1. PURPOSE

The purpose of this document is to outline the process and procedures completed by the Office of Research Compliance and Quality Assurance (RCQA) to review and verify the accuracy of the NCT numbers recorded in Velos.

2. DEFINITIONS

**Billing Task Force**
A team that consists of representatives from Research, Research Education and Innovative Medicine (RIM) and Office of Research Administration (ORA) that reviews information from a study to determine if there is a possibility of billing to Medicare.

**CMS**
Centers for Medicaid and Medicare Services

**CTD**
Clinical Trial Disclosure

**CTD Ancillary Committee**
Members of the Clinical Trial Disclosure Team or managers within the Office of Research Compliance and Quality Assurance

**DOD**
Department of Defense

**FDAAA**
Food and Drug Administration Amendment Act of 2007

**FDAMA**
Food and Drug Administration Modernization Act of 1997

**ICF**
Informed Consent Form

**ICJME**
International Committee of Journal Medical Editors

**IRB**
Institutional Review Board

**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.

**NIH**
National Institute of Health

**Principal Investigator (PI)**
An individual who actually conducts a clinical investigation (i.e. under whose immediate direction the test article is administered or dispensed to a subject

**PRS**
Protocol Registration and Result Reporting System

**RCQA**
Research Compliance and Quality Assurance
Responsible Party
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 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.

Study Team
Principal Investigator, Sponsor-Investigator, Research Coordinator, Study Coordinator, etc.

University of Miami Applicable Clinical Trial (UMACT)
Any study that meets the criteria as defined in the business rules below:

Business Rule #1 – Legal Requirement (FDAAA. FDAMA, and 42 CFR § 11)
Criteria Group 1.1
- Study is interventional and involves a Drug, Device, or Biologic; AND
- It is Phase 2-4; AND
- Study Start Date is as of September 2007 forward (not programmed); AND
- Involves at least 1 U.S. Site; AND
- PI is the Sponsor-Investigator

Criteria Group 1.2
- Study is interventional and involves a Drug, Device, or Biologic; AND
- It is Phase 2-4; AND
- Study Start Date is as of September 2007 forward (not programmed); AND
- Involves at least 1 U.S. Site; AND
- PI is the Responsible Party

Criteria Group 1.3
- Study is interventional and involves a Drug, Device, or Biologic; AND
- Study Start Date is as of September 2007 forward (not programmed); AND
- Involves at least 1 U.S. Site; AND
- Involves a Serious or Life-Threatening Disease
- PI is the Sponsor-Investigator

Criteria Group 1.4
- Study is interventional and involves a Drug, Device, or Biologic; AND
- Study Start Date is as of September 2007 forward (not programmed); AND
- Involves at least 1 U.S. Site; AND
- Involves a Serious or Life-Threatening Disease
- PI is the Responsible Party

Business Rule #2 – Federal Funding Requirement (NIH Policy on the Dissemination of Clinical Trial Information for Federally Funded Studies)
Criteria Group 2.1
- Study is interventional and involves a Drug, Device, or Biologic; AND
- It is Phase 2-4; OR
- Study is interventional and involves a Behavioral Interventions, Dietary Changes, Process of Care Changes, Surgical Procedures, or Physical Therapy; AND
- Study Start Date is as of September 2007 forward; AND
- Involves at least 1 U.S. Site; AND
- NIH or DOD Funding; AND
- PI is the Responsible Party;

Business Rule #3 – CMS Mandate Requirement
Criteria Group 3.1
- Study involves a Drug, Device, or Biologic; OR
- Study involves a Behavior, Dietary Changes, Process of Care Changes, Surgical Procedures, or Physical Therapy; AND
- PI is the Responsible Party; AND
- Clinical Study/Registry/Clinical Trial; AND
- Medicare Billing

Criteria Group 3.2 (Sponsored Studies)
- Study involves a Drug, Device, or Biologic; OR
- Study involves a Behavior, Dietary Changes, Process of Care Changes, Surgical Procedures, or Physical Therapy; AND
- Sponsor/Collaborative Group/Other Institution is responsible party; AND
- Clinical Study/Registry/Clinical Trial; AND
- Medicare Billing

**Business Rule #4 – ICMJE Requirement**
Criteria Group 4.1
- PI is the Responsible Party; AND
- Intervventional clinical trial wanting to Publish

**Business Rule #5 – Requirement for Result Reporting**
Criteria Group 5.1
- Study is interventional and involves a Drug, Device, or Biologic; AND
- It is Phase 2-4; AND
- Study Start Date is as of September 2007 forward; AND
- Involves 1 U.S. Site; OR Study is a Federally Funded interventional clinical trial

**Velos**
An electronic Clinical Trial Management System

3. RESPONSIBILITY

3.1. CTD Compliance Team Member or Designee
- Review study for CTD determination
- Make CTD determination
- Create PRS account
- Assist with protocol registration, if applicable
- Review record for consistency and regulatory compliance, if applicable
- Verify protocol registration and entry of NCT number in Velos
- Notify PI/Study Team of missing NCT number

3.2. PI and/or Study Team
- Submit study in IRB7
- Register protocol in ClinicalTrials.gov if applicable
- Record NCT number in Velos

3.3. Billing Task Force
Determine if there is a possibility of Medicare billing

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>4.1.1.</td>
<td>Generate ‘CTD Determination Review’ Report</td>
<td>The CTD Report is generated from Velos and filtered to review studies that have a CTD Determination of ‘required’ OR ‘recommended’ AND ‘Investigator’ is the Responsible Party AND the NCT Number is Missing</td>
<td>CTD Compliance team member or designee</td>
<td>Monthly</td>
</tr>
<tr>
<td>4.1.2.</td>
<td>Save Report</td>
<td>The CTD Determination Review Report is saved in the electronic folders</td>
<td>CTD Compliance team member or designee</td>
<td>Upon generation of report</td>
</tr>
<tr>
<td>4.1.3.</td>
<td>Verification of registration for IITs</td>
<td>The PRS is reviewed to ensure that studies that have been identified as ‘UMACTs’ are registered</td>
<td>CTD Compliance team member or designee</td>
<td>Within 7 business days of report generation from Velos</td>
</tr>
<tr>
<td>4.1.4.</td>
<td>Notification of missing NCT number</td>
<td>Study teams associated with studies that are registered and are missing the NCT number in Velos are notified to add the NCT number and that it has the correct ‘Unique Protocol ID’</td>
<td>CTD Compliance team member or designee</td>
<td>5 days after Velos report generation</td>
</tr>
<tr>
<td>4.1.5.</td>
<td>Study not registered</td>
<td>The study team will work with the Clinical Trial Disclosure Compliance Team or they will proceed on their own to register the protocol on <a href="https://register.clinicaltrials.gov">https://register.clinicaltrials.gov</a> Refer to SOP RCQA-709</td>
<td>Responsible Party or designee</td>
<td>Prior to enrollment of first participant</td>
</tr>
<tr>
<td>ID</td>
<td>Step</td>
<td>Description</td>
<td>Responsible</td>
<td>Timeline</td>
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</tr>
<tr>
<td>4.1.6.</td>
<td>Notification of registration</td>
<td>The study team will notify the Clinical Trial Disclosure Compliance Team that the protocol has been registered and made public on <a href="http://www.ClinicalTrials.gov">www.ClinicalTrials.gov</a></td>
<td>Responsible Party or designee</td>
<td>Upon receipt of NCT number</td>
</tr>
<tr>
<td>4.1.7.</td>
<td>Verification of registration</td>
<td>The Clinical Trial Disclosure team will verify that the protocol has been registered and has the correct ‘Unique Protocol ID’</td>
<td>CTD Compliance team member or designee</td>
<td>Within 3 days of receiving notification</td>
</tr>
<tr>
<td>4.1.8.</td>
<td>Reporting on Non-Compliance</td>
<td>The study team will notify the IRB via deviation report in the annual continuing report that they were non-compliant with policy HSR-P-101 if the study was registered after the first participant was enrolled</td>
<td>Responsible Party or designee</td>
<td>At time of continuing report</td>
</tr>
</tbody>
</table>
### 4.2. Missing NCT Number for Sponsored Trials

<table>
<thead>
<tr>
<th>ID</th>
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<th>Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.2.1</td>
<td>Generate ‘CTD Determination Review’ Report</td>
<td>The CTD Report is generated from Velos and filtered to review studies that have a CTD Determination of ‘required’ <strong>AND</strong> ‘Sponsor’ is the Responsible Party <strong>AND</strong> the NCT number is missing</td>
<td>CTD Compliance team member or designee</td>
<td>Monthly</td>
</tr>
<tr>
<td>4.2.2</td>
<td>Save Report</td>
<td>The CTD Determination Review Report is saved in the electronic folders</td>
<td>CTD Compliance team member or designee</td>
<td>Upon generation of report</td>
</tr>
<tr>
<td>4.2.3</td>
<td>Verification of registration for sponsored studies</td>
<td>ClinicalTrials.gov is reviewed to verify if the study was registered</td>
<td>CTD Compliance team member or designee</td>
<td>Within 7 business days of report generation from Velos</td>
</tr>
<tr>
<td>4.2.4</td>
<td>Notification of missing NCT number</td>
<td>Study teams associated with studies that are registered and are missing the NCT number in Velos are notified to add the NCT number</td>
<td>CTD Compliance team member or designee</td>
<td>Within 7 business days after Velos report generation</td>
</tr>
<tr>
<td>4.2.5</td>
<td>Unable to verify registration</td>
<td>If unable to verify that study was registered, the most current MCA will be consulted to determine if there is a potential for Medicare Billing</td>
<td>CTD Compliance member or designee</td>
<td>Within 5 business days of verifying that NCT number is missing</td>
</tr>
<tr>
<td>4.2.6</td>
<td>No potential for Medicare billing</td>
<td>If the study does not have the potential for Medicare billing, no further actions are required.</td>
<td>CTD Compliance member or designee</td>
<td>Upon verification</td>
</tr>
<tr>
<td>ID</td>
<td>Step</td>
<td>Description</td>
<td>Responsible</td>
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</tr>
<tr>
<td>4.2.7.</td>
<td>Potential for Medicare billing</td>
<td>Study team is notified to request an NCT number from the sponsoring organization</td>
<td>CTD Compliance member or designee</td>
<td>Within 3 business days of determining if an NCT number is needed for Medicare billing.</td>
</tr>
<tr>
<td>4.2.8.</td>
<td>Unable to obtain NCT number</td>
<td>If the Sponsoring organization notifies study team that the study will not be registered, review of contract is completed to verify that sponsoring organization will pick up any costs that the insurer will not pay. See SOP RCQA-705 for next steps</td>
<td>CTD Compliance member or designee</td>
<td>Within 30 days of determining that an NCT number is needed for Medicare billing.</td>
</tr>
</tbody>
</table>
### 4.3. Erroneous NCT Number Entered into Velos

<table>
<thead>
<tr>
<th>ID</th>
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<th>Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.3.1</td>
<td>Generate ‘CTD Determination Review’ Report</td>
<td>The CTD Report is generated from Velos and filtered to review studies that have an NCT number present and were not previously recorded.</td>
<td>CTD Compliance team member or designee</td>
<td>Monthly</td>
</tr>
<tr>
<td>4.3.2</td>
<td>Save report</td>
<td>The CTD Determination Review Report is saved in the electronic folders.</td>
<td>CTD Compliance team member or designee</td>
<td>Upon generation of report</td>
</tr>
<tr>
<td>4.3.3</td>
<td>Check for errors</td>
<td>Each newly recorded NCT number will be reviewed for accuracy.</td>
<td>CTD Compliance team member or designee</td>
<td>Within 7 business days of generating the report</td>
</tr>
<tr>
<td>4.3.4</td>
<td>Incorrect NCT number</td>
<td>If the NCT number is incorrect, review of the MCA is completed to determine if there is the potential for Medicare billing.</td>
<td>CTD Compliance team member or designee</td>
<td>In parallel with step 4.3.3</td>
</tr>
<tr>
<td>4.3.5</td>
<td>No Medicare billing implications</td>
<td>If the study does not have the potential for Medicare billing, the study team is notified to correct the NCT number in Velos.</td>
<td>CTD Compliance team member or designee</td>
<td>Within 3 business days of knowing that the study had Medicare billing.</td>
</tr>
</tbody>
</table>
## 4.3.6. Potential for Medicare billing

If the study has the potential for Medicare billing, the following occurs:

- Study team is notified to correct the NCT number
- Research IT is notified that the NCT number has been corrected
- Central Revenue Cycle is notified that the NCT number has been corrected

### Responsible

CTD Compliance team member or designee

### Timeline

In parallel with step 4.3.5

## 4.3.7. Potential for Medicare billing and participants enrolled

In addition to completing step 4.3.6, the Office of Billing Compliance is notified for follow-up

### Responsible

CTD Compliance team member or designee

### Timeline

In parallel with step 4.3.5

## 5. DOCUMENTATION

RCQA will maintain an electronic copy of all reports generated on the shared drive for a minimum of ten years.

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

## 6. REFERENCES

- HSR-P-101 Clinical Trial Disclosure Protocol Registration
- Food and Drug Administration Amendment Act Section 801: 2007
- Food and Drug Administration Modernization Act Section 113: 1997
- 42 CFR § 11: Clinical Trial Registration and Result Reporting
- NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information
- Determination of UMAC Workflow
- Identifying Responsible Party Workflow
- Instructions for completing CTD Ancillary Review in IRB7
- Instructions for entering an NCT Number in Velos
- Notification of required registration
- Notification of recommended registration
- Notification NCT number is required
7. TEMPLATES/FORMS/TOOLS

CTD Determination Review Report
University of Miami Clinical Trial Registration and Result Reporting Tool

8. REVISION HISTORY

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Revision Date</th>
<th>Author</th>
<th>Description of Changes</th>
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9. SIGNATURES

Prepared by: ____________________________ Date: ____________
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Clinical Trial Disclosure Manager, RCQA

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