

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

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.

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.

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