees the scientific aspects of cancer-related research involving human subjects, conducted by members of the UNMC faculty and students, and members of the Fred & Pamela Buffett Cancer Center. • All oncology trials must undergo review by the SRC, which can run in parallel with IRB submission. • SRC meets once per month (2nd Monday) with submission deadlines 2 weeks prior to meeting date https://unmc.edu/cancercenter/clinical/prms • Approval and/or feedback from SRC reviews are typically available within 5 business days after review.
Institutional Biosafety Committee (IBC)	The UNMC IBC is responsible for 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 compliant 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. • All studies utilizing materials of biological origin, which have the capability to produce deleterious effects on humans or animals, must be reviewed by the UNMC IBC. • The UNMC IBC meets on the second Friday of each month.
Investigational Device Review Committee (IDRC)	The IDRC is an ad hoc review committee comprised of representatives from UNMC, Nebraska Medicine, Bellevue Medical Center, and ancillary department(s) that provide the services to review study requirements involving investigational devices. The Committee is concerned with ensuring effective management and control of the receipt, storage, dispensing, and return of investigational devices pursuant to federal regulations, contractual obligations, and business controls, to ensure the integrity of research practices and the safety of patients.
Pharmacy & 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. All protocols requiring administration of any medication to human subjects must be reviewed by the P&T Committee.

Conflict of Interest Committee (COI)	The UNMC COI Committee is responsible for reviewing all disclosed financial interests of investigators at the institution. A Significant Financial Interest is one that could directly and significantly affect the design, conduct, or reporting of research. The Committee reviews Significant Financial Interests and determines if the creation of a COI Management Plan is warranted.
	Budget
	• The CRC Clinical Trials Analyst (CTA) will perform a Coverage Analysis. The CTA or department will develop the internal study budget and route through internal reviews. Once approved internally, the budget negotiator will provide an initial budget proposal to the sponsor/CRO for review and approval. • The final, sponsor-approved budget is submitted to the contracting office and becomes a part of the final, executed contract. The contract is verified by the local IRB prior to the receipt of final IRB approval.
	Contract
	• Contracts are negotiated centrally depending on the funding source by either: ○ **UNeHealth** (402) 559-7614 Contact: Amanda Leingang - amanda.leingang@unmc.edu ○ **Sponsored Programs Administration** (402) 559-6463 spadmin@unmc.edu • Contract review will begin once the study is approved internally by the department and documents have been provided to the appropriate contracting team. Final IRB approval is contingent upon final contract execution.
Site Initiation Visit (SIV)	
The SIV will be scheduled by the assigned study team member. Contact information for the study coordinator will be provided during study start-up.	

Ancillary Department Information	
Investigational Drug Services (IDS)	• A central investigational drug service (investigational pharmacy) will be used for all clinical research trials and provide support to all clinical locations where patients will be receiving investigational products.

	• The investigational pharmacy is located within the hospital outpatient pharmacy with access limited to pharmacy personnel only (badge-swipe/key code required).
	  ○ Available IP storage conditions: Ambient, 2°-8°C, -20°C, -70°
	  ○ Certified temperature monitoring is available for all storage temperatures[3]
	• The investigational pharmacy is able to accommodate products that require storage in a Nitrogen freezer; however, this should be discussed and requested early during feasibility. The sponsor is responsible for providing and maintaining liquid nitrogen storage.
	• All temperatures are monitored and recorded.
	• Vestigo®, a 21 CFR Part 11 compliant electronic accountability software application designed specifically for investigational pharmacy use is the exclusive Drug Accountability Record Form (DARF). The investigational pharmacy will not keep duplicate records for any trials and sponsor-provided DARFs will not be completed. Monitors may use Vestigo® to review DARFs electronically; copies of DARFs will not be printed, emailed or mailed to monitors; access to Vestigo® for monitors will only be made available during on-site monitor visits, during which they may save or email themselves an electronic copy of the DARFs. Vestigo® will also be used for all other drug accountability documentation including:
	  a. Master patient lists for each study
	  b. Receipt of shipments
	  c. Expiration dates of IP
	  d. Patient and IP dispensing information
	  e. Inventory counts
	  f. Returns
	  g. Destruction
	  h. Quarantined items
	  i. Monitor visits
	  j. Temperature logs
	• Expired investigational product is destroyed on site per SOP. All used vials prepared for subjects on site will be immediately destroyed. The dispense will also document the destruction. All investigational product returned to the site by the subject will be destroyed following double verification of count.
	• For studies utilizing satellite sites, investigational drug will be shipped to the main campus location and will be transported to the satellite clinics via courier, as specified in the site policy[5].
	• Investigational Pharmacy Hours of operation: M-F 8am-4:30 pm, excluding holidays.
	• Copies of pharmacy-specific SOPs and policies are available upon request.
	• A member of the pharmacy team will be available for the SIV and any monitoring visits (appointments must be scheduled in advance). Although on-site visits may be authorized by clinical staff to review the protocol, on-site pharmacy visits are not

	permissible during a pandemic. Monitors can be granted access to Vestigo as previously mentioned. IP Shipment Address Nebraska Medicine - Investigational Drug Services Attn: Jon Beck, Erin Iselin, or Kimmai McClain 4401 Dewey Ave - DOC 0631 Omaha, NE 68105 **Note:** IP shipment address will not be listed separately as "drug shipment address" on the 1572 as it is part of the clinical site address in Box 3 Contact Information Jon Beck, PharmD- Research Pharmacist Coordinator 402.559.5255 or jbeck@nebraskamed.com Erin Iselin, PharmD- Research Pharmacist 402-559-1665 or eiselin@nebraskamed.com Kimmai McClain, PharmD- Research Pharmacist 402.836.9898 or kimcclain@nebraskamed.com Jade Lindsey, CPhT- Research Technician 402.559.1666 or jlindsey@nebraskamed.com Jacob Malashock, CPhT – Research Technician 402.559.4225 or jmalashock@nebraskamed.com If needing to reach all of them, or any one of them, you can use the investigational pharmacy general email: investigationalpharmacy@nebraskamed.com or call 402.559.6600 For external monitors or other sponsor needs (not for IWRS/IRT registration or account set-up), please give this general email address to them: InvestigationalPharmacy@nebraskamed.com For IWRS/IRT registration or account set-up please give sponsors individual emails and contact information.
Biologics Production Facility (BPF)	The 20,000 square foot facility, located on the UNMC campus, includes six individual clean room suites which share a quality control laboratory for release testing of products and other assays; a media preparation room for bulk reagent production; and cleaning,

	disinfecting and sterilization equipment. The facility is jointly operated by UNMC and NM.
	
	The facility follows Good Manufacturing Practice (GMP) and Good Tissue Practice (GTP) standards and is a controlled-access facility, with fully integrated equipment monitoring systems, providing 24-hour surveillance.
	
	• The BPF holds the following accreditations:
	  • Foundation for the Accreditation of Cellular Therapy (FACT)
	  • AABB
	  • College of American Pathologists (CAP)
	• Capacity to store genetically modified products in the cryofreezer
	• Capacity to thaw cryopreserved product at a patient bedside and to infuse immediately
	  ○ 37°C water bath is used for thawing cryopreserved products
	  ○ BPF staff is responsible for overseeing thawing process
	
	https://biologics.nebraskamed.com

NM Clinic Laboratories & Clinical Research Center Laboratories: Research Specimen Processing/Shipping	Study-specific laboratory kits will be shipped to the site.
	
	Specific shipment addresses for laboratory kits will be provided at start-up.
	
	The clinic and the CRC laboratories have the following standard laboratory equipment available for use:
	  • Ambient centrifuge
	  • Refrigerated centrifuge
	  • -20°C and -80°C freezers for specimen storage
	Laboratory equipment is calibrated at least annually, if not more frequently, as needed. All laboratory personnel responsible for specimen collection and processing are IATA certified.
	  • Certifications are available upon request.

Pathology	During study early evaluation, the local pathologists review all studies requiring tissue procurement, to determine feasibility. The site will not be able to supply diagnostic formalin-fixed, paraffin-embedded tumor tissue *blocks*. However, in special circumstances, and at the discretion of the pathologist, a portion of the paraffin block ("sub-block") *may be* generated based on study needs and available tissue. It is the Institution's standard procedure to release a maximum of 10-15 unstained slides for research purposes. Tissue will not be released for banking for potential future studies.

Medical Records & Data/Information Systems (See Appendix A)	Source Data All locations utilize the electronic medical record (EMR) system, EPIC. • The EMR system is 21CFR11 compliant. • An audit trail exists for all creation, deletion, and modification of electronic source data. • Electronic signatures are verified via user ID and password. • Reviewers (such as monitors) are given read-only access once an active directory (AD) account has been set up. • The system is backed up daily. • There is a process for restoring data from backup media.
Study Monitoring	It is recommended that visits be scheduled as far in advance as possible, as space is limited. The study or data coordinator will assist with scheduling and will facilitate all monitor visits. Monitoring visits should adhere to the following guidelines: ○ be scheduled no more frequently than every 6 weeks, ○ last no more than 2 days ○ communicate if more than one monitor is requesting space Visits requiring requests outside of these standard criteria must be approved by the study coordinator in advance and may result in additional charges. Standard turnaround time for data entry/query resolution is 10 business days, to ensure accurate entry of results. If a study requires a shorter turnaround time, this *may be* negotiated at study start-up and will be incorporated into the budget and/or contract. All Study Monitors are required to have an Active Directory (AD) account in order to access any of the systems at UNMC/Nebraska Medicine. After completing a request form for the first time, a new account will be set up and the account information will be emailed to the monitor. For subsequent site visits, a monitor would still complete a visit request form but would use their account created previously. The request form and information on this process can be found here: https://www.unmc.edu/cctr/resources/crc/studymonitor.html

Electronic Regulatory Binders (E-Binders) **Merge with "Regulatory Documents" section. Add eReg info.**	For all studies in which the CRC is responsible for maintaining the study's regulatory documents, the use of an e-binder will be implemented (CRC SOP-64 & CRC SOP-64B). The regulatory files will be maintained electronically on a secure network drive or in eReg, with the exception of the following documents with original signatures: IRB approval documents (prior to April 2015), Form FDA 1572(s) (if the original is not requested by the sponsor or provided to the FDA), monitor sign-in log(s), the Delegation of Authority Log, and any other applicable study logs. There are two methods to share regulatory binders. 1. Box.com ("Box"), a cloud-based content platform for sharing and accessing digital files, will be used to provide monitors access to electronic regulatory binders maintained on a network drive. A File Transfer Protocol (FTP) will be used to transfer the digital files from the secured network drive to Box. The Box platform meets the obligations required by federal mandate to be HIPAA compliant. Box may be accessed remotely from a personal device, however, files saved on Box should not be synched to personal hard drives. The regulatory binder will be uploaded to Box and made available to monitors prior to their visit. The binder will be a mirror image of the current regulatory files stored on the secure network drive. Access will be granted by the regulatory coordinator the day of the monitor visit. After the visit, the binder will be removed from Box and monitor access will be withdrawn. 2. Advarra EReg – Advarra eRegulatory Management System (eReg) is an electronic regulatory binder maintenance system that allows organizations to store essential protocol documents, staff credentials, and organizational regulatory tracking documents. Advarra eReg allows users to share staff credentials and organizational regulatory tracking documents between protocols and manage effective and valid until dates on documents and URLs. Documents that require signature can be routed for electronic signature in a manner that is compliant with 21 CFR Part 11. Study staff, monitors, auditors and inspectors access Advarra eReg via web-based interface. The regulatory documents will be maintained for the period specified in the study protocol, clinical trial agreement, institutional policies, cooperative study group policies, and/or research regulation for whichever period is longer. Electronic documents will be archived and hard copy documents will be sent to long term storage following study closure with the IRB of record. The long-term storage location will be noted in the individual contracts. Regulatory binders will not be provided in any other format.

Advarra Applications	• Advarra products, including the Clinical Trial Management System, eRegulatory EDC are utilized for subject and regulatory document management. • Clinical Trial Management System- Supports centralized management of therap protocols and subjects. • eRegulatory- This 21CFR11 compliant system supports an online Regulatory Bi capturing electronic signatures, protocol documents, training, and credential rec • EDC- This Electronic Data Capture system is used to collect and manage data f research. Advarra EDC supports 21CFR11compliant Case Report Form (CRF) management and approval of CRFs via electronic signatures.
Imaging Capabilities (See Appendix B)	**UNMC/NM MAIN CAMPUS** 4 MRI scanners 3 CT scanners 1 PET/CT scanner 4 gamma cameras [Nuclear Medicine] • Additional questions about imaging resources and specific capabilities may be routed through the Research Project Coordinator **VILLAGE POINTE CANCER CENTER** 1 MRI scanner 1 CT scanner **FRED & PAMELA BUFFETT CANCER CENTER** 1 MRI scanner 1 CT scanner

Apheresis	**UNMC/NM Main Campus**
	• Apheresis is located in the Buffet Cancer Center
	• Apheresis holds the following accreditations:
	  ○ Foundation for the Accreditation of Cellular Therapy (FACT)
	  ○ AABB
	  ○ College of American Pathologists (CAP)
	• 6 Spectra Optia apheresis machines, calibrated every 6 months
	• Central or Peripheral venous access lines will be used
	  ○ Central venous access line is standard of care
	  ○ Standard of care is to remove access line immediately following the last collection
	• Prefer to run a higher AC ratio if high to normal HCT and platelet count to reduce the risk of citrate toxicity (up to 15:1)
	• Cell counts on the donor are run by the Clinical Hematology Department. Cell counts on the product are done by the Biologic Production Facility (BPF).

	• HypoThermosol is **not** used to dilute the final apheresis volume before shipment
	• Capacity to store genetically modified products in the cryofreezer
	• Capacity to thaw cryopreserved product at a patient bedside and to infuse immediately
	  ○ 37°C water bath is used for thawing cryopreserved products
	  ○ BPF staff is responsible for overseeing thawing process

References, Policies, and Guidelines

1. FDA publication *Information Sheet for Guidance for Sponsors, Clinical Investigators, and IRBs Frequently Asked Questions – Statement of Investigator (Form FDA 1572)*; May 2010
2. UNMC Human Research Protection Program Policy #3.5 *Retention of Research Records*; December 2015
3. Nebraska Medicine Policy # ADM 2020 – *Investigational Drug Services;* December 2017
4. The Nebraska Medical Center Policy #ADM 019 – *Destruction of Investigational Products*; March 2014
5. The Nebraska Medical Center Policy #ADM 021 – *Transport of Investigational Drug Between The Nebraska Medical Center/UNMC Clinics*; March 2014
6. UNMC SOP #14 – *Informed Consent*; November 2010
7. UNMC Oncology/Hematology Memo To File – *External Adverse Events*; September 2013
8. UNMC Study Implementation 207.5B – *Evaluating and Reporting External Safety Reports*; September 2013

Appendix A: EMR Questionnaire

EMR Questionnaire May 2024		
Questions	**Response**	**Comments**
Assessment Criteria		
What is the name and version number of the EMR used?		Epic is updated on a regular basis, to find the most current version: Log in to Epic, Select the "Epic" menu, Go to the "Help" submenu and then select the "About Hyperspace" option. The current version is noted under "Details," "Server Version."
Is the Electronic Medical Records (EMR) system built in-house at the site or a Commercial Off the Shelf (COTS) package?	Both	Foundation build is available from the vendor and then customized/optimized on site.
Is documentation of the system validation available? Please include the expiration date of the system validation in the comments Section.	Yes	
Are the medical records recorded on paper, in an electronic system or a combination of both?	Electronic	
Is the data entered directly into a computer system or is there a paper recorded created first from which they are transcribed/scanned?	Computer System	
In case of system failure, is the system regularly back-up?	Yes	
Has the restoration of backup data been tested and documented?	Yes	
Is backup data retained at another location in human readable format (i.e. paper, PDF)?	No	
Is there a plan on how to continue with business in the event of system failure?	Yes	There is a downtime procedure policy.
Have the site personnel been trained in the use of the computer system? If yes,	Yes	All enterprise employees are trained on the system. Training attendance and completion is documented in the enterprise Learning

please confirm training documentation is available upon request.		Management System (LMS). Monitors sent to Nebraska Medicine are not trained on the system.
Does the EMR system have a User Manual?	No	Tip sheets/guides are provided for various workflows as needed via an internal training website. This website can only be accessed from a network computer (or when remoted into the network).
Do written Standard Operating Procedures (SOPs) or policies exist for the use/operations/maintenance of the computer system(s)?	Yes	SOPs/Policies will be provided for review upon request.
Access		
Is the computer hardware kept in a secure location?	Yes	
Are the following controls in place to limit access to the system? - Unique user account (user Id and password) - Automatically log off user after idle periods - Locks user account after several failed log in attempts	Yes	
Is access to the electronic medical record system restricted for staff by unique, identifiable login?	Yes	
Is a list of authorized users maintained?	Yes	We use AD security for authorized users.
Are passwords kept confidential (not shared)?	Yes	
Is there a process for issuing and revoking user access?	Yes	The Security team is responsible for user access which is updated based on manager-approved Service Requests.
If satellite sites are used, how do satellite sites access the system? Provide response in the comments field. Do all satellite sites have direct access to the EMR	Yes	All NM satellite sites are set up on the internal network and have access to the EMR.

system? If not, please explain further in comments.		
Is access to certain functions controlled base upon the user's role (e.g., read, write, change, delete)?	Yes	
Audit Trail		
Is there an audit trail of all changes made to electronic medical recorded system (i.e., does the EMR retain a copy of the original entry [or entries] as well as the name of the person, date and time stamp of any changes)?	Yes	Typically, the audit trail will indicate who made the change, date/time change was made, reason for change, previously recorded value/documentation.
Is the original information, as well as the new information, still available after the change is made?	Yes	
Is the audit trail system-generated (does not require the user to create an audit trail record)?	Yes	
In the audit trail, are members of staff identified in the system either by their names or a unique ID?	Yes	Identified by name.
Is the audit trail switched on from the point of data entry?	Yes	Audits are tracked when new data is entered or a change is made to existing data.
Are the audit trail entries date-and time-stamped?	Yes	
Can the audit trail be edited?	No	The audit trail is protected from modifications by users.
Is the audit trail protected from being turned off?	Yes	
Data Security		
Does the site have a written data storage/archival policy for the electronic medical record system? (If No is marked, explain in the comments field where and how the medical records in	Yes	

the electronic record system are to be stored) (If yes is marked, provide a brief summary of the policy in the Comments section)		
Is the electronic data routinely archived as per legal record retention requirements?	Yes	
Can archive electronic medical records be retrieved for a regulatory inspection after the study is closed?	Yes	
Is the data in the system backed up (either via a network connection or onto diskette or tape, for example) in case of system failure or loss of data?	Yes	
How frequently is this done?	Yes	Nightly
Can this backed up data be restored?	Yes	
Has the restoration of backup data been tested?	Yes	
Are there SOPs in place to ensure proper management, disablement, and revoking of user accounts and passwords?	Yes	
Are cumulative user-access records kept in a human readable form to indicate the names of authorized personnel, titles, and a description of access privileges?	Yes	
Does the system capture access or attempted access by authorized and unauthorized users?	Yes	
How long will data be archived?		Anything entered in the EMR will remain visible indefinitely in a read only format.
Electronic Signatures		
Are electronic signatures used in the system?	Yes	

Are electronic signatures protected from intentional or unintentional misuse?	Yes	
When a signature is applied to a record, is it protected from cutting and pasting to other records?	Yes	
Are the name of the signer and the meaning of the signature displayed?	Yes	
When a signed record is altered, is the signature made invalid?	Yes	Addended signed records must be re-signed.
Clinical Monitor Access		
Do sponsor staff (i.e., Clinical Monitor, compliance Auditor) have individual read-only access to the EMR system for subjects participating in the clinical trial?	Yes	Access is given through EpicCare Link and is read only. Monitors do not log into Hyperspace.
Is access read-only and limited to subjects on the study?	Yes	
Will the sponsor staff (monitor) have access only to those subjects who have signed an informed consent?	Yes	The site coordinator will have to request for specific access to specific patient records for each monitoring visit.
Does the system automatically log off a user after specified period of inactivity?	Yes	
How will the site train the Clinical Monitor in the use of the EMR system? Explain in comments field.		Training is not required for EpicCare Link. A *study monitor application access guide* is provided to Clinical Monitors. If the monitor has questions about where to find certain pieces of information they can ask the study coordinator. If the study coordinator does not know the answer, they can contact the Research CIL.
If using Limited Supervised Access/Printouts:	Yes	Printed reports are not routinely signed by site staff but this can be done if requested. Over the shoulder access should not be necessary.

- Do the paper printouts display the full user ID or name, date and time? - Are printouts signed/dated by the site staff to confirm that they are a complete and true representation of the data in the system? - Is site prepared to resource over the shoulder access?	Yes No	
Training		
Are SOPs in place for use of the electronic data system?	Yes	
Who documents the training and when?		Training is documented in Apollo, our Learning Management System (LMS). Users must register for the appropriate classes, attend/complete the course, and pass any associated assessments.
Where is the training documentation stored?		Apollo-Learning Management System
Relevant Documents		
CFR Compliance		https://info.unmc.edu/its-security/_documents/onechart-compliance.pdf

Appendix B: Scanner Information for Research Studies

To Access all of the Scanner information for Research Studies at UNMC, click here.