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| Document Number: | RCQA-708-01 | Effective Date:13 Jun 2016 |
| Page No. | Page 1 of 4 | Author: Y. Davis |
| Title: | Clinical Trial Disclosure Informed Consent Review | |

## 1. PURPOSE

The purpose of this document is to describe the compliance process and procedures, supporting documents, and reports pertaining to Clinical Trial Disclosure Informed Consent Review.

## 2. DEFINITIONS

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|---|---|
| **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 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 |
| **ICF** | Informed Consent Form |
| **IRB** | Institutional Review Board |
| **IRB7** | An electronic IRB solution to facilitate tracking of Human Subject Research |
| **RCQA** | Office of Research Compliance and Quality Assurance |
| **RCQA ED** | Executive Director of the Office of Research Compliance and Quality Assurance |

## 3. RESPONSIBILITY

### 3.1. **CTD Compliance Officer or Designee**

- Initiate ICF Review for CTD language
- Issues CTD ICF Review Report Review Report
- Follow-up on responses by PI and IRB

3.2. **Executive Director of RCQA and Team**

- Review and approve ICF Review Report

## 4. PROCEDURE

| *ID* | *Step* | *Description* | *Responsible* | *Timeline* |
|---|---|---|---|---|
| **4.1. ICF Essential Element Review** | | | | |
| 4.1.1. | Generate Active Drug and Device Study Report | Excel Report generated using reporting function within IRB-7 of all currently active drug and device studies. | CTD Compliance Officer or designee | Annually |
| 4.1.2. | Merge Reports | Excel Reports will be merged and saved using the following nomenclature: ICF Essential Element Review_yyyymmdd | CTD Compliance Officer or designee | Within 1 week of report generation |
| 4.1.3. | Filter Studies | ICF Essential Element Review Report is filtered using the following criteria:<br>• Studies initiated by the IRB on or after March 7, 2012<br>• Study was not an emergency use study<br>• Study is a clinical trial | CTD Compliance Officer or designee | In parallel with step 4.5.2 |
| 4.1.4. | Review ICFs | ICFs for each of the studies meeting the above outlined criteria will be reviewed to ensure that the required essential element is unaltered and the statement is included in the currently available IRB approved ICF | CTD Compliance Officer or designee | Initiated within 2 weeks of report generation |
| 4.1.5. | Verify if ACT definition met | If the statement is not present, the protocol for the study is reviewed to ensure that the study meets the definition of an 'ACT'. | CTD Compliance Officer or designee | During step 4.5.4 |

| ID | Step | Description | Responsible | Timeline |
|---|---|---|---|---|
| 4.1.6. | Verify ClinicalTrials.gov registration | ClinicalTrials.gov will be reviewed to confirm if the study is registered | CTD Compliance Officer or designee | During step 4.5.4 |
| 4.1.7. | Document Findings | Review of steps 4.5.4 to 4.5.6 will be documented within the ICF Essential Element Review Report. | CTD Compliance Officer or designee | During step 4.5.4 to 4.5.6 |
| 4.1.8. | Discuss Findings | Findings from the ICF Essential Element review are discussed within RCQA | RCQA ED<br><br>CTD Compliance Officer or designee | Within one week after completion of review |
| 4.1.9. | Generate Report | CTD Compliance Review Report is generated, see SOP RCQA-702. | CTD Compliance Officer or designee | Within 14 days after completion of step 4.5.8 |

| ID | Step | Description | Responsible | Timeline |
|---|---|---|---|---|
| **4.2. ICF Essential Element Review Follow-Up** | | | | |
| 4.2.1. | Review IRB response for non-compliant studies | IRB7 history will be reviewed to determine what follow-up actions were requested by the IRB. | CTD Compliance Officer or designee | |
| 4.2.2. | Verify ICFs are revised | Studies are reviewed to determine if ICFs were revised to include the necessary language and approved. | CTD Compliance Officer or designee | |
| 4.2.3. | Verify IRB requested actions are completed | Studies are reviewed to determine if all actions as required by the IRB were completed. | CTD Compliance Officer or designee | |

| *ID* | *Step* | *Description* | *Responsible* | *Timeline* |
|---|---|---|---|---|
| 4.2.4. | CTD Compliance Review Follow-up Report Completed | CTD Compliance Review Follow-up report is completed (*as per SOP-RCQA-702)* documenting all of the tasks and completion date for all verifiable actions. | CTD Compliance Officer or designee. | |

## 5. DOCUMENTATION

RCQA will maintain an electronic copy

## 6. REFERENCES

SOP RCQA-702 CTD Compliance Report Generation
21 CFR § 50.25 ( c )
Food and Drug Administration Amendment Act; Section 801; 2007
Food and Drug Administration Compliance Program Guidance Manual (Form FDA 2438) March 11, 2011

## 7. TEMPLATES/FORMS

CTD Compliance Review Report
CTD Compliance Review Follow-up Report

## 8. REVISION HISTORY

N/A

## 9. SIGNATURES

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Approved by: Signature on File Date: 13 Jun 2016
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