

# Research Handbook

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A guide to navigating research at the University of Nebraska Medical Center.

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# Introduction to the Research Handbook

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Welcome to the University of Nebraska Medical Center, where research breakthroughs improve patient outcomes.

Research is a vital mission of UNMC, representing a vibrant community of researchers among its colleges, institutes, and clinical partners.

The Vice Chancellor for Research leads the research enterprise, and the Office of Research serves as the primary resource for researchers.

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# How to Use This Guide

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## Organization and Structure

### Chapters and Pages

The Research Handbook is organized using chapters and pages, which are listed in the left navigation sidebar. Some pages are stand-alone, while others are located inside chapters.

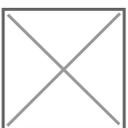


To view the pages located within a chapter, click the caret mark to expand the page list.



### Page Sections

Each page has sections, like "introduction", that provide large-scale information, and subsections that provide additional details. These are then organized into a per-page table of contents that is located in the left sidebar.



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## Content and Interactivity

The Research Handbook is a fully searchable, interactive guide that has flexible content and direct links to resources with more information.

## Search

The search bar is located at the top center of each page and can be used to quickly find what you're looking for in the handbook.

## Links

Any text in red, [like this here](#), is a link to a resource. Some links go to another section of the handbook, others go to a different [UNMC website](#), and some lead to [external resources](#).

Certain links may lead to websites that are only available while on-campus or will require you to log in using your NetID and password.

The handbook is regularly checked for links that don't appear to be working properly. Should you find one while navigating the handbook, [drop us a line](#) to let us know.

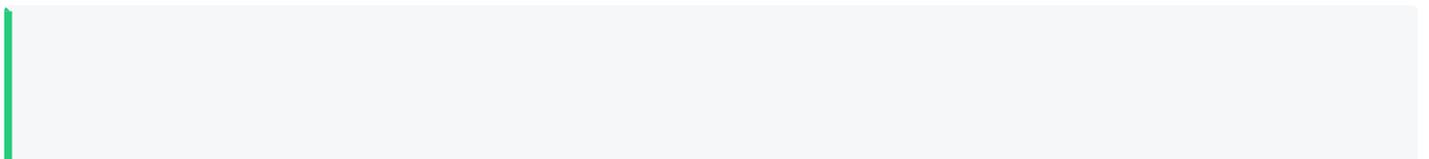
## Information Boxes

Important information that might need to be accessed frequently or otherwise needs to be called out may show up in a box like this:

**I'm a box with important information.** The content in a blue section you may find helpful to write down or keep track of for future reference.

**I'm a box with cautionary information.** The content in an orange section may need to be paid special attention and may involve multiple levels of decision-making.

**I'm a box with extremely important information.** The content in a red section indicates that it is highly restricted or will need multiple levels of review.



**I'm a box with general information.** The content in a green section is for emphasis only and does not indicate a level of severity.

# Common Numbers and Websites

Resource	Contact Information
Office of Research	402-559-8490 research@unmc.edu <a href="#">Website</a>
Vice Chancellor for Research	Jennifer Larsen, MD 402-559-4837 jlarsen@unmc.edu
Associate Vice Chancellor for Basic Science Research	Ken Bayles, PhD 402-559-4945 kbayles@unmc.edu
Associate Vice Chancellor for Basic Science Research	Chris Kratochvil, MD 402-559-8490 ckratoch@unmc.edu
Research Resources	Tess Kuenstling, PhD, MBA 402-559-6162 tess.kuenstling@unmc.edu
Web Resources	Linda Wilkie, VT, BS 402-559-7649 lwilkie@unmc.edu
Clinical Research Center	402-559-7685 <a href="#">Website</a>
Institutional Animal Care and Use Committee (IACUC)	402-559-6046 <a href="#">Website</a>
Institutional Biosafety Committee (IBC)	402-559-6463 <a href="#">Website</a>
Institutional Review Board Office (IRB)	402-559-6463 <a href="#">Website</a>
Sponsored Programs Administration (SPAdmin)	402-559-7456 <a href="#">Website</a>
UNeHealth	402-559-7456 <a href="#">Website</a>
UNeMed	402-559-2468 <a href="#">Website</a>
Research Policies	<a href="#">Website</a>

# Frequently Asked Questions

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A curated list of frequently asked questions will be featured on this page. Check back soon for updates.

Have something you'd like to see on this page? [Let us know](#)

# Abbreviations and Terms

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## A

### **AAALAC**

Association for Assessment and Accreditation of Laboratory Animal Care

### **ADIS**

Academic Department Information System: addresses record retention of specified faculty academic records including scholarly publications, research funding, faculty appointments, clinical service and teaching. ADIS is the sole repository of these records. ADIS is a UNMC-wide repository, but is not NU system-wide.

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## B

### **BMC**

Bellevue Medical Center

### **Biobank**

A biobank or tissue bank stores human biological material (HBM) to provide a resource for future, unspecified research. A bio/tissue bank may be created from leftover/extra tissue collected during a research study or non-research clinical procedure.

### **BPF**

Biologics Production Facility is a Good Manufacturing Practices (GMP) compliant facility for the manufacture, processing, cryopreservation, and/or storage of cells, tissues, and cellular and tissue-derived products for administration to humans, such as bone marrow, peripheral blood stem cells, cord blood cells, and vaccines.

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## **C**

### **Cayuse**

UNMC's Web-based tool for preparing and submitting NIH applications to grants.gov. In addition, Cayuse will support submissions to most other federal agencies, including HRSA, AHRQ, CDMRP, and NSF

### **CDA**

Confidentiality Disclosure Agreement

### **CCORDA**

Center for Collaboration on Research Design and Analysis is a UNMC center that provides expertise in the quantitative sciences, including biostatistics, epidemiology, and health services research, and coordinates the collaborative design, planning, conduct, analysis and interpretation of laboratory, clinical, and public health research studies.

### **CRC**

Clinical Research Center is a centralized clinical research unit on the UNMC/Nebraska Medicine campus that supports a broad range of sponsored, investigator-initiated, and cooperative trials, and monitors multi-center trials. The CRC provides many services for a clinical research trial and administrative support to the clinical investigator.

### **CTMM**

Clinical Trial Master Matrix is an Excel spreadsheet workbook that records basic information about a clinical trial with protocol-specific scheduling of research-related procedures/treatments and details how these will be billed. The CTMM functions as a "stand-alone" document serving as a resource for authorized personnel who do not have immediate access to the contract, budget, and/or protocol.

### **CFR**

Code of Federal Regulations the codification of the general and permanent rules and regulations of the federal government of the United States.

### **CITI**

Collaborative Institutional Training Initiative: Web-based training program in the protection of human subjects, which all personnel involved in the conduct of human subject research at UNMC are required to complete.

## **CMAG**

Comparative Medicine Advisory Group: A campus-wide advisory group that maintains and improves the quality of research animal facilities, equipment and services.

## **CMMS**

Comparative Medicine Business Management System: An online software system that integrates the IACUC and the SPAdmin databases to enhance campus regulatory compliance.

## **COIC**

Conflict of Interest Committee: The UNMC COI Committee (COIC) is appointed and operates in accordance with UNMC Policy No. 8010 and is responsible for reviewing potential conflicts of interest which have been determined to be significant by the COI Officer/designee.

## **CRO**

Contract Research Organization

## **CRSO**

Chemical and Radiation Safety. See EHS.

## **CRFCS**

Clinical Research Financial Compliance Specialist

## **CTA**

Clinical Trial Agreement

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## **D**

## **DSM**

Data Safety Monitoring. Procedures set up before the start of human subject research monitoring data to ensure subject safety, considering the risks, complexity, and nature of the research.

## **DUNS**

Data Universal Numbering System, <https://www.unmc.edu/spa/about/institutional.html>

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## **E**

### **EHS**

Department of Environmental Health & Safety: The department provides a broad range of services to the University to promote the protection of patients, students, faculty and administrative staff of the University, as well as the larger community and environment regarding the use, storage and disposal of chemicals and radiation on campus. <https://www.unmc.edu/ehs/>

### **EIN**

Entity Identification Number, <https://www.unmc.edu/spa/about/institutional.html>

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## **F**

### **F&A**

Facilities & Administrative rate Current agreement?

### **FICE**

Federal Interagency Committee on Education institutional code,  
<https://www.unmc.edu/spa/about/institutional.html>

### **FWA**

Human subject Federal Wide Assurance number,  
<https://www.unmc.edu/spa/about/institutional.html>

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# H

## HRPP

Human Research Protection Program is a comprehensive system to ensure the protection of human subjects participating in research. UNMC's HRPP consists of four IRBs, other review committees, administrative offices, and administrative officials.

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# I

## IDE

Investigational New Device Exemption. An investigational new device exemption (IDE) is an application submitted to FDA to conduct a clinical investigation with an investigational device subject to 21 CFR 812.2 and classified as an SRD. The IDE is submitted by the sponsor of the research. The FDA will provide a written authorization to conduct a clinical investigation within 30 days after receipt of the IDE. If the device is not an SRD, the investigation is considered by the FDA to have an approved IDE unless the FDA notifies the sponsor otherwise.

## IND

Investigational New Drug Application to FDA by sponsor to obtain an exemption that allows a new drug to be transported or distributed across state lines to facilitate testing diagnostic or therapeutic potential in humans. There are three IND types – Investigator IND, Emergency Use IND, Treatment IND4. There are two IND categories – Commercial and Research IACUC Institutional Animal Care and Use Committee A review committee to oversee and evaluate all aspects of the institution's animal care and use program involving any vertebrate.

## IBC

Institutional Biosafety Committee by Federal law this committee is charged with the planning and implementation of the campus Biosafety Program to ensure the health and safety of all personnel working with biohazardous agents.

## IRB

Institutional Review Board: is a board composed of members from scientific disciplines and individuals from the community, it assists investigators in the protection of the rights and welfare of human subjects in research projects conducted by anyone on the premises of UNMC, Nebraska Medicine, Children's Hospital & Medical Center (CH&MC), and the University of Nebraska at

Omaha (UNO).

## **IPF**

Institutional Profile File number, <https://www.unmc.edu/spa/about/institutional.html>

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## **M**

### **MSP&T**

Medical Staff Pharmacy and Therapeutics Committee. Clinical trials which use medication or investigational products supplied to the institution from a sponsor must have the protocol reviewed by this committee.

### **MTDC**

Modified Total Direct Cost: Includes salaries and wages, fringe benefits, materials and supplies, services, travel, and subgrants and subcontracts up to the first \$25,000 of each subgrantor subcontract (regardless of the period covered by the subgrant or subcontract). MTDC excludes equipment (defined as having a useful life of over one year and an acquisition cost of \$5,000 or more per unit), capital expenditures, charges for patient care and tuition remission, rental costs, scholarships and fellowships, as well as the portion of each subgrant and subcontract in excess of \$25,000.

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## **N**

### **NCT Number**

A unique identification code assigned to each clinical study registered on ClinicalTrials.gov. The format is the letters "NCT" followed by an 8-digit number (for example, NCT00000419). Also called a ClinicalTrials.gov identifier.

### **NRC**

Nuclear Regulatory Commission license number, <https://www.unmc.edu/spa/about/institutional.html>

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## O

### ORA

Office of Regulatory Affairs department that exercises oversight for UNMC's Human Research Protection Program (HRPP)

### One Chart

Electronic Health Record system used at Nebraska Medicine, UNMC-Physicians, Nebraska Medicine - Bellevue, and Children's Hospital & Medical Center.

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## P

### Part 11 Compliance

Refers to the part 11 of Title 21 of the Code of Federal Regulations; Electronic Records; Electronic Signatures (21 CFR Part 11). When participating in human subject research, sponsors require verification that the Nebraska Medicine electronic medical record system is compliant with these regulations. Documentation to verify this compliance is provided by UNMC/Nebraska Medicine with the following letter at [https://www.unmc.edu/spa/\\_documents/21cfrpart11document8412.pdf](https://www.unmc.edu/spa/_documents/21cfrpart11document8412.pdf)

### PRO

Pediatric Research Office. The clinical research unit supporting Pediatric Clinical Research at UNMC/ NEMed and Children's Hospital & Medical Center, PRO provides many services for clinical research trials and administrative support to clinical investigators.

### PRMS

Protocol Review and Monitoring System. The PRMS of the Fred & Pamela Buffett Cancer Center provides central management and oversight functions for all cancer-related trials involving human subjects conducted by members of the cancer center.

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## R

## **RITO**

Research IT Office is a core facility on the UNMC campus that serves the growing information technology needs of the research community.

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## **S**

### **SRC**

PRMS Scientific Review Committee: this review committee 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 and conducted by members of the University of Nebraska Medical Center (UNMC) faculty and students, and members of the Fred & Pamela Buffett Cancer Center.

### **SAP**

The centralized accounting system used by NU system campuses.

### **SPAccting**

Sponsored Programs Accounting

### **SPAdmin**

Sponsored Programs Administration

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## **T**

### **TIN**

Federal Tax Identification Number, <https://www.unmc.edu/spa/about/institutional.html>

### **Tissue Bank**

A biobank or tissue bank is a repository of human biological material (HBM) that provides resources for future, unspecified research.

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# U

## **UNeHealth**

The front door for industry-sponsored, clinical research contracting for UNMC and Nebraska Medicine. Led by representatives from these entities, UNeHealth centralizes and streamlines processes between the organizations.

## **UNeMed**

UNeMed is a for-profit corporation owned by the Board of Regents of the University of Nebraska. UNeMed is responsible for a spectrum of technology transfer activities, including protecting, marketing and commercializing UNMC inventions.

# Getting Started

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## Research Policies

Policies that affect Research at UNMC involve employee and workplace safety, financial and regulatory compliance, and research subject protection. There are policies at all levels and units of our organization that might impact your work.

A partial listing of [policies relevant to research](#) have been grouped on the VCR website.

A complete catalog of UNMC policies can be found on [the UNMC Policies and Procedures Wiki](#).

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## Conflict of Interest Reporting and Outside Employment

### When to Disclose

UNMC Conflict of Interest Procedures ([Policy #8010](#)); an initial conflict of interest (COI) disclosure must be completed by all faculty members, directors, administrators, and department heads (or equivalents) within 90 days of appointment/hire and annually thereafter. New financial interests must be added to the COI disclosure within 30 days. Complete the Annual Disclosure of Financial Interest Questionnaire.

The “Permission to Engage in Outside Activities” form per UNMC Board of Regents ([Policy #1049](#)) may also need to be added. Depending on conflicts disclosed, an investigator’s permission to engage in outside activities may require Board of Regents approval.

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### How to Disclose

UNMC uses a Web-based system, COI-SMART to identify, track, and manage COI Disclosures and Outside Professional Employment.

To access COI-SMART, log in to the UNMC [Research Support System \(RSS\)](#) website. Click on the COI tab, for the COI-SMART link.

For questions regarding COI or outside employment see the Office of Academic Affairs [compliance website](#).  
Phone: 402-559-6767

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## **UNMC-Omaha Veterans Administration Medical Center (VAMC) Memorandum of Understanding (MOU)**

Faculty with a dual appointment at UNMC and the Omaha VAMC and who wish to engage in federal research must have an internal UNMC-Omaha VAMC MOU on record at UNMC and Omaha VAMC. The MOU describes the investigator's complete professional effort and ensures there is not dual compensation for the same work.

To initiate an MOU, contact [Sponsored Programs Administration](#).  
Phone: 402-559-7456

Research conducted at the Omaha VAMC must be submitted to and receive separate regulatory approval by their human subjects and animal welfare committees, as applicable. UNMC and Omaha VAMC have reciprocity for approved animal protocols, but the protocols must still be in the format required for each institution. Likewise, CITI training can be used for both UNMC and VA personnel for human subjects training. For Omaha VAMC IRB and IACUC guidelines, see the information on the [VA research website](#).

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## **Training and Certification Requirements to Conduct Research**

Training is required of all UNMC investigators prior to participating in research. Many departments have a Compliance Training Coordinator who can direct you to the training modules required for you and your research staff. Otherwise, instructions for completing the online training modules are provided on the Vice Chancellor for Academic Affairs [compliance website](#).

NEMed employees can complete required compliance training not involving human subjects through [Apollo](#)

## Human subjects training

All who participate in human subject research are required to complete human subject research training via the [Collaborative Institutional Training Initiative](#) (CITI).

This includes faculty, employees, students, and staff at UNMC, Nebraska Medicine (NEMed), Nebraska Medicine Bellevue (NMB), Children's Hospital & Medical Center (CH&MC), and the University of Nebraska at Omaha (UNO). Individuals who work at one of these organizations and also work at the Omaha VA Medical Center (OVAMC) must designate their affiliation with both OVAMC as well as UNMC on the [CITI website](#).

## Animal welfare training

UNMC personnel must complete training prior to entering an animal facility or having contact with any research animals. Training requirements are listed on the [Comparative Medicine website](#).

Faculty, students, and personnel working with animals at the Omaha VA Medical Center (OVAMC) must also complete training. Instructions on what modules must be completed can be found at the [VA IACUC website](#).

**To gain access to training and for additional information**, contact [Comparative Medicine](#). Phone: 402-559-4034

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## Transferring to UNMC

### Grants

Grants are typically awarded to the institution, not to the investigator, so the grantee institution must first approve the transfer. The transfer is a two-step process:

1. The original institution relinquishes interests and rights to the grant
2. The new grantee institution assumes legal and administrative responsibilities for the grant

**This process requires assistance from Sponsored Programs Administration.** See their website for additional [information about grant transfers](#) or contact them to begin the transfer process.

Phone: 402-559-7456

Email: [spadmin@unmc.edu](mailto:spadmin@unmc.edu)

## Animals

Animals may be transferred between institutions with appropriate Comparative Medicine (CM) and Institutional Animal Care and Use Committee (IACUC) approval. Contact Comparative Medicine for assistance at 402-559-4034.

Additional information on conducting research using animals may be found in the Conducting Animal Research section of this manual.

**This process requires assistance from Comparative Medicine.** To initiate the process of animal transfer, contact their office. Or, [visit the CM website](#) for additional information. Phone: 402-559-4034

## Materials

To receive or send materials, you must obtain a Material Transfer Agreement (MTA). UNeMed, UNMC's technology transfer organization, or Sponsored Programs Administration (SPAdmin) if the MTA is part of a contract, negotiates incoming and outgoing MTAs on behalf of UNMC. MTAs address terms regarding use of tangible research materials.

**To request a Material Transfer Agreement,** visit UNeMed's [material transfer website](#).

## **Human Tissue Use and Transfer**

Human tissue obtained through clinical procedures or for research may be used within the Nebraska Medicine campus or transferred to external organizations consistent with the Nebraska Medicine campus mission of patient care, teaching, research, and outreach. See the Human Tissue Use and Transfer policy ([Policy #8013](#)) for details.

## **General Laboratory Equipment and Supplies**

Department administrators usually coordinate the transfer of equipment and supplies in and out of laboratories. Researchers assigned to laboratories work with the [Campus Research Resource Manager](#). If the equipment is for part of a research core facility or requires special space requirements or alterations, please contact the [Director of Research Resources](#) in the Office of the Vice Chancellor for Research.

# Research Space and Support

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## Space Allocation

### Research Laboratory Space

UNMC assigns space based on research funding, specific space requirements for the equipment or type of research, and personnel using the space, among other factors. Requests for space or space changes are made in writing by the appropriate college dean, institute director, or department chair to the Director of Research Resources, Vice Chancellor for Research Office, who will address it to the UNMC Research Space Committee.

For details, see UNMC's [Assigning Research Lab Space policy](#).

Contact the director at:

Web: [unmc.edu/vcr/cores/support-services](http://unmc.edu/vcr/cores/support-services)

Phone: 402-559-6162

### Research Animal Space

Comparative Medicine (CM) assigns animal housing. Location is based on specific investigator needs, species, and other considerations to best maintain the health and well-being of all animals, as well as established standards for animal welfare. Animals are usually housed by species rather than by investigator or department.

### What animal research space is available on campus?

Animal housing is available at several locations on the UNMC Omaha and Lincoln campuses. A separate, dedicated facility is used for rodent quarantine and testing. Procedure rooms, and a BSL 2 and 3 space are also available.

### Is there designated clinical research space available?

The Clinical Research Center (CRC) is a 3,300 sq ft outpatient clinical research facility, which serves as a central resource to investigators. The unit includes 5 general examinations rooms, 2 procedure rooms, a dedicated exercise/stress testing room, a room for dental or other chair

specialty examinations, and a specimen processing laboratory. CRC study coordinators and research assistants work in the CRC or in other outpatient facilities, Nebraska Medicine inpatient scatter beds, or community facilities as contracted for specific projects.

Web: [unmc.edu/cctr/resources/crc](http://unmc.edu/cctr/resources/crc)

Phone: 402-559-7685

A separate Clinical Research Unit is available at the Omaha VA Hospital and Medical Center. This facility is available to Omaha VA investigators or UNMC investigators with approved Omaha VA hospital protocols and is focused on medical projects of importance to veterans. The facility has exam rooms, a centrifuge, and a BODPOD for metabolic studies. Questions about use of this facility should be directed to the [Associate Chief of Staff for Research, Omaha VA Hospital](#).

The Cruzan Center of the College of Dentistry is a Clinical Research facility on the Lincoln campus. Further information regarding this facility for clinical studies is available [on their website](#).

## Who to Contact

### Laboratory research space and support questions

Contact the Director of Research Resources, Vice Chancellor for Research Office.

Web: [unmc.edu/vcr/cores/support-services](http://unmc.edu/vcr/cores/support-services)

Phone: 402-559-6162

### Clinical research space and support, including the CRC

Contact the Associate Vice Chancellor for Clinical Research or the Clinical Research Center (CRC).

Web: [unmc.edu/cctr/resources/crc](http://unmc.edu/cctr/resources/crc)

### Use of the Cruzan Center for Dental Research space in Lincoln

Web: [unmc.edu/dentistry/research/cruzan](http://unmc.edu/dentistry/research/cruzan)

### Use of Omaha VA Clinical Research Unit space

Web: [nebraska.va.gov/services/Research/admin\\_home.asp](http://nebraska.va.gov/services/Research/admin_home.asp)

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## Research Support

### What research resources are available to UNMC investigators?

The Vice Chancellor for Research Office Web site provides a directory of research support services, core facilities, funding training opportunities, and policies [on its website](#).

A directory of other campus resources can be found on the UNMC Today [Intranet Quick Links](#).

## **How do I identify potential research collaborators?**

UNMC provides Elsevier's PURE collaboration tool to investigators. This Web-based tool, branded as [Research Nebraska](#), provides up-to-date research profiles of University of Nebraska and Boys Town investigators and key word indices of potential biomedical, engineering, informatics, and life sciences research collaborators.

To receive training on Research Nebraska, [visit the VCR website](#) or call the VCR Office at 402-559-7649.

## **What Information Technology (IT) support is available for research applications?**

### **The Research IT Office (RITO)**

RITO was established to meet researchers' growing IT needs. RITO supports implementation of new equipment and research servers; application development and programming; research data transfer, management, and storage; consultation on information security; technical writing for research grants regarding proposed research IT implementation; institution-wide software applications; and UNMC core facilities. For more information, contact the Director of RITO.

Web: [unmc.edu/vcr/rito](http://unmc.edu/vcr/rito)

Phone: 402-559-9072

### **The Researcher Users Group (RUG)**

RUG was formed to share information, resources, and training related to IT skills for researchers. One-hour seminars address relevant topics including database creation, graphics programs for scientific posters and presentations, tools for grant submissions, and policy changes that impact researchers. Sessions are open to all. More information and upcoming sessions are [available online](#).

## **What assistance is available for maintaining CV's and NIH biosketches?**

The McGoogan Library of Medicine offers a toolkit for using MyNCBI resources for generating biosketches in multiple formats at [unmc.libguides.com/toolkit](http://unmc.libguides.com/toolkit)

UNMC developed a web-based faculty records system called ADIS (Academic Department Information System) where publications, grants, and contracts are automatically loaded into available templates to generate a CV or NIH biosketch.

## **Is access available to the Electronic Health Record information system and databases for research?**

The Electronic Health Record Core is available for research data sets, including health outcomes, quality improvement projects, and eligible subject lists. Applications are available on the CCTR website.

## **Is there enterprise-wide software support for research applications?**

UNMC supports several open access or site licenses for research applications, including: Freezerworks® for biobanking, caTissue™ for biobanking cancer specimens, and Research Electronic Data Capture (REDCap) for clinical trials management. Contact the Research IT Office for additional information.

# Funding

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## Announcements

### Internal & External Funding

Upcoming internal funding announcements are shared by the Office of the Vice Chancellor for Research through weekly editions of their "Research Matters" newsletter. *If you are not receiving these, you can [sign up here](#).*

Additional funding resources, are available through the VCR website on the [funding webpage](#).

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## Internal Programs

Some available internal funding programs are listed in this section. For the most up-to-date list of available internal funding opportunities, visit the VCR internal funding page.

### The Clinical Research Development Fund

Nebraska Medicine (NEMed), in partnership with the UNMC College of Medicine, created the [Clinical Research Development Fund](#) for pilot projects or to supplement extramural grants. This fund can write off costs for NEMed-based testing and support (e.g., bed costs, medications, laboratory, and radiology) but not marketing or send-out tests.

Applications are peer-reviewed by the Clinical/Translational Research Review Committee for scientific merit, relevance, and feasibility.

Information, instructions, and application forms for the fund can be found on the CCTR Pilot Grant Program website.

### Center or Program-Specific Pilot Grants

Members of the Cancer Center are eligible to apply for Cancer Center pilot grants, and many NIH Center grants have pilot grants available specific to the focus of the Center. Any faculty member can apply to be a member of the Center(s). A list of other major programs and centers is available on the VCR website.

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## **Funding for Innovations or “Proof of Concept”**

Technologies registered with UNeMed with a New Invention Notice are eligible for “Proof of Concept” grants to develop that technology to increase commercial potential and value. The “Innovation Micro-Grant Program” is designed to further develop an early stage technology if the “proof of concept” work proves promising.

Additional information can be found on the UNeMed funding opportunities page, or by contacting their office. 402-559-2468 [unemed@unmc.edu](mailto:unemed@unmc.edu)

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## **Bridge Funding**

UNMC has a bridge funding program for faculty who have a track record of research funding and are now experiencing a lapse in funding. To obtain needed pilot data or retain critical personnel, requests for bridge funding are made to the Dean or Associate Dean of Research for each College or Institute, and if approved, will be reviewed for final funding with the Vice Chancellor for Research.

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## **Other Sources**

Many colleges, institutes, and departments have foundation-specific monies available. Check with your dean or chair for further information.

# Grants and Subcontracts

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Information about navigating grant and subcontract processes.

# Introduction

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## Getting Started

### Who can help me apply for grants and subcontracts?

Your department administrator and Sponsored Programs Administration (SPAdmin) grant specialists understand UNMC's research administration infrastructure and can guide you. You should notify both as soon as you identify a funding opportunity you plan to pursue.

Identify your SPAdmin grant specialist.

SPAdmin contact information:

Web: [unmc.edu/spa/](http://unmc.edu/spa/)

Phone: 402-559-7456

Email: [spadmin@unmc.edu](mailto:spadmin@unmc.edu)

### Does UNMC offer grant writing assistance?

Yes, researchers can request grant and manuscript editing assistance through the Research Editorial Office.

Web: [unmc.edu/vcr/cores/research-editorial/](http://unmc.edu/vcr/cores/research-editorial/)

Phone: 402-559-4132

Email: [grantseditor@unmc.edu](mailto:grantseditor@unmc.edu)

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## Roles and Responsibilities for Grants and Subcontracts

### Effective sponsored project management

Effective sponsored project management is a collaboration among Principal Investigator(s); Departmental Administrators and other research staff; Sponsored Programs Administration (SPAdmin); and Sponsored Programs Accounting (SPAccount).

### **Principal Investigator**

- Leads and directs the project, intellectually, logistically, and administratively
- Oversees proposal and budget preparation
- Identifies project personnel and collaborators
- Secures appropriate research resources
- Follows departmental policies for pre-review of application for scientific merit
- Ensures integrity and timeliness of financial, administrative and technical information provided to SPAdmin
- Signs internal research routing forms and verifies that Conflict of Interest disclosures in COI-Smart are current
- Obtains regulatory approvals of research prior to initiating the research

### **Department Administrators and other research staff**

- Assists PIs with completion of the application and budget preparation
- Manages UNMC's financial systems, maintaining the integrity of the financial transactions in those systems in keeping with Policy #8012
- Generates internal forms for signature
- Submits published manuscripts or clinical trial updates to the appropriate databases

### **Sponsored Programs Administration (SPAdmin) staff**

- Provides expertise and guidance to investigators and department personnel regarding grant and contract submissions and management
- Protects the UNMC by monitoring compliance with federal, institutional, and sponsor requirements
- Reviews and submits applications, agreements, and modifications in accordance with sponsor terms, conditions and program guidelines
- Negotiates final terms for government and non-profit grants, contracts, and subcontracts
- Reviews Conflict of Interest disclosures for project personnel Approves internal forms and applications prior to institutional signature
- Prepares awards for set-up by Sponsored Programs Accounting

Web: [unmc.edu/spa/](http://unmc.edu/spa/)

Phone: 402-559-7456

Email: [spadmin@unmc.edu](mailto:spadmin@unmc.edu)

### **Sponsored Programs Accounting (SPAccting) staff**

- Oversees post-award financial compliance in accordance with the Federal Office of Management and Budget (OMB) Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards or "Uniform Guidance". (Uniform Guidance rolls OMB Circular A-21, OMB Circular A-110, OMB Circular A-133 into one document)
- Sets up awards
- Manages effort reporting certifications

- Monitors program revenue, cost-share, and cost allowability
- Invoices sponsors
- Prepares and submits financial reports to sponsors

Web: [info.unmc.edu/management/finance/spaccounting/](http://info.unmc.edu/management/finance/spaccounting/)

Phone: 402-559-5822

## Who can sign grant proposals prior to submission?

The Director of SPAdmin or a designee are the only personnel who can officially sign grant proposals, subcontracts, and internal forms as the institutional official for sponsored projects at UNMC. A SPAdmin grant specialist reviews the application first to be sure it is compliant with UNMC and sponsor policy and then will obtain the institutional signature for the applicant.

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## Preparing a Federal Grant Application

Read the instructions *early, carefully, and often*. Early in the process, investigators should review submission timelines and requirements of the Funding Opportunity Announcement (FOA) and the programmatic guidelines. The applicant should communicate the information as soon as possible to anyone helping them with their grant application, including their department administrator and designated SPAdmin grant specialist.

How are federal grant applications submitted at UNMC?

Federal grant applications are prepared by investigators and departmental personnel, and submitted using Cayuse424, a system-to-system interface that:

- Populates applications with institutional information
- Allows multiple users to work on an application
- Validates applications before submission

Link to Cayuse424 (log in with UNMC net ID and password): [unmc.cayuse424.com](http://unmc.cayuse424.com)

Contact your SPAdmin grants specialist for questions about using Cayuse424.

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## Preparing Non-federal Grant Applications

Investigators need to be aware of submission deadlines and requirements of the Request for Applications and programmatic guidelines. Communicating this information to your department administrator and SPAdmin grant specialist as soon as possible is critical for establishing timelines and generating project support.

## **How are non-federal grant applications prepared at UNMC?**

Investigators and departmental personnel prepare non-federal grant applications in accordance with sponsor guidelines. Many non-federal sponsors have their own submission website and forms.

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## **Submitting Federal and Non-federal Applications**

### **Are there prerequisites to submitting a grant application?**

NIH submissions require an eRA Commons ID and password. This eRA Commons ID is also required on every NIH Biosketch submitted. To request an ID and password for the Principal Investigator and an ID for other key personnel, including graduate students, contact SPAdmin at 402-559-7456.

Required internal budget and other forms must be routed through the appropriate Department and College units and signed by UNMC's institutional official prior to grant submission. For more information, see [Research Administration for Grants and Subcontracts](#).

### **Are there minimum time requirements for Sponsored Programs review prior to grant application?**

Draft applications should be sent to SPAdmin for review at least three business days (ideally five business days) before the submission date. SPAdmin carefully reviews all forms, including the budget and program requirements, to correct errors or inconsistencies that would disqualify the grant from review. NIH and other sponsors can and will disqualify grant applications that do not comply with instructions.

### **Who submits the final grant application?**

After SPAdmin review and signature by UNMC's institutional official, SPAdmin submits the application to the sponsor. Federal applications are submitted to [www.grants.gov](http://www.grants.gov) directly from Cayuse424, and non-federal applications are submitted electronically or shipped per sponsor guidelines. Departments may transmit or ship applications themselves if they wish, but only after receiving SPAdmin approval and by making arrangements in advance with SPAdmin.

Sponsor guidelines specify how to submit applications. Guidelines generally include an identifier (e.g. Funding Opportunity Announcement number), due date and time, paper or electronic submission instructions, required contact and format, award amount (including F&A), period of performance, and eligibility requirements. Guidelines may be program-specific or generally applicable to the sponsor. Be sure that you are working from the current version of the guidelines.

## **Additional Resources for Preparing and Submitting Applications**

- [UNMC Institutional Information required by sponsors \(Federal tax ID, etc.\)](#)
- [Link to Cayuse424 \(log in with UNMC net ID and password\)](#)
- [Request eRA Commons Account](#)
- [SPAdmin Grant Guidelines](#)
- [Workshops on Grant Writing, Formatting Applications, and More](#)

# External Collaboration

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## Subcontracting OUT to a Sub-Investigator at Another Organization

### What is a subcontract OUT?

A subcontract OUT is generated when a UNMC investigator applies for a grant and collaborates with an investigator from another organization. UNMC is thus the prime recipient, and the other organization is the sub-recipient. UNMC delegates appropriate prime award terms and funds, and the sub-recipient organization commits to performance, program, and compliance responsibilities.

UNMC remains fully responsible for the entire award when subcontracting out part of an award to another organization.

### What does SPAdmin require to generate a subcontract OUT?

Prior to submitting a grant application, Sponsored Programs Administration (SPAdmin) requires:

- Intent to Form a Consortium signed by an authorized official of the sub-recipient organization
  - Subrecipient's format
  - PHS 398 face page, or
  - UNMC's format
- Statement (or scope) of work
- Detailed budget with F&A cost calculation
- Budget justification
- Contact information ([FDP Attachment 3](#))

For details on Subcontracts OUT and links to required forms, see [unmc.edu/spa/subcontracts/subcontracts-out](http://unmc.edu/spa/subcontracts/subcontracts-out).

### How is a subcontract OUT different from a vendor contract?

Vendors supply goods and services needed to complete the project but do not have programmatic responsibilities and so are not subject to the compliance requirements of the award terms and conditions.

Finance and Business Services negotiate vendor agreements.

For additional information on sub-recipients, see [Policy #6108](#) or contact SPAdmin at 402-559-7456.

For more information regarding vendor agreements, see [Policy #6063](#) or contact the Chief Compliance Officer at 402-559-6767 or Business Services Director at 402-559-5840.

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## **Subcontracting IN from a Primary Investigator at Another Organization**

### **What is a subcontract IN?**

A subcontract IN is generated when a primary investigator from another organization applies for a grant and collaborates with a UNMC investigator. UNMC is thus the sub-recipient, and the other organization is the “sponsor.” The other organization passes on the prime award terms and funds, and UNMC commits to performance, programmatic, and compliance responsibilities.

### **What is required to initiate a subcontract IN?**

Prior to grant submission by the other organization, SPAdmin must receive and process forms required by the prime recipient to document UNMC’s intent to participate, the scope of work, qualifications, and budgetary needs. Forms may include:

- An Intent to Form a Consortium, which must be signed by one of UNMC’s institutional officials to signify understanding of our obligations and that we authorize the other organization to submit a proposal containing commitments
  - Sponsor's format, or
  - UNMC's format
- Statement (or scope) of work
- Budget justification (including F&A)
- Additional documentation required by the other organization (e.g. detail budget)
- Biographical sketch
- Resources page
- Internal forms (For more information see the section Research Administration for Grants and Subcontracts).

Identify and communicate timelines to SPAdmin early. Remember that other institutions may require more time than UNMC to process subcontracts prior to grant submission. For details on

## **Collaborating with Small Businesses**

### **How do federal grants that fund collaborations between small businesses and UNMC work?**

Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) programs allow federal agencies to fund Small Business Concerns (SBC) to work with Research Institutions on innovative research and technology transfer. The SBC is the applicant/recipient, and the Research Institution (i.e. UNMC) is the sub-recipient. University funds in this case are managed as a subcontract IN.

### **If I am UNMC faculty but also developing a new business, can I submit a SBIR or STTR grant or collaborate with a small business using SBIR or STTR funds?**

Yes. If you are the CEO of the business you would be the Principal Investigator, and you can lease space or subcontract for other UNMC services with an SBIR or STTR grant. Contact UNeMed for more information on the requirements for and help with developing and submitting a SBIR or STTR grant. You will also need to consider some of the policies and will work with the entities below.

Similarly, if a small business owner would like to collaborate with you, you should contact UNeMed to help with the process.

See UNMC [Policy #3002](#) for the entities you might need to help you, depending on your role.

- UNeMed
  - Ownership of Intellectual Property (Board of Regents Policy 4.4.2)
  - Preliminary business plan models and advice
  - License Template
- Sponsored Programs Administration
  - SBIR/STTR subcontract template
  - Letter of commitment regarding expected time and effort commitments
- Academic Affairs Compliance and COI Officers
  - Outside Employment Form (UNMC [Policy #1049](#))
  - Conflict of Interest management (as needed)
- Assistant Vice Chancellor Business & Finance
  - Contract for Use of Space and Equipment

# Administration

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## About this Section

The information in this section applies to the research administration of any grant or subcontract from federal, state, and local governments and non-profit entities, whether categorized as research, instruction, public service, or other activities.

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## Internal Forms

Internal forms document institutional support for the project and provide information about decision-making and approvals. They are signed by the Sponsored Programs Administration (SPAdmin) grant specialist, appropriate Deans/Directors and Chairs (or designees), and UNMC's official signatory.

## What internal forms are required for grant submissions?

Sponsored programs require two internal forms prior to grant submission:

- The Routing Form provides basic information about the project.
- The Internal Budget describes the proposed budget for approval by all participating units.

Personnel costs include the committed effort (as a percentage) of each participant as well as the Institutional Base Salary (IBS), which includes one or more of the following elements as well as benefits based on UNMC's federally negotiated fringe benefits rate agreement:

- UNMC base salary
- Specified UNMC stipends
- UNMC Physicians base salary or Nebraska Pediatric Practice base salary

If the project does not pay for the entire salary proposed by the effort required, as can occur with training grants or NIH salary caps, UNMC may have to commit to cost sharing. Cost sharing must be justified and approved by the unit director.

View UNMC's [Institutional Base Salary](#) and [Cost Share](#) Policies.

Other considerations:

- **Waiver of Facilities & Administrative Rate (F&A).** If you believe there is a rationale for accepting a lower F&A rate than UNMC has negotiated, you must complete an F&A waiver request when you are completing the ADIS Internal Forms.
- **International projects or partners.** All projects that include an international partner or are performed outside the country must submit an [International Projects Questionnaire](#). This should be submitted to SPAdmin before the grant is completed to be sure that all elements have been considered so grant submission is not delayed.
- **Administrative charges to sponsored projects.** If you believe there is a rationale for charging administrative costs—which are normally treated as indirect costs—directly to a grant, you must complete an Administrative Costs Checklist when you are completing your ADIS Internal Forms.
- **Consortium grant.** If a UNMC investigator applies for a grant collaborating with an investigator from another organization, an Intent Document is required. See [Intent to Form a Subcontract](#).

## How are internal forms submitted?

Your department administrator will initiate the submission of these forms using internal processes through ADIS. SPAdmin assigns user rights upon request by the Department Administrator. UNMC personnel can log in to ADIS using a UNMC Net ID and password.

## How can I obtain other Sponsored Programs forms?

Some forms are available as MS Word or Adobe PDF documents at [unmc.edu/spa/forms/forms-templates](https://unmc.edu/spa/forms/forms-templates). For questions, call SPAdmin at 402-559-7456.

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## Direct Costs

### What are direct costs?

Direct costs are those that can be specifically identified with a particular sponsored project or activity and can be assigned to that project or activity with a high degree of accuracy. Examples include lab supplies, travel expenses, animal purchases, and animal housing expenses.

### What are fringe benefits?

All salaries are accompanied by a fringe benefit rate that varies with the specific group, such as faculty, post docs, and staff. Each year, UNMC negotiates the Fringe Benefit Rate with the federal government. UNMC's current fringe benefit rates are available in the [rate agreement document](#).

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## **Indirect Costs**

### **What are indirect costs?**

Indirect costs, also known as overhead or the Facilities and Administrative (F&A) Rate, are provided to the institution proportional to the project total to cover research administrative costs such as research compliance and building upkeep.

### **What is UNMC's indirect cost rate?**

UNMC has negotiated an [F&A Rate Agreement](#) with the federal government that varies with the type of project or sponsor. Use the F&A rate agreement document to find the indirect cost rate appropriate for the project's specific activity and sponsor.

### **On what budget items is the indirect cost rate charged?**

Most federal grants use a Modified Total Direct Cost (MTDC) base, which excludes the value of each subcontract over \$25,000, equipment, participant stipends, and patient care.

For industry sponsors, we apply the indirect cost rate to Total Direct Costs (TDC) with the exception of IRB fees.

### **Can I reduce or waive F&A costs?**

UNMC will accept the published F&A rate of a sponsor. Only in special cases can UNMC accept a lower rate. The waiver process is discussed at [unmc.edu/spa/forms/forms-templates](http://unmc.edu/spa/forms/forms-templates).

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## **Computers and NIH**

### **What are the regulations regarding computers and NIH budgets?**

Office equipment (copiers, laptops, desktop computers, personal handheld computers, fax machines, scanners, etc.) used for general office purposes (rather than justified as a specific research purpose) are not allowable as direct costs; they are allowable as an F&A cost.

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## **Conflict of Interest**

### **How do my Conflict of Interest disclosures affect my grant submissions?**

All sponsored project proposals are reviewed prior to grant submission to identify any real or perceived conflict of interest. If a potential conflict is identified, it can be eliminated or managed. The Conflict of Interest Committee establishes the COI management plans.

# Pre-award Activities

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## Required Regulatory Review Processes

### **Do I need to complete regulatory review processes prior to grant submission?**

NIH and most other sponsors allow applicants to submit grants prior to obtaining final approval of required regulatory processes. This process is called “Just in Time (JIT).” After the application is submitted and approved, but prior to final determination of funding, NIH or other sponsors will request submission of regulatory approval documents. The request will be designated in eCommons using JIT next to the submitted application. However, a JIT request does not guarantee that an award is forthcoming.

### **When should I complete and submit regulatory documents?**

If regulatory approvals are required by the grant, and they are not completed and approved prior to grant application, it is best to begin the application as soon after the grant submission as possible to prevent any delays in grant award once those documents are needed. These may include human studies review (IRB), animal welfare review (IACUC), and safety review (IBC). Human studies projects involving administration of any medication or therapeutic agent also require pharmacy and therapeutics (P&T) review, and any cancer-related project will require Scientific Review Committee (SRC) review and approval. For human studies projects, all personnel on the study budget who will also interact directly with patients or human subjects’ data should complete human subjects training on the CITI Web site. For more about CITI training, see [unmc.edu/irb/citi](http://unmc.edu/irb/citi).

### **Before I receive the Notice of Award, can I hire personnel and order equipment on the grant Budget?**

If you have received indication that funding will be awarded you can request an Advance Account from SPAdmin. However, if an Advance Account is set up and the award is not made, the department covers the cost of any expenses incurred.

Access the Advance Account Request form in ADIS Internal forms. A guide is available at [unmc.edu/spa/forms/forms-templates](http://unmc.edu/spa/forms/forms-templates)

You must have processed your proposal through SPAdmin prior to requesting an Advance Account.

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## Finalizing Grant Awards

As soon as you receive a Notice of Award, please notify and forward to Sponsored Programs Administration (SPAdmin) to set up your grant. If the internal forms on file are complete and match the award, SPAdmin will prepare the award and send it to Sponsored Programs Accounting (SPAccting) for set-up within one week. If the total award or budget has been changed since the grant application was submitted, the internal forms will need to be revised to match the award. SPAdmin will contact you if changes to internal paperwork are required.

After the award is set up in UNMC's accounting system, the PI and department administrator are notified by email that the account is ready and that the project "bundle" may be accessed in ADIS. The bundle includes:

- Checklist, which lists the account number (known as the WBS), personnel, effort, budget, regulatory requirements, and budget and award periods
- Internal budget
- Award document
- Routing form signed by the PI

For more, see [Award Set-up](#)

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## Finalizing Subcontracts OUT

### What is required to finalize a subcontract OUT?

After UNMC's grant award is finalized, SPAdmin generates a subcontract OUT to any sub-recipient organizations based on the statement of work and budget collected from the PI and department prior to submission. The subcontract budget may need to be revised if there is a significant variance between the budget request and budget award.

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# Finalizing Subcontracts IN

## What is required to finalize a subcontract IN?

Once the prime recipient organization receives a notice of grant award, SPAdmin works with the organization to execute a subcontract IN based on the statement of work and budget provided by the UNMC investigator and department.

The subcontract from the prime recipient should contain:

- Statement of work
- Detailed budget
- Catalog of Federal Domestic Assistance (CFDA) number (if federally funded)
- Documentation of terms and conditions
- Copy of prime award

The budget and scope of work may need revisions if a significant variance exists between the budget requested and the budget awarded to the prime recipient.

# Managing Awards

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## Sub-site Monitoring

UNMC is obligated to the sponsor to act as a good steward of the entire award and must therefore monitor the activities of any sub-sites.

For more information on Sub-recipient Monitoring obligations, see UNMC [Policy #6108](#).

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## Progress Reports to the Sponsor (Non-competitive Renewals)

### What is a progress report?

Most sponsors require a progress report at specified intervals, which may be monthly, quarterly, or annually. Progress report requirements are described in the notice of award.

These progress reports are sometimes used to adjust the next year's budget. For grants, although the sponsor may commit in the initial award to several years of funding, the grant award is contingent on satisfactory progress. NIH and NIH-style awards are usually funded in one-year budget periods as part of a five- (or less) year "cycle." A "non-competitive" continuation of the project is triggered by the submission of a satisfactory progress report. Contracts can be revoked entirely if desired outcomes or performance milestones are not reached. It is very important to communicate to the sponsor in advance of the progress report if there are any circumstances that have adversely affected progress.

The NIH uses an electronic Research Performance Progress Report (RPPR) system for most progress reports ([NOT-OD-13-035](#)). The RPPR provides a uniform format for interim performance reporting on federally-funded research and research-related activities.

### Who submits the progress report?

The PI prepares the technical report and submits to SPAdmin for review and submission. SPAdmin's review determines whether the report contains the required elements and is in the proper format.

Internal forms are required prior to progress report submission for projects funded in one-year budget periods as part of a five (or less) year cycle. For more information see [Research Administration for Grants and Subcontracts](#).

Sponsored Programs Accounting prepares and submits the financial report based on the information in SAP, UNMC's accounting system. Financial reporting and invoicing often occur simultaneously.

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## Changes Requiring Formal Approval by the Sponsor

Most grants and sponsors allow the investigator some flexibility to change budget and project implementation from that originally proposed. However, many contracts and sponsors require formal approval by the sponsor via an amendment or revised notice of award. SPAdmin will submit the change request to the sponsor.

Some of the changes that typically require formal approval include:

- **Change in PI or Key Personnel.** UNMC must seek prior sponsor approval if the PI or other key personnel withdraw from the project or are replaced.
- **Rebudgeting.** Significant variance may occur between budget and actual costs in a funding year; and actual expenditures may be reported for grants to the sponsor via financial reports. If actual costs differ significantly from what was anticipated, it is wise to inform the sponsor. Significance varies with the sponsor, but NIH will require a justification of any change of 25% or more.
- **Leave of Absence.** Generally, UNMC must seek prior approval from the sponsor if the PI or other key personnel will be absent from the project during a continuous period of 3 months or more, whether for illness or other cause.
- **Change in Effort.** When a certain level of effort is stated in a proposal, UNMC commits to the sponsor that the named person will spend that time on the project, either paid for by the award or cost-shared by UNMC. Though month-to-month time may fluctuate, the individual must spend the stated average over the project period unless percentage of effort has been changed. It is also important to inform the sponsor if the principal investigator or other key personnel effort is significantly changed. For federal sponsors, approval is generally required if the PI or other key personnel will reduce time devoted to the project by 25 percent or more from the approved level.
- **Change in Direction or Project Scope.** It is also wise to contact the sponsor if the project moves in a new or unexpected direction. Indicators of a change in scope include:
  - Change in specific aims approved at time of award
  - Change from approved use of live vertebrate animals (including change of species) or involvement of human subjects
  - Shift of research emphasis from one disease area to another
  - Application of a new technology

- Adding a new subcontract or an international component

Your SPAdmin grant specialist should be contacted if a significant change has occurred that requires sponsor approval.

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## No-cost Extensions

If additional work is required to complete a project, an award may be extended in one of two ways, depending on sponsor requirements:

- **Under “expanded authorities,”** SPAdmin can extend the end date and notify the sponsor of the change.
- **If “prior approval” is required,** SPAdmin will request a revised Notice of Award or amendment from the sponsor.

In either case, the investigator will be required to submit an explanation (e.g., slow patient accrual, delay in completing last experiments or data analysis).

UNMC cannot extend a project solely for the purpose of spending remaining funds.

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## Competitive Renewals

When your funded grant is completed, if there are ongoing research questions that the sponsor is interested in, the investigator can often submit the project as a competitive renewal. A competitive renewal requires a new application submitted for peer review, much like the original application. UNMC’s internal process for competitive renewal submission and approval mirrors that of new applications.

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## Effort Reporting

SPAdmin verifies effort availability at the time of award, but after the award, the Office of Management and Budget's Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards requires the investigator certify the salary charged to a sponsored project is reasonable in relation to the effort expended on that project. Per UNMC’s

Effort Reporting Procedure, “effort” is the proportion of time spent on any activity, expressed as a percentage of total time.

Total effort for an employee must equal 100% of the employee’s appointment. Investigators are responsible for assigning effort to all personnel on sponsored project budgets and for monitoring effort for all budgeted personnel, including tracking effort changes. If changes in effort occur, investigators are responsible for informing the sponsor.

For more information, see UNMC’s Effort Certification [Policy #6105](#)

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## **Effort Tracking**

Sponsored Programs Accounting (SPAccting) initiates and administers Effort Certification reporting. Investigators or delegated staff with first-hand knowledge are responsible for completing the Effort Certification Reports in [Research Support System \(RSS\)](#) on the UNMC intranet.

# Industry-sponsored Contracts

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# Introduction

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## Understanding Industry Sponsored Research

Industry-sponsored contracts must be reviewed and negotiated before being signed. SPA negotiates non-clinical and clinical research agreements with the exception of Phase I-IV Clinical Trial Agreements negotiated by UNeHealth.

### Non-clinical Research

Non-clinical research is wide ranging and may be most easily defined by what it is not. Non-clinical research does not require informed consent by human subjects or involve data or specimens with Protected Health Information (PHI). The work may or may not involve animals and may be described as laboratory research, testing, or provision of services. Non-clinical industry-funded projects typically have a defined period, scope of work, and deliverables such as research data or reports.

SPAdmin negotiates non-clinical agreements.

### Clinical Research

Clinical research is defined as research that involves human subjects as participants and/or requires the informed consent of a human subject. In addition to clinical trials, clinical research encompasses physiologic studies as well as any projects involving human subject data or specimens.

With the exception of Phase I-V Clinical Trials, SPAdmin negotiates these agreements.

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## Who should review the contract?

If the work involves development of or potential for intellectual property, UNeMed, UNMC's technology transfer organization, should review the contract.

If the work involves transfer of human samples, a therapeutic product, or other biologic material, it requires a Material Transfer Agreement that should be completed by UNeMed.

UNeMed Web: [unemed.com/services/material-transfer](https://unemed.com/services/material-transfer)

UNeMed Phone: 402-559-2468

All other contracts or contracts linked to other federal or other grants should be submitted to SPAdmin.

# UNeHealth

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## What is UNeHealth

UNeHealth serves to facilitate the growth and development of industry-funded clinical research, and acts as the contracting arm for industry-funded clinical research on behalf of UNMC.

UNeHealth provides:

- A single “front door” for industry sponsored clinical trial contracting
  - Efficiencies to best support investigators conducting clinical research
  - Clinical research contracting resources for the enterprise
- 

## When to Contact

Contact UNeHealth for contract negotiation as soon as you identify an industry-sponsored clinical trial (i.e., Phase I, II, III, IV, or device trials and associated confidentiality agreements) in which you wish to participate.

## Contact information

Web: [unmc.edu/spa/clinical-trials/unehealth](https://unmc.edu/spa/clinical-trials/unehealth)

Phone: 402-559-7614

# Clinical Trial Contracts

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## Getting Started

### Who can help me with industry-sponsored clinical trials?

Your department administrator and the UNeHealth Contracts Office Associate should be notified as soon as you identify a study in which you plan to participate.

Web: [unmc.edu/spa/clinical-trials/unehealth](http://unmc.edu/spa/clinical-trials/unehealth)

Phone: 402-559-7614

Email: [amanda.leingang@unmc.edu](mailto:amanda.leingang@unmc.edu)

### What does UNeHealth require prior to reviewing the contract for a clinical trial and device studies?

Prior to contract review, UNeHealth requires:

- Editable contract template from the sponsor (i.e. a Word document)
- Protocol
- Contract Questionnaire signed by the PI
- Contact information for the sponsor's negotiator

All four items should be attached to a single email and sent to the UNeHealth Contracts Office Associate.

### Who negotiates the contract?

UNeHealth was developed to centralize contract negotiations for industry-sponsored clinical trials. Contract negotiations, budget negotiations, and regulatory review should occur at the same time to hasten start up, as follows:

- UNeHealth negotiates the contract
- Departmental staff negotiate the budget

- IRB reviews the IRB application and consent form

When both the contract and budget are finalized, they form the final contract that is signed by all parties to the agreement (i.e., sponsor, UNMC, UNeHealth).

## Who signs the contract?

The parties named in the contract are the signatories. UNeHealth coordinates the signature process. Signatures always include a UNMC institutional official and will include the sponsor, as well as a UNeHealth signatory if UNeHealth is a party to the agreement. The PI will sign as to read and acknowledge the terms but is not a party to the contract.

The Principal Investigator does not have signature authority at UNMC to contract terms.

## If a sponsor requires a Confidential Disclosure Agreement (CDA) prior to releasing their protocol and negotiating a study agreement, is it OK to sign?

UNeHealth should be contacted and will review, negotiate and obtain the proper institutional signature for execution of the CDA. Forward the CDA request and template to the UNeHealth Contracts Office Associate for handling. For more information:

Web: [unmc.edu/spa/clinical-trials/unehealth/contact](http://unmc.edu/spa/clinical-trials/unehealth/contact)

Phone: 402-559-7614

## Finalizing Industry-funded Awards

Clinical trial awards are set up only after final IRB release, which occurs only after the fully-executed contract is received from the sponsor. As soon as UNeHealth receives the signed agreement, the IRB is notified so the IRB protocol can be released when all matters are in order.

IRB release requires that the IRB has approved the protocol and there are no outstanding issues needing review.

Upon IRB release, UNeHealth prepares the award, SPAccounting sets up an account in UNMC's accounting system and the PI and department administrator are notified by email that the project "bundle" is available in ADIS. The bundle includes:

- Checklist, which lists the account number (known as the WBS), personnel, effort, budget, regulatory requirements, and budget and award periods
  - Internal budget
  - Contract
  - Routing form signed by the PI
- 

## **Defining Roles and Responsibilities for Initiation of Research**

Effective management of industry-sponsored projects is a collaborative effort among principal investigators, department administrators, clinical research coordinators, UNeHealth, and Sponsored Programs Accounting.

### **Principal investigators**

- Lead and direct all aspects of the study, including budget negotiations, regulatory submissions, and study activities
- Identify project personnel and collaborators
- Ensure the integrity and timeliness of information provided to SPAdmin
- Sign internal forms and verify that Conflict of Interest disclosures are current
- Obtain regulatory approvals of research prior to initiating the project

### **Departmental personnel (administrators and clinical coordinators if applicable)**

- Assist PIs with study start-up activities, which include negotiating budgets and submitting IRB applications and submitting and updating clinical trial matrices and coordinating consent form approvals.
- Manage UNMC's financial systems, maintaining the integrity of the financial transactions in those systems in keeping with UNMC [Policy #8012](#).
- Generate internal forms for PI signature and approval; internal forms translate the study budget attached to the contract to salary effort
- Interface with SPAdmin, sponsors, and regulatory bodies

### **UNeHealth personnel**

- Negotiate agreements and amendments to protect institutional and investigator interests and ensure compliance with sponsor and institutional requirements
- Review Conflict of Interest disclosures for project personnel
- Review and approve internal forms prior to institutional signature
- Interface with industry sponsors
- Prepare and finalize awards for set-up by SPActing

- Does not negotiate the budget. The investigator must submit the negotiated budget to SPAdmin to be attached to the final contract

## **Sponsored Programs Accounting personnel**

- Set up awards
- Manage effort reporting certifications
- Monitor program revenue, cost share, and cost allowability
- Invoice sponsors
- Prepare and submit financial reports to sponsors

# Industry Sponsored Research

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## Who can help me with industry-sponsored research?

Your department administrator and the SPAdmin Contracts Associate should be notified as soon as you identify a study in which you plan to participate.

Web: [unmc.edu/spa/contracts/non-clinical](https://unmc.edu/spa/contracts/non-clinical)

Phone: 402-559-7456

## What does SPAdmin require prior to reviewing a nonclinical contract?

To initiate the negotiation process, submit the following documents to the SPAdmin Contracts Associate:

- Editable contract template from the sponsor (i.e., a Word document)
- Scope of work
- Contact information for the sponsor's negotiator

## Who negotiates the contract?

The SPAdmin Contracts Specialist will negotiate the agreement.

## Who signs the contract?

The Director of SPAdmin (or designee) signs these agreements as the official signature authority for sponsored projects at UNMC. SPAdmin coordinates the signature process. Investigators may be asked to sign that they have read and acknowledged the terms of the agreement.

## **If a sponsor requires a Confidential Disclosure Agreement prior to releasing their protocol and negotiating a study agreement, is it okay to sign?**

SPAdmin will review, negotiate, and sign the CDA. Email the CDA request and template to the SPAdmin Contracts Associate for handling.

## **Finalizing Awards**

Awards may be set up as soon as the contract is fully executed and the internal forms are approved.

# Administration

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## Required Regulatory Review Processes

### **Do I need to complete regulatory review processes prior to grant submission?**

NIH and most other sponsors allow applicants to submit grants prior to obtaining final approval of required regulatory processes. This process is called “Just in Time (JIT).” After the application is submitted and approved, but prior to final determination of funding, NIH or other sponsors will request submission of regulatory approval documents. The request will be designated in eCommons using JIT next to the submitted application. However, a JIT request does not guarantee that an award is forthcoming.

### **When should I complete and submit regulatory documents?**

If regulatory approvals are required by the grant, and they are not completed and approved prior to grant application, it is best to begin the application as soon after the grant submission as possible to prevent any delays in grant award once those documents are needed. These may include human studies review (IRB), animal welfare review (IACUC), and safety review (IBC). Human studies projects involving administration of any medication or therapeutic agent also require pharmacy and therapeutics (P&T) review, and any cancer-related project will require Scientific Review Committee (SRC) review and approval. For human studies projects, all personnel on the study budget who will also interact directly with patients or human subjects’ data should complete human subjects training on the CITI Web site. For more about CITI training, see [unmc.edu/irb/citi](http://unmc.edu/irb/citi).

### **Before I receive the Notice of Award, can I hire personnel and order equipment on the grant Budget?**

If you have received indication that funding will be awarded you can request an Advance Account from SPAdmin. However, if an Advance Account is set up and the award is not made, the department covers the cost of any expenses incurred.

Access the Advance Account Request form in ADIS Internal forms. A guide is available at [unmc.edu/spa/forms/forms-templates](http://unmc.edu/spa/forms/forms-templates)

You must have processed your proposal through SPAdmin prior to requesting an Advance Account.

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## Finalizing Grant Awards

As soon as you receive a Notice of Award, please notify and forward to Sponsored Programs Administration (SPAdmin) to set up your grant. If the internal forms on file are complete and match the award, SPAdmin will prepare the award and send it to Sponsored Programs Accounting (SPAccting) for set-up within one week. If the total award or budget has been changed since the grant application was submitted, the internal forms will need to be revised to match the award. SPAdmin will contact you if changes to internal paperwork are required.

After the award is set up in UNMC's accounting system, the PI and department administrator are notified by email that the account is ready and that the project "bundle" may be accessed in ADIS. The bundle includes:

- Checklist, which lists the account number (known as the WBS), personnel, effort, budget, regulatory requirements, and budget and award periods
- Internal budget
- Award document
- Routing form signed by the PI

For more, see [Award Set-up](#)

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## Finalizing Subcontracts OUT

### What is required to finalize a subcontract OUT?

After UNMC's grant award is finalized, SPAdmin generates a subcontract OUT to any sub-recipient organizations based on the statement of work and budget collected from the PI and department prior to submission. The subcontract budget may need to be revised if there is a significant variance between the budget request and budget award.

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# Finalizing Subcontracts IN

## What is required to finalize a subcontract IN?

Once the prime recipient organization receives a notice of grant award, SPAdmin works with the organization to execute a subcontract IN based on the statement of work and budget provided by the UNMC investigator and department.

The subcontract from the prime recipient should contain:

- Statement of work
- Detailed budget
- Catalog of Federal Domestic Assistance (CFDA) number (if federally funded)
- Documentation of terms and conditions
- Copy of prime award

The budget and scope of work may need revisions if a significant variance exists between the budget requested and the budget awarded to the prime recipient.

# Managing Awards

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## Sub-Site Monitoring (if UNMC has subcontracted to other sites)

UNMC is obligated to the sponsor to act as a good steward of the entire award and must therefore monitor the activities of any sub-sites.

For more information on Sub-recipient Monitoring obligations, see UNMC [Policy #6108](#).

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## Changes Requiring Formal Approval by the Sponsor

### Change in PI or Key Personnel

UNMC must seek prior sponsor approval if the PI withdraws from the project entirely and the study is assigned to a new PI.

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## No-Cost Extensions

Projects may be extended at no-cost in one of two ways, depending on sponsor requirements:

- Internal extensions do not require sponsor approval and merely extend the budget period internally if additional work on the project is required or additional payments are anticipated. Extensions are obtained in collaboration with SPAdmin.
- Extensions requiring external approval formally extend the budget period through an amendment signed by both the sponsor and the institution (UNMC/NEMed), indicating additional work is required or payments are anticipated.

No-cost extension request forms can be accessed through ADIS.

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## **Residual Funds**

Upon completion of the research, no more than 25% of the funds may remain prior to transfer to another account.

# Human Subject Research

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# Human Subjects Protection Training

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## Required Human Subjects Protection Training

All research personnel planning to conduct human subject research are required to complete Web-based training on human subject protection and good clinical practice (GCP) on the Collaborative Institutional Training Initiative (CITI) website.

Instructions and registration for the CITI Training Program are also available through the UNMC Institutional Review Board (IRB) website on their CITI pages.

Additional training in clinical research is available for trainees, faculty, health providers, and research personnel at the annual Clinical Research Symposium coordinated by the Clinical Research Center (CRC). View the schedule and registration details on the CRC's website.

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## Training for Clinical Coordinators

### Required training

- CITI Training: Good Clinical Practice Course available through the UNMC Institutional Review Board (IRB) web site at [unmc.edu/irb/resources/citi](http://unmc.edu/irb/resources/citi).
- Clinical Trials Master Matrix (CTMM)/billing grid training is required for access to the secure drive where centralized Clinical Trials folders are stored. Training is provided upon request by contacting the Senior Research Billing Associate at 402-559-4939.
- Coverage Analysis instruction is required for clinical coordinators. Schedule training through the Clinical Research Manager at 402-552-6601 or the Senior Clinical Trials Analyst at 402-552-7817.
- One Chart Electronic Health Record training is required for all clinical coordinators to have access to One Chart in order to perform duties such as chart review, order entry, patient enrollments, and study visit/orders linking. Access requests may be completed in the [IT Service Requests portal](#). Coordinators may sign up for training in Apollo or reach out to [OneChartTrainingRequests@NebraskaMed.com](mailto:OneChartTrainingRequests@NebraskaMed.com) for assistance.

## Recommended training

- The Clinical Research Coordinator's Workshop is available on the [CCTR website](#). Recommended for all new clinical coordinators. A live training program is scheduled annually as well. For information and access to the workshop materials, contact the Research Subject Advocate Office, 402-559-6941.
- Clinical Coordinator Orientation is available on request from UNeHealth. Coordinators receive an overview of the contract and negotiation process and learn best practices to speed study start-up.
- IRB Orientation is available upon request by contacting the IRB Office at 402-559-6463. The session is tailored to the needs of the attendee based on the type of research conducted and their role in studies. The session includes specific information on the IRB submission process, post-approval submission requirements, informed consent training, and orientation to the electronic IRB application submission system.
- The IRB Education Series offers educational sessions for new and experienced clinical personnel. Topics range from an orientation level to research subject compensation, tips for a trouble-free IRB review, and more. For a schedule, visit the [IRB Education Series webpage](#) or contact the IRB Education Coordinator at 402-559-6463.

# Institutional Review Board

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## Introduction

The UNMC Institutional Review Board (IRB) reviews all human subject protocols conducted by anyone on the premises of UNMC, Nebraska Medicine, Children's Hospital & Medical Center, Nebraska Medicine - Bellevue, and the University of Nebraska at Omaha (UNO) or conducted by UNMC or UNO faculty or students for adequate human subjects protection. The IRB serves as a resource for questions regarding clinical research and human subject protections at UNMC. IRB review and approval is **required** before human study protocols can be initiated.

- **Exempt, expedited, or full board.** Human research studies are classified as either exempt, expedited, or full board. There are several types of research considered exempt, such as quality improvement and health outcomes data where results are shown in aggregate without individual identifiers. Exempt and expedited research is discussed further [on the IRB website](#).
- **Adult versus pediatric protocols.** Separate IRB boards review and approve adult and pediatric protocols. The adult IRBs meet on the first and third Thursday of the month (with the exception of January and July when the board meets only on the third Thursday). The UNMC-Children's Hospital & Medical Center Joint Pediatric IRB meets on the fourth Tuesday of the month. Deadlines and meeting dates for IRB meetings can be [found on the IRB website](#).

If research involves both adult and pediatric populations, the IRB Office assesses which IRB will review the study based on the majority population and other considerations. Nevertheless, all IRB applications, adult as well as pediatric, will be submitted electronically using the online RSS-Research Support System. For questions, contact the [IRB staff](#).

Studies classified as exempt or expedited are reviewed either by IRB Staff or IRB members outside of a convened meeting.

## Key Contacts

The **[Office of Regulatory Affairs \(ORA\)](#)** can answer questions and assist with the IRB submission process.

## Submission and Approval

All research involving human subjects conducted on site at UNMC, Nebraska Medicine, Children's Hospital & Medical Center, Nebraska Medicine - Bellevue or UNO, or conducted by their employees or representatives at other sites, must receive approval by a designated IRB before the research may commence. Human subject research includes all research conducted with a human subject as defined as "a living individual about whom an investigator (whether professional or student) obtains: 1) data through intervention or interaction with the individual or 2) identifiable private information."

Research involving data or human biological materials (HBM) with subject identifiers also requires IRB application and approval. A complete listing of included and exempt research can be found in the UNMC Human Research Protection Program (HRPP) Policies and Procedures Manual, [Policy #2.6](#).

Not all work on human specimens constitutes Human Subject Research. The NIH rules can be complex, and useful information can be found on the [NIH website](#).

There may be exemptions to requirements for human subject research rules, but the investigator cannot make that final determination, which must be made by the IRB. [Contact the IRB staff](#) for guidance whether your project requires IRB review and approval. HRPP Policies and Procedures, [Policy #2.6](#).

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## Submitting an Application

All IRB applications are submitted online using the [Research Support System](#) (RSS). Use your UNMC NetID or Nebraska Medical Center email username and password. If you are unsure of which IRB application to complete, please [contact the IRB Office](#).

The application requires an initial review and approval of scholarly merit and resource use by an authorized department member, such as the chairperson, an authorized delegate, or appointed review committee of the PI's department or division, prior to submission.

Instructions are in the IRB's [Procedures webpage](#).

The IRB charges a fee for review of full board or expedited industry sponsored studies. The Commercial Fee Form can be [downloaded](#) from the IRB website.

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## Additional Committee Reviews

Depending upon the nature of the research, proposals may be subject to additional review and approval by one or more of the following groups before obtaining IRB approval:

- **Fred & Pamela Buffett Cancer Center Scientific Review Committee (SRC):** The SRC must review and approve all cancer-related research involving human subjects conducted by members of the UNMC faculty, trainees, and members of the Fred & Pamela Buffett Cancer Center.
- **Pharmacy and 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. If your protocol requires administration of any medication to human subjects, you must check the P&T box in the IRB electronic application.
- **Radioactive Drug Research Committee (RDRC):** The RDRC reviews human subject protocols involving research with radioactive drugs.
- **Conflict of Interest (COI) Committee:** When an IRB application is submitted and the PI indicates that he/she or other Responsible Personnel on the application have a financial interest, the IRB must review the financial interest and a COI management plan must be developed. If the financial interest is:
  - *Not Significant*, the COI management plan must be reviewed and approved by the IRB Executive Chair before IRB final approval.
  - *Significant Financial Interest*, the COI management plan must be reviewed and approved by expedited review or the full IRB before the protocol qualifies for final approval.
- **Sponsored Programs Administration (SPAdmin)/UNeHealth** reviews all grants and contracts funding human subjects research, including the study protocol, IRB application, consent documents.

Final IRB approval will not be given until SPAdmin or UNeHealth has a fully executed contract (for industry-sponsored research) and all other reviews and the institutional requirements have been met.

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## Additional Documents to Submit

The following documents, as applicable, should be submitted with the IRB application:

- Planned subject recruitment material which must be approved and stamped

- Pharmacy and Therapeutics (P&T) Committee Investigational Drug Study Registry and/or Marketed Drug Form
  - Performance site approval for all non-UNMC, NEMed, UNO and Children's Hospital & Medical Center sites
  - Copy of all questionnaires, surveys, assessment tools, and other relevant materials
  - Detailed protocol
  - Investigator's brochure
  - Grant Application
  - IRB Review Fee Form for all commercially sponsored research projects
  - UNMC Disclosure of Potential Conflict of Interest Form for the Principal Investigator as well as any responsible personnel if a financial interest has been declared in the IRB Application for that individual(s)
  - Clinical Trial Master Matrix/Billing grid. This document identifies protocol scheduled procedures and source of payment for each of the procedures. This research billing "matrix/grid" must be submitted for any study that includes clinical care conducted at NEMed/NMB/UNMC/UNMC-Physicians clinics or facilities irrespective of funding.
    - **Where can I find information regarding the Research Matrix/Billing grid?** See the [SPAdmin Clinical Billing](#) website.
    - **Who do I contact to help develop my billing "matrix"?** The Senior Research Billing Analyst will assist with completion of the matrix/billing grid as well as review it prior to IRB submission, including Coverage Analysis if indicated. Investigators/Coordinators who have questions or would like assistance with matrix completion may contact 402-559-7421 or see the [SPAdmin Clinical Billing contact page](#).
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## Research Involving Children or Adolescents

UNMC and Children's Hospital & Medical Center have a Joint Pediatric IRB. Deadlines and meeting dates for the Pediatric IRB can be found on [the IRB website](#).

Biomedical and Behavioral-Social Science studies have an adult and pediatric application. All other applications types are the same for adult and pediatric study populations. If you are unsure of which application to complete, please [contact the IRB Office](#).

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## Assistance Preparing the Application

The UNMC IRB in the Office of the Vice Chancellor for Research is available to assist investigators from initial submission to study completion. If you have any questions regarding the IRB application, contact the [IRB office](#).

The Clinical Research Center (CRC) has research personnel who can prepare your clinical trial IRB application and all forms required for submission on a fee-for-service basis. [See the CRC website](#) for information about this service.

The Pediatric Research Office (PRO) staff can prepare your clinical trial IRB application and all forms required for submission for Pediatric Studies at UNMC and Children's Hospital & Medical Center. The PRO charges a fee for this service. For more information, please [see the PRO website](#).

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## **Compliance and Regulatory Requirements for Human Subject Research**

The Compliance Office and Officer answer questions related to research compliance. A listing of compliance areas and responsible officers is available on the [academic affairs compliance website](#).

Managing risks associated with potential conflicts of interest begins with establishing a culture of transparency. UNMC utilizes a [Web-based system called \*\*COI-SMART\*\*](#) to assist in the disclosure process. COI-SMART identifies potential conflicts of interest, documents them, and when necessary, establishes plans to manage the risk.

# Developing a Budget

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## Considerations for Preparing a Budget

For studies that require a grant or contract, the Investigator or representative is responsible for generating and/or negotiating the budget with the sponsor.

### Initiation costs and Personnel time for start-up

- **Determination of feasibility using electronic health record access core.** Potential eligible patients can be identified to ensure the study is likely to meet recruitment goals by applying to the Electronic Health Record Core.
- **Regulatory Document Preparation.** IRB application fee and personnel costs for preparation of documents for industry-sponsored trials.
- **Coverage Analysis.** The Finance Analyst is available to evaluate and verify conventional or “standard” care versus research costs and can or cannot be billed to a third party payer (either private insurance or Medicare). This is important for compliance as well as budgeting. Fees related to Coverage Analysis may be required; current rates may be found on the Clinical Research Center website.
- **Data Storage.** Data storage needs and costs vary with the type of data stored, HIPAA-compliant versus non-compliant, and duration. Consult the Research Information Technology Office (RITO) to develop a data storage plan and estimate. (phone: 402-559-9072)
- **Drug and Device.** Investigational devices may require additional clinical care costs for implantation. Devices with IDE must be submitted to Centers for Medicare & Medicaid Services (CMS) for a Coverage Determination.
- **Sample size analysis by a biostatistician.** Biostatistics consultation for study design, sample size calculation, and preparation of a biostatistical analysis plan can all be determined through consultation with the Center for Collaboration on Research Design and Analysis (CCORDA). Contact by phone: 402-559-9436.
- **Spanish language translation fees.** Spanish language translation of study materials is available through the NEMed Interpretive Services Office; however, if materials are needed rapidly, other translators may be contracted through the Center for Reducing Health Disparities.

- **Salaries.** The Clinical Research Center is available to contract clinical research support, contact the CRC 402-559-85555 for an estimate. Biostatistician salaries can be obtained from CCORDA as above.
- **Time from the Electronic Health Record Core** to obtain patient lists for on-going recruitment, contact the EHR director for an estimate.
- **Benefit rates** for each type of personnel can be found on the Sponsored Programs website.

## Study related fees

### Salaries and Effort

- **Investigator and Staff Time.** Principal investigators and key personnel are usually budgeted as FTEs.
- **Clinical personnel** who provide professional review services (e.g., Pathology or Radiology reviews) may require contracted professional fees. See Clinical Trial Professional & Technical Fee Billing Procedures Policy #8008 for guidelines on cost recovery for professional fees. Include salary and benefits, for all effort necessary (actual visits, preparation time, paperwork, queries, etc.).
- **Personnel time** needed to complete the study, including recruitment, study visits, preparation of IRB annual review, serious adverse event submissions, and changes of protocol.
- **Biostatisticians** and other collaborators.
- **Consultants.** This can include budgeted time and travel.
- **Research Pharmacy and Study Drugs.** The sponsor may provide the study drug whether the trial is investigator-initiated or not, however, the research pharmacy will charge for services provided. These could include consultation on obtaining the right drug or formula, submission of IND forms, subject randomization, study initiation, blinding, drug preparation or storage, and/or dispensing fees. The route of administration will determine if drug administration fees are required. Contact the research pharmacist at 402-559-5255 or download the price calculator.
- **Research IT Office or CCORDA** support of study database.

### Supplies

- **Study drug or placebo** may be required for investigator-initiated study.
- **Study Devices.** Costs may be required related to obtaining, storing, maintaining, and/or training to use devices.

### Travel

- **For the subject,** investigator or study personnel, or consultants.
- **Study personnel** may need to travel to the subject to obtain data or samples.
- **Subjects may require assistance** with travel to and from the study site, including bus passes or cab vouchers if local, or if distant, federally approved gas reimbursement or gas cards.

### Other expenses

- **Core Facility Use and Equipment.** Fees for campus core facilities can be found on the individual core website. A full directory of core facilities is [available on the VCR website](#). Include costs for device calibration requirements.
- **Clinical Research Center Use.** Fees for CRC facilities and staff are on the [CRC website](#).
- **Biological Production Facility.** Fees for studies utilizing cell products.
- **Pathology Fees.** For studies requiring submission of pathology slides to a central reviewer.
- **Shipping Expenses.** If samples must be shipped in dry ice, additional shipping costs will be required.
- **Subject Stipends.** IRB typically allows up to \$20/hour for participation in trials, which can include recovery or travel time. This can be provided by a check that is generated by the State of Nebraska or gift cards.
- **Postage.** Send follow-up messages or documents through the mail.
- **Record Retention Costs.** Costs of storing records during or after completion of study.

### Clinical Care costs

- **Facility Fees.** There may be room charges depending on where the study is performed.
- **Clinical tests or procedures** performed during the research study may be required (e.g., EKG, lung function testing).
- **Other supplies** needed (i.e., gowns, use of hospital owned equipment, glucose testing, IV fluids). [One Chart-Price Inquiry](#) can be used to locate these fees.

### Overall budget considerations

- **Cost of Living Increases.** Prices often increase over the duration of the grant, 3-5% annually, although these cost of living increases may not be allowed in NIH grant applications depending on the funding agency.
- **Indirect Costs.** [Current F&A rates](#) can be found on the SPA website.

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## Who are my key contacts for questions about budgeting and sources for fee information?

- Your Department Administrator
- [Clinical Trials Analysts, & Research Billing Senior Associate](#)
- [Sponsored Programs Administration](#)
- [One Chart-Price Inquiry](#)
- [UNeHealth](#), for industry-funded clinical research

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## **What is the Clinical Trials Master Matrix/Billing Grid (CTMM)**

Completion of the Clinical Trials Master Matrix/Billing Grid can assist you with budget preparation in that it sets up the budget table for the study.

A research billing “matrix” must be submitted for any study that includes clinical care conducted at Nebraska Medicine/UNMC clinics or facilities. The matrix/billing grid guides investigators through determining costs associated with a clinical trial; it is stored on a secure drive and access must be requested from the Senior Research Billing Associate.

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## **Where do I find hospital-based charges?**

Hospital-based charges can be found in One Chart, under the separate Price Inquiry tab.

Instructions on using Price Inquiry can be found in the “Tips & Tricks” in the Epic modules of the Learning Center.

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## **What requires a professional fee?**

- Any hospital or clinic visit (office visit) where a physician, nurse practitioner, or physician’s assistant would examine a patient
  - Any consultation
  - Any test that requires test review and a written report from one of the following departments, among others: Radiology, Cardiology, Pathology.
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## **Are there fees for Children’s Hospital & Medical Center facilities and services that I need for my study?**

Yes. Questions regarding clinical research fees may be directed to the Pediatric Research Office.

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## **How can I determine if study procedures, tests, items, which are “standard of care” can be billed to Medicare/insurance?**

No costs for procedures completed solely for research purposes may be billed to insurance. Medicare Qualifying Criteria are outlined in NCD 310.1 “Routine Costs of Clinical Trials.” If the study meets the qualifying criteria, routine costs and costs for diagnosis and treatment of adverse events can be billed to Medicare.

If the study does not meet the qualifying criteria, nothing can be billed to Medicare, not even routine care costs. Coverage analysis is performed to verify that research procedures listed as paid by insurance are “standard of care” and can be billed to a third party payer (either private insurance or Medicare).

Coverage analysis also compares the matrix/billing grid, informed consent document, and preliminary budget to ensure that all costs are known. This process ensures that the final study budget reflects the true cost of the research project. For additional information, see the [SPA Clinical Trials Billing FAQ](#).

The coverage analysis makes a general judgement on insurance coverage for participation in clinical trials based on Medicare rules. When a patient is identified for potential participation in a clinical trial, insurance pre-authorization is put in place to review the patient’s insurance policy and coverage. Information on the Insurance Pre-authorization process can be found at [unmc.edu/cctr/resources](http://unmc.edu/cctr/resources).

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## **Who initiates the insurance pre-authorization process?**

It is the research coordinator or study staff’s responsibility to initiate the insurance pre-authorization process with Nebraska Medicine patient financial counselors.

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## **Coverage Analysis**

### **Performing Coverage Analysis**

Clinical Trials Analysts perform coverage analyses for drug/biologics related clinical trials. Faculty/Coordinators who have questions or would like assistance can contact the Clinical Research Manager or the Senior Clinical Trials Analyst at 402-552-7817.

## **Is a coverage analysis required for all industry sponsored trials?**

A coverage analysis is required for all adult, full board clinical trials. It should be completed for any study involving billing of clinical care at the same time of the trial regardless of funding. The IRB may also require coverage analysis for specific trials.

The results of the coverage analysis are shared with the IRB to determine if subjects will be placed at additional financial risk as a result of study participation.

## **Coverage Analysis Fees**

There is a fee for coverage analyses for industry funded research. Contact the Clinical Research Manager for the fee amount.

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## **What can be charged to the sponsor in an industry-sponsored trial?**

Charge time and effort for activities, including all persons involved (investigator, coordinator, research assistants, etc.). Also include supplies needed to conduct the study. If hospital services are used you should charge for them. You can also meet directly with the manager of the CRC to discuss budgeting.

# Clinical Research

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# Resources for Clinical Research

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## Introduction

UNMC has developed many resources for clinical and translational research through the Center for Clinical and Translational Research (CCTR) as well as partnerships with other collaborators.

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## Center for Clinical and Translational Research (CCTR)

The CCTR serves as a repository of clinical research resources, policies, education and training opportunities, and has navigators to assist researchers conducting clinical and translational research. The CCTR managed core facilities include the Clinical Research Center, the Electronic Health Record Access Core, The Nebraska Biobank, and the Research Subject Advocate Office.

## Clinical Research Center

The Clinical Research Center (CRC) is an outpatient clinical research facility that supports a broad range of clinical trials. The CRC contains exam rooms, procedure rooms, a dental/ENT room, a treadmill room, a phlebotomy room, a coordinator/investigator workroom, and a processing lab. Skilled research nurses in the CRC can also assist with inpatient protocols and serve as monitors for multi-center clinical trials. Facility use and personnel support are available on a fee-for-service basis to researchers.

The CRC can provide research assistance in all aspects of developing and conducting a clinical trial. These services can include but are not limited to:

- Developing and negotiating a budget
- Coverage analysis
- Preparing and submitting IRB documents
- Case report form and order set development
- Study recruitment

- Coordinating study visits and data collection
- Administering study infusions and monitoring patients for adverse events
- Sample drawing/processing and shipping
- Monitoring multi-center protocols and working with the investigator to develop an appropriate monitoring plan.
- Providing research support for pilot studies involving our faculty.
- Providing mentoring and education for new coordinators on campus.
- Assisting with development of advertisements and brochures

## **Electronic Health Record Data Access Core**

The Electronic Health Record Data Access (EHR) core supports requests to assess the available patient population prior to initiating a clinical trial, as well as preparation of de-identified and well-annotated dataset queries of the electronic health record, including both legacy and new Epic data.

## **Nebraska Biobank**

The Nebraska Biobank is a bio-repository of de-identified human biological material (HBM) (serum/plasma, and DNA) isolated from left-over patient blood samples collected at the UNMC/Nebraska Medicine clinics and facilities.

## **Research Subject Advocate Office**

The Research Subject Advocate (RSA) Office was created as one of several mechanisms to ensure the highest level of protection for participants in a clinical research study.

The Research Subject Advocate:

- assists UNMC clinical and translational researchers in developing protocols that minimize research subject risk and optimize benefits.
- facilitates development of consent/assent documents and processes to clearly communicate to potential participants risks and benefits of the research.
- provides education and advocacy to support the safe conduct of clinical research.
- is available to research participants who are directed to the RSA office if they have concerns regarding a research study in which they are participating, or if they have questions about research in general.

## **Research Clinical Informatics Lead**

The Research Clinical Informatics Lead (CIL) is a resource for One Chart and other Clinical Information Systems (CIS). The Research CIL is available to assist with One Chart questions, training requests, workflow development, OrderSet/SmartSet requests, One Chart documentation tool requests, and the use of One Chart to assist with patient recruitment. The Research CIL is primarily responsible for One Chart requests but may also assist in the implementation and development of workflows for other Clinical Information Systems.

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## The Child Health Research Institute (CHRI)

The Child Health Research Institute aims to create vibrant interfaces between biomedical, genomics and computational approaches to drive innovative clinical and translational studies.

The CHRI is home to the Pediatric Research Office (PRO), a team of research nurses, coordinators, administrators, and support staff that oversees pediatric research being conducted at Children's Hospital and Medical Center and Nebraska Medicine.

More information about the CHRI and the PRO is [available on their website](#).

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## Investigational Pharmacy

[The Nebraska Medicine 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. Contact the Investigational Drug Services Pharmacist at 402-559-5255 or [view additional contact information](#) on their website.

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## Study Design, Biostatistics, and Epidemiology Consultation/Resources

[The Center for Collaboration on Research Design and Analysis \(CCORDA\)](#) provides expertise in the quantitative sciences, including biostatistics, epidemiology, and health services research, and coordinates the collaborative design, planning, conduct, analysis and interpretation of laboratory, clinical, and public health research studies.

Requests for CCORDA services may be made by contacting the Center Director or Associate Director or by completing a request for consultation using the [CCORDA online request](#) web page. Investigators who have previously worked with other CCORDA members may contact the center member directly.

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## Study Data Management Resources

## **Research Electronic Data Capture (REDCap) software.**

REDCap is an open-source clinical research management tool developed by Vanderbilt University, as part of its Clinical Translational Science Award (CTSA). UNMC is one of over 870 institutions in 71 countries that host this program designed to build, manage, and support clinical research including secure on-line surveys and databases. Additional information may be available on the Project REDCap website.

The UNMC Research IT Office (RITO) can orient investigators in its use and hosts the REDCap database.

## **Clinical Trial Management System**

The Clinical Trial Management System (CTMS) is available to UNMC and Nebraska Medicine researchers. The CTMS supports centralized management of therapeutic protocols and subjects. The CTMS allows administrative, regulatory, financial, and clinical functions to interact in a centralized area.

Additional information and training on the CTMS is available through the CCTR training website.

## **Forte Electronic Data Capture**

Forte's Electronic Data Capture System (EDC) is targeted to assist investigator initiated trials (IIT's). The EDC allows a research team to record subject clinical data through forms, customized by the CTMS Analysts, specifically for your study. Forte EDC is validated as 21 CFR part 11 compliant.

Additional information and training on the Forte EDC is available through the CCTR training website.

## **Centralized Protocol & Data Management Unit of the Fred & Pamela Buffett Cancer Center**

Centralized Protocol & Data Management Unit is a shared resource that provides centralized support for protocol development, quality assurance monitoring, coordination of regulatory agency compliance requirements, and evaluation of clinical research at the Fred & Pamela Buffett Cancer Center.

## **Center for Collaboration on Research Design and Analysis (CCORDA)**

CCORDA can establish a research study database for any study on which they are collaborating.

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# Biobanks and Data Registries

There are a number of biobanks available to investigators:

- The Nebraska Biobank for DNA and serum linked to de-identified health information.
- Disease specific cancer biobanks and data registries

# Clinical Trial Monitoring

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## Data Safety Monitoring

All human subject research should have an appropriate data safety monitoring plan to ensure subject safety regarding the risks, complexity, and nature of the research. Appropriate monitoring may include a data safety monitoring plan, as well as a Data Safety Monitoring Board (DSMB).

### **What is the researcher's responsibility for data safety monitoring?**

The PI is responsible for assuring that the study has appropriate outcome monitoring.

### **Who at UNMC can provide support for data safety monitoring?**

The Center for Collaboration on Research Design and Analysis (CCORDA) will coordinate data acquisition and management for research studies, including data safety monitoring. For more information, [see the CCORDA scope of services](#).

The Data and Safety Monitoring Committee (DSMC) of the Fred & Pamela Buffett Cancer Center monitors cancer trials. Forms for data and safety monitoring are available on the Fred & Pamela Buffett Cancer Center [Protocol Review and Monitoring System website](#).

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## Site Visits

All external vendors visiting the UNMC/NEMed campus, including clinical trial-related monitoring, are required to register with IntelliCentrics, prior to EACH visit, and check in once arriving on campus. It is recommended that monitors register online (Intellicentrics.com) in advance, to avoid delays once arriving on campus. Following check-in, monitors will be provided with a "Visitor" badge, which must be worn at all times while on campus. Specific registration instructions can be

found in the Clinical Research Center Standard Operating Procedures.

# Managing Clinical Trials

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## ClinicalTrials.gov Registry

### Required Registration

Registration is required for trials that meet the FDAAA 801 definition of an "applicable clinical trial" that include the following:

- **Trials of drugs and biologics.** Controlled clinical investigations, other than phase 1 clinical investigations, of drugs or biological products subject to Food and Drug Administration (FDA) regulation
- **Trials of devices.**
  - Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and
  - pediatric post-market surveillance required by FDA

"Applicable clinical trials" generally include interventional studies (with one or more arms) of FDA-regulated drugs, biological products, or devices that meet one of the following conditions:

- The trial has one or more sites in the United States
- The trial is conducted under an FDA investigational new drug application or investigational device exemption
- The trial involves a drug, biologic, or device that is manufactured in the United States or its territories and is exported for research

For complete statutory definitions and more on the meaning of "applicable clinical trial," see [Elaboration of Definitions of Responsible Party and Applicable Clinical Trial](#).

Please keep in mind that FDAAA801 regulations apply to "applicable clinical trials" regardless of the funding source or lack thereof.

As a part of the IRB review, the ClinicalTrials.gov identifier (NCT number) will be requested for applicable studies.

### Can I register a study after it has started?

Yes, you can register a study on ClinicalTrials.gov after it has started, but initial registration must occur prior to closing subject accrual. Please note that, in general, Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801) requires Applicable Clinical Trials to be registered within 21 days of enrollment of the first participant. The International Committee of Medical Journal Editors and many journals also require registration of clinical trials *prior* to enrollment of the first participant.

## **Who is responsible for submitting my study to Clinicaltrials.gov?**

Whoever is listed as the sponsor/investigator for the study has the responsibility for registering the study with ClinicalTrials.gov. If you need access to ClinicalTrials.gov, have questions, or require assistance with the submission, the Office of Regulatory Affairs can assist you. Call 402-559-6463 with questions.

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## **Epic One Chart**

Epic One Chart is used in many ways for clinical trials.

### **Building a study**

Only those designated as Clinical Research Specialists can build and activate studies. Research coordinators must submit a completed Clinical Trial Master Matrix and an IRB number to a Clinical Research Specialist. To reach a Clinical Research Specialist contact the Clinical Research Center or phone: 402-552-2983.

### **Enrolling subjects**

Research Coordinators can enroll patients in active studies using One Chart. The patient's name must be linked to the study to enroll them. Step by step instructions are available in the EPIC Research Quick Start Guide.

### **Training**

Training is provided through the [OneChart User Resource Center](#) at Nebraska Medicine.

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## **Advertising a Study**

## General Guidelines

The IRB has specific requirements for information that can be included in advertisements. See [HRPP Policy #3.5](#) for information.

The following items are appropriate to include in an ad:

- Name and address of the PI and associated institution
- A clear statement that the activity is research
- Purpose of the research
- Eligibility criteria (in shortened form)
- A brief list of potential benefits to the subject, if any
- Time or other commitments required from the subject
- Location of the research, contact person, and phone number for further information
- IRB number

If applicable, you may mention that compensation is available but you may not provide the dollar amount. Avoid words such as “new,” “improved,” and “better.”

The layout of the advertisements must conform to UNMC's requirements regarding the use of logos and brands. Templates are available on the [brand platform website, “Brand Wise”](#).

Industry-sponsored research also requires sponsor approval of any advertisement or promotional pieces in addition to UNMC IRB and campus approvals.

## Where to Advertise a Study

You are encouraged to post your IRB approved study on the [UNMC Clinical Trials database](#), an online, searchable directory of UNMC based clinical trials. To post a study, follow the instructions listed in the [Clinical Trials Database Guide](#).

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## Translating Study Materials

Translation services are available through Nebraska Medicine Interpretive Services Office. Staff interpreters translate Nebraska Medicine documents, pamphlets, consent forms, and patient education materials, including site translation of discharge forms. Research documents including IRB consent forms are translated on a first come first served basis as time allows. To request services, visit the [Interpretive Services Request form](#) on the Nebraska Medicine intranet.

The Center for Reducing Health Disparities [offers translation services](#) of IRB approved research related documents for a fee. 402-559-2095

Translation services are available at Children's Hospital & Medical Center. More information is [available on their website](#) or by calling 402-955-5418.

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## **Recruiting Underrepresented Minorities**

Assistance and consultation for recruitment of underrepresented populations may be available through the Research Branch of the Center for Reducing Health Disparities. The CRHD provides services to facilitate health disparities/health equity research including promotion and enrollment in research studies.

For additional information on this and other services provided by the Center for Reducing Health Disparities, [visit their website](#) or get in touch with their office.

Phone: 402-559-9660

Email: [crhd@unmc.edu](mailto:crhd@unmc.edu)

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## **Overnight Monitoring**

If a study requires overnight monitoring but your study staff are only working during the day, you may contact the CRC Manager to assist you in determining how best to arrange coverage for your study. CRC staff may be available to address personnel needs outside of business hours.

# Cancer Related Trials

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## Introduction

The oncology Clinical Trials Office (CTO) provides central management and oversight functions for all cancer-related trials that involve human subjects conducted on campus. The CTO is staffed by project coordinators, research nurse coordinators, clinical research assistants, data coordinators, and quality assurance personnel. The CTO staff work alongside the Oncology/Hematology faculty to implement and oversee a diverse range of clinical trials including investigator-initiated, industry-sponsored, national cooperative group, and consortium trials.

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## Special Review Requirements

All cancer-related trials (adult and pediatric) must be reviewed by The Protocol Review and Monitoring System (PRMS) and the Scientific Review Committee (SRC). The SRC oversees the scientific aspects of cancer-related research that involve human subjects conducted by members of the UNMC faculty and personnel.

The SRC is responsible for:

- evaluating all new and amended clinical research protocols for scientific merit and to ensure that there are adequate resources available to successfully complete the proposed research
- monitoring accrual to active protocols to ensure that studies meet their accrual goals and to require a reassessment of recruitment strategies and accrual goals when necessary
- ensuring that there are no competing studies with overlapping eligibility criteria for a specific disease indication
- establishing priority of each protocol based on National Cancer Institute guidelines and institutional priorities
- performing ongoing annual scientific review of cancer center protocols

The function of the SRC is complementary to the Institutional Review Board (IRB) and does not duplicate the IRB's responsibilities, which focuses on the protection of human subjects.

SRC approval is required before the IRB gives final approval or continuation of a protocol submission. If the investigator fails to obtain SRC approval prior to expiration of the IRB approval period, the protocol will be classified as “approval expired” until all requirements are met. Forms for protocol submission are available on the [PRMS website](#).

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## Data and Safety Monitoring Support

### Data and Safety Monitoring

The Data and Safety Monitoring Committee (DSMC) monitors the safety of research participants enrolled in therapeutic interventional clinical research trials sponsored by UNMC faculty as outlined in the UNMC Data Safety Monitoring Plan (DSMP).

Forms for data and safety monitoring are available on the [PRMS website](#).

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### Audit Reviews

The PRMS Audit Committee (AC) performs audits and provides oversight on all investigator-initiated therapeutic interventional trials with UNMC as the study source (i.e. sponsor). The role of the Audit Committee is to ensure:

- compliance with institutional regulatory guidelines
- confirmation of patient eligibility
- adherence to treatments
- appropriateness of adverse event monitoring and reporting; and 5) adequacy of patient follow-up as stipulated in the protocol.

For a list of all active cancer related clinical trials conducted at UNMC, visit the [cancer-related clinical trials page](#).

The site links each active trial to information on the [ClinicalTrials.gov](#) website.

The [PRMS website](#) is a useful resource which provides investigators with the most current versions of the SRC, DSMC, and AC Policies and Procedures; Conflict of Interest Policy; submission forms; and meeting dates and submission deadlines.

# Drug/Device Trials

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## Introduction

All clinical trials that use an approved drug or investigational product supplied to the institution from a sponsor must have the protocol reviewed by the Medical Staff Pharmacy and Therapeutics Committee (P&T Committee).

P&T Committee Forms must be attached to the IRB Application prior to submission. Download the forms from the [IRB Web site](#). Complete and save the form, then upload it directly to your electronic IRB application

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## Drugs

### What is an 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. There are three IND types; all require an IND application:

- An Investigator IND is submitted by the physician who both initiates and conducts an investigation and who immediately directs how the investigational drug is administered or dispensed. A physician might submit a research IND to propose studying an unapproved drug or an approved product for a new indication or in a new patient population.
- Emergency Use IND allows the FDA to authorize use of an experimental drug in an emergency situation that does not allow time for submission of an IND in accordance with 21CFR , Sec. 312.232 or Sec. 312.34.3 It is also used for patients who do not meet the criteria of an existing study protocol or if an approved study protocol does not exist.
- Treatment IND is submitted for experimental drugs showing promise in clinical testing for serious or immediately life-threatening conditions while the final clinical work is conducted and the FDA review takes place.

There are two IND categories: Commercial and Research (non-commercial). Once the IND is submitted, the sponsor must wait 30 calendar days before initiating any clinical trials. During this

time, FDA has an opportunity to review the IND for safety to assure that research subjects will not be subjected to unreasonable risk.

## Research Pharmacy for INDs

All studies using pharmaceutical agents for human administration must use the [Nebraska Medicine Investigational Drug Service](#) (Research Pharmacy). Phone: 402-559-5255

## Storing Investigational Drugs

All investigational drugs for human consumption must be stored and ordered through the Investigational Drug Service.

**Investigational drugs cannot be stored in individual clinics.**

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## Devices

### What is a medical device?

Medical devices range from simple tongue depressors and bedpans to complex programmable pacemakers with microchip technology and laser surgical devices. Medical devices also include in vitro diagnostic products, such as general purpose lab equipment, reagents, and test kits, which may include monoclonal antibody technology. If a product is labeled, promoted, or used in a manner that meets the definition outlined in [section 201\(h\)](#) of the Federal Food Drug & Cosmetic (FD&C) Act, it will be regulated by the FDA.

### What is a 510(k)?

A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR 807.92(a)(3)) that is not subject to a Premarket Approval (PMA).

### What is a post marketing trial?

A post marketing trial is one wherein the device is approved but the sponsor is required to continue to collect data to satisfy the FDA that the device is safe and effective.

## **If my study uses a device Nebraska Medicine already stocks, can I use existing inventory to keep my costs down?**

No. Study devices are strictly regulated and must be labeled and secured; substitutions of non-study devices, even when identical to hospital stocks, are prohibited. The PI is ultimately responsible for ensuring appropriate storage, security, dispensing, and record-keeping for investigational devices.

## **Investigational Device Exemption (IDE)**

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.

Information on IDE and exempt devices can be found on the [FDA Web site](#).

[Contact SPAdmin](#) for UNMC regulations for IDE, or visit their [frequently asked questions page](#) for more information.

## **Who is responsible for filing the IND/IDE seeking an exemption?**

The IND is generally obtained by the PI, their research coordinator, or the Industry Sponsor.

Investigational Device Exemption (IDE). A sponsor must submit a separate IDE for any clinical investigation involving an exception from informed consent under the provisions of 21 CFR 50.24.

For Investigator initiated research, the PI or coordinator generally obtains the IND.

For Industry initiated research, the Industry Sponsor generally obtains the IND.

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## **What is a sponsor-investigator and how do their responsibilities differ from a typical investigator?**

A sponsor-investigator both initiates and conducts, alone or with others, a clinical investigation. The role does not include a corporation or agency as the study lead, although a corporation or agency may provide funding to conduct the trial. A sponsor-investigator has the obligations of both an investigator and a sponsor. An investigator who is also a sponsor must comply with all FDA

requirements applicable to investigators and sponsors.

# Off-campus Trials

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## Special Considerations

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As the sponsor of a multi-center trial, additional considerations may be necessary, including the following:

- Choosing sites for the trial and ensuring that the sites:
  - have the needed patient population
  - conduct a feasibility assessment, perhaps using the electronic medical record
  - develop recruiting plans for the study
  - consider competing studies
  - have experience conducting similar clinical trials
  - coordinators, whether full time or part time, have a back-up if they are gone
  - have appropriate IRB approvals (Check that human protection training credentials/certifications are current for all personnel involved)
- Checking contract/agreements that may involve multiple entities
- Developing a budget for a large study has much more to consider than a single site study. It could take 2-3 years to get it funded and appropriate prices must be put into the budget.
- Confirming the supply of a study drug
- Assuring collaborators are knowledgeable about responsibilities and adherence to Good Manufacturing Practices (GMP)
- Determining if resources are necessary to have placebo made or study drug over-encapsulated
- Determining the experience of the supplier
- Calculating the drug requirements for the life of the study including expiration dates of the drug
- Making sure there is not a current shortage of the drug
- Determining who will conduct stability testing on the drug during the course of the study
- Identifying where the study drug will be kept
- Participating in a benefit/risk assessment to determine whether or not additional insurance is needed to protect UNMC/Investigator/Study Subjects
- Determining a monitoring plan that includes who will do the monitoring and what will be monitored

- Deciding who will handle data collection and analysis and if they have adequate experience
- Establishing data coordination between sites
- Determining who will be in charge of the clinical coordinating center. This is the point person for the sites to call and to push information out to the sites.
- If lab or imaging will be conducted, determining if centralized laboratories will be used
- Identifying experienced personnel to handle lab samples
- Considering the issues of removing identifiers from the samples and shipping labs or images.

The Nurse Manager of the Clinical Research Center, the Nurse Manager of the Eppley Research Institute, and the Research Pharmacist are available to assist with getting this type of project off the ground.

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## Veterans Affairs Facilities

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UNMC has an affiliation with the Veterans Affairs Nebraska Western Iowa Healthcare System (VA-NWIHCS). The Research Service for the local VA is housed at the Omaha VA at 42nd and Woolworth Avenue. Clinical studies, animal studies, and bench research all occur at the VA.

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## Regulatory Submission Process

The VA IRB and IACUC are considered subcommittees of the Research and Development (R&D) committee at VA. In order for research to begin at the VA, it must have R&D committee approval as well as relevant subcommittee approvals.

All VA forms for IRB submission, IRB Standard Operating Procedures and other resources are available online through the [VA research web pages](#).

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## Resources for Researchers

The VA has its own IRB and IACUC for human and animal studies done at VA facilities or with VA resources. The VA also provides a limited number of translational bench laboratories on the Omaha NWIHCS campus.

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## VA Funding Opportunities

There are Merit and Career Development funding programs unique to the VA with specific eligibility requirements. Contact the local VA Research office at 402-995-3542 or 402-995-3544, or through their research web pages.

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## Study Personnel

All personnel must be credentialed to do research at a VA site. To start the credentialing process, the PI must complete and turn in the New Personnel Information Form (Rev 05-13).

All persons involved with research require a scope of practice based on the individual and all their roles within research (not protocol specific). Once a year, each individual's scope of practice will require a review for any changes. Scope of Practice for Research Personnel (Rev 07-12).

# Animal Research

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# Training and Oversight

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## Training Requirements

Federal regulations require institutions to provide training in the humane practice of animal care and use, and in instruction in research and testing methods that minimize the number of animals required to obtain valid results and to minimize animal distress. All personnel involved in the use or care of live vertebrate animals must complete this training prior to contact with animals or access to the animal facilities.

UNMC complies with these federal regulations by providing the Institutional Animal Care and Use Committee (IACUC) Basics Training Program and the Occupational Health and Safety Program. Additional training for working with specific species may be required and is provided by the Office of Comparative Medicine. For requirements and access the training modules, visit the [CM Services and Training web page](#).

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## Oversight and Ideas Exchange

The Comparative Medicine Advisory Group (CMAG) promotes the exchange of information and ideas among all UNMC scientists regarding current and projected animal related research activities. The group is appointed by the Vice Chancellor for Research and consists of representatives from Comparative Medicine and research scientists who use animals. CMAG members meet with the administration of Comparative Medicine and with the Vice Chancellor for Research. For members of the CMAG, [visit their web page](#).

# Institutional Animal Care and Use Committee

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## Key Contacts

The **Office of Regulatory Affairs (ORA)** answers all questions and assists with the IACUC submission process.

Web: [unmc.edu/iacuc](http://unmc.edu/iacuc)

Phone: 402-559-6046

Email: [iacucora@unmc.edu](mailto:iacucora@unmc.edu)

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## Research Requiring IACUC Approval

Prior to project initiation, every research, testing, and teaching project involving the use of a live vertebrate animal must be reviewed and approved by the IACUC.

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## Forms

1. **IACUC Application of Animal Research/Testing/Training** are completed on-line through the [Research Support System](#) to apply for approval of research using animals if:
  - You are a faculty member or student at UNMC or UNO who proposes to use animals in research, testing, or training.
  - This is a new project or one that is due for 3-Year Review.
2. **Addendum to Experimental Application - Breeding Procedures.** Completion of this form for existing paper protocols is required only when the experimental design includes the need to breed animals. The [form is available online](#).

3. **Study Personnel: Responsibilities, Qualifications and Experience.** The IACUC ensures that personnel who conduct procedures on research animals are appropriately qualified and trained in those procedures. The IACUC application requests detailed information about experience, education, and training on each individual listed on a protocol. See detailed information on the [IACUC website](#).
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## Approval Criteria

Investigators are encouraged to pay careful attention to these criteria during both the design and conduct phases of their research projects:

- Potential Value of the Study
- Selection of an Animal Model
- Alternatives to Animal Use
- Minimization of Animal Usage
- Alternatives to Potentially Painful Procedures
- Refinement of the Protocol to Reduce Potential Pain
- Restraints
- Pain Control During Acute Procedure(s)
- Estimation of Potential Post-Operative or Post-Intervention Pain
- Post-Procedure and Chronic Care
- Euthanasia/Disposition of Animals
- Investigator(s) Qualifications, Training and Experience

For more detail regarding the criteria, see the [IACUC website](#)

# Procurement and Management

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## Pricing Information

Current pricing for Comparative Medicine charges can be found on the [Comparative Medicine Pricing page](#).

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## Ordering Animals

Comparative Medicine uses a Web-interfaced system, the Comparative Medicine Business Management System (CMMS), for animal orders. CMMS integrates the IACUC and the Sponsored Programs Administration (SPAdmin) databases to enhance campus regulatory compliance while providing detailed investigator billing/invoicing documentation, online animal ordering, barcode census, and detailed "real-time" animal care financial data. Animal orders are placed in the CMMS through the [Research Support System](#).

Use your UNMC NetID and password to log in. Select "links" from the menu bar, hover the cursor over "Comparative Medicine" and click on "Order Animals". Choose the protocol number and select "animal order".

The following information is required when placing an animal order:

- UNMC IACUC Approved Protocol Number
- Species
- Strain
- Sex of Animals
- Weight and Age
- Quantity
- PI (as listed on the protocol)
- Cost Center Number (used for billing purposes)
- Preferred Vendor
- Name of the person who is placing the order and contact information
- Any special requirements, such as specific pathogen free (SPF) status

- Date animals are required for research
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## **Animal Transfer**

### **Moving between IACUC Protocols**

Animals may be transferred from one IACUC protocol to another and from one investigator to another with certain restrictions. Animals may also be transferred between institutions with proper pre-authorization. Find additional details on the [CM website](#).

### **Quarantine Policy**

All newly received animals at UNMC should be given a period for physiological, psychological, and nutritional stabilization before use. This allows the animal to recover from shipping stress, adapt to its new surroundings, and become physiologically stable. Adequate acclimation times may vary depending on the animal species, source, type and duration of transportation, and the intended use of the animals. See [recommended quarantine periods](#).

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## **Procurement from Non-Approved Vendors**

IACUC approval can be granted to procure animals from non-approved sources or vendors such as other universities. Requests to order or receive animals from a non-approved source are coordinated through Comparative Medicine using the on-line ordering system. Unauthorized shipments of animals are not allowed. Details can be found on the CM website page for the [procurement of animals from non-approved vendors](#).

# Facilities

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## Available Facilities

Comparative Medicine operates seven animal housing and/or support facilities.

All facilities for housing animals are registered research facilities under the Animal Welfare Act and are inspected regularly by the United States Department of Agriculture (USDA).

UNMC's program also complies with

1. the US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training,
2. the US Public Health Service Policy on Humane Care and Use of Laboratory Animals,
3. the USDA implementing Regulations of the Animal Welfare Act, and
4. The Guide for the Care and Use of Laboratory Animals.

For additional information, please contact Comparative Medicine.

Web: [info.unmc.edu/comparativemed](http://info.unmc.edu/comparativemed)

Phone: 402-559-4034

# Environmental Health and Safety

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## Introduction

UNMC requires training and special review for projects that involve radioactivity or biohazards. Investigators conducting research with any of these types of agents must submit their protocol for review by the Institutional Biosafety Committee (IBC).

The Biosafety Manual has been developed by the Office of Regulatory Affairs and the Institutional Biosafety Committee (IBC) at UNMC. The Biosafety Manual provides university-wide safety guidelines, policies, and procedures for the use and manipulation of biohazards. Access it at [unmc.edu/ibc/policies-procedures](http://unmc.edu/ibc/policies-procedures).

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## Submitting Research to the Institutional Biosafety Committee (IBC)

### Key Contacts

The Office of Regulatory Affairs (ORA) answers all questions and assists with the IBC submission process.

IBC Web page: [unmc.edu/ibc](http://unmc.edu/ibc)

Phone: 402-559-6463

### Institutional Biosafety Committee (IBC)

The Institutional Biosafety Committee has been charged by Federal law with planning and implementing the campus Biosafety Program 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](#), drafts campus biosafety policies and procedures, and reviews individual research proposals for biosafety concerns.

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# Application and Approval Process

Research requiring IBC approval includes:

- the deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally
- the deliberate transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA into human research participants (human gene transfer)
- the deliberate formation of recombinant DNA containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight
- using risk group 1, risk group 2 or risk group 3 agents ([ABSA Risk Group Database](#)), as host-vector systems
- the cloning of DNA from risk group 2 or risk group 3 agents into non-pathogenic prokaryotes or lower eukaryotic host-vector systems
- the use of infectious or defective risk group 2 or risk group 3 agents
- whole animals in which the animal's genome has been altered by stable introduction of recombinant DNA or DNA derived into the germ-line (transgenic animal)
- viable recombinant DNA-modified microorganisms tested on whole animals
- genetically engineered plants by recombinant DNA methods
- culture of more than 10 liters of a biological agent
- formation of recombinant DNA molecules containing no more than two-thirds of the genome of an eukaryotic virus

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## Environmental Health & Safety (EHS)

### Biosafety

A [Biosafety Manual](#) has been developed by the Office of Regulatory Affairs and the Institutional Biosafety Committee (IBC) at UNMC. The Biosafety Manual provides university-wide safety guidelines, policies, and procedures for the use and manipulation of biohazards. Additional information on policies and procedures pertaining to biological research can be found on the [UNMC IBC website](#).

**All individuals working with biohazardous materials must take Biosafety Training**  
. Additional training is required for work with risk group 3 organisms.

## **Radiation Safety**

Radiation Safety is responsible for the management of radioactive material and the use of radiation at UNMC in accordance with Nuclear Regulatory Commission (NRC) and Nebraska Department of Health and Human Services regulatory requirements. Additional services include responding to spills/releases on a 24-hour basis, conducting internal radiation safety audits and maintaining databases to comply with the recordkeeping requirement mandated by the regulations. Radiation Safety also manages the personnel radiation monitoring program (e.g., radiation badging, bioassays). Prior to working with radioactive material, please contact EHS at 402-559-6356 and see the Radiation Safety Manual. All individuals using radioactive material must be adequately trained. See link for training requirements Radiation Safety Training.

## **Chemical Safety**

Chemical Safety is responsible for the “cradle to grave” management of chemicals, in accordance with Occupational Health and Safety Administration (OSHA) and Environmental Protection Agency (EPA) Resource Conservation and Recovery Act (RCRA) regulatory requirements. Additional services include responding to spills/releases on a 24-hour basis, conducting internal OSHA/EPA/DOT audits and maintaining databases to comply with the recordkeeping requirements mandated by the regulations. Chemical Safety also monitors the reporting of “Chemicals of Interest”, pursuant to the Department of Homeland Security regulatory requirements and on-site chemical threshold planning quantities, related to the Emergency Planning and Community Right-to-Know Act (EPCRA). Please see Hazardous Material Fact Sheets for guidance on chemical disposal.

## **Occupational Health and Safety**

Campus Safety is responsible for occupational safety and health practices and strives to reduce work-related accidents and injuries through a formal injury and illness prevention plan, in accordance with Occupational Health and Safety Administration (OSHA) regulations. The program is built on the premise that each employee has the responsibility to: plan each job to assure proper safety equipment is available and used, know what actions to take in the event of emergencies, report any injuries or potential injuries and any unsafe conditions.

Additional services include helping UNMC administrators and staff to protect UNMC property and ensuring a safe environment for patients, visitors, students, and staff. Campus Safety does this by identifying safety hazards, consulting with departments to correct and prevent safety hazard deficiencies, unsafe conditions and acts, and providing occupational and personal safety education and information. Incidents, accidents and near misses must be reported in a timely manner using the Incident/accident reporting form.

## **Lab Safety**

All research laboratories are required to be in compliance with Federal, State and University policies and procedures. Please see the EHS [Laboratory Safety](#) page for guidance. Specific regulatory information and guidance can also be found in the [Laboratory Safety Manual](#) and the [Lab Safety Audit Guide](#). Safety Data sheets must be available for all chemicals in the lab and can be accessed on the [Safety Data Sheets page](#).

## **Dangerous Goods/Hazardous Materials Shipping**

The United States Department of Transportation (DOT) and the International Air Transport Association (IATA) have regulations related to the shipping of Hazardous Materials and Dangerous Goods. Hazardous Materials and Dangerous Goods include but are not limited to chemicals, radioactive material, infectious substances, biological specimens, regulated medical waste, dry ice, lithium batteries, and equipment containing lithium batteries. UNMC EHS is the point of contact for shipping all Hazardous Materials and Dangerous Goods. EHS can provide training to research coordinators or any other study personnel for shipments of infectious substance, biological specimens, dry ice, excepted quantities of material, and regulated medical waste. EHS personnel are trained to ship all Hazardous Materials and Dangerous Goods and will assist in shipping all other Hazardous Materials and Dangerous Goods that training is not available for. To register for DOT/IATA shipping training or for assistance with shipments, please contact EHS at 402-559-6356 and see the [UNMC Hazardous Material/Dangerous Good Shipping Plan](#) for more information.

## **Patient Specimens and Cultures**

Patient specimens are those collected directly from humans or animals, including but not limited to excreta, secreta, blood and its components, tissue, tissue fluid swabs, and body parts, transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention.

Cultures are the result of a process by which pathogens are intentionally propagated.

Patient specimens and cultures that are shipped or transported have the potential to be regulated as Infectious Substances (Category A or B), Exempt Human Specimen, or Exempt Animal Specimen. In order to be compliant with DOT and IATA regulations, research study coordinators or any other study personnel who package and ship study samples or transport study samples in company or personal vehicles, are required to complete training. Contracted couriers or transportation companies may be utilized to transport study samples if they are approved by EHS. To register for DOT/IATA shipping training, please contact EHS at 402-559-6356 and see the [UNMC Hazardous Material/Dangerous Good Shipping Plan](#) for more information.

# Human Embryonic Stem Cells

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## Regulations Pertaining to hESC Research

### Key Contacts

The Scientific Research Oversight Committee (SROC) within the Office of Regulatory Affairs (ORA) can answer all questions and assist with the SROC submission process.

SROC Web: [unmc.edu/irb/sroc](http://unmc.edu/irb/sroc)

Phone: 402-559-3779

### Research Requiring SROC Approval

All studies using hESC must be SROC and IRB approved and employ federally approved hESC cell lines that are used according to all federal, state and university regulations.

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## Application and Approval Process

Research proposals utilizing hESC lines must undergo substantive scientific and scholarly merit and resource review. This review may be done by the PI's school, department, or division.

Certification of this review must be attached to the [Human Embryonic Stem Cell Research Submission Form](#) and submitted to the SROC for approval. See [unmc.edu/irb/sroc/forms](http://unmc.edu/irb/sroc/forms).

The SROC committee undertakes all of the tasks for an Institutional ESCRO and these responsibilities include:

- Provide oversight over all issues related to deviation and use of hES cell lines.
- Review and approve the scientific merit of research protocols.
- Review compliance of all in-house hES cell research with all relevant regulations and these guidelines.
- Maintain registries of hES cell research conducted at the institution and hES cell lines derived (*not relevant in Nebraska*) or imported by institutional investigators.
- Facilitate education of investigators involved in hES cell research.

The SROC is not a subcommittee of the IRB, however, it reports its actions to the UNMC IRB and the Chancellor.

# National Strategic Research Institute

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## About the NSRI

The National Strategic Research Institute (NSRI) is a partnership between the US Strategic Command (USSTRATCOM) and the University of Nebraska. It is the only biomedical research-focused, Department of Defense-funded University Affiliated Research Center (UARC) established to identify strategies to improve defenses against biologic and chemical weapons of mass destruction (WMD). The NSRI partnership provides a rapid response pipeline for researchers to compete for federal awards in core competency areas.

The mission of the NSRI at the University of Nebraska is to provide mission-essential research and development capabilities in five distinct core competencies:

- Detection of chemical and biological weapons
- Nuclear detection and forensics
- Active and passive defense against weapons of mass destruction
- Consequence management
- Mission-related research

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## Key Contacts

If you think you have expertise in or are conducting/planning on conducting research of interest to NSRI, contact any of the following individuals:

### **Director of Government Relations**

Mark Bowen

Web: [unmc.edu/govtrelations](http://unmc.edu/govtrelations)

Phone: 402-559-6669

### **Director of Research Resources**

Tess Kuenstling, PhD, MBA, PMP

Web: [unmc.edu/vcr/cores/support-services](http://unmc.edu/vcr/cores/support-services)

Phone: 402-559-6162

**For more information**

Web: [nsri.nebraska.edu](http://nsri.nebraska.edu)

# International Research

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## Introduction

All research conducted at another site, including in another country, must comply with all applicable federal and state laws and University of Nebraska policies. We have developed a [questionnaire](#) to help you prepare for research performed in collaboration with researchers located in another country or while doing research yourself in another country. Please complete the questionnaire and submit it to Sponsored Programs Administration as you plan the research.

Important considerations include:

- **Human subjects research** must still be performed to the same standards as required at UNMC, including approval by the UNMC IRB committee in addition to the collaborating institution or local review board
- **Animal research** must be performed in an approved facility and the project approved by the UNMC IACUC as well as by the collaborating institution
- **Intellectual property** or research that may result in intellectual property may require a separate New Invention Notice for the country in question
- **The Department of Transportation** has developed specific rules for the transportation of biological materials, including infectious disease specimens
- **The US Government** has established controls on the export of strategic goods and technologies as described below

Additional information for International Projects can be found at:

[unmc.edu/academicaffairs/compliance/areas/export](https://unmc.edu/academicaffairs/compliance/areas/export)

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## Getting Started

An [international project questionnaire](#) is available to prepare researchers for international projects and travel. It must be completed if you are preparing an international project or grant and may be requested for international travel.

The International Projects Questionnaire addresses these areas:

- General Project Information
- Human Subjects
- Animal Use
- Materials and Equipment
- Personnel
- Logistics
- Travel
- Conflict of Interest
- Intellectual Property

Completed questionnaires should be submitted to:

- SPAdmin with your application, if you are applying for external funding
  - The Export Control Office, [exportcontrol@unmc.edu](mailto:exportcontrol@unmc.edu)
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## Export Controls

Export controls are US government regulations that govern the export of strategic technologies, equipment, hardware, software, materials, and data, as well as the provision of technical assistance to foreign persons inside or outside the United States. See UNMC's [policies related to export controls](#).

Export controls apply to, but are not limited to, the following activities:

- Research activities conducted in the United States involving equipment, materials, or data subject to export controls, including nuclear, biological, or chemical materials, radionuclides, human and animal pathogens, and novel compounds
- Research activities conducted outside the United States
- Research where the sponsor prohibits or restricts participation by foreign nationals
- Research where the sponsor prohibits or restricts publishing the results
- Shipping or hand-carrying equipment, materials, software, or data to a foreign country
- Electronically transferring data or software to a recipient in a foreign country, or to a foreign national or entity, regardless of location
- Travel to an embargoed country for any purpose, including conducting research, attending a conference, or participating in clinical activities. Embargoed countries include:
  - Cuba
  - Iran
  - North Korea
  - Syria
- Plans to discuss unpublished research or other intellectual property with an external sponsor, vendor, collaborator, or other third party under a non-disclosure or other confidentiality agreement.

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## Hand-carrying Items Abroad for Research

Exports of physical items, including by shipping, hand-carrying, or checked luggage, are subject to federal regulations and University of Nebraska policy. Prior to shipping or traveling to another country with research items, you must complete a [Request for Export Controls Review Application form](#) and provide specific information about the items to be exported, the intended recipient and destination, and the intended end-use. More information about physical exports is available on the [safety information site](#).

- An export license may be required when carrying research items, depending on item and destination
- Any exports totaling \$2500 or more must be filed with Customs and Border Protection

The Export Control Office can assist with export license applications and other required filings. [Contact the Export Control Office](#) prior to traveling with research items.

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## Shipping Internationally

Exports of physical items, including by shipping, hand-carrying, or checked luggage, are subject to federal regulations and University of Nebraska policy. Prior to shipping or traveling to another country with research items, you must complete a Request for Export Controls Review Application form and provide specific information about the items to be exported, the intended recipient and destination, and the intended end-use. You can find more information about physical exports [on the safety information site](#).

- An export license may be required depending on the item and destination
- If you are shipping infectious substances that can affect humans or animals (Category A), biological substances (Category B), or exempt human or animal specimens and dry ice you must complete a Training and Certification of International Shippers by the [Environmental Health & Safety department](#).
- Any exports totaling \$2500 or more must be filed with Customs and Border Protection

The Export Control Office can assist with export license applications and other required filings. [Contact the Export Control Office](#) prior to shipping internationally.

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## Required Budget Authorizations

All sponsored project budgets with international components are to apply the appropriate UNMC federally negotiated F&A rate. Authorizations for contracts unrelated to research should be submitted to Associate Vice Chancellor for Business and Finance or the Director of Business Services at 402-559-5200.

Keep in mind that international activities unrelated to research may still be subject to export controls. Please [contact the Export Control Office](#) with any questions about international activities.

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## **International Material Transfer Agreements**

A Material Transfer Agreement (MTA) attaches certain terms to the use of tangible research materials and allows other researchers to use them while protecting rights associated with the materials. At UNMC, tangible materials can include molecular biology reagents, cell lines, recombinant mice, devices, or software. International Material Transfer Agreements are handled by [UNeMed](#).

Keep in mind that international activities unrelated to research may still be subject to export controls. Please [contact the Export Control Office](#) with any questions about international activities.

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## **International Travel**

All travel outside of the United States for UNMC business, education, or research purposes must be submitted to the Vice Chancellor for Business and Finance for authorization through the Concur application accessed through Firefly. See additional information regarding UNMC [travel policies and procedures](#).

International travel will be evaluated by the Compliance Office and/or the Export Control Office. International travelers may be asked to provide additional information regarding the scope of activities while traveling abroad.

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## **Carrying a Computer or Other Electronic Devices Outside the United States**

Your departmental IT workstation specialists will help you determine if you should carry your laptop or other devices to the country proposed and any restrictions that may exist. They can also help you determine how best to access email or other databases off site.

If you need to establish a database for research collaborations outside the US, contact the [Research IT Office](#).

Contact your cellular service provider to determine if your phone plan allows you to send or receive calls when outside of the United States.

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## **International Research Programs and Resources at UNMC**

- [Asia Pacific Rim Development Program](#), for questions regarding travel to and within China.
  - Pediatric International Research, for pediatric investigators interested in international research collaborations, Program Coordinator 402-559-8845
  - [International Health and Medical Education](#), for general information regarding international travel, education, and resources.
  - [Center for Global Health and Development](#), a College of Public Health resource focused on international public health education, research, and practice.
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## **Getting Answers to Questions Regarding International Research Requirements**

Contact either:

- International Research Projects: SPAdmin, 402-559-7456
- Export Controls: Export Control Office, 402-559-4518

# Research Support

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# Core Facilities and Service Centers

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## 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](http://unmc.edu/vcr/about/centers).

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## 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](http://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.

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## 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.

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## 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.

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## **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

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## 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](https://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](https://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.

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# **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](http://unmc.edu/cancercenter/clinical/prms)

Phone: 402-559-4969 or 402-559-5286

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## **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](http://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](#).

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## **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.

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## 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](https://unmc.edu/nursing/research/niedfelt-center)

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## 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.

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## 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](http://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.

# Technology Transfer

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## Technology transfer

Technology transfer is the transfer of knowledge and discoveries to the public. It can occur through publications, educated students entering the workforce, exchanges at conferences, and relationships with industry, among other things. For the purposes of this guide, technology transfer refers to the formal licensing of technology to third parties under the guidance of professionals employed by universities, research foundations, and businesses.

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## UNeMed

UNeMed is a non-profit corporation owned by the Board of Regents of the University of Nebraska that is responsible for a spectrum of technology transfer activities including protecting, marketing and commercializing UNMC and UNO inventions.

## Working with UNeMed

Contact UNeMed during your early research activities to be aware of the options that will best leverage the commercial potential of your research. UNeMed staff are trained to assist you with questions related to marketability, commercial partners, patenting and other protection methods, new start-up considerations, University policies and procedures, and much more.

## How do I protect my intellectual property when sharing the protocol with sponsors to secure funding?

A Confidential Disclosure Agreement (CDA) or Non-Disclosure Agreement (NDA) is a contract for the protection of proprietary information. CDAs require one or both parties to keep specific information confidential. Without a CDA, the individual or company receiving your information is free to use and transmit this information to others. CDAs help preserve the value of your invention or other intellectual property.

## I have an invention I want to protect. How do I start?

To report an invention to UNeMed, fill out a New Invention Notification (NIN) form. The NIN will create a written, dated record of your invention and provide information from which the patent potential and commercial potential of your invention can be evaluated. The NIN form also ensures compliance with U.S. federal laws, University policy, and the policies of several research-funding agencies.

UNeMed will evaluate the NIN to determine the scope of possible intellectual property protection and commercial potential. UNeMed will then seek appropriate intellectual property protection and begin to market the invention. Find the form at [unemed.com/services/inventions](https://unemed.com/services/inventions).

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## **Additional Information**

UNeMed answers more questions on their website at [unemed.com/faqs](https://unemed.com/faqs).

There is also a downloadable [handbook for researchers/inventors](#). Printed copies are also available.