

UConn Health
Office of Clinical & Translational Research
Standard Operating Procedures

Title: Responsibility for Negotiating Clinical Trials Contracts	
Relates to Policy/Procedure: 303-11, 304-11, 307-11	
SOP#: 309-13	Version 2.0
Prepared by: Judi Kulko	Original date: 8/21/2013
Approved by: Judi Kulko	Date approved: 8/19/16

Purpose and Applicability:

To identify the department responsible for negotiating clinical research/clinical trials involving human subjects at UConn Health

Background and Significance:

Clinical Trial:

A clinical trial is a systematic, organized, prospective intervention study in human subjects that is conducted according to a formal study plan (protocol) and that has measurable efficacy and/or safety-related outcomes that are amenable to statistical analysis. It employs one or more intervention technique(s) including prophylactic, screening, diagnostic, or therapeutic agents, devices, or procedures. It must have approval of the IRB or review with a determination of exemption. Clinical trials are distinguished from other types of clinical research (e.g., behavioral research) that may need IRB approval but do not meet the other criteria of clinical trials.¹

A Clinical Trial Agreement is a legally binding agreement that manages the relationship between the Sponsor and/or the Funding agency that may be providing:

- a) Study Drug or Device
- b) Financial Support
- c) Proprietary Information

And the Institution (UConn Health) who may be providing:

- a) Subjects
- b) Data and/or Results
- c) Publication, Input into Publication
- d) Input into further Intellectual Property

Scope:

Applies to all clinical trials/clinical research contracts involving human subjects undertaken at UConn Health.

Responsibilities:

The OCTR negotiates all sponsored/supported clinical research/clinical trials contracts involving human subjects at UConn Health. The two exceptions are noted below.

¹ Adapted from Emory University, Association of Academic Health Centers (AAHC), 2004

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The SPS (Sponsored Program Services) negotiates:

- a. all federally funded investigator initiated clinical research/clinical trials
- b. all clinical trials funded by a foundation in response to a public solicitation.

Procedural Steps:

- The UConn Health investigator wishing to open the clinical research/clinical trial identifies the funding agency/sponsor for the project.
- All supported/sponsored clinical research/clinical trials that are not investigator initiated and federally funded are sent to the OCTR.
- These contracts are negotiated by an attorney in the OCTR following all OCTR & UConn Health policies and procedures.
- If the contract is:
 - a. federally funded and investigator initiated, or
 - b. in response to a public solicitation by a foundation
- It is sent to SPS to be negotiated.

Revision date: 8/19/16	Revised by: J. Kulko
Reason for revision: 2.0 Reflect changes in which office negotiates contracts; name change	
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