1. PURPOSE

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

2. DEFINITIONS

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applicable Clinical Trial (ACT)</td>
<td>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.</td>
</tr>
<tr>
<td>CTD</td>
<td>Clinical Trial Disclosure</td>
</tr>
<tr>
<td>FDAAA</td>
<td>Food and Drug Administration Amendment Act of 2007</td>
</tr>
<tr>
<td>IIT</td>
<td>Investigator Initiated Trials</td>
</tr>
<tr>
<td>NCT #</td>
<td>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</td>
</tr>
<tr>
<td>Principal Investigator (PI)</td>
<td>An individual, who actually conducts a clinical investigation under whose immediate direction the test article is administered, dispensed or used.</td>
</tr>
<tr>
<td>PRS</td>
<td>Protocol Registration and Result Reporting System</td>
</tr>
<tr>
<td>RCQA</td>
<td>Office of Research Compliance and Quality Assurance</td>
</tr>
<tr>
<td>QC</td>
<td>Quality Control</td>
</tr>
</tbody>
</table>
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.

3. RESPONSIBILITY

Responsibilities outlined throughout the procedure section.
## 4. PROCEDURE

<table>
<thead>
<tr>
<th>ID</th>
<th>Step</th>
<th>Description</th>
<th>Responsible</th>
<th>Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1</td>
<td>Review of Studies with ClinicalTrial.gov Issues:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1.1</td>
<td>Generate PRS problem report</td>
<td>PRS problem report is generated by RCQA from the PRS and saved using the following nomenclature: PRS problem report YYYYMMDD</td>
<td>CTD Compliance Officer or designee</td>
<td>Monthly</td>
</tr>
</tbody>
</table>
| 4.1.2 | Review of UMiami ClinicalTrials.gov records for compliance | Records on ClinicalTrials.gov will be 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  
  - Updated Not Released  
Review of Problem Records is documented via PRS Problem Report and filed electronically. | CTD Compliance Officer | Within one week of generated PRS problem report |
| 4.1.3 | Notification of Issue | Study team listed within the ClinicalTrials.gov record is notified via email communication with a list of problem(s) associated with their entry. | CTD Compliance Officer | Within one week after PRS problem review has been completed |
### 4.1.4. Problem Resolution

The Study Team will work with the Clinical Trial Disclosure Compliance Team to resolve all issues identified.

- Record Owner Issues are to be resolved within 14 days of notification.
- FDAAA 801 Issues are to be resolved within 30 days of notification.
- Responsible Party Issues are to be resolved within 14 days of notification.

**Responsible Party or designee**

**Timeline:** See Description

### 4.1.5. Review of PRS Problem Report

The PRS Problem Report is reviewed to ensure that the problem(s) previously identified are now resolved.

**CTD Compliance Officer**

**Timeline:** 1 Month after Initial Review of PRS Problem Report

### 4.1.6. Notification that record is compliant or non-compliant

For studies in which the problem has been appropriately resolved, RP will receive notification that their record is now compliant.

**CTD Compliance Officer**

**Timeline:** After review of PRS system Monthly Problem Report

- **Steps 4.2.1 through 4.2.5 are repeated**

For studies in which problems have not been resolved or the resolution is not in progress, RP will receive notification that they are non-compliant.
<table>
<thead>
<tr>
<th>ID</th>
<th>Step</th>
<th>Description</th>
<th>Responsible</th>
<th>Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>• Second Notice is sent regarding issue</td>
<td>CTD Compliance Officer</td>
<td>~30 days after initial notification of issue</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Third Notice is sent regarding outstanding issue</td>
<td>Executive Director of RCQA</td>
<td>~60 days after initial notification of issue</td>
</tr>
<tr>
<td>4.1.7</td>
<td>Notification that record is non-compliant</td>
<td>90 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 be required to attend Mandatory training on ‘Managing Your Records on ClinicalTrials.gov’. If issue is 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 60 days of notice, it will be recommended to the HSRO that the study be suspended.</td>
<td>CTD Compliance Officer</td>
<td>~90 days after initial notification of issue</td>
</tr>
<tr>
<td>4.1.8</td>
<td>Document Findings</td>
<td>Review of steps 4.2.1 to 4.2.7 will be documented within the PRS Problem Report and filed in the appropriate share folder.</td>
<td>CTD Compliance Officer</td>
<td></td>
</tr>
</tbody>
</table>
5. DOCUMENTATION

RCQA will maintain an electronic copy

6. REFERENCES

RCQA

7. TEMPLATES/FORMS

PRS Problem Report
Risk Determination

8. REVISION HISTORY

N/A

9. SIGNATURES

Prepared by: Signature on File ___________________________  Date:  18 Apr 2017
Yolanda P. Davis, BS, CCRP
Sr. Research Compliance Officer, RCQA

Approved by: Signature on File ___________________________  Date:  18 Apr 2017
Johanna Stamates, RN, MA, CCRC, CHRC
Executive Director, RCQA