CLINICAL TRIAL AGREEMENT GUIDANCE DOCUMENT

Introduction and Purpose

The scope and purpose of this Guidance Document is to set forth requirements for the conduct of industry sponsored Clinical Research within the University of Utah. This Guidance should be used to direct the initiation of externally funded Clinical Research to promote compliance with University policies and to meet Good Clinical Practice standards.

Definitions and Acronyms

Clinical Research includes:

- Phase 0-4 clinical trials, or other studies involving subjects in a clinical setting, that prospectively evaluate the safety and efficacy of a drug, device or treatment intervention in humans;
- Studies comparing effectiveness of two approved drugs, devices or treatment interventions involving subjects in a clinical setting;
- Registry studies or other clinical studies that collect data on standard of care and/or tissues from patients with a specific condition in a clinical setting; and
- Prospective nutrition and nutraceutical studies involving human subjects.

Clinical Trial: Clinical trials are Clinical Research studies involving human participants assigned to an intervention in which the study is designed to evaluate the effect(s) of the intervention on the participant and the effect being evaluated is a health-related biomedical or behavioral outcome.

CTA: Clinical Trial Agreement - This document is typically provided by the sponsor and then reviewed by OSP (OSP does have templates it can use instead, if requested by the sponsor). In order for OSP to review and negotiate the CTA, it's preferred to have an editable Microsoft Word document.

DSS: Document Summary Sheet - OSP review proposals after the internal routing process is completed using an eProposal generated Document Summary Sheet. This system facilitates the review, submission, and tracking of proposed research activity. The DSS is used to collect information about the proposed project and to document the necessary approvals.

IRB: Institutional Review Board
OSP: Office of Sponsored Projects
PI: Principal Investigator

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Clinical Trial Agreement ("CTA") Procedure

1. AGREEMENT INTAKE

Once a PI and Sponsor have decided to pursue work on a Clinical Research project at the University of Utah, the PI should notify the Office of Sponsored Projects ("OSP") and the IRB. The OSP is responsible for the review, negotiation, and execution of all Clinical Trial Agreements ("CTA") on behalf of the University.

1.1. The PI/delegate notifies OSP of their intent to engage with the sponsor on a Clinical Research project by submitting a completed and approved eProposal Document Summary Sheet ("DSS") to OSP.

1.2. Administrators and PIs can initiate the DSS in eProposal via the Campus Information Systems (CIS). For more information on submission of the DSS, please visit the OSP website: https://osp.utah.edu/policies/procedure-library/DSS-creation.php.

1.3. The PI/delegate should include current sponsor contact information.

1.4. The PI/delegate should also include any other prior agreements they received from the sponsor as attachments to the DSS, i.e. confidential/non-disclosure agreements.

1.5. OSP encourages funding partners to consider using the Accelerated Clinical Trial Agreement (ACTA) templates to expedite CTA negotiations (https://www.ara4us.org/acta).

1.6. The PI/delegate should either: (a) attach a sponsor provided CTA template (preferably in Word format) in the DSS; or (b) notify OSP the sponsor prefers to use the University template CTA by adding a comment to the DSS.

1.7. OSP works on CTAs according to the order in which complete and ready-to-review materials are received.

1.8. OSP will begin agreement review after receiving the relevant DSS, CTA, and contact details for the Sponsor.

1.9. OSP will initiate the review and negotiation of a CTA by working with the sponsor directly.

1.10. In parallel to OSP's work on the CTA, the PI/delegate should engage with the IRB and any other ancillary review process required prior to the initiation of the project.

1.11. The PI/delegate is responsible for negotiating a budget with the Sponsor for the Clinical Research, and must follow the University budgeting standards

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established by UUSOP-13 Institutional Fee Schedule and 13-A Cost Structure Rationale.

2. INITIAL REVIEW

The OSP Sponsored Project Officer reviewing the CTA will contact the PI and/or Study team and other campus offices for additional details regarding the study in order to facilitate review as necessary.

The pre-award contact identified in eProposal, or such other contacts as requested by the PI and/or department, will be included in draft exchanges and follow-ups with the study sponsor.

3. CONTINUED REVIEW AND FOLLOW-UP

Following initial review of a CTA, OSP will work with the Sponsor to negotiate and finalize the CTA in preparation for execution. The length and complexity of the CTA, the responsiveness of the Sponsor, and the quantity and significance of issues that need to be negotiated, all contribute to the length of time required to reach agreement with the sponsor.

4. PRELIMINARY PROJECT / PREAWARD SPENDING

A preliminary project may be requested by the Department through eAward with the "Preliminary Project Setup Request" transaction after the DSS has been received and processed by OSP. Getting a "prelim" in place may be beneficial so that study activation expenses can be allocated to a protected funding account that will associate with the CTA once it is signed. Additional information about the eAward application is located at https://osp.utah.edu/grant-life-cycle/manage-award/eaward-faq.php.

Preliminary project requests are reviewed by OSP prior to processing. Some awards feature restricted spending dates, particularly with subaward/subcontract arrangements. Preliminary projects cannot be set up for non-monetary awards, such as if the agreement provides a resource for the study but no funding (drug/device supply arrangements).

5. AGREEMENT EXECUTION

5.1. OSP CTA negotiation is considered complete once CTA terms within OSP's control are resolved. Other issues outside of OSP's control that need resolution prior to execution include, but are not limited to: exceptional matter that require escalation, budget issues, conflict of interest matters, human subjects protections, and other compliance requirements.

5.2. After OSP and Sponsor have finalized the terms of a CTA, OSP will notify the PI and team. Prior to signing a final version of a CTA, OSP will review the final non-

budgetary content for accuracy, and the department will review the final budgetary content for accuracy.

5.3. Once OSP has received all necessary approvals, it will work with the sponsor to circulate a clean copy of the CTA for signatures.

5.4. Signatures are generally executed pursuant to the process designated by the Sponsor during negotiation. OSP can accommodate DocuSign and Adobe.

5.5. Sponsor returns a copy of the fully executed agreement and a copy is provided to study team for their records.

5.6. The PI or study team should then initiate a "New Award Setup Requests" via eAward to start the project set-up process.

5.7. The PI will be notified once a project number has been assigned by Grants and Contracts Accounting.

6. Escalation

Faculty, staff, and sponsors should contact the OSP Sponsored Projects Officer responsible for negotiating the CTA for questions or concerns about the process or timelines. Issues should be escalated to the OSP Associate Director for Contracts, or the Director.

Materials Required

- Clinical Trial Agreement (CTA)
- eProposal Document Summary Sheet (DSS)

Document Approval

April 18, 2022

Brent K. Brown, JD — DATE
Assistant Vice President for Research,
Director Office of Sponsored Projects, University of Utah

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Revision History

Version Date	Change Summary
12/APR/2022	Origional Version
DD/MMM/YYYY	

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