Clinical Trial Submission Process

March 25, 2021

Brandi Weaver, BA – Manager, Clinical Trials Development
Patricia Miranda, BBA – Manager, Research Operations

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Reminder during the Forum:

The session will be recorded

- Mute your mics to avoid echoing or background noise
- Do not activate your camera to preserve bandwidth
- In lieu of voicing your questions, use the chat function, a moderator will respond to your question

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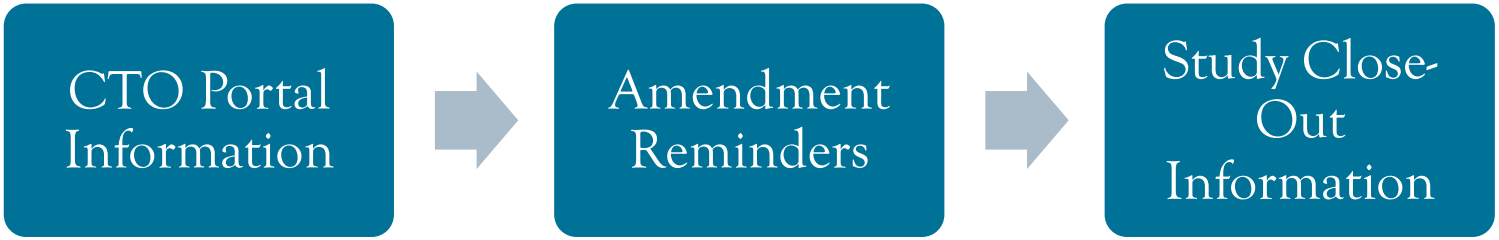
VPR CTO Overview



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Clinical Trial Portal Submissions

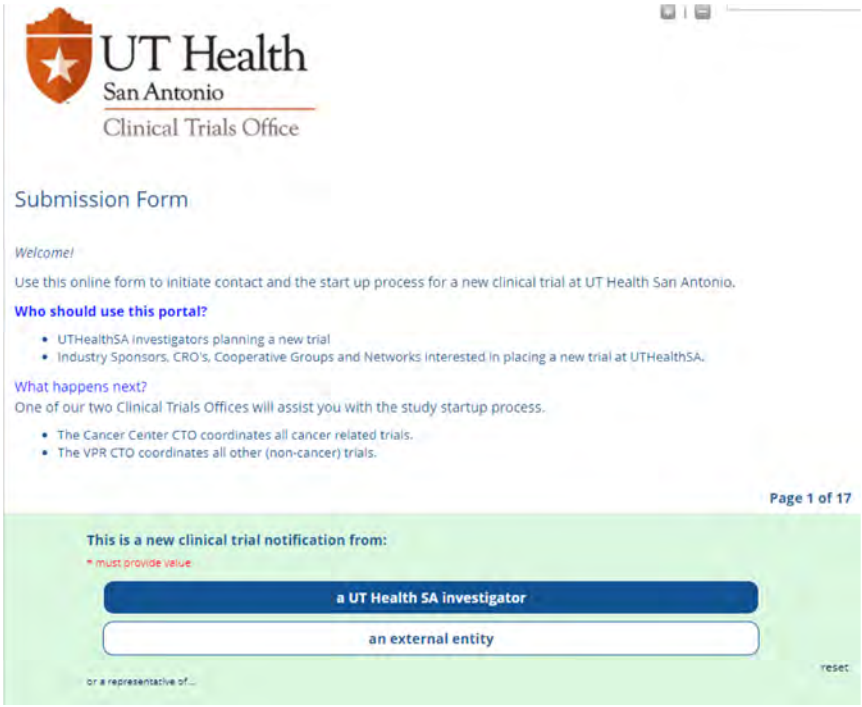
Clinical trials must be reviewed and cleared by the Clinical Trials Office (CTO) before the research application can be submitted to the Institutional Review Board (IRB).

- Be prepared to upload the following files to the portal:

If **externally sponsored trial**, the sponsor's protocol

If **industry sponsored trial**, the sponsor's protocol, Clinical Trial Agreement/Study Agreement and Proposed site budget

Clinical Trial Portal



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Clinical Trial Portal Submissions

If **investigator-initiated trial**, the **Clinical Trial Protocol Template (Form CT)** or stand-alone Investigator initiated study (IIS) protocol

If not provided in the protocol, include a list of all study procedures, frequency and timing using the

Schedule of Events Template

Clinical Trial Portal

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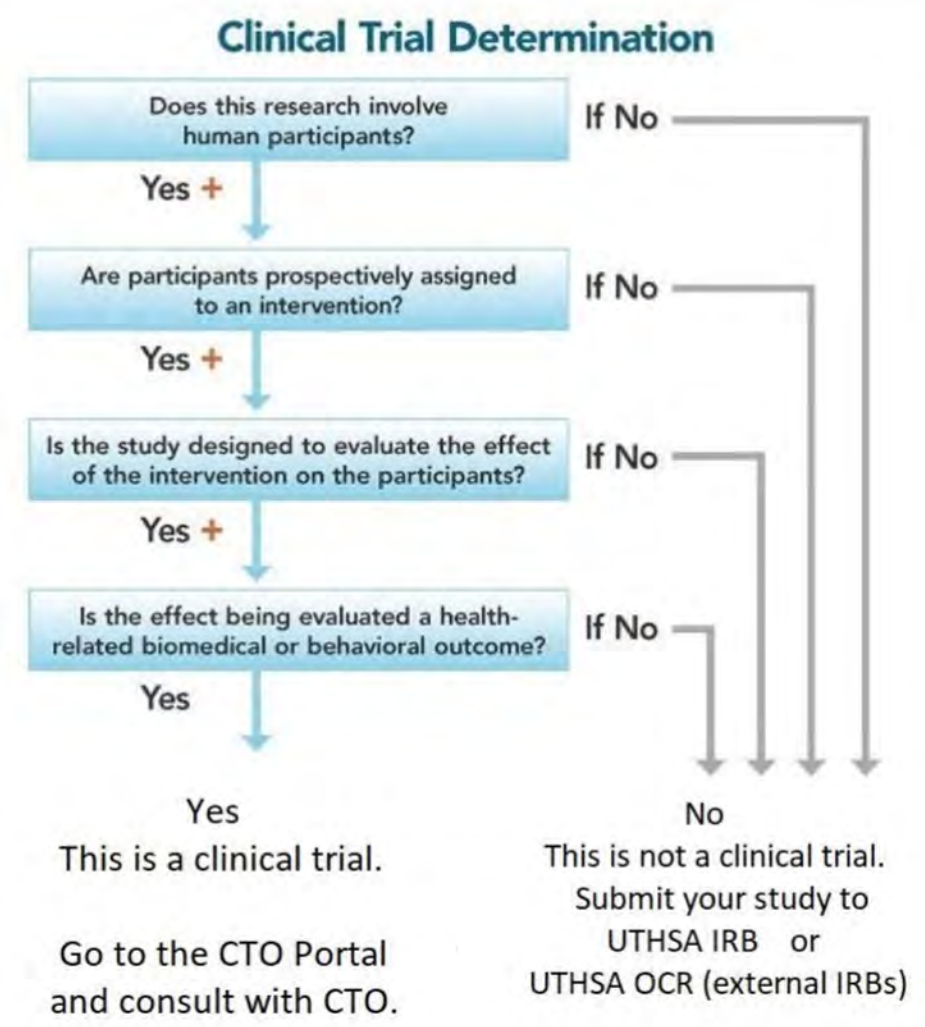
Applicable Clinical Trials



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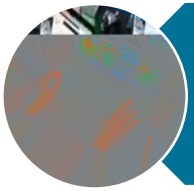
Clinical Trial Modifications

When do I submit study changes to the Clinical Trials Office (CTO)?



During CTO review for a new study

After CTO Clearance but before submission to OCR/IRB for a new study

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New Studies under CTO Review or cleared by CTO but not yet submitted to OCR/IRB

Research Team to submit modification/amendment to Clinical Trials Office (CTO) via VPRCTO@uthscsa.edu for secondary review and re-clearance.

This will include:

- Submitting CTO pertinent documents to VPRCTO@uthscsa.edu. For example, modifications to the CTO coverage analysis (CA), protocol, budget or study manuals/documents that may affect budget or study operations.
  - CTO will review for any changes to **study title, study sites, study design or procedures, personnel or finances,** and work with the research team to update coverage analysis and/or budget
- CTO will route final revised forms to Service Providers and Affiliates for secondary review and clearance (UHS, FORU, Radiology etc.), if applicable
  - Updated service provider agreements and pricing will be obtained, if applicable
- CTO will route revised budget or finance forms to OSP for review
  - Amended CTA and/or study agreement will be executed, if applicable

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Clinical Trial Modifications

When do I submit study changes to the IRB/OCR?

IRB/OCR amendment after the study is OCR/IRB approved

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New Studies submitted to OCR/IRB

(after CTO clearance and approval)

- When your new study has already been submitted to OCR/IRB or has received IRB and/or Institutional approval.
- If your new study has been approved, changes should be incorporated on the IRB/OCR approved “CA.doc” as part of an IRB/OCR amendment or modification
- OCR/IRB will trigger CTO review once amendment or modification is received, if applicable
- CTO will reach out to research team to update any applicable CTO documents (CA, budget, CTA etc.)

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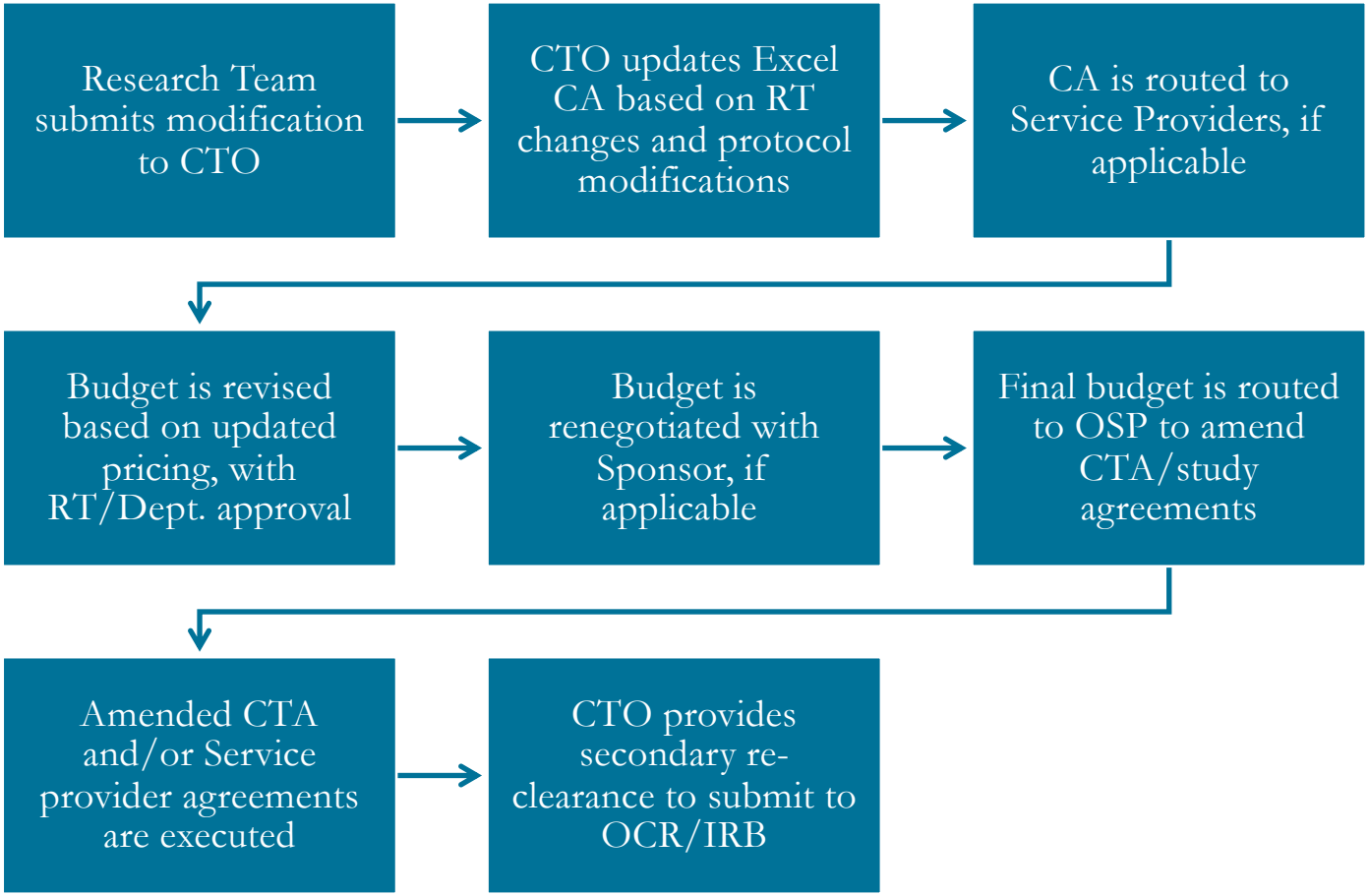
CTO Amendment Process



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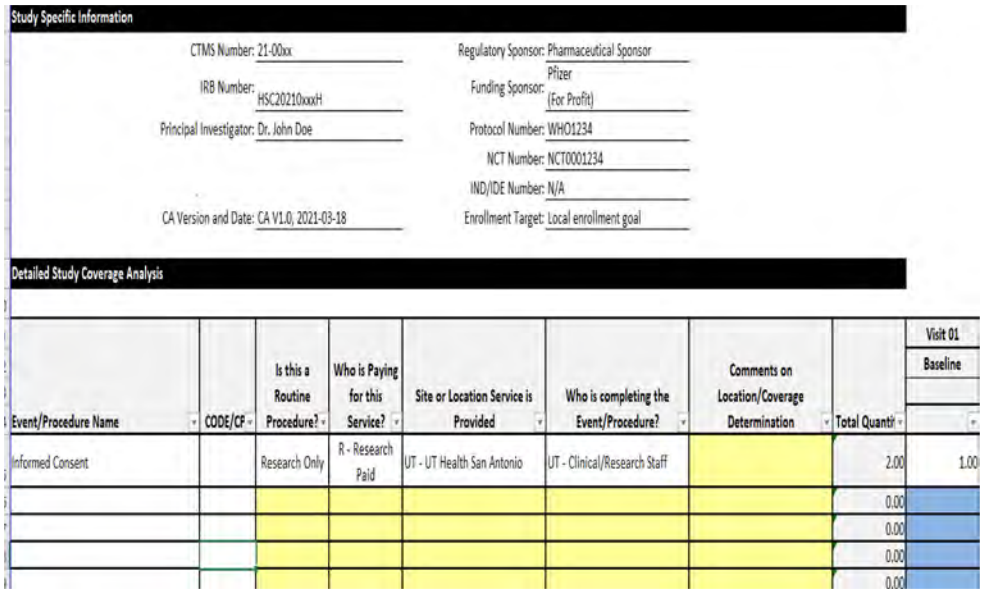
CTO Coverage Analysis (CA)

CTO Excel CA



Study Specific Information

CTMS Number: 21-00xx
IRB Number: HSC20210xxxH
Principal Investigator: Dr. John Doe
CA Version and Date: CA V1.0, 2021-03-18
Regulatory Sponsor: Pharmaceutical Sponsor
Funding Sponsor: Pfizer (For Profit)
Protocol Number: WHO1234
NCT Number: NCT0001234
IND/IDE Number: N/A
Enrollment Target: Local enrollment goal

Detailed Study Coverage Analysis

Event/Procedure Name	CODE/CP	Is this a Routine Procedure?	Who is Paying for this Service?	Site or Location Service is Provided	Who is completing the Event/Procedure?	Comments on Location/Coverage Determination	Total Quantit	Visit 01 Baseline
Informed Consent		Research Only	R - Research Paid	UT - UT Health San Antonio	UT - Clinical/Research Staff		2.00	1.00
							0.00	
							0.00	
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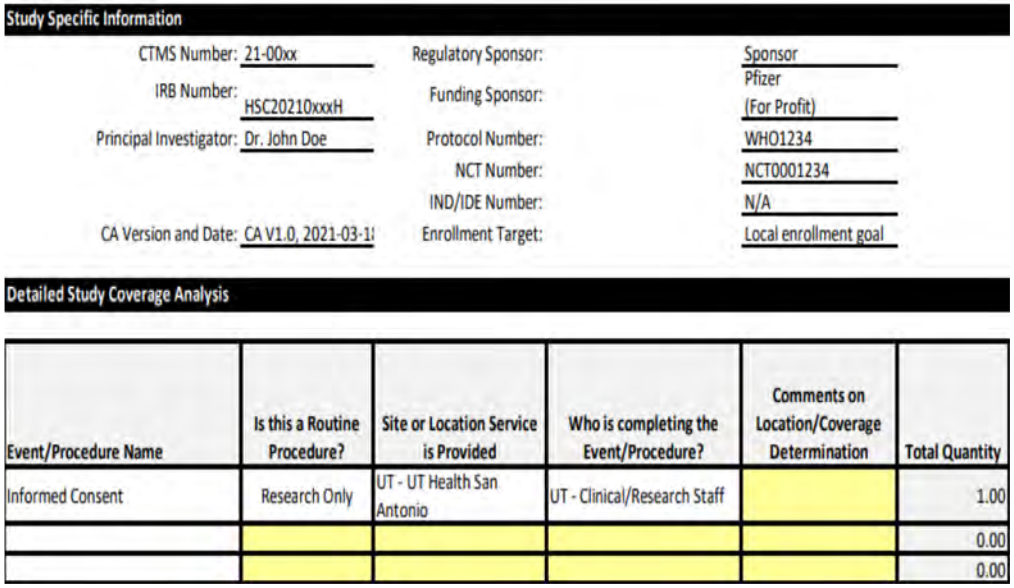
Regulatory CA (CA.doc Word document)



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Informed Consent	Research Only	UT - UT Health San Antonio	UT - Clinical/Research Staff		1.00
					0.00
					0.00

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Amendment Notification during Mid-Budget Negotiation

Timely Communication is key

- Direction from the PI and research team will be required to determine the best course of action
- CTO Budget Analyst will recommend either continuing with the current version on file if budget negotiation with the sponsor has commenced

OR

- Take immediate action to review the amendment and incorporate changes

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CTO assistance during close-out steps

Task Teams Close-Out Steps

- Billing Risk
  - EPIC Research Account Inactivation
- Participant Payments
  - ClinCard Study Closure
  - Bursar Office Notification
- Velos eResearch Study Inactivation
- Triggers Close-Out Invoices
  - (if CTO negotiated the budget)

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Questions?

Clinical Trials Office Staff

- Jason Bates, MBA – Director, CTO
- Patricia Miranda, BBA – Manager, Research Operations
- Brandi Weaver, BA – Manager, Clinical Trials Development
- Cathy Haegelin, BBA, MBA, CPA – Budget Analyst – Senior
- Lynda Schrack, BA - Clinical Trials Specialist
- Cristina Morales, BSBA - Clinical Trials Specialist
- Anna Stewart, Budget Analyst – Intermediate
- Christie Bryant, BBA - Billing Analyst

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Upcoming Forum & Concierge Dates:

Research Concierge Dates:

VPR Virtual TEAMs Meeting Scheduler (link below)

- Tuesday, **April 6, 2021**, 1pm - 4pm
- Wednesday, **April 7, 2021**, 9am - 12pm
- Wednesday, **April 21, 2021** - 9am - 12pm

Research Concierge Virtual Scheduler

Next Forum Date:

- Thursday, April 22, 2021, 1pm – 2pm
- via Zoom

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