Research Support

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Core Facilities and Service Centers

Research Service Centers/Core Facilities

To assist researchers in basic, translational and clinical research, UNMC provides extensive Core Facilities on campus. A directory of core facilities/service centers has been made available.

In addition to institutional core facilities, many Centers and Major Programs also include specialized cores or service centers, a list of programs and centers can be found at unmc.edu/vcr/about/centers.

Research Information Technology Office (RITO)

Where do I find Information Technology support for research on campus?

The Research Information Technology Office (RITO) is available to meet the growing IT needs of researchers. The discrete functions this office provides are: infrastructure; application development and programming; data management and storage; information security; research grant technical support; support for research resources; and core facilities on campus.

Some institutionally funded software available to researchers:

- Research Electronic Data Capture (REDCap) software, an open-source clinical research management tool provides audit trails for tracking data manipulation and user activity, as well as automated export procedures for data downloads to Excel, PDF, and common statistical packages (SPSS, SAS, Stata, R). Contact RITO for more information.
- Freezerworks® for biobanking. This NCI-approved and compatible software is available for biologic samples. Contact RITO for more information.
- Systems Biology analysis software. See the Bioinformatics and Systems Biology Core Facility website.

RITO Web: unmc.edu/vcr/rito
Director of RITO: 402-559-9072

Research Data Storage

The Research IT Office (RITO) oversees research data storage. RITO provides 25GB of Enterprise HIPAA Compliant data storage for all research faculty (including their laboratory personnel) at no charge. Additional secure storage can be purchased if necessary. A number of options are available depending on whether protected health information is included or not. Contact the RITO Director to discuss your data storage needs.

General Supply facilitates the storage of hard copies of research data, particularly Clinical Study Documents and Binders. Contact General Supply for current pricing.

Biosafety Facilities

Biosafety level laboratories (BSL) are designated by the Centers for Disease Control and Prevention (CDC) based on the biocontainment precautions required to isolate biological agents such as bacteria, parasites and viruses. Laboratory facilities are available for work with infectious agents, as well as with animals.

What is the difference between BSL-2 and BSL-3 facilities?

Biosafety Level 2 (BSL-2) is suitable for work involving agents that pose moderate hazards to personnel and the environment. It differs from BSL-1 in that: 1) laboratory personnel have specific training in handling pathogenic agents and are supervised by scientists competent in handling infectious agents and associated procedures; 2) access to the laboratory is restricted when work is being conducted; and 3) all procedures in which infectious aerosols or splashes may be created are conducted in biological safety cabinets or other physical containment equipment.

Biosafety Level 3 (BSL-3) is applicable to clinical, diagnostic, teaching, research, or production facilities where work is performed with indigenous or exotic agents that may cause serious or potentially lethal disease through inhalation exposure. Laboratory personnel must receive specific training in handling pathogenic and potentially lethal agents, and must be supervised by scientists competent in handling infectious agents and associated procedures. BSL-3 facilities at UNMC must be certified by the campus Biosafety Officer before first use and inspected annually.

Where are the BSL-2 facilities at UNMC?

All laboratories in the Durham Research Center (DRC) towers are constructed to BSL 2 standards. Laboratories and personnel working with BSL-2 agents must pass annual safety training and have completed the Biosafety compliance inspection checklist.

Does UNMC have BSL-3 facilities?

Yes. The Department of Pathology and Microbiology manages biosafety level 3 (BSL-3) containment laboratories on the UNMC campus. Information regarding the BSL-3 laboratories and their use can be obtained by contacting the campus Biosafety Officer at 402-559-7774.

The Department of Pharmacology and Experimental Neuroscience manages a suite of containment laboratories. Although these laboratories are designed as BSL-3, they are currently being used for HIV-1 research as BSL-2 laboratories where BSL-3 practices are followed. These laboratories have restricted access but are available to approved faculty.

To gain access to this facility, you must meet the following requirements:

- Have direct approval from the Chair of the Department of Pharmacology & Experimental Neuroscience
- Review and successfully pass the Institutional Biosafety Web-based examinations for General Biosafety and BSL-3 Containment.

Once approved access, the researcher's ID card is programmed into the security system by personnel in the Security Department.

Entering the anteroom will require the use of a proximity card and a four digit passcode.

For more information, visit the Biosafety Level III website.

Animal BSL-2 and 3 facilities.

Animal biosafety level 2 and 3 (ABSL-2 and 3) facilities are available and managed by Comparative Medicine. For additional information about the use of this facility contact the Safety/Compliance Coordinator for Comparative Medicine at 402-559-4034.

Biologics Production Facility

What is the Biologics Production Facility?

The Biologics Production Facility (BPF) is designed to support scientific and clinical investigators in developing and testing the most promising new medical therapies through the manufacturing, production, and modification of cells, tissues, and cellular and tissue-derived products. The facility is jointly operated by Nebraska Medicine and UNMC.

The Biologics Production Facility meets Good Manufacturing Practice (GMP) and Good Tissue Practice (GTP) regulations, which provide investigators with the environmental controls, quality management, and security required for the manufacture of drugs, vaccines and human cells, tissues, and cellular and tissue-based products (HCT/Ps) for medical therapy purposes.

The application to use the Biologics Production Facility is available online.

More information is available on their website, in addition to a virtual tour of the facility

Contact the facility manager at 402-559-6009.

What are the uses of the Biologics Production Facility?

The BPF currently focuses on four promising areas of therapeutic medicine: stem cell collection and processing, cellular-based vaccines and therapies, tissue-based therapies, and regenerative medicine therapies, in addition to the new and emerging field of nanomedicine.

What must I do to work with the Biologics Production Facility?

To apply to conduct a project at this facility, you must complete an application form describing your project, including its status related to required Investigational New Drug (IND) submission or IRB approvals, funding sources, whether Nebraska Medicine patients will be included in the study, whether potentially toxic materials are involved, and the types of manufacturing steps involved.

Center for Drug Delivery and Nanomedicine (CDDN)

What is the CDDN?

The Center for Drug Delivery and Nanomedicine (CDDN) unifies existing diverse technical and scientific expertise in biomedical and material science research at the University of Nebraska, creating a world-class interdisciplinary drug delivery and nanomedicine program. The CDDN integrates established expertise in drug delivery, gene therapy, neuroscience, pathology, immunology, pharmacology, vaccine therapy, cancer biology, polymer science and nanotechnology at the University of Nebraska Medical Center (UNMC), the University of Nebraska at Lincoln (UNL) and Creighton University.

What research expertise is available within the CDDN?

The Nanomaterials Characterization Core Facility provides investigators with state-of-the-art equipment, expertise and custom services for comprehensive study of polymers and nanomaterials.

Research Support and Resources

Radiologic Images for Research Studies

Can the institution upload radiology images electronically to send to a central lab?

Yes.

Who is responsible for uploading radiology images that I have to send to a central lab?

Research coordinators and other study staff are responsible for uploading radiology images to a central lab. A detailed process for uploading radiology scans has been laid out and the following documents have been developed to assist research staff.

- Process for Requesting Services
- Radiology Services Request Form
- Scanner Information for Research Studies
- Contact Information
- Research Partial De-identification Form
- Instructions for Exporting and Uploading Images from the McKesson PACS System

These documents can be found at unmc.edu/cctr/resources/rad-images.

Will the images be de-identified?

Technically, the scans are not de-identified. The scan date and time will always remain on the images; however, all other PHI will be removed. Since not all 18 of the PHI identifiers will be removed, the scans submitted to a central reader are classified as “partially de-identified.”

Who do I contact if I need help uploading scans?

Contact information for help can be found at the following website under the Clinical Service and Technology Cores Dropdown/Resource Toolkit section: unmc.edu/cctr/resources.

Does this process have an additional fee I must add to my budget?

No, there are no fees for electronically uploading radiology scans for research.

How long will the uploading process take?

This will vary depending on the size of the imaging files and the uploading program used. On average, it takes approximately 30 minutes to export and upload a scan from start to finish.

Cancer Center Protocol & Data Management Unit (CPDMU)

The CPDMU is a shared resource of the Fred & Pamela Buffett Cancer Center, which provides centralized clinical trial support to members. All cancer related clinical trial proposals flow through the protocol development process established and administered by the CPDMU and are subsequently sent for review to the Protocol Review and Monitoring System (PRMS), the PRMS Scientific Review Committee (SRC), and to the IRB. The CPDMU database of clinical trials also provides support for the PRMS CRC and Audit Committee (AC) and the Data and Safety Monitoring Committee (DSMC).

What services does the CPDMU provide?

The CPDMU assists with all aspects of a cancer clinical trial to ensure that projects are within the mission and scope of the Fred & Pamela Buffett Cancer Center.

As the centralized resource for clinical research in the Fred & Pamela Buffett Cancer Center, the CPDMU provides the following services to Fred & Pamela Buffett Cancer Center members with Director approved projects:

- Assists PI’s in writing and submitting new clinical research protocols to the IRB, SRC, Pharmacy and Therapeutics Committee, and FDA applications for INDs or IDEs.
- Assists in preparing estimated clinical budget and financial resources required for the completion of the clinical study.
- Develops data collection instruments (paper and electronic) as needed.
- Submits modifications of the research protocol, IRB application, and informed consents as needed during the course of the investigation.
- Coordinates the preparation of a Spanish version of informed consents for non-English speaking subjects.
- Promotes quality assurance, research compliance, and adherence to Good Clinical Practices (GCP).

- Recruits and screens patients for eligibility into research protocols, assist with obtaining informed consent and coordinate patient enrollment.
- Coordinates the research protocol while the patient is participating in the clinical trial to ensure that the treatment provided and the data collected adheres to the clinical research protocol requirements.
- Monitors and reports adverse and serious adverse events in accordance with DSMC and IRB policies.
- Acts as a liaison with the UNMC Investigational Pharmacy Service to order, inventory, and monitor, dispense and regulate experimental drugs.
- Coordinates investigational drug shipments and drug logs.
- Obtains study lab samples, and prepare for possible shipment of specimens.
- Collects and records data (i.e. interpret, extract and record information from source documents and patient interviews) for support of clinical research.
- Coordinates the regulatory and reporting aspects of early Phase I and II Investigator-initiated cancer related research protocols for interactions with the FDA and the efficient and ethical conduct of clinical trials.
- Maintains regulatory documentation as appropriate to meet federal and sponsoring agency guidelines.
- Prepares regularly scheduled review, internal and external adverse event, and other reports to the IRB, SRC, DSMC, FDA, and sponsoring agency as required.
- Collaborates with PIs in the preparation of publications and study results.
- Provides information regarding new research protocols and investigational trials, and update information regarding ongoing clinical trials and referral services for physicians and patients throughout UNMC and the State of Nebraska.
- Conducts protocol-specific orientation and training for Affiliate Site Investigators and Coordinators for investigator initiated therapeutic intervention trials to be opened at affiliate sites.
- Provides oversight and management of active investigator initiated therapeutic intervention trials at Affiliate Sites, including centralized reporting to the PRMS Audit Committee and to the DSMC.

How do I contact the CPDMU?

Web: unmc.edu/cancercenter/clinical/prms
Phone: 402-559-4969 or 402-559-5286

Biostatistics, Epidemiology and Research Data Design

Who should I contact?

The Center for Collaboration on Research Design and Analysis (CCORDA) is a service center which provides expertise in the quantitative sciences, including biostatistics, epidemiology, and health services research, and to coordinate the collaborative design, planning, conduct, analysis

and interpretation of laboratory, clinical, and public health research studies.

Web: unmc.edu/publichealth/centers/ccorda
Phone: 402-559-6825

When should I contact CCORDA?

Contact CCORDA when you need expertise in study design, including sample size, epidemiology, database design and management, statistical analysis, health services research and administration, health promotion, social and behavioral health sciences, and interpretation and presentation of research results. CCORDA members can supplement your area of expertise and enhance the quality, integrity, and validity of your study or project. More information about their scope of services is available on their website.

Biobanks and Registries

- The Nebraska Biobank is a biorepository of de-identified serum and DNA samples collected from leftover clinical laboratory specimens.
- Catalog of Disease Specific Biobanks and Registries
- Internal Medicine's Biobanks on campus range from rheumatoid arthritis and vascular disease to thyroid cancer and lymphoid malignancies. A full listing of these biobanks and more detailed information is available on their website

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Telehealth Devices and Expertise

What is Telehealth?

Telehealth is utilization of technology as a tool to deliver care at a distance. Telemedicine includes a growing variety of applications and services using two-way video, email, smart phones, wireless tools, and other forms of telecommunications technology.

What research opportunities are available in telehealth at UNMC?

The Rural Technology Core established under the Interdisciplinary Healthy Heart Center provides research telehealth support in rural communities.

Niedfelt Nursing Research Center (NNRC)

The NNRC team supports the College of Nursing's objective to increase national prominence as a research health sciences center. The team pursues six objectives:

- Facilitate research activities and development
- Promote collaboration and mentoring
- Enhance research resources and facilities
- Function as a liaison with UNMC research offices
- Assist nurse faculty in setting up clinical trials to improve nurse-delivered patient care
- Promote research in nursing education

Web: unmc.edu/nursing/research/niedfelt-center

Clinical Laboratory Services

The **Clinical Research Center** offers some laboratory services. See their fees website for a list of tests available.

The *Tissue Sciences Facility* provides basic and specialized histology and immunohistochemistry to support research. See https://www.unmc.edu/pathology-research/resources/tsf/ for a description of available services.

The **Department of Pathology Laboratory Services** provides some fee for service clinical research testing. See Nebraska Medicine Laboratory Services and search Research Specimens.

See the **Pediatric Research Office** (PRO) website for lab services available at Children's Hospital & Medical Center.

Research Pharmacy Services

When must I contact the Investigational Drug Service?

Per Joint Commission standards and hospital policy, clinical trials using medications or investigational products supplied to the institution from a sponsor (including funding to purchase these products) must utilize investigational drug services. All protocols that utilize any medication, investigational or not, must be submitted to the Pharmacy and Therapeutics Committee (P&T) for review. This includes herbal supplements, vitamins, nutritional supplements, dietary supplements,

probiotics or similar products. Notify the Investigational Drug Service (Research Pharmacy) Pharmacist for direction.

How do I contact the research pharmacy?

Web: unmc.edu/cctr/resources/pharmacy
Phone: 402-559-5255
Pager: 402-888-3418

What services are provided?

The following services are available to investigators:

- Protocol assistance and design, including blinding, randomization, compounding, IV admixture, drug procurement, study logistics
- Regulatory
- Inventory control
- Documentation
- Dispensing
- Drug information

Are there pharmacy services for pediatric trials at Children's Hospital & Medical Center?

Yes. Contact the Research Pharmacist at 402-955-6175

Are there fees for the services? Do I need to budget for pharmacy services?

Yes, please contact the investigational pharmacist during the budgeting process to discuss pharmacy fees so they can be added to the budget.

What fees are assessed for study drug storage?

Each study varies in its requirements and its complexity. To aid in calculating costs for budget preparation, a "Pharmacy Cost Estimator" has been developed for investigators. This estimator can be found on the Clinical and Translational Research website.

How do I order pharmaceuticals for non-human use?

Investigational drugs not for human use can be ordered through pharmacy supply by faxing an order to 402-559-9070, include the Investigator's name and grant/study account number.