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.

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