Industry-sponsored Contracts

Introduction

Understanding Industry Sponsored Research

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

Non-clinical Research

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

SPAdmin negotiates non-clinical agreements.

Clinical Research

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

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

Who should review the contract?

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

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

UNeMed Web: unemed.com/services/material-transfer
UNeMed Phone: 402-559-2468

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

UNeHealth

What is UNeHealth

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

UNeHealth provides:

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

When to Contact

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

Contact information

Web: unmc.edu/spa/clinical-trials/unehealth
Phone: 402-559-7614

Clinical Trial Contracts

Getting Started

Who can help me with industry-sponsored clinical trials?

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

Web: unmc.edu/spa/clinical-trials/unehealth
Phone: 402-559-7614
Email: amanda.leingang@unmc.edu

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

Prior to contract review, UNeHealth requires:

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

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

Who negotiates the contract?

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

- UNeHealth negotiates the contract
- Departmental staff negotiate the budget
- IRB reviews the IRB application and consent form

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

Who signs the contract?

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

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

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

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

Web: unmc.edu/spa/clinical-trials/unehealth/contact
Phone: 402-559-7614

Finalizing Industry-funded Awards

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

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

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

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

Defining Roles and Responsibilities for Initiation of Research

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

Principal investigators

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

Departmental personnel (administrators and clinical coordinators if applicable)

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

UNeHealth personnel

- Negotiate agreements and amendments to protect institutional and investigator interests and ensure compliance with sponsor and institutional requirements
- Review Conflict of Interest disclosures for project personnel
- Review and approve internal forms prior to institutional signature

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

Sponsored Programs Accounting personnel

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

Industry Sponsored Research

Who can help me with industry-sponsored research?

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

Web: unmc.edu/spa/contracts/non-clinical

Phone: 402-559-7456

What does SPAdmin require prior to reviewing a nonclinical contract?

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

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

Who negotiates the contract?

The SPAdmin Contracts Specialist will negotiate the agreement.

Who signs the contract?

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

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

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

Finalizing Awards

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

Administration

Required Regulatory Review Processes

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

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

When should I complete and submit regulatory documents?

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

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

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

Access the Advance Account Request form in ADIS Internal forms. A guide is available at unmc.edu/spa/forms/forms-templates

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

Finalizing Grant Awards

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

After the award is set up in UNMC’s accounting system, the PI and department administrator are

notified by email that the account is ready and that the project "bundle" may be accessed in ADIS. The bundle includes:

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

For more, see Award Set-up

Finalizing Subcontracts OUT

What is required to finalize a subcontract OUT?

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

Finalizing Subcontracts IN

What is required to finalize a subcontract IN?

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

The subcontract from the prime recipient should contain:

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

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

Managing Awards

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

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

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

Changes Requiring Formal Approval by the Sponsor

Change in PI or Key Personnel

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

No-Cost Extensions

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

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

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

Residual Funds

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