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Title:	CTD ClinicalTrials.gov Problem Records	

1. PURPOSE

The purpose of this document is to outline the compliance processes for ClinicalTrials.gov Problem Records.

2. DEFINITIONS

Applicable Clinical Trial (ACT)	The term used in the Food and Drug Administration Amendments Act (FDAAA) to designate interventional studies of drugs, biologics and devices for which information must be submitted to the Clinical Trial Registry Data Bank. An applicable drug clinical trial is a controlled clinical investigation, other than a phase 1 clinical investigation, of a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of FDAAA. An applicable device clinical trial is either: (1) a prospective clinical study of health outcomes comparing an intervention with a device subject to sections 510(k), 515, or 520 (m) of the Federal Food, Drug, and Cosmetic Act against a control in human subjects (other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes); or (2) a pediatric post market surveillance of a device as required under section 522 of the Food, Drug, and Cosmetic Act.
CTD	Clinical Trial Disclosure
FDAAA	Food and Drug Administration Amendment Act of 2007
IIT	Investigator Initiated Trials
NCT #	National Clinical Trial (NCT) number, another term for the ClinicalTrials.gov registry number unique to each record. The format for the ClinicalTrials.gov registry number is “NCT” followed by an 8-digit number, e.g.: NCT00000419
Principal Investigator (PI)	An individual, who actually conducts a clinical investigation under whose immediate direction the test article is administered, dispensed or used.
PRS	Protocol Registration and Result Reporting System
RCQA	Office of Research Compliance and Quality Assurance
QC	Quality Control

Responsible Party (RP)	The term used by FDAAA to designate the entity or individual responsible for the clinical trial and for the submission of clinical trial information. This can mean: • The sponsor of the clinical trial, or • The principal investigator if so designated
Sponsor	A person who initiates, but does not actually conduct, the investigation; that is, the investigational drug device or biologic is administered, dispensed or used under the immediate direction of another individual.
Sponsor-Investigator	An individual who both initiates and conducts a clinical investigation and under whose immediate direction the investigational drug, device or biologic is being administered, dispensed or used.
Study Team	Principal Investigator, Sponsor-Investigator, Research Coordinator, Study Coordinator, etc.
VPR	Vice Provost for Research

3. RESPONSIBILITY

3.1. CTD Team Member

- Generate PRS Problem Report
- Check for problems with study record
- Send notifications of identified issues to responsible party
- Review problems for resolution
- Escalate non-compliant studies

3.2. Responsible Party or Designee

- Resolve issues from problem notification

3.3. Executive Director of RCQA

- Send third notification of non-compliant issues

4. PROCEDURE

ID	*Step*	*Description*	*Responsible*	*Timeline*
4.1. Review of Studies with ClinicalTrial.gov Issues:				
4.1.1.	Generate PRS filtered report and create a problem report	RCQA generates a PRS filtered report from the PRS, and saves this report by using the following nomenclature: PRS filtered report_YYYYMMDD into the CTD Compliance folder	CTD Team member	Monthly

4.1.2.	Review of UMiami ClinicalTrials.gov records for compliance	Records on ClinicalTrials.gov are reviewed for:
		• Record Owner issues
		  ○ Pending QA Review Comments
		  ○ Not Completed
		  ○ Not Recently Updated
		  ○ Not Recently Updated-Not Recruiting
		• FDAAA 801 Issues
		  ○ Missing FDAAA Information
		  ○ Late Results – per FDAAA
		• Responsible Party Issues
		  ○ Ready for Review and Approval
		  ○ Never Released
		  ○ Updates Not Released
		
		Review of Problem Records is documented via PRS filtered Report and filed electronically.
			CTD Team member	Within one week of the generated PRS problem report

ID	Step	Description	Responsible	Timeline
4.1.3.	Check for other possible problems	For records within the problem record report, other information will be reviewed. • Review of eProst for any protocol amendments that could affect the record and require updates • Review of Velos for any recruitment status changes that are needed	CTD Team Member	Within one week of generating PRS Filtered report
4.1.4.	Notification of Issue	Study team listed within the ClinicalTrials.gov record is notified via email communication with any issues associated with their entry.	CTD Team member	Within one week after PRS problem review has been completed
4.1.5.	Problem Resolution	The Study Team will work with the Clinical Trial Disclosure Team to resolve all issues identified within 10 business days of the notification.	Responsible Party or designee	See Description
4.1.6.	Review of PRS Problem Report	The PRS Problem Report is reviewed to ensure that the problem(s) previously identified are now resolved.	CTD Team member	1 Month after Initial Review of PRS Problem Report

ID	Step	Description	Responsible	Timeline
4.1.7.	Notification that record is compliant or non-compliant	For problems that have been sufficiently resolved, RP will receive notification that their record is now compliant. -or- For problems not resolved or the resolution is not in progress, RP will receive notification that their records are non-compliant. ***Steps 4.1.1 through 4.1.6 are repeated*** • Second Notice is sent regarding issue • Third Notice is sent regarding outstanding issue	CTD Team member	After review of PRS system Monthly Problem Report
			CTD Team member	~15 business days after initial notification of issue
			Executive Director of RCQA	~30 business days after initial notification of issue

ID	Step	Description	Responsible	Timeline
4.1.8.	Notification that record is non-compliant	For records with 60 business days of continued non-compliance (receipt of 3 consecutive notices, or 3 notices within 1 year), it will be recommended to the VPR that the study team shall be required to attend Mandatory training on 'Managing Your Records on ClinicalTrials.gov. ' • If issues are related to FDAAA 801, the study might be suspended. If the study team (identified on ClinicalTrials.gov record) does not attend the mandatory training within 90 days of notice, it will be recommended to the VPR and/or IRB that the study be suspended.	CTD Team member	~60 business days after initial notification of issue
4.1.9.	Document Findings	Review of steps 4.1.1 to 4.1.7 will be documented at time of review within the PRS Problem Report and filed in the appropriate share folder.	CTD Team member	XX

5. DOCUMENTATION

RCQA will maintain an electronic copy of all data used on the shared drive for a minimum of five years to document the Problem Records.

For example: S:\RCQA\Clinical Trial Disclosure\CTD Compliance

6. REFERENCES

Food and Drug Administration Amendment Act Section 801: 2007
42 CFR § 11: Clinical Trial Registration and Result Reporting
NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information

7. TEMPLATES/FORMS

PRS Problem Report
Risk Determination

8. REVISION HISTORY

Effective Date	Revision Date	Author	Description of Changes
09 Jun 2020	29 Apr 2020	Yolanda Davis	• Changed CTD Compliance team to CTD team. • Added clarification that the PRS Filtered report is generated from PRS and saved as the PRS Problem Report. • Changed timeline associated with notifications • Changed the escalation process for the 2nd and 3rd notice to 15, then 30 business days for non-compliant records. • Changed timeline as to when a study would be recommended for suspension. • Outlined the responsibilities within the responsibility section of the SOP.

9. SIGNATURES

Prepared by: Yolanda P. Davis Digitally signed by Yolanda P. Davis Date: 2020.06.09 12:55:41 -04'00' Date: _____
Yolanda P. Davis, BS, CCRP
Clinical Trial Disclosure Manager, RCQA

Approved by: Johanna Stamates Digitally signed by Johanna Stamates Date: 2020.06.11 14:06:59 -04'00' Date: _____
Johanna Stamates, RN, MA, CCRC, CHRC
Executive Director, RCQA