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.

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