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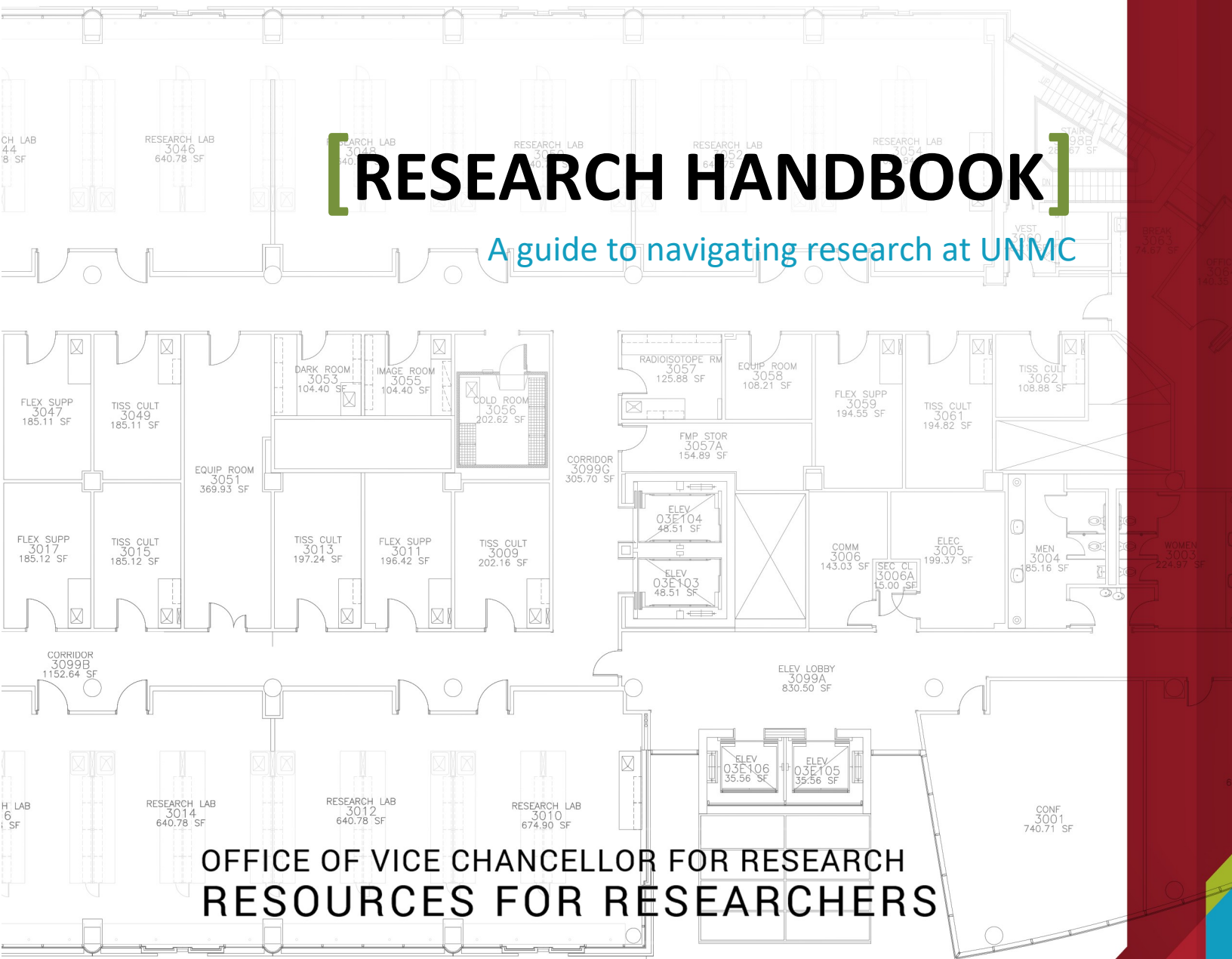
BREAKTHROUGHS FOR LIFE.®

[RESEARCH HANDBOOK]

A guide to navigating research at UNMC



OFFICE OF VICE CHANCELLOR FOR RESEARCH

RESOURCES FOR RESEARCHERS

BREAKTHROUGHS FOR LIFE.®

Welcome to the University of Nebraska Medical Center (UNMC) 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.

Jennifer Larsen, MD
Vice Chancellor for Research

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

WWW.UNMC.EDU/VCR

Version Date: 04/2019

Frequently Called Numbers and Web sites

Office of Research	www.unmc.edu/vcr 402-559-8490 email: research@unmc.edu
Vice Chancellor for Research	402-559-4837 Jennifer Larsen, MD email: jlarsen@unmc.edu
Associate Vice Chancellor for Basic Science Research	402-559-4945 Ken Bayles, PhD Email: kbayles@unmc.edu
Associate Vice Chancellor for Clinical Research	402-559-8490 Chris Kratochvil, MD Email: ckratoch@unmc.edu
Research Resources	402-559-6162 Tess Kuenstling, PhD, MBA Email: tess.kuenstling@unmc.edu
Web Resources	402-559-7649 Linda Wilkie, VT, BS Email: lwilkie@unmc.edu
Clinical Research Center	https://www.unmc.edu/cctr/resources/crc/ 402-559-7685
Institutional Animal Care and Use Committee (IACUC)	https://www.unmc.edu/iacuc/ 402-559-6046
Institutional Biosafety Committee (IBC)	https://www.unmc.edu/ibc/ 402-559-6463
Institutional Review Board Office (IRB)	https://www.unmc.edu/irb/ 402-559-6463
Sponsored Programs Administration (SPAdmin)	https://www.unmc.edu/spa/ 402-559-7456
UNeHealth	https://www.unmc.edu/spa/clinical-trials/unehealth/ 402-559-7456
UNeMed	https://www.unemed.com/ 402-559-2468
UNMC Research Policies	https://www.unmc.edu/vcr/policies/
My Favorites:	

* Note: An asterisk next to a Web site indicates access is only available through the UNMC Intranet.

1. Getting Started: Important Information for UNMC Investigators

a. Conflict of Interest Reporting and Outside Employment

i. When and where do I disclose potential conflicts of interest?

UNMC Conflict of Interest Procedures (Policy #8010, http://wiki.unmc.edu/index.php/Conflict_of_Interest); 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 (http://wiki.unmc.edu/index.php/Outside_Employment) 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.

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) Web site https://net.unmc.edu/rss/*. Click on the COI tab, for the COI-SMART link.

For questions regarding COI or Outside Employment:
Web: https://www.unmc.edu/academicaffairs/compliance/areas/conflict.html
Phone: 402-559-6767

b. 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 Omaha VAMC. The MOU describes the investigator's complete professional effort and ensures there is not dual compensation for the same work.

To request an MOU, contact Sponsored Programs Administration
Web: https://www.unmc.edu/spa/
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, contact https://www.nebraska.va.gov/Research/index.asp.

c. Training and Certification Requirements to Conduct Research

i. What training and certification are required before I begin?

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 Web page at https://www.unmc.edu/academicaffairs/compliance/training-requirements/index.html.

NEMed employees can complete required compliance training not involving human subjects through the NEMed Learning Connection at http://elearn.nebraskamed.com/TPOnline/TPOnline.dll/home.*

1. **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) (https://www.unmc.edu/irb/citi/index.html).

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 Web site at https://www.unmc.edu/irb/citi/index.html.

2. **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 at https://info.unmc.edu/comparativemed/services/index.html *

Contact Comparative Medicine for questions and to obtain access.
Web*: https://info.unmc.edu/comparativemed/about/contact.html
Phone: 402-559-4034

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 http://www.nebraska.va.gov/Research/index.asp.

d. Transferring in to UNMC: Grants, Contracts, Animals, and Materials

i. How do I transfer grants from another institution to UNMC?

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:

- The original institution relinquishes interests and rights to the grant

- The new grantee institution assumes legal and administrative responsibilities for the grant

Contact Sponsored Programs Administration (SPAdmin) at 402-559-7456 or spadmin@unmc.edu for assistance with this process. For more information, see also https://www.unmc.edu/spa/grants/special/transfers.html.

ii. How do I transfer animals from another institution to UNMC?

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.

iii. How do I transfer materials from another institution to UNMC?

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 an MTA, go to https://www.unemed.com/services/material-transfer

iv. What are the requirements for 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.
Web: https://wiki.unmc.edu/index.php/Human_Tissue_Use_and_Transfer

v. How do I transfer general laboratory equipment and supplies from another institution to UNMC?

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 (https://www.unmc.edu/vcr/about/research-facilities.html). 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, Vice Chancellor for Research Office, at https://www.unmc.edu/vcr/about/contact.html.

2. Research Space and Support

a. Space Allocation

i. How is research laboratory space allocated?

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. Contact the director at:
Web: https://www.unmc.edu/vcr/cores/support-services.html
Phone: 402-559-6162.

For details, see UNMC's Assigning Research Lab Space policy at https://wiki.unmc.edu/index.php/Assigning_Research_Lab_Space.

ii. How is research animal space assigned?

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.

iii. 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 ABSL 2 and 3 space are also available.

iv. 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: https://www.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 (ACOS-Research), Omaha VA Hospital at https://www.nebraska.va.gov/services/Research/admin_home.asp.

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 at https://www.unmc.edu/dentistry/research/cruzan.

v. Whom do I contact about research space questions focused on the following?

1. **Laboratory research space and support questions**

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

Web: https://www.unmc.edu/vcr/cores/support-services.html .
Phone: 402-559-6162

2. **Clinical research space and support, including the CRC**

Contact the Associate Vice Chancellor for Clinical Research or the Clinical Research Center (CRC).
Web: https://www.unmc.edu/cctr/resources/crc

3. **Use of the Cruzan Center for Dental Research space in Lincoln**

Web: https://www.unmc.edu/dentistry/research/cruzan/

4. **Use of Omaha VA Clinical Research Unit space**

Web: https://www.nebraska.va.gov/services/Research/admin_home.asp

b. RESEARCH SUPPORT

i. 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 at https://www.unmc.edu/vcr/. A directory of other campus resources can be found on the UNMC Today Intranet Quick Links at https://info.unmc.edu/services/index.html*.

ii. 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.

PURE™ "Research Nebraska": https://nebraska.pure.elsevier.com/
Find an Expert training: https://www.unmc.edu/vcr/expert or call the VCR Office at 402-559-7649.

iii. What Information Technology (IT) support is available for research applications?

1. **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: https://www.unmc.edu/vcr/rito
Phone: 402-559-9072

2. **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:
Web: https://www.unmc.edu/vcr/education/rug.

iv. What assistance is available for maintaining CV's and NIH biosketches?
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. Simply log in to ADIS from the UNMC login page* (https://edge.unmc.edu/adis/)*.

v. 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 at https://www.unmc.edu/cctr/resources/ehr.

vi. 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 at https://www.unmc.edu/vcr/rito.

3. Funding Resources, Including Pilot Grant Funds

a. Funding Announcements

i. Find funding announcements from the UNMC Web site Research tab
The UNMC Web site Research tab provides a link (Research Resources) to the Vice Chancellor for Research Web pages that lists upcoming internal funding announcements and a resource for finding extramural funding opportunities.
Web: https://www.unmc.edu/vcr/funding

ii. Locate extramural funding opportunities through Funding Institutional™
The Vice Chancellor for Research Office sponsors a commercial funding tool, Elsevier's Funding Institutional™ (https://www.unmc.edu/vcr/funding/funding-institutional/) for campus researchers. This application catalogs funding opportunities from more than 4,000 sponsors and incorporates them into a searchable database with personalized searches and alerts. The tool is accessible from any UNMC IP addressed workstation. For questions and training:
Web: https://www.unmc.edu/vcr/funding/funding-institutional.html
Phone: 402-559-7649.

b. Internal Funding Programs

i. Some available Internal Funding Programs

1. **The Clinical & Translational Research Support Fund**

Nebraska Medicine (NEMed), in partnership with the UNMC College of Medicine, created the CTR Support 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 CT Research Support Fund can be found on the CCTR Pilot Grant Program website (https://www.unmc.edu/cctr/resources/pilot-grant/)

2. **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 at https://www.unmc.edu/vcr/about/centers/.

ii. 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.

Contact UNeMed at:
Web: https://www.unemed.com/resources/funding-opportunities
Phone: 402-559-2468
Email: unemed@unmc.edu

iii. 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.

iv. Other funding sources

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

4. Grants and Subcontracts

a. Getting Started

i. Who can help me navigate UNMC's research infrastructure?

Your department administrator and Sponsored Programs Administration (SPAdmin) grant specialists understand UNMC's research 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 at https://www.unmc.edu/spa/about/my-contact.html.

SPAdmin contact information:
Web site: https://www.unmc.edu/spa/
Phone: 402-559-7456
Email: spadmin@unmc.edu

ii. Does UNMC offer grant writing assistance?

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

Web: https://www.unmc.edu/vcr/cores/research-editorial/
Phone: 402-559-4132
Email: grantseditor@unmc.edu

b. Roles and Responsibilities for Research Administration

i. 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).

1. **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

2. **College, Department, or Unit 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 (http://wiki.unmc.edu/index.php/Principles_of_Financial_Stewardship)
- Generates internal forms for signature
- Submits published manuscripts or clinical trial updates to the appropriate databases

3. **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: https://www.unmc.edu/spa/
Phone: 402-559-7456
Email: spadmin@unmc.edu

4. **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 site*: https://info.unmc.edu/management/finance/spaccounting/*
Phone: 402-559-5822

ii. 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 complete and then will obtain the institutional signature for the applicant.

c. Considerations When 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 Research Funding Announcement (RFA) 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.

i. 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)
Web: https://idp.unmc.edu/idp/profile/SAML2/Redirect/SSO?execution=e1s1 *
Contact your SPAmin grants specialist for questions about using Cayuse424.

d. Preparing Non-federal Grant Applications

Investigators need to be aware of submission deadlines and requirements of the Research Funding Announcement 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.

i. 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 also use federal NIH forms, such as the PHS 398 face page and the detailed budget, checklist, biosketch, and other support forms. Be sure you are using the most current version of the guidelines and required forms, which are on the NIH Web site at https://grants.nih.gov/grants/forms.htm.

e. Submitting Federal and Non-federal Applications

i. 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 section 6 below, Research Administration for Grants and Subcontracts.

ii. 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.

iii. 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 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.

f. Additional Resources for Preparing and Submitting Applications

- UNMC Institutional Information required by sponsors (Federal tax ID, etc.): https://www.unmc.edu/spa/about/institutional.html
- Link to Cayuse424 (log in with UNMC net ID and password): https://idp.unmc.edu/idp/profile/SAML2/Redirect/SSO?execution=e2s1 *
- Request eRA Commons Account: https://www.unmc.edu/spa/about/contact.html
- SPAdmin Grant Guidelines: https://www.unmc.edu/spa/grants/
- Workshops on Grant Writing, Formatting Applications, and More: https://www.unmc.edu/vcr/education/

5. Collaborating with Investigators at Other Organizations

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

i. 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.

ii. 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 (https://www.unmc.edu/spa/subcontracts/subcontracts-out/proposal-stage.html) signed by an authorized official of the sub-recipient organization (https://www.unmc.edu/spa/forms/forms-templates.html)
- Statement (or scope) of work

- Detailed budget with F&A cost calculation
- Budget justification
- Contact information (FDP Attachment 3, http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_153538.pdf)

For details on Subcontracts OUT and links to required forms, see https://www.unmc.edu/spa/subcontracts/subcontracts-out/.

iii. 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 negotiates the vendor agreements.

For additional information on sub-recipients, see Policy #6108 at https://wiki.unmc.edu/index.php/Subrecipient_Policy or contact SPAdmin at 402-559-7456.

For more information regarding vendor agreements, see Policy #6063: https://wiki.unmc.edu/index.php/Vendors or contact the Chief Compliance Officer at 402-559-6767 or Business Services Director at 402-559-5840.

b. SUBCONTRACTING IN FROM A PRIMARY INVESTIGATOR AT ANOTHER ORGANIZATION

i. 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.

ii. 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 (https://www.unmc.edu/spa/subcontracts/sub-in/proposal-stage.html), 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
- 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 Subcontracts IN, go to https://www.unmc.edu/spa/subcontracts/sub-in.html

c. Collaborating with Small Businesses

i. 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.

ii. 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.
Web: https://wiki.unmc.edu/index.php/SBIR/STTR_Program_Participation

- 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
  - Memorandum of Understanding regarding expected time and effort commitments
- Academic Affairs Compliance and COI Officers
  - Outside Employment Form (UNMC Policy #1049, https://wiki.unmc.edu/index.php/Outside_Employment)
  - Conflict of Interest management (as needed)

- Associate Vice Chancellor Business & Finance
  - Contract for Use of Space and Equipment

6. Research Administration for Grants and Subcontracts

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

a. 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.

i. 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 (https://wiki.unmc.edu/index.php/Institutional_Base_Salary) and Cost-Share (https://wiki.unmc.edu/index.php/Sponsored_Project_Cost_Share) Policies. Other considerations:

1. **Waiver of Facilities & Administrative Rate (F&A).**
Sponsors that require a lower F&A rate than negotiated or if the investigator feels there is a rationale for an F&A waiver must complete the F&A Cost Waiver Request form (https://www.unmc.edu/spa/forms/forms-templates.html).

2. **International projects or partners.**

All projects that include an international partner or are performed outside the country must have an International Check List form. 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. International Projects Questionnaire at https://www.unmc.edu/spa/forms/forms-templates.html.

3. **Administrative charges to sponsored projects.**

If Administrative costs are to be charged to the sponsored project, a checklist must be completed.
Web: Checklist for Charging Administrative Costs to Sponsored Projects (https://www.unmc.edu/spa/fpr,s/forms-templates/)

4. **Consortium grant.**

If a UNMC investigator applies for a grant collaborating with an investigator from another organization, a Memorandum of Understanding (MOU) may be required. See Intent to Form a Subcontract (https://www.unmc.edu/spa/forms/forms-templates.html)

ii. 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.

iii. How can I obtain other Sponsored Programs forms?

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

b. DIRECT COSTS

i. 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.

ii. 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 on page 3 of the linked document: https://www.unmc.edu/spa/_documents/unmc_rate_agreement.pdf.

c. INDIRECT COSTS

i. 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.

ii. **What budget items are excluded from indirect costs?**
Indirect costs (F&A) applies to all study costs except IRB fees.

iii. **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 following document to find the indirect cost rate appropriate for the project's specific activity and sponsor: https://www.unmc.edu/spa/about/fa-rateagreement1.pdf

iv. **Can I reduce or waive F&A costs?**
Only in special cases can UNMC reduce or waive F&A. This could include a required lower rate by a Foundation sponsoring research, for example. The waiver process is discussed at https://www.unmc.edu/spa/forms/forms-templates/

d. COMPUTERS AND NIH

i. **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.

e. CONFLICT OF INTEREST

i. **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.

7. Completing Pre-award Activities

a. REQUIRED REGULATORY REVIEW PROCESSES

i. **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.

ii. **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 https://www.unmc.edu/irb/citi/.

iii. Once I receive the Notice of Grant Award, can I hire personnel and order equipment on the grant Budget?

If you receive a Notice of Grant award, you can request an Advance Account from SPAdmin. However, if an Advance Account is set up and the award is not granted, the department covers the cost of any expenses incurred.
Access the Advance Account Request form in ADIS. A guide is available at: https://www.unmc.edu/spa/forms/forms-templates.html

b. FINALIZING GRANT AWARDS

As soon as you receive a Notice of Grant 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 in order to prevent a delay in the set-up of the award account. 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 (https://www.unmc.edu/spa/grants/set-up/)

c. FINALIZING SUBCONTRACTS OUT

i. 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.

d. FINALIZING SUBCONTRACTS IN

i. 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.

To complete the subcontract, SPAdmin needs the following from the other institution:

- Statement of work
- Detailed budget
- Catalog of Federal Domestic Assistance (CFDA) number
- 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.

8. Managing Grants and Subcontract Awards

a. 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: https://wiki.unmc.edu/index.php/Subrecipient_Policy.

b. Progress Reports to the Sponsor (Non-competitive Renewals)

i. 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, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-035.html). The RPPR provides a uniform format for interim performance reporting on federally-funded research and research-related activities.

ii. 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 section Research Administration for Grants and Subcontracts.

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

c. 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. Some of the changes that typically require formal approval include:

i. 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.

ii. 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.

iii. 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.

iv. 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.

v. 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.

d. 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).

e. 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.

f. Effort Reporting

Why is "effort" tracked on a sponsored project? SPAdmin verifies effort availability at the time of award, but after the award, OMB Circular A-21 requires the investigator certify he 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. See https://info.unmc.edu/media/spaccounting/effort_6105_procedure_pat_62309.pdf*.

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 at https://wiki.unmc.edu/index.php/Effort_Certification#Effort_Certification_Report_Process

g. 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 at https://net.unmc.edu/rss/*.

9. UNeHealth: UNMC, NEMed, and UNMC-P as Partners in Clinical Research

i. 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.
Web:https://www.unmc.edu/spa/clinical-trials/unehealth/index.html

ii. Why UNeHealth?

The 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

iii. When do I contact UNeHealth?

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

iv. How do I contact UNeHealth?

Contact information is available at:
Web: https://www.unmc.edu/spa/contracts/unehealth/
Phone: 402-559-7614

10. Industry-sponsored Contracts

a. Getting Started

i. Who can help me navigate UNMC’s infrastructure for industry-sponsored research?

Notify your department administrator and the UNeHealth contracts office when as you identify a study in which you plan to participate.
Web: https://www.unmc.edu/spa/clinical-trials/unehealth/
Phone: 402-559-7614
Email: amanda.leingang@unmc.edu

b. 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, Sponsored Programs Administration (SPAdmin), and Sponsored Programs Accounting (SPAccting)

i. 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

ii. 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 (https://wiki.unmc.edu/index.php/Principles_of_Financial_Stewardship)
- Generate internal forms for PI signature and sign-off; internal forms translate the study budget attached to the contract to salary effort
- Interface with SPAdmin, sponsors, and regulatory bodies

iii. 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
- Coordinate with industry sponsors
- Prepare and finalize awards for set-up by SPAccting
- Does not negotiate the budget. The investigator must submit the negotiated budget to SPAdmin to be attached to the final contract

iv. 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

c. Starting up a Non-clinical Study Funded by Industry

Nonclinical studies do not involve informed consent by human subjects or data or specimens with personal health identifiers. The scope of work could include laboratory investigations, other testing, or provision of services.

i. 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: https://www.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.

ii. What does UNeHealth require prior to reviewing a contract?

Prior to contract review, UNeHealth requires three items:

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

All three items should be attached to a single email and sent to the SPAdmin Coordinator for Industry https://www.unmc.edu/spa/about/contact.html OR submitted through the ADIS Contract Intake https://edge.unmc.edu/adis/index.php*.

iii. Who negotiates the contract?

As noted above, depending on the focus of the research, UNeMed or SPAdmin will negotiate the agreement.

iv. Who signs the contract?

The Director of SPAdmin or their designee signs nonclinical agreements as the official signature authority for sponsored projects at UNMC.

v. Finalizing Awards

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

d. STARTING UP A CLINICAL STUDY FUNDED BY INDUSTRY

Studies that involve the participation of or require informed consent by human subjects are considered clinical studies, whether trials are of new therapeutics or devices, observational studies, registries involving identified data or specimens, or physiologic studies.

i. What does UNeHealth require prior to reviewing the contract for a clinical trial or device study?

Prior to contract review, SPAdmin requires:

- Editable contract template from the sponsor (Word document)
- Protocol

- Contract Questionnaire signed by the PI (https://www.unmc.edu/spa/clinical-trials/unehealth/forms.html)
- Contact information for the sponsor's negotiator

All four items should be attached to a single email and sent to the UNeHealth Coordinator.

UNeHealth Coordinator contact information is available at https://www.unmc.edu/spa/clinical-trials/unehealth/contact.html. The SPADMIN Coordinator can also give access rights to and train users on the ADIS Contract Intake.

ii. Who negotiates the contract?

UNeHealth was developed to centralize contract negotiations for industry-sponsored research 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.

iii. Who signs the contract?

Signatory to any contract will be the parties to the agreement. UNeHealth coordinates the signature process. Signatures always include a UNMC institutional official and will include a UNeHealth signatory if UNeHealth is a party to the agreement. The PI will read and sign acknowledgement of the terms but is NOT a part to the contract. NOTE: PI's do not have signature authority to mind UNMC to contracts.

iv. 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/SPAdmin should be contacted and should review a CDA prior to signing, which is typically done by an institutional official. Forward the CDA request and template to the SPAdmin Coordinator for Industry for negotiation. For more information:
Web: https://www.unmc.edu/spa/clinical-trials/unehealth/contact.html.
Phone: 402-559-7614.

v. 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..

Upon IRB release, SPAdmin prepares the award, SPAccting 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
- Award document
- Routing form signed by the PI

11. Research Administration for Industry-funded Contracts

The information in this section applies to sponsored projects whose primary funding source is a commercial, for-profit entity and whose recipient is UNMC or UNeHealth. Funds may be received directly from the commercial entity or from another institution that receives commercial funds and then subcontracts to UNMC. The industry-funded projects may be clinical or nonclinical.

a. Internal Forms

i. What internal forms are required for industry contracts?

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

At least two internal forms are required for all industry-sponsored projects:

- The Routing Form provides basic information about the project
- The Internal Budget calculates the budget based on institutional rates

Personnel costs are calculated as follows: Each participant and amount of effort (as a percentage) from that participant are entered. The salary requested is based on each participant's Institutional Base Salary (IBS), which is comprised of:

- UNMC base salary
- Specified UNMC stipends
- UNMC Physicians base salary
- Children's Specialty Physicians base salary

The benefits requested are based on UNMC's federally-negotiated fringe benefits rate agreement.

Cost sharing by UNMC is discouraged for industry-sponsored studies but may be allowed in rare exceptions with proper justification. Cost share occurs when UNMC pays a portion of the project cost instead of the sponsor.

See UNMC's Institutional Base Salary (https://wiki.unmc.edu/index.php/Institutional_Base_Salary) and Cost-Sharing Policies (https://wiki.unmc.edu/index.php/Sponsored_Project_Cost_Share).

SPAdmin may request additional internal forms, depending on the nature of the project. Examples include:

- F&A Waiver (generated automatically by the internal forms when F&A is less than UNMC's institutional rate).
- International Projects Questionnaire.

Access forms at https://www.unmc.edu/spa/forms/forms-templates/.

ii. How are internal forms accessed and submitted?

User rights are required to access the internal forms. UNeHealth assigns user rights upon request by the Department Administrator.

To learn more or access additional internal forms go to https://www.unmc.edu/spa/forms/forms-templates/. For training, call SPAdmin at 402-559-7456 or UNeHealth at 402-559-7614.

b. EFFORT REPORTING

i. What do you mean by "effort" on a sponsored project?

Per UNMC's Effort Reporting Procedure https://info.unmc.edu/media/spaccounting/effort_6105_procedure_pat_62309.pdf "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.

OMB Circular A-21 (http://www.whitehouse.gov/omb/circulars_a021_2004) requires that the salary charged to a sponsored project be certified as reasonable in relation to the effort expended on that project.

For more information, see UNMC's Effort Certification Policy #6105 at https://wiki.unmc.edu/index.php/Effort_Certification#Effort_Certification_Report_Process

ii. How is effort tracked?

Responsibilities for effort tracking and reporting are as follows:

- Investigators assign effort to all personnel on sponsored project budgets
- Investigators monitor effort for all personnel on the budget
- Investigators or delegated staff with first-hand knowledge track effort for all departmental personnel and complete Effort Certification Reports in RSS (Research Support System) on the UNMC intranet
- SPAccting administers the Effort Reporting System and initiates Effort Certification reporting

- SPAdmin verifies effort availability prior to submission of new grants and subcontracts

c. Direct Costs

i. 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.

ii. What is the relationship between fringe benefits and sponsored projects?

UNMC negotiates a Fringe Benefit Rate agreement with the federal government each year that identifies specific rates for each personnel group, such as faculty, post-docs, and staff. Fringe benefits at the appropriate rates should be included in the budget you request from the sponsor. UNMC's fringe benefit rate agreement appears on page 3 of the Current Agreement posted on https:/www.unmc.edu/spa/about/institutional/

d. Indirect Costs

i. What are indirect costs?

Indirect costs, also known as overhead or Facilities and Administrative (F&A) costs, are costs that cannot be identified specifically with a particular project or activity. Examples include administration, accounting, office supplies, equipment, postage, lighting, heating, and refrigeration.

ii. What indirect costs can I charge to the sponsor?

The F&A rate for industry-funded studies is 26 percent. This amount should be included in the budget total you request from the sponsor.

UNMC's F&A Rate Agreement is posted on the SPAdmin Web page at https://www.unmc.edu/spa/about/institutional.html.

e. Conflict of Interest

i. Could my Conflict of Interest disclosure impact the conduct of my research?

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

12. Managing Industry Awards

a. 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: https://wiki.unmc.edu/index.php/Subrecipient_Policy.

b. Changes Requiring Formal Approval by the Sponsor

i. 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.

c. 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.

d. Residual Funds

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

13. Conducting Department of Defense Research in Collaboration with the National Strategic Research Institute (NSRI)

i. What is the NSRI?

The National Strategic Research Institute (NSRI) is a partnership between the US Strategic Air Command (USSTRATCOM) and the University of Nebraska. It is the first 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:

- Nuclear detection and forensics
- Chemical and biological weapons detection
- Passive defense against weapons of mass destruction
- Consequence management

- Space, cyber, and telecommunications law

ii. If I think I have expertise in or am conducting research of interest to NSRI, who should I contact?

Contact any of the following:

Director of Government Relations: Mark Bowen
Web: https://www.unmc.edu/govtrelations
Phone: (402) 559-6669

Director of Research Resources: Paula Turpen, PhD
Web: https://www.unmc.edu/vcr/cores/support-services/
Phone: 402-559-6162

For more information:
Web: https://nsri.nebraska.edu/
Phone: (402) 559-1843

14. Conducting International and/or Export Controlled Research

a. Conducting Research Outside the United States

All research conducted at another site, including in another country, must meet all US and University of Nebraska regulatory guidelines and laws. 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. Examples of 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 research review process of the collaborating institution
- Animal research must be performed in an approved facility and the project approved through the UNMC IACUC as well as by the collaborating institution
- Intellectual property or research that may result in intellectual property may require separate New Invention Notice for the country in question
- The Department of Transportation has developed specific rules for the transport of biologic or infectious disease specimens
- The US Government has established controls on the export of strategic technologies as described further below

Additional information for International Projects can be found at:
https://www.unmc.edu/academicaffairs/compliance/areas/export/

b. Getting Started

An international project questionnaire/checklist is available to prepare researchers for international projects and travel. It must be completed if you are preparing an international project or grant and is requested for international travel.

i. What information is addressed in the International Projects Questionnaire?

The questionnaire covers 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; Business and Finance for other contracts; UNeMed for material transfer agreements.

c. Export Controls

Export controls are US government regulations that govern the export of strategic technologies, equipment, hardware, software, or provision of technical assistance to foreign persons inside or outside the United States. UNMC's policies related to export controls are here: https://wiki.unmc.edu/index.php/Export_Control.

d. Types of Activities Export Controls Apply To

- Research activities conducted outside the United States
- Shipping or hand carrying equipment, materials, or electronically transferring data to a foreign country, foreign national, or entity
- Traveling to, training, collaborating, or providing payments or items to foreign nationals/entities in a sanctioned/embargoed country
- Sharing, shipping, transmitting, or transferring encryption software in source code or object code to anyone outside the US including travel outside the US with this software
- Plans to discuss or address any of the following under a non-disclosure or confidentiality agreement with an external sponsor, vendor, collaborator, or other third party:
    - Nuclear materials, facilities
    - Material, chemicals, micro-organisms or toxins
    - Materials processing
    - Telecommunications and information security
    - Lasers and sensors
    - Navigation and avionics
    - Marine
    - Propulsion systems, space vehicles, or military (ITAR) items
    - Equipment, assemblies, and components

- Test, inspection, or production equipment
- Software
- Technology

e. Hand Carrying Items Abroad for Research

- An export license may be required when carrying research items, depending on item and destination
- Automated Export System (AES) reporting is required before departure for items valued over $2,500
- Contact the Export Control Compliance Officer prior to traveling with research items: 402-559-4518

f. Shipping Internationally

- 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 can receive Training and Certification of International Shippers by the Department of Environmental Health & Safety (https://www.unmc.edu/ehs/chemical-safety/).
- Prior to shipping internationally, contact the Export Control Compliance Officer at: 402-559-4518

g. Budget Authorizations Required for International Projects

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

h. Authorizing 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 at https://www.unemed.com.

i. Authorizing 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”. Information regarding UNMC travel policies and procedures can be found at: https://info.unmc.edu/procurement/travel/index.html*.

j. 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 lap top 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 https://www.unmc.edu/vcr/rito.

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

k. International Research Programs and Resources at UNMC

- Asia Pacific Rim Development Program, for questions regarding travel to and within China: https://www.unmc.edu/aprdp/
- 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: https://www.unmc.edu/ihme/
- Center for Global Health and Development, a College of Public Health resource focused on international public health education, research, and practice: https://www.unmc.edu/publichealth/cghad/

l. Getting Answers to Questions Regarding International Research Requirements

Contact either:

International Research Projects: SPAdmin, 402-559-7456

Export Controls: Export Control Compliance Officer, 402-559-4518

15. Conducting Human Subject Research

a. Training Required to Conduct Human Subject Research

i. Human Subject 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) Web site at https://www.citiprogram.org.

Instructions and registration for the CITI Training Program are also available through the UNMC Institutional Review Board (IRB) Web site at https://www.unmc.edu/irb/citi/.

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 at https://www.unmc.edu/cctr/education/seminars/symposium/.

Recommended training for Clinical Coordinators includes the following:

- The Clinical Research Coordinator's Workshop is available on the CCTR website: https://www.unmc.edu/cctr/education/clinicalcoordinators/. 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 Sponsored Programs Administration (SPAdmin) at 402-559-7614. 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 Web page at https://www.unmc.edu/irb/research-education/ or contact the IRB Education Coordinator at 402-559-6463.

Additional required training for Clinical Coordinators includes:

- CITI Training Good Clinical Practice Course available through the UNMC Institutional Review Board (IRB) Web site at https://www.unmc.edu/irb/citi/.
- Clinical Trials Master Matrix (CTMM) training is required for access to the secure drive where centralized Clinical Trials folders are stored. Training is provided upon request by contacting the Clinical Research Financial Compliance Specialist at 402-559-7421.
- Coverage Analysis instruction is required for clinical coordinators. Schedule training through the Finance Analyst at 402-552-6601.

  Electronic Health Record (Epic One Chart) training is required for all clinical coordinators to perform duties such as chart review, order entry, etc. Email One Chart Training Requests through Nebraska Medicine Learning Home.

b. INSTITUTIONAL REVIEW BOARD

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 at https://www.unmc.edu/irb/procedures/submission/.
- 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 Web site at https://www.unmc.edu/irb/procedures/schedule-dates/.

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 at irbora@unmc.edu or the Pediatric IRB staff at https://www.unmc.edu/irb/peds-irb/staff/.
Studies classified as exempt or expedited are reviewed either by IRB Staff or IRB members outside of a convened meeting.

i. Who are my key contacts for IRB submissions?

The Office of Regulatory Affairs (ORA) can answer questions and assist with the IRB submission process.
Web: https://www.unmc.edu/irb
Phone: 402-559-6463
Email: irbora@unmc.edu

ii. How do I know if IRB submission and approval is required?

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 #2.7 https://net.unmc.edu/rss/*.

Not all work on human specimens constitutes Human Subject Research. The NIH rules can be complex, and useful information can be found here: https://humansubjects.nih.gov/human-specimens-cell-lines-data.

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. Web: HRPP Policies and Procedures, Policy #2.7 https://net.unmc.edu/rss/*.

iii. How do I submit an IRB Application?

All IRB applications are submitted online using the Research Support System (RSS) at https://net.unmc.edu/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.
Phone: 402-559-6463
Email: irbora@unmc.edu

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 e-manual: https://net.unmc.edu/rss *

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 Web site. https://www.unmc.edu/irb/forms/miscellaneous/*

iv. Are there additional committee reviews that my research may require?

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) 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 has a fully executed contract (for industry-sponsored research) and all other reviews and the institutional requirements have been met.

v. What other documents should be submitted with the IRB application?

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. This document identifies protocol scheduled procedures and source of payment for each of the procedures. This research billing "matrix" 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?** https://www.unmc.edu/spa/clinical-trials/billing/
  - **Who do I contact to help develop my billing "matrix"?** The Clinical Research Financial Compliance Specialist will assist with completion of the matrix as well as review the matrix 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. For more information see: https://www.unmc.edu/spa/clinical-trials/billing/contact/.

vi. What do I need to know if my protocol involves 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 Web site at www.unmc.edu/irb/.

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 www.unmc.edu/irb/.

vii. Is there help available for preparation of my IRB 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 by phone 402-559-6463 or email irbora@unmc.edu.
- 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 Web site for information: https://www.unmc.edu/cctr/resources/crc/fees.html
- 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 Web site: https://www.unmc.edu/pediatrics/research/pro/

viii. 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 can be found at https://www.unmc.edu/academicaffairs/compliance/areas/.

Managing risks associated with potential conflicts of interest begins with establishing a culture of transparency. UNMC utilizes a Web-based system named **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. See section Getting started: For Investigators New to UNMC and/or New to Research.

c. DEVELOPING 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.

i. What should be considered as you are preparing the budget?

1. **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: https://www.unmc.edu/cctr/resources/crc/fees/.
- 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 Web: https://www.unmc.edu/publichealth/centers/ccorda/ or 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. See https://www.unmc.edu/cctr/resources/ehr/contact/.
- Benefit rates for each type of personnel can be found at https://www.unmc.edu/spa/about/institutional/.

2. **Study related fees**

- Salaries
  - 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.). https://wiki.unmc.edu/index.php/Clinical_Research_and_Clinical_Trial_Professional_and_Technical_Fee_Billing
  - 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 at https://www.unmc.edu/cctr/resources/pharmacy/fees-services/.
    - 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 core Web site at https://www.unmc.edu/vcr/cores/. Include costs for device calibration requirements.
    - Clinical Research Center Use. Fees for CRC facilities and staff are on the CRC Web site https://www.unmc.edu/cctr/resources/crc/fees/.
    - Shipping Expenses. If samples must be shipped in dry ice, additional shipping costs will be required.
    - Subject Stipends. IRB typically allows up to $15/hour for participation in trials, which can include recovery or travel time. This can be provided by cash 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. http://newintranet.nebraskamed.com/commandcenter/Default.aspx?c=13

3. **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 are not currently allowed in NIH grant applications.
- Indirect Costs. Current F&A rates can be found at https://www.unmc.edu/spa/about/institutional.html

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

- Your Department Administrator
- Clinical Research Center Manager, Finance Analysts, & Research Billing Senior Associate https://www.unmc.edu/cctr/resources/crc/contact/
- Sponsored Programs Administration https://www.unmc.edu/spa/about/contact/
- One Chart-Price Inquiry
- UNeHealth for industry-funded clinical research https://www.unmc.edu/spa/clinical-trials/unehealth/contact/

Completion of the Clinical Trials Master Matrix may assist you with budget preparation.

iii. What is the Clinical Trials Master Matrix (CTMM)

A research billing "matrix" must be submitted for any study that includes clinical care conducted at NEMed/NEMed-Bellevue/UNMC clinics or facilities. The matrix guides investigators through determining costs associated with a clinical trial; it matrix is stored on a secure drive and access must be requested from Clinical Research Financial Compliance at https://www.unmc.edu/spa/clinical-trials/billing/contact/.

iv. 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. http://newintranet.nebraskamed.com/commandcenter/Default.aspx?c=13

v. 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.

vi. 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 at https://www.unmc.edu/pediatrics/research/pro/.

vii. 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, 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 https://www.unmc.edu/spa/clinical-trials/billing/faqs/.

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 https://www.unmc.edu/cctr/resources/.

viii. 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.

ix. Who do I contact to perform a Coverage Analysis for clinical trials?

The Finance Analyst performs coverage analyses for drug/biologics related clinical trials. Faculty/Coordinators who have questions or would like assistance can contact the Finance Analyst at 402-552-6601 or https://www.unmc.edu/spa/clinical-trials/billing/contact/

The Compliance Senior Analyst at (402) 559-7421 performs coverage analyses for device trials.

x. Is a coverage analysis required for all industry sponsored trials?

A coverage analysis is required for all Phase I 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.

xi. Is there a fee for performing a coverage analysis?

Yes, there is a fee for coverage analyses for industry funded research. Contact the Finance Analyst for the fee amount at 402-552-6601 or https://www.unmc.edu/spa/clinical-trials/billing/contact/.

xii. 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. https://www.unmc.edu/cctr/resources/crc/contact/

d. CLINICAL RESEARCH RESOURCES

UNMC has developed many resources for clinical and translational research through the Center for Clinical and Translational Research (CCTR) https://www.unmc.edu/cctr/ as well as partnerships with other collaborators.

i. 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. CCTR resource information can be found at https://www.unmc.edu/cctr/. The CCTR managed core facilities include:

- The Clinical Research Center (CRC). The 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. Web: https://www.unmc.edu/cctr/resources/crc/

  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 multicenter 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

- The Electronic Health Record Core (EHR). The 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.

Web: https://www.unmc.edu/cctr/resources/ehr/

- The Nebraska Biobank. The Nebraska Biobank is a biorepository 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.

  Web: https://www.unmc.edu/research/biobank/

- 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

  Web: https://www.unmc.edu/vcr/policies/regulation/rsao/.

ii. Pediatric Research Office (PRO)

The Pediatric Research Office (PRO) provides infrastructure support to research activities of Pediatric faculty at the University of Nebraska Medical Center (UNMC) and Children's Hospital & Medical Center. For contact information of the PRO staff, see https://www.unmc.edu/pediatrics/research/pro/.

iii. 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 more information at https://www.unmc.edu/cctr/resources/pharmacy/.

iv. 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. See the CCORDA Web site for more complete information https://www.unmc.edu/publichealth/centers/ccorda/.

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.

v. Study Data Management Resources

1. **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 (http://project-redcap.org/).

The UNMC Research IT Office (RITO) can orient investigators in its use and hosts the REDCap database. (https://www.unmc.edu/vcr/rito/redcap/)

2. **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.

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

CCORDA can establish a research study database for any study they are collaborating on https://www.unmc.edu/publichealth/centers/ccorda/.

vi. 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- https://www.unmc.edu/cctr/resources/biobank/
- Disease specific cancer biobanks and data registries https://www.unmc.edu/cctr/resources/registries.html

e. 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).

i. What is the researcher's responsibility for data safety monitoring?

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

ii. 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 CCORDA scope of services at https://www.unmc.edu/publichealth/centers/ccorda/scope.html.

- 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 Web site at https://www.unmc.edu/cancercenter/clinical/prms.html.

f. MANAGING A CLINICAL TRIAL

i. Which studies must be registered on Clinicaltrials.gov?

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. 1) Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies; and 2) 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 (http://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf).

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.

ii. 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.

iii. 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.

iv. How is Epic One Chart used for clinical trials?

- Building a study in One Chart. 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 in One Chart. 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 is provided through the OneChart User Resource Center* (http://newintranet.nebraskamed.com/onechartusers/) at Nebraska Medicine.

v. I need an advertisement for my study, are there guidelines to what can be included?

The IRB has specific requirements for information that can be included in advertisements. See HRPP Policy #3.6 (IRB Policies and Procedures Manual, https://net.unmc.edu/rss) 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 the Organization's requirements regarding the use of logos and brands. Templates are available on the brand platform Web site "Brand Wise" from the Templates page at https://brandwise.unmc.edu/unmc/templates/.

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

vi. Where may I advertise my study on campus?

You are encouraged to post your IRB approved study on the UNMC Clinical Trials database (http://net.unmc.edu/ctsearch/index_unmc.php), a Web-based, searchable directory of UNMC based clinical trials by following the instructions

listed in the Clinical Trials Database Guide
https://www.unmc.edu/cctr/_documents/Posting2ClinicalTrialsDatabase.pdf

vii. How can I translate my study materials into Spanish or other languages?

Translation services are available through Nebraska Medicine Interpretive Services Office. Staff interpreters translate NEMed 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 at http://newintranet.nebraskamed.com/translation/*

The Center for Reducing Health Disparities offers translation services of IRB approved research related documents for a fee.
Web: https://unmc.edu/publichealth/crhd/services/translationservices.html.
Phone: 402-559-2095

Translational services are available at Children's Hospital & Medical Center.
Phone: 402-955-5427

viii. Is there any assistance or consultation available for recruiting underrepresented minorities?

The Research Branch of the Center for Reducing Health Disparities provides services to facilitate health disparities/health equity research including promotion and enrollment in research studies.
Web: https://unmc.edu/publichealth/crhd/
Phone: (402) 559-9660
Email: crhd@unmc.edu

ix. If a study requires overnight monitoring but my staff works 8:00-5:00, what are my options?

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.

g. CANCER RELATED TRIALS

The Fred & Pamela Buffett Cancer Center provides central management and oversight functions for all cancer related trials involving human subjects conducted on campus. This systematic management of cancer related trials is coordinated by the Centralized Protocol Review and Data Management Unit.

i. Are there special review requirements related to oncology studies?

Yes, all cancer related trials (adult and pediatric) must be reviewed by The Protocol Review and Monitoring System (PRMS) Scientific Review Committee (SRC). The SRC oversees the scientific aspects of cancer-related research involving human subjects conducted by members of the UNMC faculty and students and members of the Fred & Pamela Buffett Cancer Center. 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 IRB responsibilities, which focus on the protection of human subjects.

SRC approval is required before the IRB gives final release or continuation. 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 Fred & Pamela Buffett Cancer Center Web site at https://www.unmc.edu/cancercenter/clinical/prms.html.

ii. Is there data and safety monitoring support for oncology studies?

1. **Data and Safety Monitoring**

The standing Cancer Center Data and Safety Monitoring Committee (DSMC) monitors all internal toxicities and adverse events that occur on therapeutic intervention trials not monitored by an independent board specifically designed for the individual study.

Forms for data and safety monitoring are available on the Fred & Pamela Buffett Cancer Center Web site at https://www.unmc.edu/cancercenter/clinical/prms.html.

2. **Audit Reviews**

The PRMS Audit Committee audits all Fred & Pamela Buffett Cancer Center investigator-initiated, multi-center, and other externally peer-reviewed therapeutic intervention trials to ensure: 1) compliance with institutional regulatory guidelines; 2) confirmation of patient eligibility; 3) adherence to treatments; 4) appropriateness of adverse event monitoring and reporting; and 5) adequacy of patient follow-up as stipulated in the protocol.

Staff from the two clinical units; the Early Phase Therapeutic Clinical Trial Unit and Adult Hematology/Oncology Section, are available to assist researchers in all aspects of cancer related clinical trials.

For a list of all active cancer related clinical trials conducted at the Fred & Pamela Buffett Cancer Center, see https://www.unmc.edu/cancercenter/clinical/clinical-trials.html.
The site links each active trial to information on clinicaltrials.gov.

The PRMS Office also maintains an intranet Web site at https://www.unmc.edu/cancercenter/clinical/prms.html*, which provides Investigators with the most current versions of the SRC, AC, and DSMC Policies and Procedures; Conflict of Interest Policy; submission forms; and meeting dates and submission deadlines.

h. DRUG/DEVICE TRIALS

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

i. Can I store an investigational drug in my clinic?

No; all investigational drugs for human consumption must be stored and ordered through the Investigational Drug Service.

ii. My trial involves an Investigational New Drug (IND) or new indication for an approved drug; do I need the research pharmacy?

Yes, all studies using pharmaceutical agents for human administration must use the Nebraska Medicine Investigational Drug Service (Research Pharmacy).
Web: https://www.unmc.edu/cctr/resources/pharmacy/
Phone: 402-559-5255

iii. 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.

iv. 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.

v. 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).

vi. 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.

vii. 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.

viii. What is an 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 http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/investigationaldeviceexemptionide/default.htm
- Contact SPAdmin for UNMC regulations for IDE at https://www.unmc.edu/spa/clinical-trials/billing/faqs.html.

ix. 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.

x. 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.

i. OFF CAMPUS TRIALS (MULTI-CENTER, VAMC)

i. What special considerations are there as the sponsor of a multi-center trial?

- 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.

ii. Conducting Research at Veterans Affairs Facilities

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.

1. **What is the 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 at https://www.nebraska.va.gov/research/index.asp.

2. **What resources does the VA-NWIHCS have available 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.

3. **Are there funding opportunities unique to the VA?**

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.
Web: https://www.nebraska.va.gov/Research/index.asp

4. **What if my study personnel are not affiliated with the VA?**

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)

(http://www.nebraska.va.gov/services/Research/admin/credentialing/New_Personnel_Information_Form.pdf)

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) (http://www.nebraska.va.gov/services/Research/admin_home.asp)

16. Conducting Animal Research

a. Training

i. What are the 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, go to *https://info.unmc.edu/comparativemed/services/index.html.

b. Submitting an Institutional Animal Care and Use Committee (IACUC) Protocol

i. Who are my key contacts?

The Office of Regulatory Affairs (ORA) answers all questions and assists with the IACUC submission process.
Web: https://www.unmc.edu/iacuc/
Phone: 402-559-6046
Email: iacucora@unmc.edu

ii. How do I know when IACUC approval is required?

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.

iii. What forms do I complete?

1. IACUC Application of Animal Research/Testing/Training are completed on-line through the RSS 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.
   - Research Support System (RSS)

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 on the Web site at https://www.unmc.edu/iacuc/docs/addendum-to-experimental-application-breeding-procedures.doc

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. Find detailed information here https://www.unmc.edu/iacuc/education/requirements/.

iv. What are the IACUC's 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 Web page at https://www.unmc.edu/iacuc/forms/critical-points.html

c. DEVELOPING A BUDGET

i. Where do I find pricing information?

Current pricing for Comparative Medicine charges can be found on the *Comparative Medicine Pricing Web page at *https://info.unmc.edu/comparativemed/procurement/pricing/index.html.

d. ORDERING ANIMALS

i. How do I order animals for my research project?

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, "on-line" animal ordering, bar-code census, and detailed "real-time" animal care financial data. Animal orders are placed in the CMMS through the campus Web-portal, Research Support Systems (RSS) at https://net.unmc.edu/rss/.

Use your UNMC NetID or Olympus ID 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

e. ANIMAL TRANSFER

i. Can I move animals between IACUC protocols?

Yes, 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 details on the CM Web page at *https://info.unmc.edu/comparativemed/procurement/transfer/.

ii. What is UNMC’s 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 at *https://info.unmc.edu/comparativemed/procurement/quarantine-acclimation.html.

f. PROCUREMENT FROM NON-APPROVED VENDORS

i. Can I receive animals from a colleague at another university?

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 Web page *procurement of animals from non-approved

vendors at *https://info.unmc.edu/comparativemed/procurement/nonapproved-sources.html.

g. Animal 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.

Comparative Medicine (CM) operates seven animal housing and/or support facilities. For additional information, please contact Comparative Medicine.
Web: *https://info.unmc.edu/comparativemed/index.html
Phone: 402-559-4034

h. Oversight of Facilities

i. How do research personnel and the Comparative Medicine program interact and exchange ideas?

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, see the Comparative Medicine Web page at *https://info.unmc.edu/comparativemed/about/oversight.html.

17. Conducting Human Embryonic Stem Cell (hESC) Research

a. Regulations Pertaining to hESC Research

i. Who are my 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: https://www.unmc.edu/irb/sroc/
Phone: 402-559-3779

ii. When is SROC approval required?

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.

b. SROC Application and Approval Process

i. How do I get approval to use hESC lines?

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 https://www.unmc.edu/irb/sroc/forms.html.

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.

18. Conducting Research with Select Agents, Radioactivity, or Biohazards

UNMC requires training and special review for projects that involve select agents, radioactivity, or other 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 https://www.unmc.edu/ibc/policies-procedures/.

a. Submitting Research to the Institutional Biosafety Committee (IBC)

i. Who are my key contacts?

The Office of Regulatory Affairs (ORA) answers all questions and assists with the IBC submission process.
IBC Web page: https://www.unmc.edu/ibc/
Phone: 402-559-6463

ii. What is the Institutional Biosafety Committee (IBC)?

The IBC 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 (http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.htm) and the Select

Agent Rule (http://www.cdc.gov/od/sap/) drafts campus biosafety policies and procedures, and reviews individual research proposals for biosafety concerns.

b. IBC Application and Approval Process

i. What research must be reviewed and approved by the IBC?

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 anima)
- 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

Select agents, a sub-group of risk group agents regulated by the Department of Health and Human Services and/or the USDA, require special procedures for transfer and possession. Contact the Biosafety Officer for further information concerning select agents. Biosafety Officer, UNMC/UNO, 402-559-7774.

c. Environmental Health & Safety (EHS)

i. 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 and select agents.

ii. 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.

iii. 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.

iv. 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.

v. 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.

vi. 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.

vii. 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.

19. Intellectual Property and Technology Commercialization

a. The Process

i. What is 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.

ii. What is UNeMed?

UNeMed is a for-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 inventions. http://www.unemed.com/

iii. How do I work 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.

iv. 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.

v. I have an invention I want to market. 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, UNMC 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 http://www.unemed.com/services/inventions.

vi. Where do I get more information?

UNeMed answers more questions on their Web page at http://www.unemed.com/services.
There are also downloadable handbooks for researchers/inventors at http://www.unemed.com/resources.

20. Core Facilities, Research Resources, and Support Services

a. Research Policies

Policies that effect 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 relevant policies have been grouped here https://www.unmc.edu/vcr/policies/. A complete catalog of UNMC policies can be found on the UNMC Policies and Procedures Wiki (http://wiki.unmc.edu/index.php/Policies_and_Procedures)

b. Research Service Centers/Core Facilities

To assist researchers in basic, translational and clinical research, UNMC provides extensive Core Facilities on campus.

Directory of Core Facilities/Service Centers: https://www.unmc.edu/vcr/cores/

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: https://www.unmc.edu/vcr/about/centers/.

c. Research Information Technology Office (RITO)

i. 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 Bioinformatics and Systems Biology Core Facility Web site at https://unmc.edu/bsbc/.

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

d. 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 at https://www.unmc.edu/vcr/rito/data-management/.

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

e. Biostatistics, Epidemiology and Research Data Design

i. 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 page: https://www.unmc.edu/publichealth/centers/ccorda/
Phone: 402-559-6825

ii. 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. For more information about their scope of services, see https://www.unmc.edu/publichealth/centers/ccorda/scope/.

f. BIOBANKS AND REGISTRIES

i. What biobanks are available on campus?

- The Nebraska Biobank https://www.unmc.edu/cctr/resources/biobank/ is a biorepository of de-identified serum and DNA samples collected from leftover clinical laboratory specimens.
- Catalog of Disease Specific Biobanks and Registries https://www.unmc.edu/cctr/resources/registries.html
- 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 at https://www.unmc.edu/intmed/research/biobanks.html

g. 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.

i. 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.

ii. 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 (https://www.unmc.edu/ibc/forms/).
Web: https://www.unmc.edu/ibc/
Phone: 402-559-6463

iii. 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 (https://www.unmc.edu/pharmacology/research/cores/biosafety-core.html)
- 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.

iv. IV. 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.

h. BIOLOGICS PRODUCTION FACILITY (GOOD MANUFACTURING PRACTICE FACILITY)

i. 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.

For an application to use the Biologics Production Facility:
http://biologics.nebraskamed.com/facility.shtml

For more information or to take a virtual tour:
http://biologics.nebraskamed.com/virtual_floor_1.shtml

Contact the facility manager at 402-559-6009.

ii. 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.

iii. 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. To download an application online, go to
http://biologics.nebraskamed.com/applications.shtml.

i. CENTER FOR DRUG DELIVERY AND NANOMEDICINE (CDDN)

i. 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.

ii. 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.
(http://cddn.unmc.edu/template_view.cfm?PageID=69)

j. RESEARCH PHARMACY SERVICES

i. 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.

ii. How do I contact the research pharmacy?

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

iii. 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

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

Yes. Contact the Research Pharmacist at 402-955-5481

v. 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.

vi. 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 Web page at https://www.unmc.edu/cctr/resources/pharmacy/fees-services.html.

vii. How do I order pharmaceuticals for non-human consumption?

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

k. CLINICAL LABORATORY SERVICES

i. What clinical research laboratories are available?

- *The Clinical Research Center* offers some laboratory services. See https://www.unmc.edu/cctr/resources/crc/fees.html 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) Web page at https://www.unmc.edu/chri/pro/ for lab services available at Children's Hospital & Medical Center.

l. RADIOLOGIC IMAGES FOR RESEARCH STUDIES

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

Yes.

ii. 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
- Scanner Information for Research Studies
- Contact Information
- Research Conquest Form
- Instructions for Exporting and Uploading Images from the McKesson PACS System

These documents can be found at the following website: https://www.unmc.edu/cctr/resources/rad-images.html.

iii. 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." Request for De-Identification of Images https://www.unmc.edu/cctr/_documents/DeID-Form.pdf

iv. Whom 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: https://www.unmc.edu/cctr/resources/.

v. 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.

vi. 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.

m. TELEMEDICINE DEVICES AND EXPERTISE

i. What is Telemedicine?

Telemedicine includes a growing variety of applications and services using two-way video, email, smart phones, wireless tools, and other forms of telecommunications technology.

ii. What research opportunities are available in telemedicine at UNMC?

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

n. NIEDFELT NURSING RESEARCH CENTER (NNRC)

i. What is the NNRC?

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

- Facilitate research activities and development;
- Promote collaboration and mentoring;
- Enhance research resources and facilities;
- Function as a liaison with UNMC research offices.

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

o. 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).

i. 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.

ii. How do I contact the CPDMU?

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

21. Academic Department Information System (ADIS)

UNMC uses the Academic Department Information System (ADIS) for record retention of specified academic records. ADIS acts as the sole repository of these records. ADIS is a campus-wide repository, but is not NU system-wide.

Access to an academic member's information stored in ADIS is restricted to the individual member, higher-level administration, and college, unit staff who are typically allowed access to the original paper documents for processing.

ADIS is also used to collect information needed for CV's and Biosketches. Publications and extramural support are automatically loaded into ADIS and templates are available to generate both CV's and biosketches.

Access to ADIS* is available at https://edge.unmc.edu/adis/.*

For login, use: UNMC NetID and password

Abbreviations and Terms

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.

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.

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.

CIOC: 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

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

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

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

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.

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

P&T Committee: 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 two years 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.

NCT Number (ClinicalTrials.gov identifier): 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).

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

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.

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

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.

Protocol Review and Monitoring System (PRMS): 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.

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.

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

SAP: The centralized accounting system used by NU system campuses.

SPAccting: Sponsored Programs Accounting

SPAdmin: Sponsored Programs Administration

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.

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.