1. PURPOSE

The purpose of this document is to outline the Clinical Trial Disclosure (CTD) Ancillary Committee review process and procedures completed by the Office of Research Compliance and Quality Assurance (RCQA) and to verify compliance with required disclosure determination.

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.

**Clinical Trial**
A research study\(^1\) in which one or more human subjects\(^2\) are prospectively assigned\(^3\) to one or more interventions\(^4\) (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.\(^5\)

\(^1\)See Common Rule definition of *research* at 45 CFR 46.102(d).

\(^2\)See Common Rule definition of *human subject* at 45 CFR 46.102(f).

\(^3\)The term “*prospectively assigned*” refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

\(^4\)An *intervention* is defined as a manipulation of the subject or subject’s environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.
Health-related biomedical or behavioral outcome is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects’ biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and/or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.

**Abbreviations**

- CMS: Centers for Medicaid and Medicare Services
- CTD: Clinical Trial Disclosure
- CTD Ancillary Committee: Any member of the Clinical Trial Disclosure Compliance Team or any manager from RCQA
- DOD: Department of Defense
- FDAAA: Food and Drug Administration Amendment Act of 2007
- FDAMA: Food and Drug Administration Modernization Act of 1997
- HSRO: Human Subject Research Office
- ICF: Informed Consent Form
- ICJME: International Committee of Journal Medical Editors
- IRB: Institutional Review Board
- IRB7: Electronic Institutional Review Board submission system
- 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
- ORA: Office of Research Administration
- Primary Contact: Designated regulatory contact person listed within the IRB7 system.
- 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
## Primary CTD Ancillary Review Committee PRS

Team members of the Clinical Trial Disclosure Compliance Team

## QCT

Qualifying Clinical Trial - A qualifying clinical trial (QCT) is a trial that meets the requirements set forth in Clinical Trial Policy (NCD 310.1) by the Center for Medicare and Medicaid Services (CMS). This policy delineates the requirements that a trial must meet to be designated as a QCT.

## RCQA Responsible Party

Research Compliance and Quality Assurance

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
- Interventional 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

3. RESPONSIBILITY

3.1. CTD Ancillary Committee
- Review study for CTD determination
- Make CTD determination
- Review ICF for applicable CTD language
- Review Federal grant documentation for dissemination plan
3.2. PI and/or Study Team
   - Submit study in IRB7
   - Register protocol in ClinicalTrials.gov if applicable
   - Revise ICF if requested

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

3.4. HSRO Staff Member
   - Follow-up on ICF revisions if applicable

3.5. ORA
   - Follow-up on grant revisions if applicable

4. PROCEDURE

<table>
<thead>
<tr>
<th>ID</th>
<th>Step</th>
<th>Description</th>
<th>Responsible</th>
<th>Timing</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1</td>
<td>Determining if study is a UMACT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1.1</td>
<td>Create new study in IRB7</td>
<td>Data is entered into smart form in IRB7 using the relevant information from the protocol and logistics surrounding the conduct of the study.</td>
<td>PI and/or designated study team member</td>
<td>NA</td>
</tr>
<tr>
<td>4.1.2</td>
<td>Submit study</td>
<td>Study is submitted in IRB7 for IRB review.</td>
<td>PI or Designee</td>
<td>NA</td>
</tr>
</tbody>
</table>
## Automated UMACT study notification

The CTD Ancillary Committee is notified that the study might require registration in ClinTrials.gov if any of the following criteria is met:
- Funding Source = Federal
- Study Scope = ‘Yes’ for Drug, Biologic, or Device
- Clinical Trial = ‘Yes’ or if ‘No,’ behavioral interventions, process of care changes, physical therapy, surgical procedures or dietary interventions is checked
- Study involves a drug and is Phase 1 – 4
- AND, Submission is a new study

<table>
<thead>
<tr>
<th>ID</th>
<th>Step</th>
<th>Description</th>
<th>Responsible</th>
<th>Timing</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1.3</td>
<td>Automated UMACT study notification</td>
<td>The CTD Ancillary Committee is notified that the study might require registration in ClinTrials.gov if any of the following criteria is met: Funding Source = Federal, Study Scope = ‘Yes’ for Drug, Biologic, or Device, Clinical Trial = ‘Yes’ or if ‘No,’ behavioral interventions, process of care changes, physical therapy, surgical procedures or dietary interventions is checked, Study involves a drug and is Phase 1 – 4, AND, Submission is a new study</td>
<td>IRB7 System</td>
<td>At time of submission</td>
</tr>
<tr>
<td>4.1.4</td>
<td>Review of study to determine if study meets UMACT Business Requirements</td>
<td>The study is reviewed in IRB7 to determine if it meets any of the business rules indicating a UMACT study.</td>
<td>CTD Ancillary Committee</td>
<td>Within 10 business days of receipt of notification via IRB7</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Final determination can exceed timeline window while awaiting study team feedback</td>
</tr>
<tr>
<td>4.1.5</td>
<td>Forward to Billing Task Force for review</td>
<td>If unable to determine if a study meets business rule #3, the details of the study are forwarded to the Billing Task Force for review.</td>
<td>CTD Ancillary Committee</td>
<td>Within 3 business days of CTD Ancillary Committee review</td>
</tr>
<tr>
<td>ID</td>
<td>Step</td>
<td>Description</td>
<td>Responsible</td>
<td>Timing</td>
</tr>
<tr>
<td>------</td>
<td>----------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>----------------------</td>
<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td>4.1.6.</td>
<td>Determine if study has the potential for Medicare billing</td>
<td>Billing Task force will review the study and determine if study is a QCT and has item(s) potentially billable to Medicare.</td>
<td>Billing Task Force</td>
<td>Within 10 business days of receiving CTD Ancillary Committee request for review</td>
</tr>
<tr>
<td>4.1.7.</td>
<td>Notify CTD Ancillary Committee of Billing Task Force Decision</td>
<td>Once the determination is made, the Billing Task Force will provide their decision in writing to the CTD Ancillary Committee.</td>
<td>Billing Task Force</td>
<td>Within 3 business days of Billing Task Force determination</td>
</tr>
<tr>
<td>4.1.8.</td>
<td>UMACT review</td>
<td>Confirmation of UMACT business requirements review and that a business rule was met, if applicable.</td>
<td>CTD Ancillary Committee</td>
<td>Within 3 business days of receipt by CTD Ancillary Committee of Billing Task Force determination</td>
</tr>
<tr>
<td>4.1.9.</td>
<td>CTD Determination and Exception to timeline</td>
<td>Complete CTD Determination and submit within the IRB7 system using the electronic CTD Ancillary Review Form. <strong>Refer to “Instructions for Completing CTD Ancillary Review” document</strong>&lt;br&gt; If the primary members of the CTD Ancillary Committee are not available, designated team members within RCQA will complete the CTD Review on an as needed basis</td>
<td>CTD Ancillary Committee</td>
<td>Upon completion of steps 4.1.1 to 4.1.8 or if exception at time of request</td>
</tr>
<tr>
<td>ID</td>
<td>Step</td>
<td>Description</td>
<td>Responsible</td>
<td>Timing</td>
</tr>
<tr>
<td>--------</td>
<td>-----------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-----------------------------------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>4.1.10.</td>
<td>Review of ICF</td>
<td>Confirm that ICF has essential element per 21 CFR § 50.25 (c ) if study is an ‘Applicable Clinical Trial’&lt;br&gt;If study is not an ‘Applicable Clinical Trial,’ review of relevant ClinicalTrials.gov registration information.&lt;br&gt;Document step on electronic CTD Ancillary Review form</td>
<td>CTD Ancillary Committee</td>
<td>At time of CTD Determination review</td>
</tr>
<tr>
<td>4.1.11.</td>
<td>Notification ICF revision needed</td>
<td>PI/Proxy, Primary Contact, and HSRO team member are notified if modification to ICF language is needed</td>
<td>IRB7 System</td>
<td>At time of CTD Determination review</td>
</tr>
<tr>
<td>4.1.12.</td>
<td>Review of Dissemination Plan</td>
<td>If study is federally funded, grant application is reviewed to verify that a plan for the dissemination of information is present.&lt;br&gt;Document step on electronic CTD Ancillary Review form</td>
<td>CTD Ancillary Committee</td>
<td>At time of CTD Determination review</td>
</tr>
</tbody>
</table>
4.1.13. Notify Study Team via IRB7 of Final Determination

The PI and Primary Contact listed in IRB7 receive confirmation that their study requires registration on ClinicalTrials.gov.

The CTD Ancillary Committee has the final authority in deciding whether a protocol must be registered on ClinicalTrials.gov.

Refer to “Notification of required registration,” “Notification of recommended registration,” or “Notification that NCT number is required.”

CTD Ancillary Committee / IRB7 System

Upon completion of determination

4.1.14. Register protocol in the PRS

Study registered in the PRS. See SOP RCQA-709

PI and/or study team

Prior to enrollment of the first participant

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 UMACT Workflow
Identifying Responsible Party Workflow
Review of ICF for CTD Language Workflow
Review of Dissemination Plan Workflow
Instructions for completing CTD Ancillary Review in IRB7
Notification of required registration
Notification of recommended registration
Notification NCT number is required

7. TEMPLATES/FORMS/TOOLS

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>
</tr>
</thead>
<tbody>
<tr>
<td>26 Oct 2015</td>
<td>20 Oct 2015</td>
<td>Y. Davis</td>
<td>• Clarified grammatical errors throughout the document.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Added the CTD Determination Report to the Template/Forms section of the SOP.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Added section 4.2 ‘Review of Studies that are UMACT per HSR-P-101’</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Change title of SOP to reflect the entire review process.</td>
</tr>
<tr>
<td>11 Aug 2017</td>
<td>26 Jun 2017</td>
<td>Y. Davis</td>
<td>• Added exception rules for CTD Ancillary review in section 4.1.9</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Clarification of how PI and study team are notified regarding CTD Determination in section 4.1.11</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Incorporated changes to align with 42 CFR § 11 effective January 18, 2017 in section 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Added additional criteria for Rule # 3 to indicate when a sponsored study would need to have an NCT number in section 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Deleted UMACT Checklist and added the use of the University of Miami Clinical Trial</td>
</tr>
</tbody>
</table>
### Description of Changes

- Registration and Result Reporting Tool in section 7
- Included Workflows to accompany SOP
- Built out the responsibility section for SOP consistency in section 3
- Added step for ICF review and Follow-up during CTD Determination in section 4.1.10 and 4.1.11
- Added steps for review and escalation process of federally funded grant for verification of plan to disseminate information in step 4.1.12 and 4.1.13
- Added additional definitions for Clinical Trial, HSRO, ORA, Primary Contact, and QCT
- Added Clarification to timeline for CTD Determination
- Clarified the business rules to be more specific to clinical trials

### SIGNATURES

**Prepared by:** Yolanda P. Davis, BS, CCRP  
Quality Assurance Manager – Clinical Trial Disclosure, RCQA  

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