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## When should a new clinical trial be submitted to the CTO?

Please submit **as soon as you are aware** that the trial is being considered.

You can't submit it too soon! Remember that the CTO will assist in all stages of development:

- Initial inquiry by sponsor – CTO will help identify a PI
- Confidentiality – CTO will forward to OSP for review and approval
- Site qualification and selection – CTO will coordinate with sponsor
- Draft contract– CTO will forward contact to OSP for review and approval
- Draft budget – CTO will develop a coverage analysis and budget proposal

## Do I still need to submit if my clinical trial isn't funded by industry?

Yes. All clinical trials, regardless of the source of funding must be submitted to the CTO as the first step toward study approval.

## How do I submit a new clinical trial?

Please use the electronic submission form

<https://redcap.uthscsa.edu/REDCap/surveys/?s=FPJEP8NFTR>

## What information do I need before I can submit the study?

Although we would like as much information as possible, the application has very few required fields.

You must provide the following:

- A working title for the project
- Principal Investigator's contact information
- Regulatory sponsor's contact information
- Whether there is a Contract Research Organization (CRO), research network or cooperative group associated with the trial
- If you have a preference which IRB will review
- Which start-up tasks you've already completed, if any.
- Anticipated local study sites

All other fields are optional.

## Why do I have to submit my project to the CTO before the IRB?

There are several issues that should be addressed before the trial is submitted to either the Institutional Review Board (IRB) or the Office of Clinical Research (OCR).

The CTO is responsible for the following:

- Determine whether there is a risk of billing errors (most clinical trials are a billing risk)
- Complete or verify the research coverage analysis to determine which procedures are part of standard clinical care or research-driven
- Develop and negotiate a study budget with the sponsor and any service providers
- Document the participant payment plan, if applicable
- Create a study record in the Clinical Trial Management System application (Velos eResearch)
- Register the study in EPIC, if applicable

## Can I submit projects that are not Clinical Trials?

**Yes**, studies that do not meet the definition of a clinical trial can still be submitted to the CTO portal. We recommend submitting any study that needs the services provided by CTO:

- Coordination of confidentiality agreements and contracts with OSP
- Coverage analysis for standard care and research driven procedures
- Billing risk assessment for studies involving clinical procedures or services
- Budget development for externally sponsored studies
- Velos eResearch (Clinical Trial Management application) setup and training

## Who should I contact if I have questions about the submission process or form?

Please contact the applicable Clinical Trials Office

Mays Cancer Center CTO Finance – CTOFinance@uthscsa.edu

VPR CTO - VPRCTO@uthscsa.edu

## How do I know that the Submission Form was received?

- At the end of the form, after you click the submit button, you have the option of sending a confirmation email to the email address of your choosing
- In addition, the applicable CTO office will verify receipt of the form after it has been in-processed

## Why do I need a Return Code?

The return code is a unique number that is required if you decide to return to the submission form in the future to modify or complete your responses.

You will need the code if you:

- Did not complete all of the mandatory fields (need to complete the form later)
- Decide to modify or add information to a form that is already submitted

## While the CTO staff perform their review, what am I responsible for?

The CTO staff will contact you to begin the planning process. It is very important that you and the CTO communicate and coordinate during the development phase.

While the staff of the CTO are completing their tasks, you will be responsible for the following:

- Building the study team and completing applicable training
- Determine where the study procedures will be performed (locations)
- Develop study documentation (e.g., reg binder, CRFs, logs)
- Completing any sponsor required documentation, training or communications
- Submit the trial to the IRB or OCR

## Why does the CTO coordinate the budget development?

Providing centralized budget development is intended to:

- Improve compliance with Medicare billing rules
- Standardize the process for obtaining price quotes from service providers
- Increase use of internal pricing for UTMedicine services
- Prevent or minimize budget-cost gaps
- Streamline the process and shorten the development phase of study start up process

## What is a clinical trial?

A clinical trial is a research study in which one or more human participants 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](#).

**Prospectively assigned** means a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

An **"intervention"** is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and diagnostic strategies.

A **"health-related biomedical or behavioral outcome"** is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.