Sponsored Programs Administration Guidebook

This guidebook includes all of the information previously found on the UNMC SPAdmin website.

After clicking into a topic, navigation within the book or page can be found on the left side of your screen. Above the page lists your current location within the content structure. If needed you will find a search function at the top of the page which may also be used for fast navigation.

If you have any questions, please contact us at 402-559-7456 or by email at spadmin@unmc.edu

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About Us

Sponsored Programs Administration (SPAdmin) offers services to faculty and grant administrators to support their pursuit and management of external funding.

SPAdmin is the official authorized signature authority of UNMC for sponsored program grants and contracts.

CONTACT INFORMATION:
Sponsored Programs Administration
987835 Nebraska Medical Center
Academic and Research Services Building
Omaha, NE 68198-7835
Phone: 402-559-7456

Email

More details and information can be found in the pages below:

Purpose & Responsibilities

Purpose

SPAdmin's purpose is three-fold:

- To facilitate a principal investigators' pursuit and management of external funding

- To protect UNMC as an organization that is subject to the requirements of the Board of Regents; federal, state, and local agencies; and regulatory bodies

- To support UNMC's efforts to improve the health of Nebraska through premier educational programs, innovative research, the highest quality patient care, and outreach to underserved populations

Services

SPAdmin is the official authorized signature authority of UNMC for sponsored program grants and contracts. Responsibilities include:

- Assisting faculty and administrators complete external applications based on the policies and procedures of the university and sponsors

- Negotiating final terms for government and non-profit grants, contracts, and subcontracts

- Reviewing and approving budgets and applications to outside sponsors

- Establishing accounts and set up budgets for all federal, non-profit, and for-profit awarded grants and contracts based on sponsor regulation

- Processing budget revisions, no-cost extension requests, and grant transfers

- Maintaining the grant and contract database and tracking pending and funded projects

Project Management

Effective sponsored project management is a collaborative effort among:

- **Principal investigators** are responsible for leading and directing the project, intellectually and logistically.

- **Departmental administrators** are responsible for assisting principal investigators with the completion of internal and external, paper and electronic forms.

- **Sponsored Programs Administration** is responsible for reviewing and submitting applications, agreements, and modifications.

- **Sponsored Programs Accounting** is responsible for preparing and submitting to sponsors financial reports and invoices.

Sponsored Programs Administration recognizes that departmental capacity and principal investigator preference for administrative tasks vary, but in general at UNMC, departmental administrators, Sponsored Programs Administration, and Sponsored Programs Accounting focus on the administrative aspects of sponsored projects so that principal investigators can focus on the programmatic aspects.

Staff Listing & Dept Assignments

SPAdmin is under the direction of the Vice Chancellor for Research and is organized as follows:

- **Director**
  - David Doty
- **Assistant Directors**
  - Beth Decarolis (*Grants Team*)
  - Kris Morrissey (*Contracts Team*)
  - Laura Wise (*Grants Team*)
- **Grants/Contracts Specialists & Office Associates** (see below)

Staff Contact Information

Name	Title	Phone	Email
DeCarolis, CRA; Bethany (Beth)	Assistant Director	402-559-7424	email
Dejano, Sara	Grants and Contracts Specialist	402-559-2017	email
Doty, David	Director	402-559-3696	email
Dexter, Julie	Contracts Specialist	402-559-2051	email
Griebel, Michele	Grants and Contracts Specialist	402-559-3772	email
Hamel, Pamela (Pam)	Associate (part-time)	402-559-7456	email
Hoiberg, JD; Anna	Contracts Specialist	402-559-7494	email
Jaramillo, MS, CPRA; Lee	Grants and Contracts Specialist	402-559-3694	email
Lewis, JD; Helen	Grants and Contracts Specialist	402-559-7156	email
Monte De Ramos, JD; Kyle	Contracts Specialist	402-559-2175	email

Name	Title	Phone	Email
Moravec, JD; Micah	Grants and Contracts Specialist	402-559-6399	email
Morrissey, JD; Kristin (Kris)	Assistant Director	402-559-1028	email
Nathan, Cori	Grants and Contracts Specialist	402-559-7456	email
Phelps, JD; Kaia	Contracts Specialist	402-836-9118	email
Robinson, MS; Shannon	Grants and Contracts Specialist	402-559-7458	email
Sievers, JD; Christopher (Chris)	Contracts Specialist	402-836-9042	email
Stewart, Lori Ann	Office Associate II	402-559-7456	email
Wise, MPA; Laura	Assistant Director	402-559-7456	email
Zimmer, CPRA; Stephen	Grants and Contracts Specialist	402-836-9161	email

Unit/Department Assignments for Grants Team

Effective 08/12/24

Unit	Contact
Academic Affairs	Micah Moravec
Business and Finance	Sara Dejano
Child Health Research Institute	Michele Griebel
College of Allied Health Professions	Micah Moravec
College of Dentistry	Lee Jaramillo
College of Medicine (*see department below*)	
Anesthesiology	Lee Jaramillo
Biochemistry	Micah Moravec
Cellular/Integrative Physiology	Michele Griebel
Dean's Business Office	Micah Moravec
Dermatology	Sara Dejano
Emergency Medicine	Micah Moravec
Family Medicine	Michele Griebel
Genetics, Cell Biology, and Anatomy	Michele Griebel

Unit	Contact
Internal Medicine (*see division below*)	
Administration Office	Micah Moravec
Allergy	Sara Dejano
Cardiology	Sara Dejano
Diabetes, Endocrinology, and Metabolism	Helen Lewis
Gastroenterology	Lee Jaramillo
General Medicine	Lee Jaramillo
Geriatrics	Sara Dejano
Hospital Medicine	Micah Moravec
Infectious Disease	Lee Jaramillo
Nephrology	Sara Dejano
Oncology	Sara Dejano
Pulmonary	Sara Dejano
Rheumatology	Micah Moravec
Neurological Science	Helen Lewis
Neurosurgery	Helen Lewis
OB/GYN	Helen Lewis
Ophthalmology	Micah Moravec
Orthopedics	Michele Griebel
Otolaryngology	Helen Lewis
Pathology/Microbiology	Shannon Robinson
Pediatrics	Michele Griebel
Pharmacology	Michele Griebel
Physical Medicine & Rehabilitation	Helen Lewis
Psychiatry	Shannon Robinson
Radiation Oncology	Sara Dejano
Radiology	Shannon Robinson
Surgery	Helen Lewis
College of Nursing	Helen Lewis
College of Pharmacy	Sara Dejano
College of Public Health	Lee Jaramillo
Eppley Institute	Shannon Robinson
Information Technology Services	Sara Dejano

Unit	Contact
McGoogan Library	Micah Moravec
Munroe Meyer Institute	Sara Dejano
Office of the Chancellor	Michele Griebel
Vice Chancellor for Research	Michele Griebel

Institutional Information

The following table contains institutional information that is frequently requested by sponsors, including <u>F&A Rates</u> and <u>Fringe Benefit Rates</u>.

Animal Care Accreditation number Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC)	00031 Continuous since 12/15/1966 Latest letter issued 2020
Animal Welfare Assurance number Office of Laboratory Animal Welfare (OLAW)	D16-00189 (A3294-01) Effective 10/07/2020 Expires 10/31/2024
Audit information	<u>Comprehensive Annual Financial Report</u> <u>A-133 Audit of Federal Programs</u>
Authorized Institutional Official	David Doty Director, Sponsored Programs Administration 987835 Nebraska Medical Center Omaha, NE 68198-7835 402-559-7456 <u>Email</u>
CAGE code for DOD	1PPD6
Checks should be made payable to	University of Nebraska Medical Center 985100 Nebraska Medical Center Omaha, NE 68198-5100

Cognizant federal agency	U.S. Department of Health and Human Services Individual responsible for negotiating F&A rates: Theodore Foster, 214-767-3261
Congressional district	NE-002 NE-001 (for Lincoln)
Data Universal Numbering System (DUNS) number	168559177 **Being replaced with Unique Entity Identifier (UEI) G15AG3BLLMH4**
Entity Identification Number (EIN) and Federal Tax Identification Number (TIN)	470049123 1470049123A6 (for PHS/NIH)
Facilities & Administrative (F&A) rate	Current Federal agreement dated 05/09/2024 *Effective from **07/01/2024** until amended.* **53.5%** of Modified Total Direct Costs (MTDC), except - DoD Research: **54.5**% of MTDC - DoD Off campus: **27.5**% of MTDC - Industry-sponsored Research: **53.5%** of Total Direct Costs - Instruction: **38.5**% of MTDC - Other Activities: **40.0**% of MTDC - Off campus: **26.0**% of MTDC - Industry-sponsored Clinical Trials: **30.0**% of Total Direct Costs Contact SPAdmin for assistance with determining the appropriate F&A rate for your project.
Federal Interagency Committee on Education (FICE) institutional code	006895

Financial Official	Linda Combs, BSBA Manager, Sponsored Programs Accounting 985100 Nebraska Medical Center Omaha, NE 68198-5100 Phone: 402-559-5825 Fax: 402-559-3181 Email
Fringe benefits rate	Current Federal agreement dated 05/09/2024 *Effective from **07/01/2024** until amended:* - Faculty **29.9%** - House officers **24.9%** - Staff **27.7%** - Post docs **17.2%** - Graduate assistants **0.4%** - Students **3.8%** - Temp personnel **7.5%** *Sponsored projects should be budgeted using the approved rates in effect at the time of application.*
Human Subject Assurance number	FWA 00002939 (Valid through 02/14/2028)
Inflation factor recommended	Generally 3 - 4% (*if allowed by funding mechanism*)
Institutional Profile File (IPF) number	0578104
Legal name	The **Board of Regents of the University of Nebraska**, a public corporate body, acting by and on behalf of the **University of Nebraska Medical Center**
NIH salary cap	$221,900 (effective January 1, 2024)

North American Industry Classification System (NAICS) code	611310 Colleges, Universities, and Professional Schools
Nuclear Regulatory Commission (NRC) license number	01 50 01
System for Award Management (SAM) expiration date - previously Central Contractor Registry (CCR)	02/19/2025
Type of organization	State-controlled, non-profit, educational institution, exempt under Section 501(c)3
Unique Entity Identifier (UEI) - *replacing Data Universal Numbering System (DUNS) number*	G15AG3BLLMH4
USDA APHIS registration	47-R-0018 (no expiration)

Grants

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 (SPAccting).

SPAdmin Role

- Provides expertise and guidance to investigators and department personnel related to grant and contract submissions and management
- Protects the institution by monitoring for 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 personnel on the project
- Approves internal forms and applications prior to institutional signature
- Prepares awards for set-up by Sponsored Programs Accounting

Information related to each step in the grant submission, administration and close-out process can be found in the following pages:

Internal Deadlines

To reduce the risk of a proposal missing the sponsor's deadline or being withdrawn for non-responsiveness, the following internal deadlines are in effect:

- **At least two weeks before the sponsor's deadline**
  - Notify SPAdmin of your plan to submit a proposal
    - Identify sponsor and program
    - Provide a copy of the program guidelines, if they're not readily available online

- **At least three whole business days before the sponsor's deadline**
  - Provide a copy of your proposal to SPAdmin for review
    - All elements, *although the following can be in draft form*:
      - Abstract
      - Bibliography
      - Research plan
    - For electronic submissions
      - Grant access to SPAdmin
      - If access cannot be granted, then please download a copy and send to SPAdmin
    - For paper Submission
      - Send a copy to SPAdmin
      - Please wait for our approval before printing the final copy, in case any changes are needed
  - Route ADIS Internal Forms to SPAdmin for review

  For example: if your proposal must be received by the sponsor at 5:00 p.m. on Friday, then it is due to SPAdmin by 8:00 a.m. on Wednesday.

Per the Vice Chancellor for Research:

If you're submitting any of the following:

- Complex grants, such as <u>NIH Program Project/Center Grants (P series)</u>
- International collaboration
- Single IRB (sIRB) or Central IRB
- Subcontracts-out
- Voluntary cost-sharing

then:

- Notify SPAdmin *at least* **one month** *before the sponsor's deadline*
- Provide a copy and route ADIS Internal Forms *at least* **one week** *before the sponsor's deadline*

Additional Timelines:

- Your college or department's internal deadlines for preparing proposals will be earlier than SPA's
- <u>Limited submissions</u> require two-months notice in order to identify the applicant(s)
- Major projects and programs require 90-days notice in order to obtain VCR approval

Please Note:

- After you provide your proposal to SPAdmin, please remain available by telephone or email so we can communicate with you about any changes needed.
- SPAdmin's regular office hours are from 8:00 a.m. to 5:00 p.m., Monday through Friday. SPAdmin submits proposals during regular business hours.
- If UNMC is a subcontractor on another university's proposal, our external deadline may be earlier than the proposal due date. That is, our information may be due to the other university in time for its sponsored programs office to review it before proposal submission.

Frequently Asked Questions:

- ***Do "days" include weekends and holidays?***
  - No, "days" refer to business days.

- ***What time is "close of business" for SPA?***
  - If we request an item by the "close of business," then we need it before the start of business on the next business day. For example, you may email it to us after 5:00 p.m., as long as it's in our inbox when we arrive the next business morning.

- ***Can I continue to work on my research plan after the three-day mark?***
  - Yes, but please provide us with a draft of the research plan at the three-day mark so we can review for regulatory requirements.

- ***What exactly do you need when?***
  - Final version due three days before:
    - All form pages
      - SF424 RR
      - RR Performance Sites
      - RR Other Project Information
      - RR Key Persons
      - RR Budget / PHS 398 Modular Budget
      - PHS Human Subjects and Clinical Trials Information

- RR Subaward Budget Attachment
- PHS 398 Cover Page Supplement
- PHS 398 Research Plan
- PHS Assignment Request
  - Attachments, as appropriate
    - Cover letter
    - Relevance
    - Facilities & Other Resources
    - Equipment
    - Biosketches
    - Other Support
    - Budget justification(s)
    - Human Subjects and Clinical Trials Information attachments, such as
      - Inclusion of Women, Minorities, and Children
      - Recruitment and Retention Plan
      - Study Timeline
      - Protection of Human Subjects
      - single IRB Plan
      - Data and Safety Monitoring Plan
      - Overall Structure of the Study Team
      - Statistical Design and Power
    - Specific aims
    - Vertebrate Animals
    - Select Agent Research
    - Multiple PD/PI Leadership Plan
    - Consortium/Contractual Arrangements
    - Letters of Support
    - Resource Sharing Plan
    - Authentication of Key and/or Chemical Resources
- Draft due three days before; final version due on day before:
  - Abstract
  - Bibliography
  - Research plan

Pre-Award Guidelines

SPAdmin can assist you with many aspects of developing and submitting a proposal. Once you identify a funding opportunity to which you intend to apply, please notify SPAdmin so that we can prepare to answer any questions you may have, discuss any special considerations, and submit your application in a timely manner.

Funding Opportunities

A funding opportunity announcement (FOA) can take the form of a Broad Agency Announcement (BAA), program announcement (PA), PA with special referral guidelines (PAR), Request for Applications (RFA), or Request for Proposals (RFP). Generally, a FOA may be seeking PI-initiated projects ("unsolicited") or sponsored-defined projects ("solicited").

GUIDELINES

A sponsor's guidelines generally include an identifier (e.g., FOA number); due date and time; paper or electronic submission instructions; required content and format; award amount, including F&A; period of performance; and eligibility requirements. These may be program-specific or applicable to the sponsor as a whole. Care should be taken to be sure you are accessing the current version of the guidelines.

APPLICATIONS

A completed application generally is comprised of mandatory and optional forms, which are then submitted either in paper or electronically. Care should be taken to be sure you are accessing the most current version of any forms.

Types of Proposals

A sponsor can require that proposal be submitted in one or two (or more) steps. Care should be taken to be sure your proposal meets the sponsor's expectations for each step in their process so that it will be accepted.

Pre-Proposals

A sponsor may require an applicant to initiate consideration of a project via the submission of a pre-proposal. The sponsor may use the pre-proposals in order to invite full proposals only from

applicants who are evaluated to be more competitive. Alternatively, the sponsor may use the pre-proposals to provide a mechanism to all applicants to submit full proposals. A white paper can serve as a pre-proposal. A Letter of Intent allows a sponsor to gauge interests but generally does not function as a pre-proposal. Care should be taken to determine whether a pre-proposal is required or allowed.

Unsolicited Proposals

If a sponsor does not require a pre-proposal, an applicant generally is welcome to submit a full proposal without first receiving feedback from the sponsor.

Solicited Proposals

If a sponsor requires a pre-proposal, an applicant generally should submit a full proposal only after receiving feedback from the sponsor

Proposal Development and Submission

The administrative aspects of developing and submitting a proposal are listed below:

INSTITUTIONAL POLICES & PROCEDURES

SPAdmin reviews the sponsor's terms and conditions, the program guidelines, and the proposal to ensure compliance with UNMC's policies and procedures. It is important to keep in mind that a proposal must comply with both sponsor and UNMC policy. In cases in which sponsor policy is more restrictive, UNMC must manage the project carefully (e.g., if the sponsor does not allow any budget variance). In cases in which UNMC policy is more restrictive, sponsor policy does not override UNMC policy (e.g., if the sponsor allows the direct charging of facilities and administrative costs). SPAdmin welcomes discussion about differences in policy.

BUDGET DEVELOPMENT

SPAdmin encourages you to use the internal budget form to calculate your budget and transfer the information onto sponsor budget forms. The internal budget form takes into account UNMC's fringe benefits, inflation factor, and F&A rates and UNMC's Institutional Base Salary and cost-sharing policies. Care should be taken to ensure that the requested amount is sufficient to complete the proposed project and is within sponsor parameters.

ADMINISTRATIVE DATA & SPONSOR FORMS

Sponsors frequently request such institutional information as legal name, federal employer identification number, Data Universal Numbering System (DUNS) number, and federally negotiated facilities and administrative rates. This information is available on the Institutional Information page . If a sponsor asks for institutional information that is not on the on-line list, contact SPAdmin for assistance.

PROPOSAL REVIEW & CLEARANCE

SPAdmin is UNMC's official signature authority for sponsored projects. SPAdmin is responsible for verifying UNMC's eligibility and the accuracy, validity, and conformity with the most current institutional guidelines of all the administrative, fiscal, and scientific information in an application. SPAdmin's Director's ink signature on a paper application or electronic signature in an on-line system certifies that UNMC will be accountable both for the appropriate use of any funds awarded and for the performance of the grant-supported project or activities resulting from the application.

Generally, SPAdmin will submit the application on a department's behalf to the sponsor after review. A department can make arrangements with SPAdmin to submit an application. Ideally, the department will provide SPAdmin with a review copy of the complete application, but SPAdmin will accept a subset of "key components."

> **In cases in which a sponsor accepts proposals that are not signed and/or submitted by an institutional official, the department remains responsible for obtaining SPAdmin's approval before submitting.**

In addition to the application, SPAdmin requires a set of internal forms, signed by the appropriate parties. These forms provide SPAdmin with the information needed to understand your project and the documentation that your unit supports your application.

TERMS & CONDITIONS

By submitting an application to a sponsor, UNMC is certifying to the sponsor that it will comply with the terms and conditions of the grant, if awarded. SPAdmin must review a sponsor's terms and conditions prior to application submission.

SIGNATURE AUTHORITY & DELEGATION

The Director of SPAdmin is the official signature authority for sponsored project applications. If the Director is unavailable, other UNMC personnel are authorized to sign on the Director's behalf and SPAdmin will route your proposal to the appropriate signer.

DEADLINE MANAGEMENT

SPAdmin will make every effort to submit your application in a timely manner. To ensure successful submission, SPAdmin strongly encourages early actions, including:

- Notifying SPAdmin of a PI's intent to submit an application at least two weeks before the deadline
- Submitting signed internal forms to SPAdmin at least three business days before the deadline
- Providing a review copy of the application to SPAdmin at least three business days before the deadline
- Planning to submit your application
  - For electronic applications, at least one day before the deadline

- For paper applications, at least two days before the deadline

Just In Time

"Just in Time" refers to the period after application submission and peer review and before selection for funding. During this period, the sponsor may request additional information that was not required to be submitted with the application. "Just in Time" balances the sponsor's need for accurate, timely information with the desire to minimize the burden on the applicant.

Frequently required information under the "Just in Time" period include:

- Other Support
- Proof of Regulatory Compliance
  - CITI Training
  - IRB
  - IACUC
  - IBC
- Advance Accounts

Brief descriptions of each of these and what you might be required to provide are listed below.

Other Support

"Other Support" includes all financial resources available in direct support of an individual's research endeavors. It is used by the sponsor to identify and resolve potential overlaps in the science, budget, or effort. For each active and pending project, the following information should be provided:

- Project number
- PI
- Source
- Project period
- Annual direct costs
- Effort (cannot exceed 12 person months)
- Title
- Description
- Overlap (if applicable)

ADIS can be used to generate NIH-compliant "Other Support."

Proof of Regulatory Compliance

CITI Training If your project involves human subject research, personnel must be trained in the protection of human subjects. UNMC uses the web-based Collaborative IRB Training Initiative (CITI), which was developed by a consortium of ten research institutions, including UNMC. SPAdmin will provide a letter that certifies those personnel have completed CITI training, as tracked in the IRB's database. Read more about CITI Training.

IRB If your project involves human subject research, an IRB protocol must be approved and active for the project. You must provide the IRB protocol number to SPAdmin. Read more about IRB requirements.

IACUC If your project involves research using live vertebrate animals, an IACUC protocol must be approved and active for the project. At "Just in Time," SPAdmin initiates a "compare" of the application and the IACUC protocol; the IACUC office reviews both and certifies to SPAdmin that they match. You must provide the IACUC protocol number to SPAdmin in order for the "compare" to be requested.   Protocols which have been determined to "match" will be linked to the award so that animal work may be requested during the project. Read more about IACUC requirements.

IBC If your project involves research using recombinant DNA molecules or select agents, an IBC protocol must be approved and active for the project.   You must provide the IBC protocol number to SPAdmin. Read more about IBC requirements.

Advanced Accounts

A "Just in Time" request is no guarantee that an award will be made. You may want to consider establishing an advance account, if your PI has received other indications that funding is likely. Request an advance account.

Award Set-up

When a notice of award is received, SPAdmin and SPAcctng work with the department to set up the award in UNMC's sponsored program systems.

The information below will guide you through the award set-up process, unique terminology, and issues that impact award set-up.

Award Process

Types of award

How a project is categorized has ramification for administration, including application of F&A rates, WBS numbering in SAP, and institutional reporting. Awards at UNMC are generally categorized as follows:

RESEARCH (per Uniform Guidance)

Research and Development means all research activities, both basic and applied, and all development activities that are performed by non-Federal entities. The term research also includes activities involving the training of individuals in research techniques where such activities utilize the same facilities as other research and development activities and where such activities are not included in the instruction function. "Research" is defined as a systematic study directed toward fuller scientific knowledge or understanding of the subject studied. "Development" is the systematic use of knowledge and understanding gained from research directed toward the production of useful materials, devices, systems, or methods, including design and development of prototypes and processes.

INSTRUCTION (per Uniform Guidance)

Instruction means the teaching and training activities of an institution. Except for research training as provided in subsection b, this term includes all teaching and training activities, whether they are offered for credits toward a degree or certificate or on a non-credit basis, and whether they are offered through regular academic departments or separate divisions, such as a summer school division or an extension division. Also considered part of this major function are departmental research, and, where agreed to, university research.

PUBLIC SERVICE (otherwise fits UNMC's mission)

To lead the world in transforming lives to create a healthy future for all individuals and communities through premier educational programs, innovative research and extraordinary patient care.

Award Document Types

Award documents are generally categorized as follows:

- Grant: Financial assistance for the conduct of a program in which the sponsor anticipates no substantial programmatic involvement
- Cooperative agreement: Financial assistance for the conduct of a program in which the sponsor will have substantial programmatic involvement
- Contract: Mechanism for procurement of a product or service with specific obligations

How a project is categorized has ramification for administration and negotiation of terms and conditions.

Award Review

To accept external funding, UNMC must agree to the sponsor's terms and conditions for spending funds, conducting the project, and reporting on outcomes. Careful review of the sponsor's requirements is needed to ensure UNMC can meet them.

Note: Some sponsors require an applicant at the time of application to agree to accept their terms and conditions, should an award be made.

Award Acceptance

Once SPAdmin has determined that the award terms and conditions are acceptable, UNMC accepts the award, by signing an agreement and accessing funds (e.g., cashing a check).

Authorized Official

The Director of SPAdmin is the official signature authority for sponsored project agreements. If the Director is unavailable, other UNMC personnel are authorized to sign on the Director's behalf.

Documentation and notification of project requirements

UNMC uses "checklists" and "halfsheets" to communicate between offices about new projects and changes to existing projects.

Checklists are used when the award amount is being changed:

- New project set-up
- Non-competing continuations
- Supplements
- Renewals
- Closeouts with adjustments

Halfsheets are used if the award amount is not being changed:

- No-cost extension
- Rebudgeting
- Approval to charge administrative costs directly to a project
- Subcontract-out being executed
- Subcontract-out being modified
- Closeouts with no adjustments

Once SPAdmin and SPAcctng have completed award set-up or modification, departments can access the checklist and halfsheets in ADIS.

Basic Agreements

SPAdmin reviews every agreement to ensure that UNMC can comply and is protected. Agreements can be categorized broadly as follows.

Federal

Typically, UNMC receives Notices of Award (NOAs) or Notices of Grant Awards (NGAs or NOGAs) from federal sponsors, including NIH and HRSA. An NOA (or NGA or NOGA) typically provides project-specific details about funding commitments, start and end dates, and any special restrictions. It also incorporates the sponsor's grants policy by reference.

UNMC also receives Contracts/Agreements from federal sponsors, including DOD. A Contract/Agreement typically provides more specific details about applicable regulations, including Federal Acquisition Regulations (FAR) clauses.

State

The NE DHHS uses a standard template with all NU campuses.

Non-profit

Many national non-profit foundations use a standard template with universities and refer to posted policies and procedures. Some smaller organizations may issue very detailed or very brief award documents. Although many of UNMC's non-profit sponsors tend to follow the NIH's general award process, others may have unique requirements. For example, many sponsors allow UNMC to rebudget up to 25%; some sponsors limit rebudgeting to 10% or lower.

Industry

SPAdmin's Contracts team handles industry-sponsored agreements. UNeHealth handles industry sponsored Clinical Trials agreements.

Terms & Conditions

At a minimum, a sponsored project agreement should address:

- Scientific, administrative, financial, and reporting requirements
- Identification of the key personnel, with roles and responsibilities
- Compensation, including dollar ceiling, method and schedule of reimbursement, type of supporting documentation required, and timing
- Ownership and disposition of intellectual property and real property
- Applicable public policy requirements

Terms and conditions that may require negotiation are described below:

Choice of law and venue "Choice of law" refers to the legal jurisdiction while "Venue" refers to the physical location.

Indemnification refers to a guarantee to compensate another party for any loss or damage that occurs in the future.

Copyrights refers to the intellectual property right granted to an author.

Patents refers to the intellectual property right granted to an inventor.

Publications Board of Regents Policy on Ownership of Intellectual Property states that "the prompt and open dissemination of the results of research undertaken at the University of Nebraska and the free exchange of information among scholars are essential to the fulfillment of the University's obligations as an institution committed to excellence in research, education, and service."

Payment Schedules Typically, payment to UNMC by a sponsor is made:

- ○ In response to a quarterly invoice from UNMC SPAcctng office for reimbursement of actual expenses
  ○ In response to an invoice from the department based on deliverables met
  ○ On a set payment schedule

Incorporated by Reference Some agreements may not specifically state every term or condition but instead refer to other documents.

Federal Acquisition Regulations (FAR) clauses define how to do business with the federal government in a procurement environment. Link to the FAR website.

Sub-award Set-up

Once a sub-award is received and the agreement is signed by both parties, SPAdmin sets up the sub-award in the SPAdmin database. SPAdmin then sends data electronically to SPAcctng to set up accounts in SAP. When this is complete, a "checklist" (or "halfsheet") with project information is posted to ADIS for the PI and department to access.

Post Award Guidelines

Reporting Requirements

Technical

The PI is responsible for preparing the technical report. Either the PI or SPAdmin can be responsible for submitting the report, either via an electronic system and/or in paper. SPAdmin's review of a technical report is focused on whether it contains the required elements and is in the proper format; scientific content is the incumbent on the PI.

Financial

SPAcctng is responsible for preparing and submitting the financial report, via an electronic system and/or in paper, based on the information in SAP. Financial reporting and invoicing often occur simultaneously. Contact SPAccounting for questions related to post award financial compliance.

Changes

In general, UNMC is allowed some flexibility to implement a project differently than was proposed. Depending on the sponsor's guidelines and the nature of these changes, they may be made:

- At the PI's discretion
- With approval from SPAdmin
- With notification to the sponsor
- Only with approval from the sponsor

Changes are formalized as a revised Notice of Award or amendment. They may include changes to:

1. **Scope**
   It is understood that an investigator will make adjustments as new information is received throughout the project. These adjustments are often reported to a sponsor via the next progress report. Should the investigator take the project in a new direction, it may be necessary to involve the sponsor earlier.

Potential indicators of a change in scope include:
  - Change in the specific aims approved at the time of award
  - Change from the approved use of live vertebrate animals or involvement of human subjects
  - Shift of the research emphasis from one disease area to another
  - Application of a new technology
  - Adding a new subcontract or an international component
  - Change in other senior/key personnel not specifically named in the NOA

2. **Re-budgeting**

It is understood that actual costs might not equal what was anticipated on a proposal budget. Actual expenditures are reported to a sponsor via the next financial report. Should the actual costs differ significantly from what was anticipated, it may be necessary to involve the sponsor.

"Significant rebudgeting" generally refers to an expenditure in a single direct cost budget category that deviates (increases or decreases) from the categorical commitment level established for the budget period by 25 percent or more of the total costs awarded.

Sponsors may set lower thresholds or set line-item restrictions (e.g., equipment). Also, any funding restrictions contained in the funding opportunity announcement would still apply (e.g., if the FOA did not allow salaries, one could not re-budget into the salary line-item).

3. **Effort**

When a certain level of effort is stated in a proposal, either in terms of Person Months or percent effort, UNMC has made a commitment to the sponsor that that individual will spend that time on the project, either paid for by the award or cost-shared by UNMC. It is understood that month to month time may fluctuate, but the individual must spend the stated average over the project period.

Generally, we must seek prior approval by the sponsor if the PI or other key personnel will:
  - Withdraw from the project entirely
  - Be absent from the project during any continuous period of 3 months or more
  - Reduce time devoted to the project by 25 percent or more from the approved level

It is important to monitor incremental effort changes in order to engage sponsors when the threshold is crossed.

4. **Carry-forward**

Most NIH (and NIH-style) awards are funded in one-year budget periods as part of a five- (or less) year "cycle." Treatment of funds that remain at the end of each year vary by sponsor and program.

For most NIH awards ("SNAP"), UNMC has been granted "expanded authorities" to carry "forward" (or carry "over") funds from one budget period to the next, without prior agency approval. For these awards, if the amount remaining is greater than or equal to 25% of the amount awarded for that year (exclusive of any other funds), then UNMC must explain in the progress report why there is a significant balance and how those funds will be used

in the next budget period.

For some NIH awards (non-"SNAP"), UNMC must request prior agency approval to carry "forward" (or carry "over") any funds from one budget period to the next, by:
- Submitting a request that explains why there is a significant balance and how those funds will be used in the next budget period
- Reporting the balance on the financial report

Other sponsors' policies may:
- Be similar to NIH
- Be more restrictive (e.g., no movement of funds between budget years)
- Be less restrictive (e.g., no segregation of funds between budget years)

In order to manage cash flow, it is important to understand a sponsor's carry-forward policies. Some investigators may think it is prudent to conserve funds during the award, in order to have sufficient funds on hand for unforeseen emergencies or to extend the project period (see No-Cost Extension below), but they run the risk of the sponsor determining the funds are not needed and pulling them back.

5. **No Cost Extension (NCE)** For most NIH awards ("SNAP"), UNMC has been granted "expanded authorities" to extend the project end date once for up to one year in order to complete the project. To extend the end date a second time and/or beyond one year, UNMC must require approval from the sponsor.

Other sponsors' policies may:
- Be similar to NIH
- Be more restrictive (e.g., end date cannot be changed)
- Be less restrictive (e.g., end date can be changed multiple times)

Continuation

After the initial award is made, the project may continue with additional funding from the sponsor.

Non-competitive (progress report)

A sponsor may initially commit to several years of funding, contingent on satisfactory progress. Most NIH (and NIH-style) awards are funded in one-year budget periods as part of a five- (or less) year "cycle." A non-competitive continuation of the project may be triggered by the submission of a progress report. It does not have to be peer reviewed again.

Competitive (renewal)

A sponsor may consider funding a project again. Most NIH (and NIH-style) awards can be renewed. A competitive continuation of the project takes the form of a complete application. It has

to be peer reviewed again.

Award Close-Out

After the funded project is complete, UNMC must administratively close out the project with the sponsor and internally.

Technical Reporting

In general, a final technical report should include:

- Summary of progress made toward the achievement of the originally stated aims
- List of significant results (positive or negative)
- List of publications
- Report on the inclusion of study subjects (gender, minority, children)
- Description of any data, research materials (such as cell lines, DNA probes, animal models), protocols, software, or other information resulting from the research that is available to be shared with other investigators and how it may be accessed

Please see your notice of award for project- and sponsor-specific requirements, due date, and submission mode.

Financial Reporting

Sponsored Programs Accounting will work with you to reconcile the SAP account and submit the final financial report to the sponsor. In order to close the account,

- All financial activity must be recorded
- All funds due to UNMC must be received
- Any unexpended funds must be returned to the sponsor or moved to a non-sponsored account, as allowed by sponsor policy

UNMC typically has 90 days to submit the final financial report, covering activity since the last report and all cumulative activity.

Invention Reporting

If any inventions were conceived or first actually reduced to practice during the project:

- <u>UNeMed</u> must report them to the federal government via the iEdison system (if federally funded) or the sponsor's Intellectual Property office
- SPAdmin must report them to the sponsor's Grant Management office, using the:
  - HHS 568
  - DD 882
  - Other form

Auditing

After a project is completed and closed out, UNMC's reporting responsibilities continue for a period of time, including:

- Sponsored Programs Accounting including the award (if federal) on UNMC's A-133 audit
- Sponsored Programs Accounting makes the results of the audit available to sponsors (e.g., other universities that have subcontracted to UNMC)
- Sponsors can choose to examine UNMC's financial records

Record retention

UNMC must retain financial and programmatic records and supporting documents after the close of the project. Disposition schedules vary by NU and sponsor policy and by document type. UNMC's Director of Business Services serves as UNMC's records retention officer.

Subcontracts

When an investigator at UNMC is collaborating with an investigator at another organization, the organization submitting the application is considered the prime applicant. The other organization is considered a subrecipient.

If funding is awarded, the prime applicant enters into a subrecipient agreement with the other organization. In general, the funding terms and conditions that apply to the prime also apply to the subrecipient.

Subcontracts In

?When the principal investigator of the overall project is at another institution.

UNMC is considered a subrecipient if UNMC:

- Has performance measured against whether the objectives of the program are met
- Has responsibility for programmatic decision-making
- Has responsibility for adherence to applicable program compliance requirements

The other organization, as our "sponsor," generates a subaward agreement and "flows down" the terms of the prime source of funding. As a subrecipient, UNMC is entitled to Facilities and Administrative (F&A) costs and ownership of Intellectual Property.

SUB-IN: What to do at the proposal stage?

In addition to the appropriate internal forms, SPAdmin requires the following documents for UNMC's part prior to submission to the other institution:

1. Intent to Form a Consortium, to be signed by UNMC's authorized official (SPAdmin's signature signifies that we understand our obligations and authorize the other organization to submit a proposal containing commitments on UNMC's behalf)
   - The other institution's standard form, or
   - UNMC's template

2. Statement of Work

3. Budget justification

4. Copy of any other documentation the other institution requires; e.g.
   - Detailed budget
   - Biographical sketch
   - Resources page

SUB-IN: What to do at the award stage?

SPAdmin requires a subaward agreement for negotiation from the other institution that includes:

1. Statement of work
2. Detailed budget
3. CFDA number (if the source of funding is federal)
4. Documentation of terms and conditions
5. Copy of prime award

Because receipt of our subaward agreement may be delayed after issuance of the prime Notice of Award (NOA), close communication on the status of subawards is important.

Vendor Agreements

UNMC is considered a vendor if UNMC:
— Provides goods and services within normal business operations
— Provides similar goods or services to many different purchasers
— Operates in a competitive environment

These agreements are negotiated by Finance & Business Services pursuant to Policies #8009 and #6063.

Contact Business Services for information at 402-559-5221 or by email.

Subcontracts Out

?When the principal investigator of the overall project is at UNMC.

If the other organization:

- Has performance measured against whether the objectives of the program are met
- Has responsibility for programmatic decision-making
- Has responsibility for adherence to applicable program compliance requirements

then the other organization is considered a **subrecipient**, and SPAdmin will generate a subaward agreement for the other institution.

If the other organization:

- Provides goods and services within normal business operations
- Provides similar goods or services to many different purchasers
- Operates in a competitive environment

then the other organization is considered a **vendor**, and SPAdmin will **not** generate a subaward agreement for the other institution. Finance and Business Services negotiates vendor agreements.

SUB-OUT: Responsibilities

UNMC's Responsibilities

As the prime recipient, UNMC is responsible for:

- Advising subrecipients of relevant regulations and flow-down provisions from the prime agreement
- Routinely receiving and reviewing technical reports
- Routinely receiving and reviewing invoices
- Periodically performing on-site visits or making other contact, if necessary
- Reviewing A-133 audit reports filed by subrecipients (or other financial reports), any audit findings, and any corrective actions cited by subrecipients in response to audit findings Performing "audits," if necessary
- Performing examinations, if necessary
- Considering corrective action for subrecipients in cases of serious or continued inability or unwillingness to have required audits or correct non-compliant actions

Sub-Award Agreements

The subaward agreement identifies:

- Key personnel and their roles and responsibilities
- Procedures for directing and monitoring the project
- Reimbursement procedures, including dollar ceiling, method and schedule of reimbursement, type of supporting documentation required, procedures for review and approval of expenditures, and timing of applicable reporting requirements
- Policies for travel reimbursement and Financial Conflict of Interest

- Provisions for disposition of data, data sharing, and inventions and patent ownership and reporting, property (other than intellectual property), program income, publications, reporting, and audit
- Incorporation of applicable public policy requirements

SUB-OUT: What to do at the proposal stage?

In addition to the application and appropriate internal forms, SPAdmin requires the following documents for each subcontract prior to submission:

1. Intent to Form a Consortium, signed by an authorized official of the subrecipient organization. Use:
   - <u>UNMC's template</u>, or
   - <u>PHS 398 Form Page 1</u> (face page), or
   - Subrecipient's standard form, if it provides the information requested in UNMC's template, including DUNS number

2. Statement of Work

3. Detailed budget, with Facilities and Administrative (F&A) cost calculation

4. Budget justification

5. Contact information - *if not available in FDP Expanded Clearinghouse*
   - Intent to Form a Consortium may provide this information, or complete:
   - <u>FDP Attachment 3</u>

SUB-OUT: What to do at the award stage?

SPAdmin will generate a subaward agreement based on:

- Terms of the prime award
- Subrecipient risk assessment
- Information previously provided
  - Statement of work
  - Detailed budget

Subrecipient Policy

Per UNMC Policy #6108:

"As a condition of its acceptance of funding from sponsors, UNMC is obligated in its role as primary recipient to undertake certain stewardship activities as well as to comply with federal, state and local regulations. When UNMC assigns responsibility for conducting a portion of the work sponsored by an award to a subrecipient, UNMC remains responsible to the sponsor for both the management of funds and the meeting of performance goals"

Note: This policy does excludes agreements for vendors (covered in UNMC Policy #6063), including items such as consulting services or purchase orders for equipment, materials or other services.

Industry Contracts

SPAdmin negotiates a wide range of research-related agreements on behalf of UNMC faculty-investigators and is a resource to help determine who can best support your contracting needs.

SPAdmin Negotiation Process

When a contract is initiated, either the PI or the sponsor contacts SPA to begin the negotiation process. The contract process works in parallel. SPA is responsible for negotiating the contract language. While SPA negotiates the language, PIs negotiate the budget and, if applicable, begin the regulatory approval process.

See Also: UNeHealth (for industry-sponsored clinical trials)

Roles & Responsibilities

As soon as you determine interest in a particular project or study, be sure to contact your department administrator, clinical coordinator if applicable, and the SPAdmin Coordinator. They are familiar with the research infrastructure and administrative requirements and can help you get off to a good start. Roles and responsibilities are as follows:

Principal Investigators

- Lead and direct all aspects of the project
- Recruit personnel and collaborators
- Negotiate budget with the sponsor (or assign to departmental staff)
- Arrange for lab space and equipment
- Obtain regulatory approvals prior to initiating project
- Ensure the integrity and timeliness of information provided to SPAdmin
- Verify that Conflict of Interest disclosures are current
- Communicate with staff who generate your internal forms for institutional approval
- Sign internal forms

Departmental Staff (Administrators and Coordinators if applicable)

- Assist investigators with project or study start-up activities, which may include negotiating budgets, submitting regulatory applications and 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 (

  http://wiki.unmc.edu/index.php?title=Principles_of_Financial_Stewardship)
- Generate internal forms for signature
- Interface with SPAdmin, sponsors, and regulatory bodies

SPAdmin Personnel

- Negotiate agreements and amendments to protect institutional and investigator interests and to ensure compliance with sponsor and institutional requirements
- Attached finalized study budget provided by investigator to contract prior to contract signature

- Review Conflict of Interest disclosures for personnel on the project
- Review and approve internal forms prior to institutional signature
- Interface with regulatory bodies
- Prepare and finalize awards for set-up

SPAccting Personnel

- Set up awards in SAP
- Monitor revenue, cost share, and expenditures for allowability
- Invoice sponsors for cost reimbursable or fixed price amounts
- Prepare and submit financial reports to sponsors
- Reconcile and lock SAP WBS

Industry Sponsored Clinical Research

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

Depending on the type of contract, research, or sponsor, the following will be handled by Sponsored Programs Administration (SPAdmin) or UNeHealth (in the case of industry-sponsored clinical trials).

Submit a New Contract

Submit your request to <u>Amanda Leingang</u>, Contracts/office Associate with the following documents:

1. Final scope of work (protocol)
2. Editable contract template
3. SPAdmin/UNeHealth questionnaire

Your email communication with the sponsor may also provide valuable information to SPAdmin/UNeHealth that helps ensure timely negotiation.

Who Negotiates

A SPAdmin/UNeHealth contract negotiator will review and negotiate your contract. New contracts are parked in a queue and available to all until a negotiator is able to start the review.

Projects involving intellectual property development may require specialized contract terms that are best negotiated by UNeMed, the for-profit arm of the university that provides intellectual property protection and commercialization services for inventions. If SPAdmin/UNeHealth determines your contract is a better fit for UNeMed, SPAdmin/UNeHealth will transfer the agreement to them and keep you informed.

Who Signs

Industry-sponsored clinical research contracts are signed by the sponsor and an authorized institutional signatory. The investigator also signs but only as having read and acknowledged the contract terms. SPAdmin/UNeHealth coordinates the signature process.

How Long

SPAdmin/UNeHealth strives to execute contracts within 75 days of receiving the required documents from the department. Some take less time; some more. Variables that impact timelines include volume of contracts under review, sponsor responsiveness, terms requiring negotiation, and whether UNMC has an institutional master agreement with the sponsor.

Next Steps

SPAdmin/UNeHealth sets up the WBS as soon as the contract is fully-executed, the IRB is released, financial conflicts of interest are managed, and internal forms are fully-approved. SPAdmin/UNeHealth monitors each process to completion, then bundles the award and notifies the investigator and department administrator when the WBS account is set up.

SPAdmin/UNeHealth also handles WBS account set-up for contracts negotiated by UneMed. However, UNeMed stays involved for the life of the project. Click here to view the UNeMed site.

Industry-Sponsored Non-Clinical Research

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

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

> **NOTE: SPA negotiates non-clinical agreements**

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

> **NOTE: With the exception of Phase I-V Clinical Trials, SPA negotiates these agreements**

Your Role

To initiate the negotiation process, submit these documents to SPA contracting:

- A Protocol or Scope of Work
- An editable Word version of the sponsor's contract template
- A completed SPAdmin Contract Questionnaire

Contract negotiations begin **after** SPA receives all three components.

SPA's Role

SPA negotiates the terms and conditions of your contract with the sponsor's legal representatives. Our negotiation standards balance the need to protect our investigators and institution with maintaining long-term relationships with our sponsors.

Who Signs

SPA coordinates the signature process for industry sponsored agreements. Typically, the sponsor and an authorized institutional signatory (e.g., SPA Director) sign industry-sponsored research contracts. On occasion investigators may be asked to sign that they have "Read and Acknowledged" the terms of the agreement.

Strategies to Avoid Delays

SPA offers these tips to minimize time to contracts:

- Determine if the study is a "right fit" before moving forward
  - Consider availability of staff, space, time, $
- If study is complex, consider meeting with SPA early in the process
  - e.g. multiple sites
- If you have concerns, communicate them to us via phone, email or one-on-one
  - Some studies are creating first-time experiences for the PI, coordinators, and SPA
- Understand your role and responsibility in the contracting process
- Become familiar with SPA process
  - SPA uses first-come, first-serve and prioritization *with some exception*
  - SPA consults with multiple UNMC offices
    - Compliance Office
    - Legal Counsel
    - IRB
    - Risk Management
    - More…
- If you have several contracts under negotiation, prioritize the order in which they should be negotiated and let SPA staff know
- If you change your mind about a study and no longer want to participate, remember SPA staff also need to know
  - This action maximizes limited resources
- Prepare COI Disclosures and regulatory documents (e.g., IRB) in parallel with SPA's contract negotiation
- Consider copying SPA on your email communication with the sponsor as your email may offer valuable information to SPA in contract negotiations

Confidential Disclosure Agreements (CDAs or NDAs)

Confidential Disclosure Agreements – also known as Non-disclosure Agreements, CDAs or NDAs – protect confidential information shared between a sponsor and investigator as they determine mutual interest in working together. The information may belong to the investigator or the sponsor and the agreement may bind one party or both.

Depending on the type of contract, research, or sponsor, these agreements will be prepared by Sponsored Programs Administration (SPAdmin) or UNeHealth (in the case of industry-sponsored clinical trials).

Submit a New CDA

Forward the email from the sponsor with the CDA template attached to Amanda Leingang, Contracts/Office Associate. If the sponsor does not provide a template, SPAdmin/UNeHealth is glad to generate the agreement at your request. If sharing proprietary information with a potential sponsor for a PI-initiated project, executing a CDA prior to information sharing is highly recommended.

Who Signs

CDAs are between the institution and the sponsor and must be signed by an authorized institutional signatory.

Investigators are not authorized to sign, nor is it in their best interest to do so. Prior to institutional signature, SPAdmin/UNeHealth negotiates the CDA terms to protect the interests of the investigator while also meeting the needs of the sponsor.

Next Steps

After the CDA is signed by both parties, SPAdmin/UNeHealth will forward you the fully-executed agreement and the sponsor will send you the protocol for review.

Other Contract Types

In addition to negotiating industry-sponsored research agreements, SPAdmin negotiates many other types of agreements as a service to faculty investigators. If SPAdmin isn't authorized to handle a particular agreement, we can direct you to someone who is.

A list of common contracts and primary contacts for each can be found below. The list is not exhaustive, so please contact SPAdmin at 402-559-7456 or by email if the agreement you need is not listed.

Amendment to Contract Negotiated by SPAdmin

An amendment is an agreement signed by both parties to accept changes to an earlier agreement. Changes may pertain to:

- Change in investigator (required for all agreement types)
- Scope of work
- Terms and conditions
- Period dates or extension of project
- Costs (addition or removal of funds)
- Change in payment schedule

Contact: SPAdmin

Business Associate Agreements

Business Associate Agreements are required when a covered entity such as UNMC shares protected health information (PHI) with an external entity that perform a business service for UNMC but has no research interest. Examples may include data extraction or telehealth services. A business associate may be an academic partner providing a business service, or it may be industry partner. Always, they are external to the covered entity that owns the data.

- Contact SPAdmin if PHI sharing is directly related to a funded research project (402-559-7456 or email)

- Contact Procurement if PHI sharing is tied to a vendor agreement (Procurement Director, Jeff Elliott, at 402-559-9688 or <u>email</u>)

Consulting Agreements

Consulting Agreements are entered into when a UNMC faculty member agrees to lend his/her expertise to an outside entity for a fee. Consulting agreements fall into two categories:

- **University consulting agreements** are reviewed by SPAdmin and executed between the university and sponsor when UNMC resources are used to support the work and UNMC receives funds that are placed in the investigator's development account. Contact SPAdmin to submit a university consulting agreement (402-559-7456 or <u>email</u>)
- **Personal consulting agreements** are reviewed by the investigator and executed between the investigator and sponsor when UNMC resources are *not* used to support the work and UNMC does *not* receive payment. Prior to signing, the investigator is encouraged to submit the contract to UNeMed for review. NOTE: Personal consulting agreements **cannot** pertain to human subject research in any way. Contact <u>UNeMed</u> for a personal consulting agreement.

Additional Requirements: Consulting agreements often create conflict of interest concerns and may necessitate a conflict management plan. All consulting agreements trigger a need for the investigator to submit an Outside Employment Form to Compliance and to disclose the activity in COI-SMART within 60 days of performing the work.

Cooperative Group Agreements

Cooperative Group Agreements are most often federally funded and mirror grants in that the key purpose is **public good vs. commercial profit**. They are essentially an "assistance" mechanism in which the institution receives limited funds to perform work in which the sponsor is substantially involved. Such involvement often means the investigator can expect federal programmatic collaboration or participation in carrying out the effort.

 Contact: SPAdmin Associate, 402-559-7456 or <u>email</u>

Data Use Agreements

 Contact: SPAdmin Associate, 402-559-7456 or <u>email</u>

Master Agreements

Master Agreements include terms and conditions that apply broadly to multiple studies by a given sponsor. They may be institution-wide or specific to an investigator who plans to conduct a series of projects with that sponsor. Masters have no funding but become part of subsequent work orders, each of which receives funding for a specific protocol or scope of work.

Significant time is required to arrive at terms that broadly apply across numerous projects, but work orders that flow under them are expedited and therefore an excellent way to reduce contract timelines. Click her for a list of institutional master clinical trial agreements. If a study is PI-initiated and/or the master does not sufficiently address intellectual property concerns for a given study, a stand-alone agreement may be executed instead of a work order.

Contact: UNeHealth Coordinator, 402-559-7614 or email

Material Transfer Agreements or MTAs

A material transfer agreement is required when transferring drug for patient-oriented research or human samples or biologic material for research purposes.

- Contact SPAdmin (402-559-7456 or email) for transfer of drug; or
- Contact UNeMed (Jeff Anderson or 402-559-3274 or email) for transfer of human samples or biologic material.

SBIRs and STTRs

Small Business Innovation Research (SBIR) and Small Business Technology Transfer Program STTR) projects are typically backed by federal funding and are therefore managed by the SPA grant team. Contact your grant specialist for more information.

Tech Transfer

UNeMed provides intellectual property protection and commercialization services for inventions developed at the University of Nebraska Medical Center. When a sponsored project is likely to lead to significant discoveries involving intellectual property UNeMed negotiates the contract and partners with SPAdmin to manage the award. Click here to transfer to the UNeMed website.

Vendor Agreements

UNMC Procurement manages and signs vendor agreements that may be needed to support your project. Click here to transfer to the Sapphire portal.

Clinical Trials

Information relevant to clinical trials can be found on the pages within this section. While SPAdmin is involved in parts of these projects, the majority of the effort is handled by UNeHealth and the CRC's clinical research billing team.

UNeHealth (Industry-Sponsored Clinical Trials)

UNeHealth is the contracting and fiscal arm for industry-funded clinical trials on behalf of University of Nebraska Medical Center. It is housed under Center for Clinical and Translational Research (CCTR), operating under the direction of Dr. Christopher Kratochvil, Chief Medical Officer for UNeHealth and Associate Vice Chancellor for Clinical Research.

Clinical Research Billing

The Clinical Trial Master Matrix (CTTM) is a tool that is used to record basic information about a clinical trial along with protocol specific scheduling of research related procedures/treatments and details on how these procedures/treatments will be billed. A CTTM or "Matrix" must be completed for any study that includes clinical care activities conducted at Nebraska Medicine, UNMC, or UNMC-Physicians clinics or facilities irrespective of funding. Information on the Matrix and UNMC's policy for Clinical Trial Billing (#8008) can be found on the UNMC policy wiki.

UNeHealth

UNeHealth is the contracting and fiscal arm for industry-funded clinical trials on behalf of University of Nebraska Medical Center. It is housed under Center for Clinical and Translational Research (CCTR), operating under the direction of Dr. Christopher Kratochvil, Chief Medical Officer for UNeHealth and Associate Vice Chancellor for Clinical Research.

Which Contracts Run Through UNeHealth

UNeHealth contracts include:

- CDAs (non-disclosure agreements)
- Clinical trial agreements involving investigational drugs or devices
- Master clinical trial agreements
- Compassionate use agreements
- Emergency use agreements
- PI-initiated clinical trial agreements
- Material transfer of drug related to patient-oriented research or compassionate use

Submit a New Contract

All new clinical trial submissions are to be submitted through the CRC.
Instructions for submission can be found on their Intake Form page.

The following documents will be required by UNeHealth to begin negotiation:

- Editable contract template from sponsor
- Protocol

Your email communication with the sponsor may also provide valuable information to UNeHealth to help ensure timely negotiation.

UNeHealth Information for Sponsors (Tax ID, etc)

Sponsors typically require information from sites for the purpose of setting up contract templates, vendor payment systems, etc. In most cases, they request this information from clinical coordinators, so it is important for coordinators to understand that the information for UNeHealth contracts is different than for UNMC contracts. Please share UNeHealth information for the following when working with an industry sponsor:

- CDAs (non-disclosure agreements)
- Clinical trial agreements involving investigational drugs or devices
- Master clinical trial agreements
- Compassionate use agreements
- Emergency use agreements
- PI-initiated clinical trial agreements
- Material transfer of drug related to patient-oriented research or compassionate use

Exceptions: All new master clinical trial agreements will be through UNeHealth, but existing UNMC masters are still in use until they can be converted.

UNeHealth Information	
Parties to Agreement	UNeHealth and Board of Regents, acting by and behalf of the University of Nebraska Medical Center
Indirect Rate	30% (From UNMC's Negotiated Rate for Industry-Sponsored Clinical Trials)
Fringe Benefit Rate	Standard UNMC Rates
Legal Name	UNeHealth
Organization Type	Non-profit ancillary organization of the University of Nebraska formed by UNMC, authorized by the Board of Regents
Payee	UNeHealth

UNeHealth Information	
Payee Type	UNeHealth is the fiscal arm of the University of Nebraska Medical Center for the conduct of clinical trials
Financial Official Payment Address	Linda Combs, BSBA Accounting Manager 985090 Nebraska Medical Center Omaha, NE 68198-5090 Phone: 402-559-5825 email: lvondras@unmc.edu or Craig Poole (cpoole@unmc.edu)
EIN/Federal Tax ID	47-0771713
W-9	UNeHealth W9 (Effective 1/1/22) Contact UNeHealth Contract Associate
Contracting Address	UNeHealth Attn: Chris Kratochvil, MD 985331 Nebraska Medical Center Omaha, NE 68198-5331 Phone: 402-559-7614 email: unehealthdist@unmc.edu
Human Subject Assurance Number	FWA 00002939
NPI Number	1790042786

Clinical Research Billing

Clinical Trial Master Matrix

The Clinical Trial Master Matrix (CTTM) is a tool that is used to record basic information about a clinical trial along with protocol specific scheduling of research related procedures/treatments and details on how these procedures/treatments will be billed. A CTTM or "Matrix" must be completed for any study that includes clinical care activities conducted at Nebraska Medicine, UNMC, or UNMC-Physicians clinics or facilities irrespective of funding. Information on the Matrix and UNMC's policy for Clinical Trial Billing (#8008) can be found on the UNMC policy wiki.

Coverage Analysis

Coverage Analysis uses the Matrix to verify what is conventional "standard" care as opposed to research only costs to identify what can or cannot be billed to a third party payer (either private insurance or Medicare). The Coverage Analysis process also compares the Matrix, Informed Consent Document (ICD), and preliminary budget to ensure that all costs are covered, thereby assuring that the study budgets reflect the true cost of research.

When is a Matrix and/or Coverage Analysis Required?

Any study that includes clinical care activities conducted at Nebraska Medicine/UNMC/UNMC-Physicians clinics or facilities regardless of the funding source or lack of funding source. Examples may include but are not limited to:

- Federal, state, foundation, external hospital, or university funding
- Research that may or may not have funding provided
  - Investigator initiated
  - Consortium
  - Cooperative group
  - Collaborative group
- Commercially funded clinical research
- CCTR Pilot Grant Fund

Research that *DOES NOT* Require a CTMM and CA

Any study that does not include clinical care activities or has no potential to create a bill for technical fees and/or professional fees for Nebraska Medicine/UNMC/ UNMC-Physicians clinics or

facilities. Examples may include but are not limited to:

- Retrospective studies that evaluate events that have already occurred including studies that rely exclusively on previously collected administrative records, medical data or other available data
- Laboratory analysis studies utilizing residual human tissue samples or human tissue samples obtained from another entity (non-clinical bio-banked materials)
- Studies conducted at sites other than Nebraska Medicine/UNMC/UNMC-Physicians clinics or facilities
- Observational studies
- Survey studies

When and How to Submit Documents

- Materials should be submitted prior to IRB submission
  - IRB will not issue approval without:
    - a reviewed copy of the Clinical Trial Master Matrix **and**
    - a completed Coverage Analysis report **or**
    - a completed CTMM/CA Determination Checklist stating that the study does not require CTMM or CA
  - Documents should be submitted in electronic format via e-mail to:
    - Clinical Research Financial Compliance Specialist (Grace Videtich)
    - Clinical Trials Business Analyst (Katie Penas)

Policies

Administration of sponsored programs requires compliance with applicable UNMC and sponsor policies.

The order of precedence is as follows:

- Award terms & conditions
- Program guidelines
- Sponsor/Agency terms & conditions
- Uniform Guidance

Plus any applicable state or institutional regulations.

Questions or concerns about conduct that may violate UNMC policies and procedures or any law or regulation may be shared with the Institutional Compliance Office.

UNMC-specific Policies

A partial listing of frequently referenced policies related to grants and contracts administration are described below. A complete catalog of UNMC policies can be found on the UNMC Policies & Procedures Wiki.

Conflict of Interest	***Policy #8010*** UNMC identifies, manages, and if necessary, reduces potential conflicts of interest to maintain the public's trust in UNMC's teaching, research, patient care, and service mission.
Contracts	***Policy #8009*** The Board of Regents delegates the administrative authority to approve and execute certain types of university contracts.
Sponsored Project Cost Share	***Policy #6104*** Cost share committed on sponsored projects is to be limited to the minimum amount necessary to meet sponsors' requirements.
Sponsored Programs Costing	***Policy #6100*** Direct costs must be reasonable, allocable, allowable, and treated consistently in budgeting and expending.
Effort Certification	***Policy #6105*** UNMC uses the Effort Certification Report as its method of documenting employee effort performed on sponsored projects.
Export Control	***Policy #8005*** Export controls, set forth in regulations administered by several federal agencies, impose access, dissemination, and participation restrictions on the transfer and retransfer of "controlled" information and on the export and re-export of tangible items.
Institutional Base Salary	***Policy #6102*** UNMC's Institutional Base Salary (IBS) represents combined salary from UNMC and its affiliate practice plans, UNMC Physicians and Nebraska Pediatric Practice.
Outside Employment	***Policy #1049*** UNMC employees may be employed by other external organizations, provided such activities do not interfere with their regular duties at UNMC or create a conflict of interest.
SBIR & STTR Program Participation	***Policy #3002*** UNMC encourages the commercialization of applied research by faculty and staff and supports collaboration between its entrepreneurial researchers and outside companies.

Service Centers	**Policy #6107** Service centers can result in charges to sponsored projects. Billing rates should be designed to recover the direct operating costs of providing the goods/services on an annual basis, excluding all unallowable costs.
Subrecipient	**Policy #6108** When UNMC subcontracts part of an award to another organization, UNMC remains fully responsible to the sponsor for the entire award.
Cost Transfer	**Policy #6106** Although it is preferable to charge costs to the correct account when they are incurred, cost transfers may occasionally be necessary and must be properly documented and processed within a reasonable time.

One Chart Compliance with 21 CFR Part 11

The electronic medical records are maintained within the One Chart powered by EPIC System which is installed and operated by Nebraska Medicine. This system is run as a closed system as defined by 21 CFR 11.10. Download the 21 CFR 11 compliance document.

Nebraska Medicine Policies

Policies for our hospital partner can be found here (select "Go to keyword search" and type "Research" locate research-specific policies).

Sponsor-specific Policies

Federal	
Uniform Guidance	Effective December 26, 2014 the Office of Management and Budget combined eight circulars into the single "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards."

Sponsor	
NIH Grants Policy Statement	The National Institutes of Health Grants Policy Statement is intended to make available to NIH grantees, in a single document, the policy requirements that serve as the terms and conditions of NIH grant awards.
HHS Grants Policy Statement	The Department of Health and Human Services Grants Policy Statement is intended to make available, in a single document, the general terms and conditions of HHS discretionary grant and cooperative agreement awards.
NSF Award and Administration Guide	The Award and Administration Guide sets forth National Science Foundation policies regarding the award and administration of grants and cooperative agreements.

F&A Rates Policy

UNMC Facilities and Administration (F&A) Rates

(formerly known as Indirect Cost Rates)

The full recovery of F&A costs (up to the level allowed by the sponsor's written policy) is expected on all grants and contracts.

Current F&A Rates & Agreement

Definitions

TDC (Total Direct Cost): All costs that can be specifically identified with a particular project and can be assigned to that project with a high degree of accuracy.

MTDC (Modified Total Direct Costs):

- 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)
- Excludes equipment (defined as having a useful life of over one year and an acquisition cost of $5,000 or more per unit), capital expenditures, charges for patient care and tuition remission, rental costs, scholarships and fellowships, as well as the portion of each subgrant and subcontract in excess of $25,000

F&A is charged on either a TDC or MTDC basis.

F&A Waivers are considered on a case-by-case basis by the Vice Chancellor for Research. Download the F&A Waiver Form.

Use of Embryonic Stem Cells

In accordance with all Federal Guidelines, the University of Nebraska and Board of Regents policy, the Scientific Research Oversight Committee (SROC) must review and approve all research using hESC lines and **ONLY** lines from the NIH Human Embryonic Stem Cell Registry are allowed. Cell lines which are not on this registry are not allowed to be used for NU System research. The NIH Registration Number for a proposed stem cell line must be cited on your application for hESC use when submitting your application to the SROC.

More information about these procedures can be found in the SROC chapter of the IRB Guidebook.

NDAA Whistleblower Notice

Pilot Program for Enhancement of Employee Whistleblower Protections

In order to encourage employees to report fraud, waste, and abuse in federally-funded programs, the National Defense Authorization Act for Fiscal Year 2013 established a pilot program for enhancing contractor employee whistleblower protections. These protections extend to all individuals working in federally-funded programs, including sponsored research.

As an employee of the University of Nebraska working on a federally-sponsored research project, you are entitled to the rights and remedies provided by the pilot program. Specifically, the University of Nebraska is prohibited from discharging, demoting, or otherwise discriminating against you as a reprisal for whistleblowing. These protections cannot be waived by any agreement, policy, form, or condition of employment.

Whistleblowing is defined as disclosing information that you reasonably believe is evidence of any of the following:

- Gross mismanagement of a federal contract or grant;
- Gross waste of federal funds;
- Abuse of authority relating to a federal contract or grant;
- A substantial and specific danger to public health or safety; or
- A violation of law, rule, or regulation related to a federal contract or grant (including the competition for, or negotiation of, a contract or grant).

In order to qualify for whistleblower protection under the pilot program, your disclosure must be made to one of the following persons or entities:

- A member of Congress or a representative of a congressional committee;
- An Inspector General that has oversight over contracts awarded for, or on behalf of, the federal agency concerned in the contract or grant;
- The Government Accountability Office;
- A federal employee responsible for contract or grant oversight or management at the relevant agency;
- An authorized official of the Department of Justice or other law enforcement agency;
- A court or grand jury; or
- A management official or other employee of the contractor, subcontractor, grantee, or subgrantee who has the responsibility to investigate, discover, or address misconduct.

If you believe that you have been discharged, demoted, or otherwise discriminated against as a reprisal for whistleblowing related to a federal contract or grant, you may submit a complaint to the Inspector General of the agency concerned.   Procedures for making disclosures can be found on the Office of the Inspector General's Whistleblower Hotline (http://www.oig.doc.gov/pages/hotline.aspx). Keep in mind that you cannot file a complaint more than three years after the date on which the alleged reprisal took place.

You may also contact the UNMC Chief Compliance Officer at (402)559-6767 or report your concern through the UNMC Compliance Hotline at 1-(866) 568-5430.

More information may be found at:

http://uscode.house.gov/view.xhtml?req=(title:41%20section:4712%20edition:prelim)

NIH Data Management & Sharing Policy

The National Institutes of Health (NIH) announced a new data management & sharing (DMS) policy to foster good data stewardship. This page includes information and resources for UNMC researchers to help them prepare, create, and submit a DMS Plan with their NIH applications, including:

- an overview on the new policy and to whom it applies
- information about data types and repositories
- UNMC-specific tools, templates, and resources for writing and submitting your DMS Plan and budget with your NIH application
- a list of frequently asked questions, as well as recorded webinars and other resources

Since January 25, 2023, the policy requires that all application types (new, resubmission, renewal, and revision) that generate Scientific Data, regardless of funding level, include a detailed plan for how the data will be managed and shared during the entire funding period.

NOTE: The new DMS Policy does not apply to funded NIH projects that do not generate scientific data, such as applications for Training (Ts), Fellowships (Fs), Construction (C06), Resources (Gs), etc.

> **For each of the categories below, click the arrow to expand the content.**

Overview: What's New?

The National Institutes of Health (NIH) has issued a new Data Management and Sharing Policy (DMS Policy) starting January 25, 2023.

The new policy requires a Data Management and Sharing Plan (DMS Plan) for ALL NIH-funded projects that generate scientific data. Previously, the NIH only required a DMS Plan for projects over $500,000. This policy places proper data management and reusability of data at the center of research practices so that we can all advance scientific findings and support the integrity of those findings. This policy helps researchers use best practices in data management and sharing to facilitate the shift to open science and open data.

The NIH has also created a website dedicated to <u>Scientific Data Sharing</u>, but these pages on the SPA website aim to provide UNMC-specific information for our researchers while also summarizing the information from the NIH. Below, we include upcoming and recorded webinars (given by UNMC, NIH, or others), as well as provide links to other resources.

Types of Data

There are two "large bucket" categories of data that most researchers work with on a regular basis: quantitative and qualitative data.

In the biomedical sciences, <u>quantitative data</u> is used to provide measurements, calculate change over time, and generally used in raw data gathering. This raw data can then be used as the basis of statistical analyses.

<u>Qualitative data</u> is often thought of as social sciences data because many researchers in the social sciences use surveys and oral responses—in other words, natural language—as the basis of analyses. However, researchers in the sciences often use these same techniques when describing a particular set of data or when mapping data geographically.

Both types of data are used in the sciences, and both can be used as the basis for <u>primary data</u> and <u>secondary data</u>.

Quantitative Data

When using a variable that can be counted, measured, and given a numerical value, it is considered a type of quantitative data. Quantitative variables can answer the "how" questions: "how many," "how much," or "how often."

Many researchers will also call quantitative data "numerical," because of its capacity to measure and thus bridge empirical observation with mathematical expression. Because of the relationship between observation and mathematical expression, a researcher uses statistical analyses in experiments to find significant differences that can be replicated using similar methods.

There are two main types of quantitative or numerical data: discrete and continuous.

Discrete data is usually defined as a type of data that can be counted. These data cannot be made more precise, and so they involve integers, or numbers that cannot be made divisible. A classic example of a discrete data type would be a member of a family: you cannot have 1.3 or 4.2 children in a family. Another example might be how many doctor visits one may have in a year.

Continuous data can be divisible into smaller parts using decimal points. Continuous data, when graphed, create a distribution of values on a continuum. A classic example of continuous data is a person's height.

Both discrete and continuous quantitative data use measures of central tendency (mean, median, mode) and dispersion (Standard Deviation, standard error, Interquartile Range) to measure results. Which measurement a researcher chooses to use is based on the type of data on which a hypothesis is tested.

Qualitative Data

Qualitative data is defined as variable categories using verbal groupings rather than numbers. Many people tend to confuse qualitative research with qualitative data: qualitative research is the method of collecting data from first-hand observations, interviews, or questionnaires that researchers use to study society using unstructured or semi-structured techniques like those mentioned above. Data is qualitative when the variables in a data set are verbal rather than numerical.

Qualitative data is also called "categorical" data, or data that can be placed into organized categories.

There are two main types of qualitative or categorical data: nominal and ordinal.

> **Nominal data** variables have two or more categories that have "names" and no inherent order to them. For example, gender is a nominal category (female, nonbinary, male). When a variable only has two possible categories, it is called binary or dichotomous data. For example, asking if someone has a driver's license (yes/ no).

> **Ordinal data** can be places in categories with a clear order or hierarchy. For example, education level has a clear hierarchy ("high school," Bachelor's," "Master's," "PhD").

When analyzing qualitative data, a researcher will use frequency distribution in the form of a pie chart (nominal data), column, or bar chart (nominal or ordinal data).

Primary Data

Primary and secondary data have less to do with the variables used in data analyses and more to do with who generates the data that a researcher uses for analyses.

Primary data is data generated by the researcher for the primary use of the researcher. At a future time, this primary data may transform into secondary data when uploaded into a repository for use by others. Primary data is data used and collected in the moment and is used in current experiments. Because it is up to the researcher/ researcher's team to collect data, the process takes time and is very involved.

Primary data is largely available in its raw form; thus, it has not been processed or refined. But, because it has not been processed or refined, it is more accurate and reliable.

Secondary Data

Secondary data is usually defined as data that someone else has collected. This can come from large healthcare organizations, the government, or other large organizations. It can be used after the fact of collection. Thus, it is data that has already been used in earlier experiments.

Researchers can find such data in internal healthcare systems, data repositories, either specific to one's field of research or in a more generalist repository, or as part of a publication.

Choosing a Repository

What is a data repository?

A data repository is a type "of sustainable information infrastructure which produces long-term storage and access to research data" (re3data.org). A data repository provides long-term storage and searchability of data used in scientific research.

Why use a data repository?

The NIH mandates the writing of a data management and sharing plan as of January 25, 2023 for all grant applications. Beyond NIH's DMS Policy plan mandate, a data repository ensures accessibility and encourages reuse of data beyond the life of a grant or a single research project.

How to choose a data repository?

Choosing a data repository can depend on the research type, the grant type, or the data type. There are two main types of data repositories: "discipline-specific" and "generalist" repositories.

Discipline-specific repositories should be given primary consideration, since they will allow for optimal discovery and reuse. The NIH has compiled a list of scientific data repositories for making data available, which is organized by discipline. The NIH DMS Policy does not endorse

or require the use of a data repository affiliated with the NIH.

If no discipline-specific repository exists, it is appropriate to choose a generalist repository.

Discipline-Specific Repositories:

You can find a searchable table of NIH-supported, discipline-specific data repositories here:

https://sharing.nih.gov/data-management-and-sharing-policy/sharing-scientific-data/repositories-for-sharing-scientific-data

You can find a registry of research data repositories here:
https://www.re3data.org/

Generalist Repositories:

UNMC is recommending the use of several generalist repositories, including

- Dataverse
- Dryad
- figshare
- Zenodo

More generalist repositories may be recommended by UNMC later, or you can choose another one that suits your needs.

Writing Your Plan (DMPTool)

The NIH has provided a sample Data Management and Sharing Plan format page that you may use to assist in preparing the document. You can also see the format page with example responses here.

The NIH recommends that the Data Management and Sharing Plan document, which should be in a narrative format, is not more than two pages in length.

Your DMSP must include information pertaining to:
- Data Type
- Related Tools, Software, and/ or Code
- Data Preservation, Access, and Associated Timelines
- Access Distribution, or Reuse Considerations

- [Oversight of Data Management and Sharing](#)

You can find detailed definitions of each of these components on the [NIH's Grant Guide](#) or learn about these elements and see UNMC-specific examples [here](#).

To draft your plan, UNMC requires that you use [DMPTool](#), an online Data Management Plan builder that uses the 2023 NIH template to quickly guide you through the process. UNMC's Sponsored Programs Administration office expects investigators to use this tool to develop their DMS Plans.

DMPTool Frequently Asked Questions

We will continue to gather answers to new questions and update this page. For general questions about data sharing, go to the [Frequently Asked Questions](#) section below.

How do I ensure that the summary text provided by DMPTool to guide me through the writing process does not appear on my downloaded data management and sharing plan?

When you are about the download your data management and sharing plan, under download settings, the "question text" box is automatically selected. Unselect that box. That de-selection ensures that the summary text provided by DMPTool is not downloaded with your plan. See the [Using DMPTool](#) section below for further customization of your data management and sharing plan.

Can I get feedback on my data management and sharing plan before turning it in with my application?

Yes. Use the Request Feedback option in DMPTool. You can also email researchdata@unmc.edu directly. Please allow a 48-business hour turnaround time for a full review.

I have PIs from other universities as well as my own university who are a part of my grant. Can they access the draft data management and sharing plan on DMPTool?

Yes. After "Project Details," there is a "Collaborators" tab. Click on that tab. You will see two titles: "Project Contributors" and "DMP Collaborators." You will need to add the Principal Investigators to BOTH Project Contributors AND DMP Collaborators. After adding PIs to "DMP Collaborators," you can "Invite collaborators" via email and give them permission to comment on the data management and sharing plan. They will receive an email from DMPTool notifying them that they've been added to your data management and sharing plan.

Can I add references, hyperlinks, or URLs to my data management and sharing plan?

> No. NIH policy explicitly prohibits the use of hyperlinks in any grant application materials, and the new data management and sharing plain is no exception. The NIH may withdraw your application from consideration if you include hyperlinks.
>
> Please see the NIH's policy on hyperlinks here:
>
> https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-174.html

Using DMPTool

To draft the DMS Plan for your NIH applications, UNMC requires that you use <u>DMPTool</u> (log in with UNMC credentials), an online Data Management Plan builder, where you can use NIH 2023 template to guide you through the process. See the information below on how to <u>access and begin using this tool</u>, as well as how to <u>download your DMS Plan from DMPTool</u> once it is ready.

Why use DMPTool to write your data management and sharing plan?

- DMPTool (<u>https://dmptool.org/</u>) allows for deeper engagement and reflection on your collected data:
  - The Tool has built-in, customized commentary from the NIH, DMPTool, and UNMC
  - Commentary is built by NIH's Office of Data Science, the California Digital Library, and UNMC data professionals.
- You can "Request Feedback" with a push of a button
  - The "Request Feedback" tab allows UNMC's data professionals to review the plan and make comments for improving the Plan.
- Using DMPTool helps UNMC make decisions about investing in further data management and curation of our research data
  - UNMC will be better informed and situated to find gaps in researcher knowledge, types of data used on campus, and build momentum for a more fully fleshed-out data management infrastructure.
- A group of researchers and librarians from across the country are in the process of evaluating the grant-writing burden and are using resources like DMPTool in the hopes of lightening the burden on research requirements in the future.

How to Access the DMPTool

Follow along with <u>the video recording</u> or use these step-by-step instructions on how to access the DMPTool and start a plan:

1. Go to DMPTool's website at: <u>https://dmptool.org/</u>
2. On the right-hand side of the screen, there is a **Sign in/Sign up** section
3. Enter your UNMC email address for access
4. Press **Continue**
5. The screen will automatically recognize your email address and ask if you want to sign in through the UNMC system
6. Press **Okay**
7. Enter your UNMC credentials
8. Once signed in, you will see **My Dashboard**, which displays the data management plans that you have written using DMPTool
9. To create a new plan, click **Create Plan** in the lower left-hand side of the screen
10. Enter the title of you research project
11. If not automatically entered, select **University of Nebraska Medical Center (unmc.edu)** as your primary research organization
12. Begin to type **NIH** into **Select the primary funding organization**
13. Click on **National Institutes of Health (nih.gov)**
14. You will then be prompted to choose a template
15. Choose **NIH-GEN DMSP (2023)** from the drop-down menu.
16. Click **Create plan**

How to Download your DMS Plan from DMPTool

Follow along with <u>the video recording</u> or use these step-by-step instructions on how to download your data management and sharing plan:

1. Click on the **Download** tab at the far-right header.
2. You will see options for **Format**, **Download Settings**, and **PDF Formatting**.
3. DMPTool Automatically defaults to PDF Download; however, you can also download as a Word Doc, A Text File, a JSON file, or a CSV by choosing the file format option in the Format drop-down menu.
4. If you choose the default **PDF Format**:
   1. Focus on the four options for **download settings**.
   2. There are two automatically checked options, **"section headings"** and **"question text"**:
   3. **Un-check the "question text" option**.
      - When you un-check the **"question text"** option, you will not get the extra DMPTool summaries for each element. This helps to keep your

DMPTool to the appropriate length without the directions, examples, or summaries from DMPTool.

4. Choose the appropriate font type (sans-serif), size of the font (11-point), and margins according to the NIH guidelines.
5. Click the **Download Plan** button at the bottom of the page.

5. If you choose **docx format** (downloaded as a Word document):
   1. You will only have the four **download settings**
   2. There are two automatically checked options, **"section headings"** and **"question text"**:
   3. **Un-check the "question text" option**.
      - When you un-check the **"question text"** option, you will not get the extra DMPTool summaries for each element. This helps to keep your DMPTool to the appropriate length without the directions, examples, or summaries from DMPTool.
   4. Click **Download Plan** at the bottom of the page. Your document will download as a Word document, where you can make further changes to the font type, font size, margins, and further add or revise the document.
   5. When you are ready for upload, save your Word document as a PDF for upload with your application using the "Save As" under File in Word.

DMS Plan Elements

The NIH is requiring this information in a narrative form, which can be easily created via the UNMC-required DMPTool (https://dmptool.org/).

Here is the expected information as part of the six elements for the two-page DMSP to be uploaded as with the application submission (see the Submitting Your DMS Plan section below).

Element 1: Data Type

A. Types and amount of scientific data expected to be generated in the project:

From the NIH:
Summarize the types and estimated amount of scientific data expected to be generated in the project.

For example:
"This project will produce sequencing, transcriptomic, and epigenetic data generated from 10x snRNAseq. Data will be collected from 100 patients, generating approximately 350 datasets. Estimated size of data is about 10,000 gigabytes (Gb). Data file types include: comma separated values (CSVs), fastq sequencing files, and R code (R)."

B. Scientific data that will be preserved and shared, and the rationale for doing so:

From the NIH:
Describe which scientific data from the project will be preserved and shared and provide the rationale for this decision.

For example:
"Raw sequencing files, validated data, processed data collected from raw sequencing files, and the code used to process files will be preserved and shared. Research participants and family member identities will be de-identified using masking techniques. Only de-identified individual data will be made available."

C. Metadata, other relevant data, and associated documentation:

From the NIH:
Briefly list the metadata, other relevant data, and any associated documentation (e.g., study protocols and data collection instruments) that will be made accessible to facilitate interpretation of the scientific data.

For example:
"README files, code, clinical metadata in the form of persistent unique identifiers, biospecimen metadata such as specimen IDs, and assay metadata such as valid barcode reads will be shared to help interpret the data."

Element 2: Related Tools, Software and/or Code

From the NIH:
State whether specialized tools, software, and/or code are needed to access or manipulate shared scientific data, and if so, provide the name(s) of the needed tool(s) and software and specify how they can be accessed.

For example:
"Raw sequencing files in fastq format will be made available and may need specialized

programs to be manipulated. Metadata and processed sequencing data is available in comma separated format (.csv files) and do not need specialized tools to access or manipulate."

Element 3: Standards

From the NIH:
State what common data standards will be applied to the scientific data and associated metadata to enable interoperability of datasets and resources, and provide the name(s) of the data standards that will be applied and describe how these data standards will be applied to the scientific data generated by the research proposed in this project. If applicable, indicate that no consensus standards exist.

For example:
"FAIR Data sharing protocols will be applied, so that data is Findable, Accessible, Interoperable, and Re-usable. Sequencing data will be structures and described using the following standards: 1) Description of the biological system, samples, and variables studied, 2) Sequence read data of each assay, 3) Final processed data for the set of assays, 4) General information about the experiment and sample-data relationships, and 5) Metadata appropriate to the datasets so that they can be linked."

Element 4: Data Preservation, Access, and Associated Timelines

A. Repository where scientific data and metadata will be archived:

From the NIH:
Provide the name of the repository(ies) where scientific data and metadata arising from the project will be archived; see Selecting a Data Repository).

For example:
"All sharable datasets will be deposited int eh National Institute on Aging Genetics of Alzheimer's Disease Data Storage (NIAGADS) repository"

B. How scientific data will be findable and identifiable:

From the NIH:
Describe how the scientific data will be findable and identifiable, i.e., via a persistent unique identifier or other standard indexing tools.

For example:
"The NIAGADS repository proves metadata, persistent identifiers (DOIs), and long-term access."

C. When and how long the scientific data will be made available:

From the NIH:
Describe when the scientific data will be made available to other users (i.e., no later than time of an associated publication or end of the performance period, whichever comes first) and for how long data will be available.

For example:
"The data will be made available as soon as possible or at the start of the publication process, whichever comes first."

Element 5: Access, Distribution, or Reuse Considerations

A. Factors affecting subsequent access, distribution, or reuse of scientific data:

From the NIH:
NIH expects that in drafting Plans, researchers maximize the appropriate sharing of scientific data. Describe and justify any applicable factors or data use limitations affecting subsequent access, distribution, or reuse of scientific data related to informed consent, privacy and confidentiality protections, and any other considerations that may limit the extent of data sharing. See Frequently Asked Questions for examples of justifiable reasons for limiting sharing of data.

For example:
"Following all federal, Tribal and state laws, all data from donors that do not allow for sharing will be excluded from shared datasets. Most participants allow for sharing for study of neurodegenerative diseases, with some allowing for sharing only for academic research use. Those allowing for partial sharing will be shared with NIAGADS with the conditions specified in the consent documentation."

B. Whether access to scientific data will be controlled:

From the NIH:
State whether access to the scientific data will be controlled (i.e., made available by a data

repository only after approval).

For example:
"All data will be shared in the controlled access data repository, NIAGADS. The access to this repository is limited to qualified investigators with a legitimate research interest, and is approved by an independent committee of researchers (the Data Use Committee) designated by NIAGADS."

C. Protections for privacy, rights, and confidentiality of human research participants:

From the NIH:
If generating scientific data derived from humans, describe how the privacy, rights, and confidentiality of human research participants will be protected (e.g., through de-identification, Certificates of Confidentiality, and other protective measures).

For example:
"IRB documentation and informed consent documents will include language describing plans for data management and sharing data, describing the motivation for sharing, and explaining that personal identifying information will be removed. To protect participant and family member privacy and confidentiality, shared data will be de-identified according to all federal and state guidelines and following the safe-harbor method. Only the minimum of PHI will be collected for the purposes of the study, and all team members are HIPAA trained."

Element 6: Oversight of Data Management and Sharing

From the NIH:
Describe how compliance with this Plan will be monitored and managed, frequency of oversight, and by whom at your institution (e.g., titles, roles).

For example:
"The following individual, XXXX, will ultimately be responsible for data collection, management, storage, retention, and dissemination of project data, including updating and revising the Data Management and Sharing Plan when necessary, and will report on data sharing and compliance in the annual project progress reports. This person is the Principal Investigator of the project, an Associate Professor of XXXX at UNMC. His email is xxxxx@unmc.edu. This other person is Research Project Coordinator in Dr. XXXX's lab, will also maintain the Data Management and Sharing Plan, and coordinate permissions with data repositories."

Example DMS Plans

Using the UNMC-approved DMPTool to generate DMS Plans, we provide examples below of different versions of DMS plans to fit various needs based on discipline and research type. More example plans may be added over time.

Example plans created by DMPTool

- Qualitative Data
- Genomics Data
- Basic Science Data
- Clinical Trial Data

Example plans in NIH format (provided by Babu Guda)

- Example 1 - Collecting genomic/phenotypic/clinical data from human subjects
- Example 2 - Collecting clinical and MRI/fMRI data from human subjects
- Example 3 - Collecting gene expression data from human or non-human subjects

Example plans from NIH

The NIH has created example DMS plans for different contexts, including:

- Clinical and/or MRI data from human research participants
- Genomic data from human research participants
- Genomic data from a non-human source
- Secondary data analysis
- Human genomic data
- Technology development
- Human clinical and genomics data
- Non-human (zebrafish) data

Since these may be updated frequently, we recommend that you visit their website to see the latest plans that have been provided.

Budgeting for DMS

Each application for research funding should include a budget for data management and sharing. This budget should be included as part of your overall budget for the project on either:

- the **R & R Detailed Budget Form** under "F. Other Direct Costs" or
- the **PHS 398 Modular Budget Form** under "Additional Narrative Justification."

Please see the NIH's Budgeting for Data Management and Sharing webpage here

https://sharing.nih.gov/data-management-and-sharing-policy/planning-and-budgeting-for-data-management-and-sharing/budgeting-for-data-management-sharing#after for links to the forms, information on allowable costs, and how the budget will be assessed.

UNMC Budget Worksheet

The following budget worksheet has been created for UNMC researchers to estimate data management and sharing costs. This worksheet shows how to estimate a budget, showing each broad category of the data management and sharing lifecycle, how many hours to project for each activity based on the size of the grant request, and the justification for inclusion into a budget.

Because not all researchers will need to budget for every item on this list, a cost calculator is forthcoming. This cost calculator will help researchers customize a data management and sharing budget for individual project proposals.

Please note that **all activity hours are estimates**; we underscore that a researcher's individual project may require more or fewer hours over the lifespan of the project. Also note that a research project may or may not contain data management for every item on this list. For instance, not every project will need image management, in which case a researcher not using image data would be expected to omit that item from that project's overall budget.

Download the Budget Worksheet (PDF)

Submitting Your DMS Plan

Starting January 25, 2023 and thereafter, the NIH requires applicants to use the FORMS-H application package, which is a new, updated application package that incorporates the new DMS Policy requirements.

This new FORMS-H application package should be used for:

- Applications submitted for due dates on or after January 25, 2023
- All application types (New, Resubmission, Renewal, Revision)
- Applications submitted early for intended due dates on or after January 25, 2023

The major changes to the FORMS-H application show two new additions for submitting the plan and budget items, as described in the following sections:

DMS Plan (narrative created with DMPTool)

After creating your DMP Plan narrative using the DMPTool, you will attach it under the "Other Plans" section of the appropriate PHS 398, which may be different depending on the type of application:

- **For most applications**: this should be attached under "11. Other Plans" in the PHS 398 Research Plan
- **For career development award applications**: this should be attached under "17. Other Plans" in the PHS 398 Career Development Award Supplemental Form sections

For more details, see the highlighted sections in the annotated forms for the Research Plan or Career Development Award Supp Form.

DMS Budget (costs & justification)

You will use the R&R Budget Form to add budget items pertaining to the Data Management and Sharing Plan in two places:

- **Costs** - add a "Data Managment and Sharing Costs" line item within section "F. Other Direct Costs"
- **Justification** - add a "Data Managment and Sharing Justification" section to your full budget justification document and upload within the usual section, "L. Budget Justification"

See the highlighted sections in the annotated form for the R&R Budget Form.

DMS Budget Guide

UNMC is working to develop a budgeting guide along with a "menu" of DMS costs that can be used by investigators and administrators as you develop your DMS budget. This website will be updated with this content once it is developed.

Note: Failure to include a budget for DMS costs may result in your project not having sufficient funds to meet the guidelines laid out in the NIH's DMS Policy and/or your specific management and sharing needs as described in your DMS Plan. It is better to budget for something (and potentially have the NIH cut things back) rather than not budget at all.

Webinars & Resources

While the NIH rolls out their new DMS Policy, additional information is being provided via webinars (hosted by UNMC and the NIH) and through the variety of other resources included below.

Past UNMC-Specific Webinars

UNMC held several webinars leading up to the policy start date in January 2023, and continued to hold additional webinars to provide updates on guidance. Click on the title of each webinar to view the recorded video.

NIH DMSP Update and Budget Guidance (May 2023)

Choosing a Repository for Scientific Data (January 2023)

Writing a Data Management & Sharing Plan with DMPTool (January 2023)

Open Forum: The NIH Data Management and Sharing Policy Explained (January 2023)

NIH DMS Policy Overview & Workshop (December 2022)

NIH Data Management and Sharing Introduction (August 2022)

Past NIH-Hosted Webinars

At this time, the NIH has hosted two webinars covering the new DMS Policy. Recordings of these are included below, but additional information including slide decks can be found on their DMS Learning page.

Understanding the New NIH Data Management and Sharing (DMS) Policy
This NIH webinar was held in August 2022.

Diving Deeper into the new NIH Data Management and Sharing Policy
This NIH webinar was held in September 2022.

Other Resources

UNMC-Focused Resources for DMS

- **This SPA DMS page and its <u>FAQ section below</u>** - Includes UNMC-focused answers based on NIH guidance
- **<u>McGoogan Health Sciences Library</u>** - Includes support and consultation on Data Management Plans
- **<u>DMPTool</u>** - UNMC-required platform that provides customized templates to construct DMS Plans
- **<u>Research IT Office</u>** - Their Research Data Management pages provide general tips and tools for all types of data management, not necessarily specific to the new NIH DMS Policy.

External Guides and Recommendations

- <u>AAU/APLU Guide to Accelerate Public Access to Research Data</u>
- <u>COGR/ARL NIH Data Management and Sharing Readiness Guide</u>
- <u>Wilkinson et al. The FAIR Guiding Principles for scientific data management and stewardship</u>

Applicable NIH Policies (Effective Jan 25, 2023)

- <u>NIH-OD-21-013</u> – Final NIH Policy for Data Management and Sharing
- <u>NOT-OD-21-014</u> – Supplement: Elements of an NIH Data Management and Sharing Plan
- <u>NOT-OD-21-015</u> – Supplement: Allowable Costs for Data Management and Sharing
- <u>NOT-OD-21-016</u> – Supplement: Selecting a Repository for Data Resulting from NIH-Supported Research
- <u>NOT-OD-22-131</u> – Request for Public Comments on DRAFT Supplemental Information to the NIH Policy for Data Management and Sharing: Protecting Privacy When Sharing Human Research Participant Data
- <u>NOT-OD-22-189</u> – Implementation Details for the NIH Data Management and Sharing Policy
- <u>NOT-OD-22-195</u> – New NIH "FORMS-H" Grant Application Forms and Instructions

Federal Agency Policy References and Reports

- <u>NIH Data Sharing Policy</u>
- <u>NIH Data Management and Sharing Activities Related to Public Access and Open Science</u>

- [Informed Consent for Research with Data and Biospecimens](#)
- [Selecting a Repository for Data Resulting from NIH-Supported Research](#)
- [2021 OSTP Public Access Congressional Report](#)

If you are aware of other DMS resources that may be helpful to UNMC researchers, please reach out to researchdata@unmc.edu to share.

Frequently Asked Questions

General questions and answers about the new DMS Policy that may not be covered on other pages, as well as questions pertaining to UNMC-specific elements and procedures are included below. We will continue to gather answers to new questions and update this page. Review the section above titled [Writing Your Plan (DMPTool)](#) for specific questions about DMPTool.

Many additional questions specific to the NIH policy have been compiled and disseminated by the NIH and can be found on their [DMSP FAQ page](#).

Where can I get help at UNMC for the NIH Data Management and Sharing Policy?

Several groups on campus will play a role in assuring UNMC and its researchers are ready to meet these new policy changes. Please direct any questions you have to researchdata@unmc.edu.

Alternatively, set up a consultation with UNMC's Data Services Librarian using the [bookings page](#) through the McGoogan Health Sciences Library.

Who is checking my data management and sharing plan?

The UNMC Sponsored Programs Office will check for presence of a plan within your application. They will not review your plan's quality or confirm that all plan parts are present for your type of research. For a thorough review of your plan, please contact researchdata@umnc.edu.

Am I expected to share all data generated during my research?

No. Under the DMS Policy, researchers are expected to maximize the appropriate sharing of scientific data, which is defined as data commonly accepted in the scientific community as being of sufficient quality to validate and replicate the research findings.

How does the DMS Policy fit in with other NIH data sharing policies and requirements (e.g., individual NIH Institute/Center or Office (ICO) funding

polices, the NIH Genomic Data Sharing (GDS) Policy, the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information)?

> The DMS Policy establishes the foundation for NIH's data management and sharing expectations, which NIH ICOs and programs may build upon to meet their programmatic needs (e.g., designated repositories, specific data collection standards). Current NIH policies specific to certain types of research (e.g., clinical trials, research generating large-scale genomic data) continue to apply and complement the goals of the new DMS Policy.

If researchers are reusing existing, shared data to generate new datasets, are they expected to reshare the primary data they incorporated into their new analysis? Are the derived data generated considered scientific data and expected to be shared?

> The DMS Policy applies to research that results in the generation of scientific data.? Scientific data can result from secondary research, but researchers are not expected to share the existing, shared primary data used to conduct the secondary research. Researchers are, however, expected to maximize appropriate sharing of any new, derived data generated as a result of their research.

Does the DMS Policy apply to social and behavioral scientific research? Can qualitative data be "scientific data"?

> Yes, NIH-supported social and behavioral scientific research that results in the generation of scientific data are subject to the DMS Policy. Qualitative data may constitute scientific data if it meets the definition in the DMS Policy.

What steps does the DMS Policy take to ensure institutions and researchers protect research participants?

> Award recipients must comply with any applicable laws, regulations, statutes, guidance, or institutional policies related to research with human participants and that protect participants' privacy.

Does the DMS Policy expect that research informed consent obtained from research participants must allow for broad sharing and the future use of data (either with or without identifiable private information)?

> No. Informed consent for participation in research remains the cornerstone of trust between researchers and research participants and thus the DMS Policy does not dictate how this process is achieved. Rather, researchers' intention for scientific data management and sharing, as proactively described in Plans, is strongly encouraged to be part of the informed consent process. The DMS Policy does not expect that informed consent given by participants will be obtained in any particular way.

How will noncompliance with the NIH DMS Policy be handled?

NIH will monitor compliance with Plans over the course of the funding period during regular reporting intervals (e.g., at the time of annual Research Performance Progress Reports (RPPRs)). Noncompliance with Plans may result in the NIH ICO adding special Terms and Conditions of Award or terminating the award. If award recipients are not compliant with Plans at the end of the award, noncompliance may be factored into future funding decisions.

What is a data or metadata standard?

The National Center for Data Services describes metadata as "information that describes, explains, locates, classifies, contextualizes, or documents an information resource." In the context of data management, metadata allows you to track the provenance, or original source of a dataset, and help you to track which version of the data you are analyzing. Describing data in a machine-readable format allows you to search for data in a repository.

How will data management plans be assessed?

The evaluation of DMS Plans will be conducted by the agency, with input from the Contracting Officer's Representative (COR) and other NIH subject matter experts as part of the proposal evaluation process.

Are projects establishing repositories or creating data infrastructure subject to the DMS Policy (i.e., establishing a data coordinating center with no research question proposed)?

No. Projects that?only?develop or support infrastructure resources (e.g., repository or knowledgebase establishment) and do not generate findings or scientific data are not subject to the DMS Policy. However, NIH recommends that the infrastructure developed with NIH resources comport with the desired characteristics for repositories (see "Selecting a Repository for Data Resulting from NIH-Supported Research").

How should we handle situations where there are proprietary considerations about confidential data or intellectual property?

The NIH covered this briefly as part of a webinar, which can be found during this section of their recording. For more information specific to your situation, we would recommend you reach out to researchdata@unmc.edu.

How granular does the stored data have to be? Most of the time data are reduced from original capture to make it more manageable. Should it be original data or reduced data?

You should be storing all data, both raw and processed. The data management and sharing plan will ask where you plan to store data 1) during the lifetime of the project and 2) after the grant has ended. You will need to have a plan for storage during and beyond

the life of the project. Thus, storing is only the first component. Secondly, you'll need to think about preservation of the data. Where will this data live after the project is over? This is where data repositories—and finding and appropriate data repository in the grant application phase—is of the utmost importance. Thirdly, you'll be asked about your data sharing plan. Do you plan to share the raw and processed data, or just the processed data? It is up to you to ask what "manageable" means for your project. That being said, the policy is about making your data replicable and reusable by other researchers, so if the data that you usually share is reduced data, then can another researcher re-use that data and replicate the results adequately? If not, then you may need to think about sharing the raw and reduced data. If so, then you are sharing the data adequately.

How are we addressing patent implications? My reading of the policy is that when the grant ends, data needs to be available.

If there are patent implications for an invention, we recommend reaching out to UNeMed at the point at which you are writing your data management and sharing policy. In terms of general intellectual property, PIs own rights in data resulting from sponsored projects.? Sponsored projects are not works for hire, and thus the sponsor does not own the data.

Data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health.? Sponsors generally endorses the sharing of final research data.? One exception is personal health information.

Have agencies other than the NIH also mandated data management/sharing plans, and will these work via the same DMP tool we now have?

Yes. Almost every grant-funding agency—both federal and private—in the country is either in the process of developing a data management and sharing policy or has one in place. All grant-funding agencies have templates uploaded in to DMPTool. Simply choose the appropriate funding agency when creating a DMPTool data management and sharing policy and use the subsequent template.

How long should data be shared beyond the term of the NIH-funded grant? Can this be budgeted into the cost of Data Management and Sharing?

Data should be shared for at least 3-5 years after the award period. However, most repositories share data in perpetuity. Data repositories do not charge for ongoing storage of your data. Once the data is uploaded to the repository, a repository will not ask for further monetary assistance. Should you find a data repository that is asking for more funding after upload of data, please reach out to <u>researchdata@unmc.edu</u>.

Do K99/R00 grants require a plan?

No. At this time, the NIH is not requiring training grants to include a data management and sharing plan, because the DMSP is only required for the collection of scientific data.

However, the NIH has made it clear that this exception may change in the near future.

Are there repositories for qualitative (narrative transcripts) data?

Absolutely. There are discipline-specific repositories (found on re3data.org) and generalist repositories (listed in the above section titled Choosing a Repository). You can also reach out to researchdata@unmc.edu for a consultation on qualitative data repositories.

Contact Information

Several groups on campus will play a role in assuring UNMC and its researchers are ready to meet these new policy changes. Please direct any questions you have to researchdata@unmc.edu.

Consultations

Set up a consultation with UNMC's Data Services Librarian using the bookings page through the McGoogan Health Sciences Library.

Forms, Templates, and Electronic Systems

Internal forms are a means for providing needed information to SPAdmin and SPAcctng and for documenting decision-making for the file.

To ensure a sponsored project is handled correctly by SPAdmin, departmental administrators are asked to complete internal forms as accurately and completely as possible and submit them for processing in advance of deadlines.

If you have any questions or concerns with a form, please contact SPAdmin for assistance.

INTERNAL DEADLINES

To reduce the risk of a proposal missing the sponsor's deadline or being withdrawn for non-responsiveness, the following internal deadlines are in effect:

1) Departments notify SPAdmin of their plan to submit a proposal **at least two weeks before the sponsor's deadline**.

2) Complete proposals are due to SPAdmin **at least three whole business days before the sponsor's deadline.**

Read the guidelines for special circumstances.

Forms & Templates

Administrative Costs Checklist for charging to Sponsored Projects	Documents institutional authorization to budget (and expend, if funded) costs inconsistent with UNMC's standard financial practice; i.e., to charge indirect (facilities and administrative) costs as direct costs for projects that meet certain criteria

ADIS Quick Glance	**SPA Tool: Quick Glance (Routing ADIS Internal Forms)**
	Scope: This SPA Tool covers only the routing of ADIS Internal Forms for SPA purposes, specifically for grants. It focuses on the movement of the ADIS IFs between statuses and actions needed by PIs, Department Administrators, or SPA personnel.
	Questions about other ADIS functionality (e.g., Personnel Records, Reports) should be referred to the responsible unit or the IT Help Desk (402-559-7700).
Advance Account Request (done in ADIS)	Establishes a WBS number prior to the complete set-up of a sponsored project in order to ensure the proper accounting of project-related expenses ADIS Advance Account guide
Budget - Parent / Child	Provides information for SPAdmin to initiate the set-up of sub-accounts to track separate parts of a complex grant. Child budgets should roll up into the Parent budget in ADIS.
Budget - Standalone	Basic budget form that can be used if the sponsor doesn't provide a template.
Contract Questionnaire - SPAdmin	Provides information about industry-sponsored projects to assist SPAdmin negotiate agreements with industry sponsors.
Contract Questionnaire - UNeHealth	Provides information about industry-sponsored projects to assist UNeHealth to negotiate agreements with industry sponsors.
Data Use Agreement (DUA) / Data Transfer Agreement (DTA) Intake Form	Guides Sponsored Programs Administration staff in negotiating DUA/DTA terms and in establishing workable timelines.
Facilities & Administrative (F&A) Cost Waiver Request	Required in order to use an F&A rate lower than the rate allowed by the sponsor. In order to maximize UNMC's F&A recovery, waivers are considered on a case-by-case basis by the Vice Chancellor for Research.
IACUC Protocol Association with Non-Sponsored Accounts *Non-sponsored accounts begin with 31, 33, or 37.* *To modify an IACUC for a sponsored project (an account beginning with 34, 35, or 36) contact your RA.*	To link or unlink a non-sponsored cost center to an IACUC protocol: **Option # 1**: Self-service in RSS *OR* **Option # 2**: Email the information below to SPAdmin@unmc.edu and CC the Principal Investigator and Department Administrator. - IACUC Protocol Number: - IACUC Protocol Title: - Principal Investigator for the IACUC Protocol: - Department Administrator: - Cost Center number: - To link account, provide: - Begin date: - End date: - To unlink an account, provide: - End date:

International Projects Questionnaire	Provides information about international travel and sponsored projects, business agreements, and Material Transfer Agreements with international components for review and management by Business & Finance, SPAdmin, UNeMed, and/or other units
Non-Sponsored Projects and IRB Protocol Association	To link or unlink a non-sponsored cost center to an IRB protocol: - Email the information below to SPAdmin@unmc.edu and - CC the Principal Investigator - CC the Department Administrator Non-Sponsored Projects and IRB Protocol Association Non-sponsored accounts begin with 31, 33, or 37 - IRB Protocol Number: - IRB Protocol Title: - Principal Investigator for the IRB Protocol: - Department Administrator: - Cost Center number: - To link account, provide: - Begin date: - End date: - To unlink an account, provide: - End date: To modify an IRB for a sponsored project (an account beginning with 34, 35, or 36) contact your RA.
Intent to Form a Consortium – Subcontract-in	Used when another organization is submitting an application that includes UNMC as a consortium participant. It meets the NIH requirement that the other organization represents that UNMC is prepared to establish the necessary inter-organizational agreement consistent with sponsor policy.
Intent to Form a Consortium – Subcontract-out	Used when UNMC is submitting an application that includes another organization as a consortium participant. It meets the NIH requirement that UNMC represents that the other organization is prepared to establish the necessary inter-organizational agreement consistent with sponsor policy.

Electronic Systems

UNMC uses various internal and external systems to aid in the preparation and submission of proposals.

Login for Electronic Application Systems:
? ADIS
? Cayuse424

ADIS

UNMC's Academic Department Information System allows you to:

- Initiate SPAdmin processing of a proposal via Internal Forms, which
  - Gather basic information about the project, submission instructions, and a PI certification statement
  - Calculate a sponsored project budget, based on UNMC's fringe benefits and F&A rates, for SPAdmin's review and approval. Information is easily transferred to sponsor budget forms.
  - Are routed electronically to the PI, Department chair, and the College dean (or designee) for review and signature
- Initiate SPAdmin negotiation of industry-sponsored agreement via Contract Intake
- Access SPAdmin information about new awards and changes to awards via checklists and halfsheets bundles
- Generate Biographical Sketches and Other Support documents
- Access UNMC-Omaha VA MOUs

Cayuse424

UNMC uses a "system-to-system" interface for submitting grant applications electronically via Grants.gov to the National Institutes of Health and other federal agencies. Cayuse424 enables faculty and administrators to:

- Pre-populate applications with institutional information
- Allow multiple users to work on an application
- Validate applications before submission

COI-SMART

UNMC uses COI-SMART to collect disclosures of financial interests from "investigators" in order to determine whether a real or perceived conflict of interest exists or could potentially exist, for which a management plan may be required.

Training

SPAdmin offers a number of formal and informal educational opportunities for departmental administrators and investigators:

- Monthly "Buzz" sessions on timely topics - fourth Wednesday of the month EXCEPT November and December
- Special sessions on emerging topics

Please contact us if you would like to schedule one-on-one training on any electronic system.

Archive of Past "Buzz" Sessions

Below are dates of past sessions with the topic in parenthesis. For those with slides available, click the date to open a link to the PDF file.

- January 22, 2025 (NIH Updates)
- November 20, 2024 (NE DHHS LB 506)
- October 23, 2024 (NIH updates)
- September 25, 2024 (Research administrator resources)
- August 28, 2024 (Cayuse Proposals [S2S] demo)
- July 24, 2024 (DOD CDMRP Grants; the Ticker)
- June 26, 2024 (NIH F Grants)
- May 22, 2024 (NIH K Grants)
- April 25, 2024 (SPA 101)
- March 27, 2024 (Contracts 101)
- February 28, 2024 (SPA Systems and Roles)
- January 24, 2024 (NIH updates)
- November 15, 2023 (NE Opioid and LB 506 RFPs)
- October 25, 2023 (Co-Is, OSCs, Consultants, and other project roles)
- September 27, 2023 (Subrecipient versus Contractor determinations)
- August 23, 2023 (Gift versus Grant determination)
- July 26, 2023 (Other Support and Foreign Influence)
- May 24, 2023 (ADIS Internal Forms demo)
- April 26, 2023 (NIH updates)

- [February 22, 2023](#) (Ticker updates)
- [October 26, 2022](#) (SPA 101)
- [September 28, 2022](#) (NIH FORMS-H)