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Page No.	Page 1 of 6	Author: Y. Davis
Title:	Clinical Trial Disclosure Compliance Report Generation	

1. PURPOSE

The purpose of this document is to outline the Clinical Trial Disclosure (CTD) Compliance Report generation process and to describe the templates and the content of CTD Compliance Review Reports issued by the office of Research Compliance and Quality Assurance (RCQA).

2. DEFINITIONS

CTD	Clinical Trial Disclosure
ICF	Informed Consent Form
RCQA	Research Compliance and Quality Assurance
Responsible Party	The term used by FDAAAA 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 or device 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 or device is being administered, dispensed or used.
UMACT	University of Miami Applicable Clinical Trial

3. RESPONSIBILITY

3.1. **CTD Compliance Officer or designee**

3.1.1. Initiate CTD Compliance Review Report and/or CTD Compliance Review Follow-up Report if applicable

3.1.2. Issue CTD Compliance Review Report and/or CTD Compliance Review Follow-up Report if applicable

3.1.3. File CTD Compliance Review Report and/or CTD Compliance Review Follow-up Report if applicable

3.2. **ED RCQA**

3.2.1. Review CTD Compliance Review Report and/or CTD Compliance Review Follow-up Report if applicable

3.2.2. Approve CTD Compliance Review Report and/or CTD Compliance Review Follow-up Report if applicable

4. PROCEDURE

ID	*Step*	*Description*	*Responsible*	*Timeline*
6.1. CTD Compliance Review Report Generation				
4.1.1.	CTD Compliance Review Report Template	CTD Compliance Review Report template is used for designated CTD Compliance reviews as per SOP RCQA-701	CTD Compliance Officer or designee	Upon completion of review / investigation

4.1.2.	CTD Compliance Review Report sections	CTD Compliance Review Report will consist of the following sections*: (see CTD Compliance Review Template)*
		• Executive Summary
		  o Review Details
		  o Objective
		  o Summary
		  o Impact Analysis *if applicable*
		• Information and Instructions
		  o Finding Risk Assessment Definitions
		• Abbreviations and Definitions
		• Background
		• Purpose and Objectives
		  o Objectives
		• Methodology
		• Findings
		• Summary of Findings
		• Recommendations and Follow-Up Activities
		• References
		• Appendices
		• Signature
			CTD Compliance Officer or designee	

ID	Step	Description	Responsible	Timeline
4.1.3.	CTD Compliance Folder Structure	CTD Compliance electronic folders are created following the structure below: 🗁 CTD Compliance 🗁 YYYY 🗁 Annual CTD Review	CTD Compliance Officer or designee	
4.1.4.	CTD Compliance Review Report Naming Convention	CTD Compliance Review reports will be given the names as follows: CTD Tracking Number *(as per SOP RCQA-700)*_Compliance Review Report VDRAFT_YYYYMMDD (example CTD201601_Compliance Review Report_VDRAFT_20160101)	CTD Compliance Officer or designee	
4.1.5.	CTD Compliance Report completion	Complete the report with the relevant details	CTD Compliance Officer or designee	Within 14 days of completion of the review/investigation
4.1.6.	CTD Compliance Report review	Send the completed CTD Compliance report via email to RCQA ED or designee for review.	CTD Compliance Officer or designee	Immediately following step 4.1.5
4.1.7.	CTD Compliance Report review	ED of RCQA or designee will return draft report with comments, changes, and/or corrections.	RCQA ED	Within 7 days of receiving report

ID	Step	Description	Responsible	Timeline
4.1.8.	CTD Compliance Report review steps and naming conventions	If additional reviews are necessary then steps X.X.X to X.X.X are repeated. Each version will have an updated version number until final. Once final, the report will be given the name as follows: CTD Tracking Number *(as per SOP RCQA-700)*_Compliance Review Report VFINAL_YYYYMMDD (example CTD201601_Compliance Review Report_VFINAL_20160101)	CTD Compliance Officer or designee	Within 3 days of receiving comments
4.1.9.	CTD Compliance Report supporting documentation	All other electronic files related to the audit, such as excel reports, published manuscripts, notification letters should be placed in the corresponding folder.	CTD Compliance Officer or designee	In parallel with step 4.1.8
4.1.10.	CTD Compliance Report conversion	Convert the final report to a non-editable PDF and save with the same name as the originating document.	CTD Compliance Officer or designee	Within 7 days of receiving comments.
4.1.11.	CTD Compliance Report Issuance	Issue the CTD Compliance review report to the appropriate personnel.	CTD Compliance Officer or designee	Within 7 days of receiving comments.

ID	Step	Description	Responsible	Timeline
4.2. Follow-Up CTD Compliance Review Report				
4.2.1.	CTD Compliance Report Follow-up	If warranted by the Recommendation and Follow-up activities section, a Follow-up report will be issued.	CTD Compliance Officer or designee	When all Follow-up activities have been completed

ID	***Step***	***Description***	***Responsible***	***Timeline***
4.2.2.	CTD Compliance Review Follow-up report sections	The Follow-up report will contain the following sections: • Executive Summary o Review Details o Objective o Summary o Impact Analysis *if applicable* • Abbreviations and Definitions • Documentation of follow thru with Recommendations and Follow-Up Activities • Signature	CTD Compliance Officer or designee	Within 14 days of receiving notice that follow-up activities have been completed
4.2.3.	CTD Compliance Follow-up report naming conventions	CTD Compliance Review Follow-up reports will be given the names as follows: CTD Tracking Number *(as per SOP RCQA-700)*_Compliance Review FU Report VFINAL_YYYYMMDD (example CTD201601_Compliance Review FU Report_VFINAL_20160101)	CTD Compliance Officer or designee	Within 3 days of completing report
4.2.4.	CTD Compliance Follow-up report conversion	Convert the final report to a non-editable PDF and save with the same name as the originating document.	CTD Compliance Officer or designee	In parallel with step 4.2.3
4.2.5.	CTD Compliance Follow-up report issuance	Issue the CTD Compliance review report to the appropriate team members.	CTD Compliance Officer or designee	In parallel with step 4.2.3

5. DOCUMENTATION

RCQA will maintain an electronic copy

6. REFERENCES

RCQA-700 Clinical Trial Disclosure Review Procedures During a QA Audit
RCQA-701 Clinical Trial Disclosure Compliance Activities
RCQA-707 Clinical Trial Disclosure Follow-up Activities

7. TEMPLATES/FORMS

CTD Compliance Review Template
CTD Compliance Follow-up Template

8. REVISION HISTORY

N/A

9. SIGNATURES

Prepared by: Signature on File Date: 13 Jun 2016
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Approved by: Signature on File Date: 13 Jun 2016
Johanna Stamates, RN, MA, CCRC, CHRC
Executive Director, RCQA