

Clinical Research Support Office (“CRSO”) STANDARD OPERATING PROCEDURE

SOP NUMBER 1006	TITLE Clinical Trial Determination Escalation Policy
EFFECTIVE DATE 1/7/2026	WRITTEN BY Jessica Heskell

APPROVAL	
	Electronically signed by: William Stoops Reason: Approver Date: Feb 11, 2026 13:02:16 EST
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1. POLICY STATEMENT

The Office of the Vice President for Research Clinical Trial Determination Committee (CTDC) consisting of leaders from the Clinical Research Support Office (CRSO), Office of Research Integrity (ORI) and Proposal Development Office (PDO) will determine whether a study protocol meets the definition of a clinical trial, as defined by the decision tools referenced in item 6, on behalf of the institution to improve standardization across all University of Kentucky Research offices and systems.

2. PURPOSE

To standardize the process for the determination of study protocols as subject to federal and institutional clinical trial definitions and criteria within a single body across all UK Research offices.

3. SCOPE

The CTDC will serve as the institutional entity responsible for assessing all protocols involving human subjects that may meet the definition of a clinical trial and make final determinations.

DEFINITIONS

NIH definition of a clinical trial:

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

FDA definition of a clinical trial:

Any experiment that involves a test article and one or more human subjects and is subject to requirements for submission to the Food and Drug Administration. Clinical investigations must not be initiated unless that investigation has been reviewed and approved by an Internal Review Board (IRB).

4. PROCEDURE

- Protocols requiring CTDC committee review will be submitted via Microsoft Forms
 - Submissions will require the study information, protocol document and any drug or device information.
- CRSO Research Program Administrator will review all requests for completeness and triage to the CTDC review committee.
 - CRSO Research Program Administrator will communicate with the committee regarding any requests and provide all documents and communication from the study team.
- The CTDC review committee will review all documents based on the FDA and NIH definitions of a clinical trial and communicate the final decision to the study team, CRSO, ORI and OSPA

5. ATTACHMENTS

NA

6. REFERENCES

NIH Decision Tool <https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials/definition>

ORI Decision Tool <https://research.uky.edu/office-research-integrity/clinical-research-vs-clinical-trial/clinical-trials>

FDA Information <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-50>

SOP Clinical Trial Determination CAD-GD-1006-Draft

Final Audit Report

2026-02-11

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