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
- Industry Sponsored Clinical Research
- Industry-Sponsored Non-Clinical Research
- Confidential Disclosure Agreements (CDAs or NDAs)
- Other Contract Types

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 Amanda Leingang, 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 email)

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 email)
- **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 UNeMed 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 email

Data Use Agreements

Contact: SPAdmin Associate, 402-559-7456 or email

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.