

RESEARCH COMPLIANCE AND QUALITY ASSURANCE  
STANDARD OPERATING PROCEDURE

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## 1. PURPOSE

To define the process by which the office of Research Compliance and Quality Assurance (RCQA) hosts federal audits or inspections of a research site at the University of Miami. Federal audits may be conducted by organizations such as, but not limited to, the FDA, OHRP, NIH, DOD, EMA, etc. or any other external federal organization. Note that portions of these audits or inspections may be conducted remotely.

Refer to policy: Hosting External Governmental Audits of Clinical Research.

**Note:** The terms “audit” and “inspection” are used interchangeably throughout this document.

## 2. DEFINITIONS

CAPA – Corrective Action Preventive Action

CRORS – Clinical Research Operations and Regulatory Support

DOD – Department of Defense

EMA – European Medicines Agency

FDA – Food and Drug Administration

HSRO – Human Subjects Research Office

JHS CTO – Jackson Health System Clinical Trial Office

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/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 a clinical investigation and under whose immediate direction the investigational drug, device or biologic is administered, dispensed or used.

UM – University of Miami

VPR – Vice Provost for Research

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### 3. RESPONSIBILITY

#### 3.1 RCQA

- Receives notification from the research site of upcoming inspection from a federal auditing entity
- Notifies leadership of the announced federal inspection
- Conducts an audit preparation discussion with the PI and study team to coach them on how to interact with federal inspectors
- Schedules an External Audit Preparation Assessment, if time permits
- Attends the audit's initial meeting, interviews, debriefings and close-out meeting
- Acts as facilitator to ensure that requests from the federal inspector(s) are quickly addressed
- Acts as the institutional representative

#### 3.2 Principal Investigator (PI) or Sponsor-Investigator

**Note:** The term Sponsor-Investigator may be used in place of PI, wherever PI is stated throughout this document.

- Notifies RCQA immediately upon receiving notification of an inspection from a federal auditing entity
- Notifies study sponsor, CRORS, research pharmacy, JHS CTO, if applicable
- Provides all relevant study records for inspection
- Makes themselves available during the inspection
- Ensures that study personnel are available throughout the entire inspection to answer questions and/or respond to requests from the federal inspector(s), such as retrieving additional documents

### 4. PROCEDURE

#### 4.1 Federal Inspection Notification

Upon receiving notification of an upcoming federal 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

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#### **4.2 Leadership Notification**

Upon receiving notification of a federal inspection, the RCQA Executive Director or designee will notify the following leadership members, via email:

- Departmental chairperson, Division Chief and Center Director (if applicable)
- Dean of the respective school
- Chief Compliance Officer of Medical School
- Chief Compliance Officer for the University
- IO/VPR
- Associate Vice President, Regulatory Affairs and Assessment
- Provost
- Executive Dean for Research (if this is an inspection at the Medical School)
- CRORS Director or designee (if CRORS is monitoring the study to be inspected)
- CEO of UHealth and Senior Vice President of Health Affairs
- Director for Human Subjects Research
- Chief Risk Officer, Risk Management
- General Counsel
- RCQA Executive Director, Director GxP Compliance, QA Manager, CAPA Manager and CTD Manager

This notification will include:

- Protocol number and title of research study to be inspected
- Name of Principal Investigator or Sponsor-Investigator
- Dates of the inspection
- Name of FDA Investigator, if available

#### **4.3 Request for List of Studies**

Federal inspectors such as the FDA typically request a list of the PI's studies. For this reason, the RCQA Executive Director or designee will request the PI to provide a list of the PI's studies. The list should be available to the federal inspector at the beginning of the inspection and should include at minimum, all of the PI's opened and closed studies from the last five (5) years and the following information: IRB protocol number, study title, investigational product, IND/IDE # and study status. Additional information may be provided at the inspector's request.

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#### **4.4 Preparation for Inspection**

- 4.4.1 For on-site inspections, RCQA will offer to host the federal audit in a dedicated room of Dominion Tower maintained especially for federal audits. Access to the room is limited via badge access.

If the PI agrees to have the audit take place at the designated room at Dominion Tower, RCQA will contact UM Security to obtain a visitor's badge for the federal inspector(s). The badge will:

- Be labeled with the name of the auditing entity. For example: "FDA Investigator."
- Grant access to this room, as specified by RCQA in the request to Security.
- Be valid for a defined period of time.

- 4.4.2 If the PI agrees to use this room, it is the responsibility of the PI and study team to transfer all relevant study records to this room in time for the inspection.
- 4.4.3 RCQA will schedule a meeting with the PI and study team to advise them on how to prepare for the audit as described in SOP RCQA-204.
- 4.4.4 If time permits, RCQA will conduct an External Audit Preparation Assessment as per SOP RCQA-204, by reviewing the study records prior to the start of the federal inspection.

#### **4.5 Initial Meeting With Federal Inspector(s)**

- 4.5.1 Representatives from RCQA will attend the initial meeting (whether on-site or conducted remotely) with the federal inspector(s), PI and any individuals selected by the PI from his/her study team.

RCQA members attending the meeting may consist of:

- RCQA Executive Director and/or Director GxP Compliance and/or QA Manager and/or CAPA Manager
- QA Auditors

- 4.5.2 If the initial meeting is held on-site, RCQA will provide the federal inspector(s) with a visitor's badge.

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- 4.5.3 RCQA representatives will introduce themselves to the federal inspector(s), provide their contact information and explain their role as facilitators and institutional representatives for the duration of the inspection.

#### **4.6 Inspection Debriefings**

- 4.6.1 RCQA representatives will attend all debriefings with the federal inspector(s).
- 4.6.2 The CAPA Manager will attend the debriefings to gain an understanding of the issues detected during the inspection. The CAPA Manager will begin working with the PI and study team immediately to clarify or resolve any issues identified. See section 4.7 Responding to Questions and Requests.
- 4.6.3 If serious issues are detected by the federal inspector(s), RCQA will immediately notify leadership via email. RCQA may also facilitate meetings or conference calls with leadership to discuss such issues in more detail.
- 4.6.4 If the sponsor requests to be present during the federal inspection, they will be allowed on site; however, they may not attend any of the inspection debriefings with the federal inspector(s). If communication between the sponsor and the federal inspector(s) is needed, RCQA will be present.

#### **4.7 Responding To Questions and Requests**

During the conduct of the federal audit/inspection, the CAPA Manager will work closely with the PI and study team to facilitate and expedite the process of responding to questions or requests from the federal inspector(s).

- 4.7.1 Following each debriefing with the federal inspector(s), the CAPA Manager will meet with the PI and study team to address issues that have been identified by the federal inspector(s). This may entail reviewing records and gathering the requested documentation to be presented to the federal Inspector(s).

#### **4.8 Interviews**

RCQA representatives will attend all interviews of the PI and study team conducted by the federal inspector(s).

- 4.8.1 RCQA will coach interviewees prior to each interview with federal inspector(s).
- 4.8.2 RCQA will take notes of what was asked and answered during the interviews. These notes are for RCQA use only and are used to update leadership on the

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progress of the inspection. The PI and study team must have a note taker present during the interviews.

#### **4.9 Affidavits**

During the conduct of interviews, a federal inspector may request the PI or other personnel to sign an affidavit. It is the University's process/advice that affidavits not be signed by UM faculty or personnel. If an affidavit is requested, RCQA will inform the federal inspector(s) that it is the practice at UM not to sign an affidavit. RCQA will then immediately notify General Counsel, Risk Management and the IO/VPR of the request for a signed affidavit.

#### **4.10 Close-out Meeting**

- 4.10.1 Prior to the close-out meeting, RCQA will coach the PI and study team on how to interact with the federal inspector(s) at the meeting.
- 4.10.2 RCQA representatives will attend the close-out meeting in order to understand any observations identified by the federal inspector(s). Observations may include written observations such as on Form FDA 483 and/or verbal observations. Written observations may also be issued at a later date such as with EMA inspections.
- 4.10.3 The PI and study team as well as RCQA should take notes on what was discussed during the meeting.
- 4.10.4 At the close-out meeting, RCQA will retrieve the visitor's badge from the federal inspector(s).

#### **4.11 Notification to Leadership of Audit Conclusion**

At the conclusion of the audit, the RCQA Executive Director or designee will notify leadership (as listed in step 4.2) of the outcome of the audit/inspection and forward to them a copy of the inspection report or Form FDA 483 as applicable. Additional personnel as applicable, may also be included in this communication.

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#### 4.12 Responding to Federal Inspection Reports

The CAPA Manager and/or a designated RCQA member will assist the PI and study team in the development of a response to the federal inspection report, as outlined in SOP RCQA- 800.

#### 5. DOCUMENTATION

N/A

#### 6. REFERENCES

Policy: Hosting External Governmental Audits of Clinical Research  
SOP RCQA-204: External Audit Preparation Assessment  
SOP RCQA-800: Federal Organization CAPA or CAPA Plan

#### 7. TEMPLATES / FORMS / TOOLS

N/A

#### 8. REVISION HISTORY

Effective Date	Author	Description of Changes
19 Apr 2017	H. Miletic	Updated the Purpose and Definitions section to remove the specific cooperative groups as they are captured as NIH groups. Added the Chief Compliance Officer of Medical School, CEO of UHealth/Senior Vice President of Health Affairs, CRORS Director, Center Director and CTD Manager to the list of leadership to be notified of inspection in section 4.2. Updated section 4.3 to state that the PI will provide his/her list of studies.
30 Mar 2018	H. Miletic	Changed the term “audit” to “Quality Review” in section 2.
02 Apr 2019	H. Miletic	Modified sections 3.2 and 4.1 to remove the IO from the notification. Modified section 4.2 to add Executive Director for Human Subject Research, Director GxP Compliance and designee. Added Director GxP Compliance to section 4.5.1. Changed QA Manager to designee in sections 4.2 and 4.11.

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28 Aug 2020	H. Miletic	Removed reference to Roles and Responsibilities Form in sections 3.1 and 7. Referred to policy “Hosting External Governmental Audits of Clinical Research” in sections 1 and 6. Added statement to section 1 that portions of inspections may be conducted remotely. Added definitions for JHS-CTO and VPR. Added Associate Vice President, Regulatory Affairs and Assessment, and Risk Management to list of leadership in step 4.2 Changed Executive Director to Director for Human Subjects Research in section 4.2. Added CRORS, research pharmacy and JHS-CTO to section 3.2. Clarified which steps apply to on-site inspections vs remote. Minor edits made throughout document.
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**9. SIGNATURES**

Prepared by: \_\_\_\_\_ Date: \_\_\_\_\_  
Helen Miletic, MA, CHRC, RQAP-GCP  
Director, GxP Compliance, RCQA

Approved by: \_\_\_\_\_ Date: \_\_\_\_\_  
Johanna Stamates, RN, MA, CCRC, CHRC  
Executive Director, RCQA