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

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