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 an external 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 external audit. External audits may be conducted by federal 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

DOD – Department of Defense
EMA – European Medicines Agency
External Audit – An audit conducted by an outside organization such as FDA, NIH, EMA, etc., or any other external federal organization.
FDA – Food and Drug Administration
IO – Institutional Official
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) is administered to subjects.
RCQA – Research Compliance and Quality Assurance
Sponsor-investigator – An individual who both initiates and conducts an investigation and holds both sponsor and investigator responsibilities.

3. RESPONSIBILITY

3.1 IO

- Receives copies of External Audit Preparation Assessment summary reports

3.2 RCQA

- Assigns QA Auditors to conduct External Audit Preparation Assessments
- Notifies PI and schedules the External Audit Preparation Assessments
- Performs the External Audit Preparation Assessments
- Issues summary reports of External Audit Preparation Assessments
3.3 Principal Investigator

- Notifies the IO and RCQA immediately upon receiving notification of an inspection from the external auditing entity
- Schedules External Audit Preparation Assessments with RCQA QA Auditors
- Provides all study-related documents
- Allows study staff to be available to answer questions
- Receives copy of External Audit Preparation Assessment summary report
- Implements corrective actions, if needed

4. PROCEDURE

4.1 External Inspection Notification

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

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

4.2 External 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 external investigators
- Advising the team on who should be present at the initial and exit interviews with the external investigators
- Reviewing what needs to be documented during the inspection, such as:
4.3 Notification of External Audit Preparation Assessment

4.3.1 RCQA will notify the PI, his/her departmental chairperson and the IO via email, of the External Audit Preparation Assessment to be conducted.

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 the observations with the PI and study team.

- The PI will not have the choice to refuse RCQA’s External Audit Preparation Assessment.

Note: The External Audit Preparation Assessment should 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 Review should be conducted as scheduled.

4.4 Conduct of External Audit Preparation Assessment

4.4.1 RCQA will assign two QA Auditors (if possible) 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 External 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 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

An exit meeting will be held with the PI and study team to discuss any observations or discrepancies. Recommendations for corrective and preventive actions will be provided.

4.6 Summary Report

Observations will be summarized in bullet-point form in a summary report. Responses to the External Audit Preparation Assessment summary report will not be required from the PI.
The report will be generated immediately after the completion of the assessment and sent to the PI via email. The following leadership personnel will be copied on the email:

• Departmental chairperson
• IO
• CRORS Director or designee (if study is monitored by CRORS)
• RCQA Executive Director and QA Manager
5. DOCUMENTATION

RCQA will maintain an electronic copy of the summary report on the RCQA Box drive under the PI’s last name for a minimum of ten years. 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

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Revision Date</th>
<th>Author</th>
<th>Description of Changes</th>
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<tr>
<td>26 Aug 13</td>
<td>21 Aug 13</td>
<td>H. Miletic</td>
<td>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.</td>
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<tr>
<td>25 Aug 2014</td>
<td>H. Miletic</td>
<td>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.</td>
</tr>
<tr>
<td>19 Apr 2017</td>
<td>H. Miletic</td>
<td>Updated the Purpose and Definitions sections to remove the cooperative groups as they are captured as NIH audits. Updated section 3.3 to add that the PI receives the External Audit Preparation Assessment report. Modified section</td>
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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.

9. SIGNATURES

Prepared by:____________________________________  30 Mar 2018
Signature on file
Date: ____________
Helen Miletic, MA, CHRC, RQAP-GCP
Quality Assurance Manager, RCQA

Approved by:___________________________________  30 Mar 2018
Signature on file
Date: ____________
Johanna Stamates, RN, MA, CCRC, CHRC
Executive Director, RCQA