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**

<table>
<thead>
<tr>
<th>ID</th>
<th>Step</th>
<th>Description</th>
<th>Responsible</th>
<th>Timeline</th>
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<tbody>
<tr>
<td>4.1</td>
<td>Review of Studies with ClinicalTrials.gov Issues:</td>
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<tr>
<td>4.1.1</td>
<td>Generate PRS filtered report and create a problem report</td>
<td>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</td>
<td>CTD Team member</td>
<td>Monthly</td>
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</tbody>
</table>
| 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 |
### 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

**Responsible:** CTD Team Member  
**Timeline:** 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.

**Responsible:** CTD Team member  
**Timeline:** 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:** Responsible Party or designee  
**Timeline:** 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.

**Responsible:** CTD Team member  
**Timeline:** 1 Month after Initial Review of PRS Problem Report
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<th><strong>ID</strong></th>
<th><strong>Step</strong></th>
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<th><strong>Responsible</strong></th>
<th><strong>Timeline</strong></th>
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</table>
| 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 |
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**
7. TEMPLATES/FORMS

- PRS Problem Report
- Risk Determination

8. REVISION HISTORY

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

Prepared by: Yolanda P. Davis, BS, CCRP
Clinical Trial Disclosure Manager, RCQA

Approved by: Johanna Stamates, RN, MA, CCRC, CHRC
Executive Director, RCQA