

# *Clinical Trials Research*

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## Clinical Research Initiatives Office

The Clinical Research Initiatives Office serves as the first point of contact for clinical faculty interested in developing a research program or expanding their current research interests, including providing information on the clinical research infrastructure and on-campus centralized resources.



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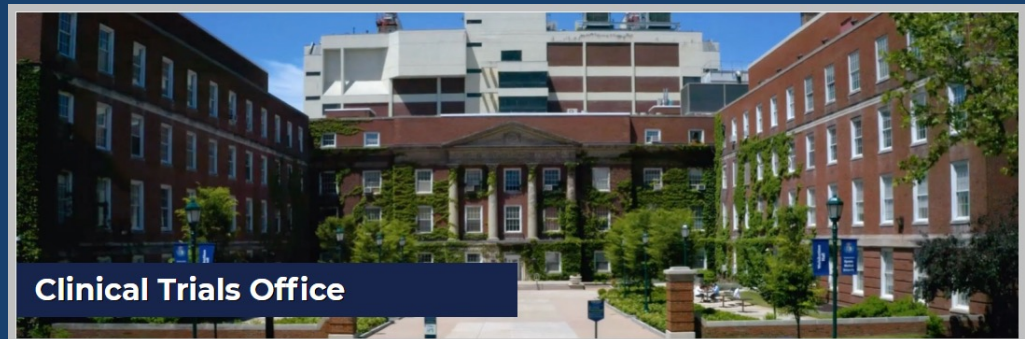
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# Upstate Medical University Clinical Trials Office (CTO)

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<https://www.upstateresearch.org/clinical-trials/>

# What is research?

According to **45 CFR 46.102 (d) and (f)**:

**Research** is defined as:

- ▶ A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. (**45 CFR 46.102 (d)**)

**Human Subjects Research** is defined as:

- ▶ A systematic investigation involving living individuals from whom researchers obtain data through intervention, interaction, or by collecting identifiable private information or biospecimens.  
[\[grants.nih.gov\]](https://grants.nih.gov) (**45 CFR 46.102 (f)**)

## Decision Tree for NIH Clinical Trial Definition

Does the study involve human participants research?

YES

NO

Are participants prospectively assigned to an intervention?

YES

NO

Is the study designed to evaluate the effect of the intervention on the participants?

YES

NO

Is the effect being evaluated a health-related biomedical or behavioral outcome?

YES

NO

This study is a clinical trial.

The study is NOT a clinical trial.

# What makes a human subjects research study a Clinical Trial?

NIH's Definition of a Clinical Trial  
<https://grants.nih.gov/policy/clinical-trials/CT-decision-tree.pdf>



# Clinical Trials Office (CTO) Services

## **Central Resource for Industry Sponsored Clinical Trials**

CTO reviews all Clinical Trials sponsored by external pharmaceutical sponsors.

## **Agreement Management**

Manages review, negotiation, and signing of:

- Confidentiality Disclosure Agreements (CDAs),
- Non-Disclosure Agreements (NDAs), and
- Clinical Trial Agreements (CTAs)

## **Financial Management**

Manages review, negotiation, and signing of:

- Coverage Analysis
- Budget Reviews



# Clinical Trials Office (CTO) Services

## **Clinical Trial Management System**

CTMS provides a centralized tracking platform to manage all aspects of a clinical trial efficiently and consistently.

## **Regulatory Support**

Ensures compliance with academic standards, policies, and laws, in CTAs and budget reviews.

## **Education and Training**

Training and resources to enhance quality and compliance.

A background image showing a group of medical professionals in a hallway. On the left, a woman in a white lab coat is looking towards a man in a white lab coat. In the center, a woman in a white lab coat is looking down at a tablet. On the right, a man in blue scrubs is holding a black folder and looking towards the group. The image is partially covered by a dark blue diagonal overlay on the left side.

# CTO Impact

## **Protection of Institution and Researcher Interests**

Ensures the institution and researches are not exposed to undue legal or financial risk, such as liability for injuries, intellectual property disputes, or breach of confidentiality.

## **Financial Accuracy and Sustainability**

Ensures the funding covers all costs to maintain the research infrastructure supporting long-term accessibility to research.

## **Advancing Medical Research**

Supports clinical trials helping to advance medical knowledge and treatment.