Document Number:	RCQA-207-01	Effective Date: 01 Oct 2020
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Title:	Role of RCQA With Cooperative Group Audits	

1. PURPOSE

The purpose of this document is to define the role of the office of Research Compliance and Quality Assurance (RCQA) prior to, during, and after completion of audits conducted by the National Cancer Institute (NCI) National Clinical Trials Network at the University of Miami. Audits conducted by any of the member organizations of the NCI's National Clinical Trials Network are herein referred to as "Cooperative Group Audits."

2. DEFINITIONS

AVP – Associate Vice President, Regulatory Affairs and Assessment
HSRO – Human Subjects Research Office
IRB – Institutional Review Board
JHS – Jackson Health System
NCI – National Cancer Institute
OHRP – Office for Human Research Protections
PI – Principal Investigator
QA – Quality Assurance
QA Auditor- A member of RCQA that performs Quality Reviews
RCQA – Research Compliance and Quality Assurance
SCCC – Sylvester Comprehensive Cancer Center
Velos – Clinical Trial Management System
VPR – Vice Provost for Research

3. RESPONSIBILITY

3.1 Sylvester Comprehensive Cancer Center (SCCC)

- Notifies RCQA of an upcoming Cooperative Group audit
- Provides RCQA with available dates for the Preparatory Assessment
- Receives Preparatory Assessment Summary Reports from RCQA
- Invites RCQA to Cooperative Group Audit Meetings (Initial, Debriefing, and Exit Meetings)
- Provides RCQA a copy of the Cooperative Group Audit Report upon receipt
- Works with the RCQA CAPA Manager to respond to observations in the Cooperative Group Audit Report

3.2 RCQA

- Assigns QA Auditors to conduct Preparatory Assessments
- Schedules Preparatory Assessments
- Performs Preparatory Assessments
- Issues Preparatory Assessment Summary reports to PI and SCCC
- Attends Cooperative Group Audit Meetings (Initial, Debriefing, Exit Meeting)
- Assists PI and Study Team with drafting response to the Cooperative Group Audit Report

3.3 Principal Investigator (PI)

- Is available for meetings during the Preparatory Assessments
- Provides all study-related documents
- Allows study staff to be available to answer questions
- Is responsible for submitting deviations identified in Preparatory Assessment Reports, to the IRB or External IRB (if applicable), per the requirements of the IRB of record

4. PREPARATORY ASSESSMENT PROCESS

4.1 Cooperative Group Audit Notification by SCCC

In accordance with the University's policy *Hosting External Governmental Audits of Clinical Research (PolicyStat ID 7973338)*, the SCCC PI or designee immediately informs RCQA upon notification of a Cooperative Group Audit. RCQA will then work with the PI or designee to schedule a Preparatory Assessment, based on the confirmed date of the Cooperative Group Audit, as communicated by SCCC.

The SCCC PI or designee will provide RCQA with the list of applicable study protocols and subjects, as previously identified in the Cooperative Group auditor's correspondence to the SCCC.

4.2 Preparatory Assessment Notification

4.2.1 Confirm with the PI

The QA auditor assigned by the QA Manager/Executive Director (ED) to conduct the review, will email a Preparatory Assessment Confirmation Memo to the PI to confirm the date for the Preparatory Assessment, and the selected study(ies). The following personnel will be copied:

- RCQA Executive Director, QA Manager, CAPA Manager
- The SCCC central email address: **sccrcqa@miami.edu**
- Both SCCC Executive Directors, Clinical Research Services:
    - nxn319@med.miami.edu
    - parlen@med.miami.edu

The Assessment will be scheduled for one day; however, if more time is needed, the QA auditor will inform the QA Manager/ED.

4.3 Assessment Preparation by RCQA

4.3.1 Prior to the Preparatory Assessment, the QA Auditor may review the study documentation found in the IRB, Velos, and Complion (SCCC electronic regulatory binder) systems.

4.3.2 The QA Auditor should review and be familiar with the *NCI Guidelines for Auditing Clinical Trials for the NCI Clinical Trials Network Program* (https://ctep.cancer.gov/branches/ctmb/clinicalTrials/monitoring_coop_ccop_ctsu.htm)

4.5 Preparatory Assessment Conduct

4.5.1 These assessments are intended to assess the research team's overall level of audit readiness, and to provide guidance and recommendations for good research practices.

Preparatory Assessments may consist of a review of the following, for completeness and organization:

- Overall review of the research files if they were prepared according to NCI guidelines and audit expectations
- Review of 100% of the informed consent and HIPAA authorization records for the previously identified subjects
- Limited review of regulatory documentation, if needed
- Limited review of study team protocol training and human subject research training records
- Records of receipt, administration, and return of investigational product, if applicable
- Limited review of previously identified subject records

4.5.2 During the course of the assessment, the QA Auditor will notify the RCQA Executive Director of any issues that may jeopardize the safety and welfare of human subjects or data integrity, as well as any potential observations related to JHS.
The RCQA Executive Director will then immediately notify the VPR, AVP, the Director for Human Subject Research, and the office of the Executive Dean for Research, as applicable.

4.6 Preparatory Assessment Summary Report

4.6.1 Observations will be reported in a bullet-point format that may also include recommendations to the PI and/or study team for addressing identified issues.

4.6.2 The Preparatory Assessment Summary Report will be reviewed within RCQA prior to issuance.

4.6.3 **Within two (2) business days** of completing the assessment, the QA Auditor will issue the Preparatory Assessment Summary Report to the PI and main study team members. The following personnel will be copied on the email:

- SCCC QA Manager
- SCCC central email: **sccrcqa@miami.edu**
- Both SCCC Executive Directors, Clinical Research Services:
  - nxn319@med.miami.edu
  - parlen@med.miami.edu
- RCQA Executive Director and QA Manager

4.6.4 The QA Auditor will offer to schedule an exit meeting with the PI and study team to review the report together, if desired.

4.6.5 The PI will **not** be required to respond to the Preparatory Assessment Summary Report.

4.6.6 The PI will be responsible for reporting to the IRB any deviations identified in the Preparatory Assessment Summary Report.

4.7 Cooperative Group Audit and SCCC CAPA Plan

4.7.1 SCCC will **i**nvite the following RCQA members to the Cooperative Group Audit Meetings (Initial, Debriefing, and Exit Meetings):

- RCQA Executive Director and QA Manager
- CAPA Manager

4.7.2 SCCC will provide RCQA with a copy of the Cooperative Group Audit Report upon receipt.

4.7.3 The RCQA CAPA Manager will provide assistance with the creation of a CAPA Plan in response to the Cooperative Group Audit.

4.7.4 The PI or designee must send the CAPA Plan to the CAPA Manager/designee for review prior to submission to the Cooperative Group.

4.8 Post- Study Review Customer Satisfaction Survey

Within **five (5) business days** of issuing the Preparatory Assessment Summary Report, the QA Auditor will email the RCQA administrative assistant and request that a customer satisfaction survey be sent to the PI and study team.

5. DOCUMENTATION

RCQA will maintain a copy of the Preparatory Assessment Summary Report and any correspondence concerning the report in the RCQA shared drive as follows:

S:\RCQA\Auditing\Audits\Audit Preparation Assessment\PI Name

6. REFERENCES

- Policy: Hosting External Governmental Audits of Clinical Research (PolicyStat ID 7973338)
- NCI Guidelines for Auditing Clinical Trials for the NCI Clinical Trials Network Program

7. TEMPLATES / FORMS / TOOLS

The following templates and forms can be found on the shared RCQA Box drive: S:/RCQA/Auditing/Auditing Forms/Current Templates & Forms

- Preparatory Assessment Summary Report Template

8. REVISION HISTORY

Effective Date	Author	Description of Changes
01 Oct 2020	N. Vega	New procedure

9. SIGNATURES

Prepared by: Nelson A. Vega Digitally signed by Nelson A. Vega Date: 2020.10.01 16:34:05 -04'00' Date: _____

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Approved by: Johanna Stamates Digitally signed by Johanna Stamates Date: 2020.10.01 14:39:11 -04'00' Date: _____

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