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

Revision #1
Created 19 February 2025 07:15:12 by Max V. Kuenstling
Updated 19 February 2025 07:24:21 by Max V. Kuenstling