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| Document Number: | RCQA-204-08 | Effective Date: 27 Aug 2020 |
| Page No. | Page 1 of 6 | Author: H. Miletic |
| Title: | Federal Audit Preparation Assessment | |

## 1. PURPOSE

To define the process by which the office of Research Compliance and Quality Assurance (RCQA) conducts an assessment of a research site's preparation and readiness for a federal audit. This process is intended to assess the level of compliance with applicable regulations and requirements for the conduct of a human subject research study for which the Principal Investigator (PI) has received notice of an upcoming federal audit.
Federal audits may be conducted by organizations such as the FDA, DOD, OHRP, NIH, EMA, etc. or any other external, federal organization.
At the request of a PI, an external audit preparation assessment may be conducted for sponsor audits, as time and resources allow.

## 2. DEFINITIONS

AVP – Associate Vice President, Regulatory Affairs and Assessment
DOD – Department of Defense
EMA – European Medicines Agency
Federal Audit – An audit conducted by a federal organization such as FDA, NIH, EMA, etc., or any other federal organization.
FDA – Food and Drug Administration
NIH – National Institutes of Health
OHRP – Office for Human Research Protections
PI – Principal Investigator
QA – Quality Assurance
QA Auditor - a member of RCQA that performs Quality Reviews
Research Site – Site where investigational product (drug/device/biologic) is administered to subjects, or the site at which subjects are participating in a medical or social behavioral study
RCQA – Research Compliance and Quality Assurance
Sponsor-investigator – An individual who both initiates and conducts an investigation and holds both sponsor and investigator responsibilities.
VPR – Vice Provost for Research

## 3. RESPONSIBILITY

### 3.1 RCQA

- Assigns QA Auditors to conduct Federal Audit Preparation Assessments
- Notifies PI and schedules the Federal Audit Preparation Assessments
- Performs the Federal Audit Preparation Assessments
- Issues summary reports of Federal Audit Preparation Assessments

### 3.2 Principal Investigator

- Notifies RCQA immediately upon receiving notification of an upcoming federal inspection
- Schedules Federal Audit Preparation Assessments with RCQA QA Auditors
- Provides all study-related documents
- Allows study staff to be available to answer questions
- Receives copy of Federal Audit Preparation Assessment summary report
- Implements corrective actions, if needed

## 4. PROCEDURE

### 4.1 Federal Inspection Notification

**4.1.1** Upon receiving notification from the federal auditors of an upcoming inspection, the PI must immediately notify RCQA of the following information:

- Protocol number and title of research study to be inspected
- Dates of the inspection

### 4.2 Federal Audit Preparation

**4.2.1** RCQA will arrange to meet with the PI and his/her study team as soon as possible to begin advising the team on how to prepare for the inspection.

**4.2.2** Audit preparation advice provided by RCQA will consist of:

- Conducting the presentation "Preparing for an FDA Audit."
    - Note that this presentation can be applied and adapted to all types of audits
- Offering recommendations/suggestions on how to organize research files
- Reviewing the relevant regulations (i.e. FDA/NIH/EMA, etc.) pertaining to this research study. For example, applicable regulations for sponsor-investigators; studies involving minors, etc.
- Reviewing the list of required documents to be presented during the inspection
- Advising personnel on proper conduct when interacting with FDA or other federal investigators
- Advising the team on who should be present at the initial and exit interviews with the federal investigators
- Reviewing what needs to be documented during the inspection, such as:
    - A list of documents provided to the investigator(s)

- Questions asked by the investigator(s)
- Answers provided to the investigator(s)

### 4.3 Notification of Federal Audit Preparation Assessment

**4.3.1** RCQA will notify the PI, his/her departmental chairperson and division chief if applicable, the AVP and VPR via email, of the Federal Audit Preparation Assessment to be conducted. The RCQA Executive Director, Director GxP Compliance and the CAPA Manager will be copied on the email.

**4.3.2** An attempt will be made to agree on a mutually convenient date; however, time may be limited and sufficient time will need to be allotted to conduct the assessment and review identified observations with the PI and study team.

- The PI will not have the option to refuse RCQA's Federal Audit Preparation Assessment.

**Note:** The Federal Audit Preparation Assessment must take priority over any routine Quality Review already scheduled by RCQA. Routine Quality Reviews may be re-scheduled at the discretion of RCQA's Executive Director. Directed Quality Reviews should be conducted as scheduled.

### 4.4 Conduct of Federal Audit Preparation Assessment

**4.4.1** RCQA will assign a QA Auditor to conduct an assessment of the audit preparation.

- This assessment will not be conducted like a routine or directed Quality Review, but rather as a focused review of a selected number of subject records and key documents.

**4.4.2** The following is a general plan for conducting the Federal Audit Preparation Assessment:

- Review and become familiar with applicable regulations: FDA, OHRP, NIH, EMA, etc.
- Review and become familiar with audit requirements of FDA, OHRP, NIH, EMA, etc.
- Select a percentage of subject records to be reviewed in detail
- Verify that source documents support reported data

- Review the following key components:
  - Study protocol and amendments
  - Informed consent forms and informed consent process documentation
  - IRB communications and approvals
  - Documentation of any deviations/violations
  - Delegation of Authority Logs
  - Drug accountability records
  - Serious adverse event, adverse event and unanticipated problems identification, documentation and reporting
  - Investigator responsibilities
  - Sponsor-investigator responsibilities (if applicable)
  - Case report forms and any database used

**Note:** This plan may be modified by RCQA as needed for each particular study. In addition, the plan may need to be modified due to limited time, if the audit notification was received shortly prior to the audit.

### 4.5 Exit Meeting

The QA Auditor will offer to schedule an exit meeting with the PI and study team to discuss any observations or discrepancies identified during their review. Recommendations for corrective and preventive actions will be provided in a summary report. If the PI is not available to meet, a summary report will be issued as outlined below.

### 4.6 Summary Report

Upon completion of the assessment, observations will immediately be summarized in bullet-point form in a summary report. The PI will not be required to respond to the report.
The report will be sent to the PI via email within 24 hours after completion of the summary report, with the following leadership personnel copied on the email:

- Departmental chairperson and division chief
- CRORS Director or designee (if study is monitored by CRORS)
- RCQA Executive Director and QA Manager
- AVP
- VPR

## 5. DOCUMENTATION

RCQA will maintain an electronic copy of the summary report on the RCQA shared drive under the PI's last name, indefinitely.
For example: S:\RCQA\Auditing\Audits\FDA Audits\PI Name.

## 6. REFERENCES

N/A

## 7. TEMPLATES / FORMS / TOOLS

- Audit Preparation Assessment Report Template

## 8. REVISION HISTORY

| Effective Date | Revision Date | Author | Description of Changes |
|---|---|---|---|
| 26 Aug 13 | 21 Aug 13 | H. Miletic | Updated the term Compliance Officer to QA Auditor throughout the document. Removed the Senior Associate Dean for Clinical Research and QA Director from the document. Removed sponsor company from the definition of external audit in section 2. Replaced QA Director with QA Manager in section 4.5. Updated section 5 to reflect the location of the files on the shared drive. |

| Effective Date | Author | Description of Changes |
|---|---|---|
| 25 Aug 2014 | H. Miletic | Changed the name of the office from Regulatory Support and Quality Assurance (RSQA) to Research Compliance and Quality Assurance (RCQA) throughout the document. Updated section 5 to add that the report will be maintained for a minimum of ten years. Updated section 6 to remove the document retention policy. Modified the format of the revision history table. |
| 19 Apr 2017 | H. Miletic | Updated the Purpose and Definitions sections to remove the cooperative groups as they are captured as NIH audits. |

| Effective Date | Author | Description of Changes |
|---|---|---|
| | | Updated section 3.3 to add that the PI receives the External Audit Preparation Assessment report. Modified section 4.4.2 to remove the cooperative groups. Added section 4.5 to specify that an exit meeting will be held with the PI and study team. Added CRORS Director to section 4.6. Eliminated the section on Follow-up as it was incorporated into sections 4.5 and 4.6. |
| 23 Oct 2017 | H. Miletic | As requested, removed the Dean from list of leadership personnel receiving summary report in step 4.6. |
| 30 Mar 2018 | H. Miletic | All references to internal audits were renamed to Quality Reviews. Updated the Purpose section to include that audit preparation assessments may be done for sponsor audits at the request of a PI. Removed the Provost and Executive Dean for Research from section 4.6. Added Audit Preparation Assessment Report Template to section 7. Minor edits made throughout. |
| 02 Apr 2019 | H. Miletic | Updated section 3 as External Audit Preparation Assessment summary reports will not be submitted to the IO. Removed the IO from sections 3.2, 4.1.1 and 4.6. Modified step 4.5 to state that an exit meeting will be offered. |
| 27 Aug 2020 | H. Miletic | Changed "External" to "Federal" throughout document including title. Added AVP to definitions and to section 4.3. Replaced IO with VPR throughout. Removed IO definition. Updated definition of Research Site. Added AVP and VPR to section 4.6. Updated section 5 to change Box drive to shared drive and to state that electronic files will be maintained indefinitely. Minor edits to text. |

## 9. SIGNATURES

Prepared by: Helen Miletic Digitally signed by Helen Miletic Date: 2020.08.27 16:45:06 -04'00' Date: _____
Helen Miletic, MA, CHRC, RQAP-GCP
Director, GxP Compliance, RCQA

Approved by: Johanna Stamates Digitally signed by Johanna Stamates Date: 2020.08.27 19:08:30 -04'00' Date: _____
Johanna Stamates, RN, MA, CCRC, CHRC
Executive Director, RCQA