Document Number:	RCQA-720-01	Effective Date: 09 Jun 2020
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Title:	CTD Determination	

1. PURPOSE

The purpose of this document is to describe the processes for Principal Investigators or designated study team members, if their study has been determined to be a clinical trial and requires registration on ClinicalTrials.gov

2. DEFINITIONS

CTD	Clinical Trial Disclosure
CTD language	"A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time." -Or- "This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials."
HSRO	Human Subject Research Office
ICF	Informed Consent Form
IRB	Institutional Review Board
PI	Principal Investigator
Primary Contact	Individual designated
QC	Quality Control
RCQA	Office of Research Compliance and Quality Assurance
RCQA ED	Executive Director of the Office of Research Compliance and Quality Assurance

3. RESPONSIBILITY

3.1. Principal Investigator

- Modify CTD language in ICF if applicable
- Resubmit revised ICF if applicable
- Resubmit revised protocol if applicable

- Register protocol on ClinicalTrials.gov prior to enrollment of first participant

3.2. **Clinical Trial Disclosure Team**

- Make any changes on Clincialtrials.gov as needed

3.3. **HSRO Team Member**

- Verify that requested CTD language changes were made by PI and/or study team

4. PROCEDURE

ID	*Step*	*Description*	*Responsible*	*Timeline*
4.1. Notification that study is a Clinical Trial				
4.1.1.	Automatic notification to register study	PI and Primary Contact listed in the electronic IRB system will receive an automatic notification informing them that their study requires an NCT number and needs registration on ClinicalTrials.gov	Electronic IRB system	At the time CTD Ancillary review has determined that registration is required
4.1.2.	Disagreement with clinical trial determination	PI and/or study team member may contact CTD Ancillary review committee by emailing ctgovum@miami.edu to request an additional review of their protocol submission if they disagree with the determination made by the committee.	PI and/or study team	Prior to enrollment of first participant
4.1.3.	Change in determination	If the CTD Ancillary review committee changes their initial determination, the PI is responsible for making any changes to affected documentation, including, but not limited to the ICF.	PI	Prior to enrollment of first participant
4.1.4.	Verification of ICF change	The HSRO team member will verify that the necessary changes have been made to the ICF.	HSRO Team member	Prior to IRB approval

ID	Step	Description	Responsible	Timeline
4.2. Notification received that ICF requires modification				
4.2.1.	Automatic notification that the ICF requires modification	PI, designated primary contact in the electronic IRB system and assigned IRB coordinator/analyst will receive automatic notification that the ICF CTD language requires modification	Electronic IRB system	At the time CTD Ancillary review has determined that modification to ICF is required
4.2.2.	Receipt of notification to modify ICF	PI or designated team member will access the electronic IRB system and navigate to the study for which the notification was received and follow the steps below: 1. Find the Submit CTD Ancillary Review Activity 2. Click on the Submit CTD Ancillary Review activity 3. Scroll down to the comments section 4. Apply the changes to the ICF as stated in the comment section. 5. Review all versions of the ICF and make the necessary changes if applicable 6. Upload the revised document to the electronic IRB system; PI or PI proxy must resubmit	PI or designated team member	At the time CTD Ancillary review has determined that modification to ICF is required
4.2.3.	Review if required changes were made	At the time of reviewing the ICF document, HSRO team member will verify that the appropriate CTD language is in the ICF as determined by the CTD Ancillary review committee.	HSRO team member	Prior to submitting to IRB committee for review

ID	*Step*	*Description*	*Responsible*	*Timeline*
4.3. Notification received that Protocol is 'Not Registration Ready'				
4.3.1.	Automatic notification received that the protocol is 'Not Registration Ready'	PI, designated primary contact in the electronic IRB system and assigned IRB coordinator/analyst will receive automatic notification that the protocol is 'not registration ready'	Electronic IRB system	At the time CTD Ancillary review has determined that registration is required
4.3.2.	Responding to comments and tracking of changes	PI or designated team member will respond to any recommendations by clicking new comment after placing their cursor in the comment they are responding. In addition, if they agree with the changes suggested, they should accept all changes suggested by the CTD Ancillary review team.	PI or designated team member	Prior to submitting study to IRB committee for review
4.3.3.	Clarifications needed	PI or designated team member will contact the CTD Ancillary Review Committee to discuss all suggested changes to the protocol, if applicable	PI or designated team member	Prior to submitting study to IRB committee for review
4.3.4.	Upload revised protocol to IRB system	PI or designated team member will upload the revised protocol into the electronic IRB system.	PI or designated team member	Prior to submitting study to IRB committee for review
4.3.5.	Notify CTD Ancillary team	PI or designated team member will notify the CTD Ancillary review committee via email that the revised protocol is available for review.	PI or designated team member	Prior to submitting study to IRB committee for review

ID	*Step*	*Description*	*Responsible*	*Timeline*
4.3.6.	Review of protocol changes	CTD Ancillary review team will review the changes made and the responses to any questions within the tracked change protocol.	CTD Team member	Within 5 business days of receiving notification that revised protocol is available for review
4.3.7.	Complete CTD Ancillary review	CTD determination will be completed within the electronic IRB system. If the protocol remains 'Not Registration Ready,' then steps 4.3.1 to 4.3.6 will be repeated. If the protocol is registration ready, the CTD Ancillary review will be completed as per SOP-RCQA-703.	CTD Ancillary Team member	Within 5 business days of receiving notification that revised protocol is available for review

5. DOCUMENTATION

RCQA will maintain an electronic copy of all documentation used for the purpose of QC, on the shared drive for a minimum of five years, to document the QC of the study record.

For example: S:\RCQA\Clinical Trial Disclosure\Study LifeCycle\Study eProst ID Number\01_Determination

6. REFERENCES

Clinical Trial Disclosure: Determination and Protocol Registration Policy
SOP-RCQA-703 CTD Ancillary Review
SOP-RCQA-710 Registration Ready Protocol Review

7. TEMPLATES/FORMS

N/A

8. REVISION HISTORY

N/A

9. SIGNATURES

Prepared by: Yolanda P. Davis Digitally signed by Yolanda P. Davis Date: 2020.06.09 21:45:43 -04'00' Date: _____

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Clinical Trial Disclosure Manager, RCQA

Approved by: Johanna Stamates Digitally signed by Johanna Stamates Date: 2020.06.11 14:09:06 -04'00' Date: _____

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