

RESEARCH COMPLIANCE AND QUALITY ASSURANCE  
STANDARD OPERATING PROCEDURE

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## 1. PURPOSE

The purpose of this document is to define the process by which the office of Research Compliance and Quality Assurance (RCQA) conducts Focused Quality Reviews of the receipt, storage, distribution and disposal of study-related medications, biologics, devices and other test articles. These Quality Reviews are conducted for studies where the test articles are not stored or dispensed via the research pharmacy and are intended to assess the research team's level of compliance with Federal and State regulations and guidelines, and University policies and procedures.

## 2. DEFINITIONS

AVP – Associate Vice President, Regulatory Affairs and Assessment

CAPA – Corrective and Preventive Action

CRORS – Clinical Research Operations & Regulatory Support

CTO – Clinical Trials Office at JHS

HIPAA – Health Insurance Portability and Accountability Act

HSRO – Human Subjects Research Office

IRB – Institutional Review Board

IRB system - Electronic protocol submission and tracking system

JHS – Jackson Health System

QA - Quality Assurance

QA Auditor - A member of RCQA that performs Quality Reviews

RCQA – Research Compliance and Quality Assurance

SCCC – Sylvester Comprehensive Cancer Center

SOP – Standard Operating Procedure

Test articles – Study-related medications, biologics, devices or other test articles. This includes investigational products as well as FDA licensed/approved products.

University – University of Miami

VPR – Vice Provost for Research

## 3. RESPONSIBILITY

### 3.1 VPR and AVP

- The VPR may request Quality Reviews of test article storage and handling.
- Both receive copies of Quality Review reports.
- Both receive notification of potentially serious non-compliance issues.

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### **3.2 Human Subjects Research Office (HSRO)**

- Receives Quality Review reports and PI CAPA Plans and distributes them to the appropriate IRB committee.
- Notifies RCQA of required follow-up actions requested by the IRBs.
- Notifies RCQA of Quality Review closures and IRB determination letters.

### **3.3 Institutional Review Boards (IRBs)**

- May request a Quality Review of test article storage and handling
- Receives and reviews Quality Review reports and PI CAPA Plans.
- Determines the need for required follow-up actions.

### **3.4 QA Function of RCQA**

- Assigns QA Auditors to conduct Quality Reviews.
- Notifies investigator of planned Quality Reviews and schedules Quality Reviews.
- Performs Quality Reviews.
- Issues Quality Review reports.

### **3.5 Principal Investigator (PI)**

- Schedules Quality Review with RCQA QA Auditor.
- Provides all documents related to the test article.
- Allows study staff to be available to answer questions.
- Responds to Quality Review observations.

## **4. PROCEDURE**

### **4.1 Investigator/protocol selection**

- 4.1.1** A protocol may be selected for a Quality Review if the test article is not stored and/or dispensed from a research pharmacy.
- 4.1.2** A Quality Review of test article storage and handling may be requested by the IRB, SCCC, VPR or RCQA.

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## 4.2 Notification

### 4.2.1 Notify the PI

The QA Auditor will email a PI Quality Review Notification Memo to the PI of the selected study and copy the following leadership personnel:

- Departmental chairperson, Division Chief and Center Director (if applicable)
  - VPR
  - AVP
  - CRORS Director or designee (if study is monitored by CRORS)
  - RCQA Executive Director and QA Manager
  - RCQA CAPA Manager
  - For Quality Reviews at the SCCC, include the SCCC central email address: [scrcrcqa@miami.edu](mailto:scrcrcqa@miami.edu), and the applicable Site Disease Group Leader.
  - For Quality Reviews at Bascom Palmer Eye Institute (BPEI), include the BPEI Vice Chair and Director Clinical research Services.
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- Attach the RCQA Electronic Quality Review Process Flow to this notification.
  - The PI Notification Memo will outline the required documents to be provided during the Quality Review and the date to conduct this one-day Quality Review.

### 4.2.2 Notify JHS CTO

If the study to be reviewed is also conducted at JHS and/or includes JHS patients, email the JHS Quality Review Notification memo to the JHS CTO, stating the scheduled Quality Review dates.

## 4.3 Quality Review Preparation

To prepare for the Quality Review, the QA Auditor will review study materials found in the IRB system for specific product requirements listed in the study protocol, Investigational Drug Brochure, package inserts, etc.

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#### **4.4 Initial Meeting with PI and Study Team**

The QA Auditor will conduct an initial meeting with the PI and study team at the beginning of the Quality Review to discuss the scope of the Quality Review, the process, and what to expect from the auditors. The PI will be asked to describe the systems in place for storing and dispensing the investigational product.

#### **4.5 Quality Review Conduct**

**4.5.1** Review informed consent forms and HIPAA forms to determine that subjects agreed to participate in the research study.

**4.5.2** Review qualifications of personnel involved in the preparation, dispensation, and administration of test articles.

**4.5.3** Inspect storage areas for security and temperature control. Review systems in place for:

- Temperature monitoring
- Documentation of temperature monitoring
- Alarm system
- Emergency back-up power
- Restricted access

**4.5.4** Inspect preparation areas for cleanliness and organization.

**4.5.5** Review test article labeling for clear identification.

**4.5.6** Review documentation of test article accountability:

- Shipping receipts
- Quantity received and receipt dates
- Temperature records during transit
- Storage location and temperature
- Lot or batch numbers
- Quantity dispensed and date of dispensing
- Name of person dispensing/receiving
- Subject identification
- Quantity returned and date of return (from subject and to sponsor)

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- Quantity disposed/destroyed and date
- Name of person disposing/destroying test article
- Blinding/randomization procedures
- Chain of custody

**4.5.7** Review SOPs and all study documentation pertaining to the receipt, storage, distribution and disposal of test articles.

**4.5.8** During the course of the Quality Review, the QA Auditor will notify the RCQA Executive Director of any issues that may jeopardize the safety and welfare of human subjects. The Executive Director will then immediately notify the VPR, AVP, the Director for Human Subject Research, and the office of the Executive Dean for Research.

#### **4.6 PI Debriefing**

At the conclusion of the onsite Quality Review, if possible **on the last day** of the review, the QA Auditor will review the main observations with the PI and study team at a debriefing meeting.

#### **4.7 Quality Review Report**

**4.7.1** Observations will be reported in a standardized format as defined in SOP RCQA-402 and will be issued as described in SOP RCQA-403.

**4.7.2** RCQA will issue a Draft Quality Review Report within **five (5) business days** of the completion of a Quality Review. If additional time is needed, it will be discussed with the RCQA Executive Director and QA Manager and will be documented in the RCQA database.

**4.7.3** The Draft Quality Review Report will be reviewed within RCQA prior to issuance.

**4.7.4** The Draft Quality Review Report will be issued to the PI via email with instructions to review it for factual content.

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#### 4.8 Exit Meeting

- 4.8.1 The QA Auditor will aim to schedule an exit meeting with the PI and study team within **three (3) business days** of issuing the draft report to review the draft report for accuracy and to clarify any issues.
- 4.8.2 Based on discussions at the exit meeting, the QA Auditor will finalize the Quality Review report and issue the Final Report as per SOP RCQA-403.

#### 4.9 Quality Review Response (CAPA Plan)

- 4.9.1 Responses to the Quality Review observations should be submitted to the RCQA CAPA Manager within **ten (10) business days**.
  - 4.9.1.1 Additional time to provide responses may be granted to the PI, if requested. Additional time must be approved by the RCQA Executive Director and CAPA Manager.
  - 4.9.1.2 The CAPA Manager will offer assistance to the PI in the creation of the CAPA Plan.
  - 4.9.1.3 The CAPA Manager will review the PI's draft CAPA Plan and provide feedback to the PI in order to obtain responses that are specific and measurable.
  - 4.9.1.4 The RCQA Executive Director will conduct the final review of CAPA Plans.
- 4.9.2 After **ten (10) business days**, RCQA should receive the PI's final CAPA Plan. The Final Quality Review Report and PI CAPA Plan will be submitted to the HSRO via email and leadership personnel will be copied on the email as per SOP RCQA-403.

#### 4.10 Post Quality Review Customer Satisfaction Survey

Within **two (2) business days** after issuing the final Quality Review Report, the QA Auditor will email the RCQA administrative assistant to request that a customer satisfaction survey be sent to the PI and study team.

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#### **4.11 IRB Determination Letter**

The IRB will review the final Quality Review Report and PI CAPA Plan and issue an IRB determination letter. This letter will notify RCQA, the VPR, and AVP if a follow up Quality Review is requested by the IRB, or if this Quality Review is considered closed. If the Quality Review did not identify any observations, an IRB determination letter will not be issued.

### **5. DOCUMENTATION**

RCQA will maintain electronic copies of the final Quality Review Report, PI CAPA Plan and any correspondence concerning the report in the RCQA shared drive indefinitely.

### **6. REFERENCES**

SOP RCQA-402: Quality Review Report Generation  
SOP RCQA-403: Issuing and Maintaining Quality Review Reports

### **7. TEMPLATES / FORMS / TOOLS**

**These templates and forms can be found on the RCQA shared drive:  
S:/RCQA/Auditing/Auditing Forms/Audit Email Templates & Memos**

- PI Quality Review Notification Memo
- JHS Quality Review Notification
- Draft Quality Review Report Submission Memo

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

- Quality Review Flowchart
- Quality Review Report Template
- PI CAPA Plan template

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## 8. REVISION HISTORY

Effective Date	Revision Date	Author	Description of Changes
1 Apr 05	30 Mar 05	G. Lapinski	Name of office from ORC to RCA; Deletion of text “according to the HSRO Standard Operating Procedures Request to Access Protocol Files dated 26 Dec 2002” in section 4.3; Reports for investigators in the Department of Medicine; Deleted reference HSRO Standard Operating Procedures Request to Access Protocol Files dated 26 Dec 2002 in section 6.
25 Oct 06	25 Oct 06	K. Roach	Name of Vice Provost for Research changed to Richard Bookman, PhD
16 Jun 08	16 Jun 08	L. Smith	Name of office from RCA to ORCA
06 Nov 09	06 Nov 09	J. Stamates	Addition of Associate Director Section 4.2: addition of VP for research and JHS CTO Section 4.3: addition of eProst
19 Oct 10	11 Oct 10	H. Miletic	Changed numbering format of document and added version number 01. Minor changes to text throughout. Updated references. Changed approval signature from Vice Provost for Research to ORCA Associate Director. Moved revision history to end of document. Added author signature.
10 Mar 11	10 Mar 11	H. Miletic	Revised the version number and effective date in the header. Added the Dean of the respective school to the list of individuals who will receive audit notifications and audit reports in sections 4.2 and 4.5. The ORCA Associate Director was removed throughout the document.
08 Jun 12	01 Jun 12	H. Miletic	Changed the name of the department from Office of Research Compliance Assessment (ORCA) to Regulatory Support and Quality Assurance (RSQA) throughout the document. Changed Compliance Officer to QA Auditor throughout the document. Added the Institutional Official (IO) and removed the OR from section 3. Changed the Vice Provost for Research to the IO

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Effective Date	Revision Date	Author	Description of Changes
			throughout the document. Added detailed instructions to the audit conduct in section 4.4. Deleted steps 4.5.3 to 4.5.6 and referred to SOPs RSQA-402 and RSQA-403. Updated references. Reformatted the entire document. Updated the ORCA Director to the RSQA Executive Director.
26 Aug 13	21 Aug 13	H. Miletic	Updated the title of the Executive Dean for Research in section 2. Updated section 3.4 to state that QA and Compliance function of RSQA reports to Vice Provost for Research. Modified section 4.2.3 to state that RSQA Executive Director or QA Manager will notify IO of audits to be scheduled. Replaced QA Director with QA Manager in sections 4.2.1 and 4.2.3. Added a step in section 4.4 to review consent and HIPAA forms.  Removed QA Director and Senior Associate Dean for Clinical Research throughout document. Updated section 7 to reflect location of templates and forms.

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. Added IRB-7 to sections 2 and 4.3. Updated section 5 to state that audit reports 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.
17 Feb 2016	H. Miletic	Updated section 4.2.1 to remove the Provost from the list of leadership personnel receiving the audit notification and added the SCCC central email. Deleted step 4.2.4 requiring a separate notification to SCCC. Updated step 4.5.2 to change the audit report issuance timeframe to within 7 days. Added step 4.7 to state that post audit survey will be sent to PI and study team.
19 Feb 2016	H. Miletic	Added the CEO of UHealth and Senior Vice President of Health Affairs to section 4.2.1.

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Effective Date	Author	Description of Changes
19 Apr 2017	H. Miletic	Added Center Director, Chief Compliance Officer of Medical School, BPEI Vice Chair and central mailbox to section 4.2.1. Updated section 4.2.2 to specify who will receive the HSRO Audit Notification. Sections were renumbered as the following processes were added: debriefing meeting with PI and issuing a draft audit report to PI.
23 Oct 2017	H. Miletic	Modified section 4.2.1 to remove the following leadership personnel from the initial audit notification, as per their request: Dean, Chief Compliance Officer, and CEO of UHealth. Added CRORS Director to section 4.2.1. Added a step to include the Audit Flowchart to the initial PI Audit Notification. Added Audit Flowchart to section 7.
30 Mar 2018	H. Miletic	Changed the term “audits” to “Quality Reviews” throughout the document and title of the SOP. “Audit responses” was changed to “CAPA Plan” throughout the document. Removed the Executive Dean for Research from section 4.2.1. Replaced HSRO personnel with the HSRO mailbox in section 4.2.2.
02 Apr 2019	H. Miletic	Modified section 4.2 to add the Director Clinical Research Services and remove the BPEI mailbox when notifying the PI. Steps within section 4.2 were renumbered. Removed the HSRO notification and the <a href="mailto:Quality.Determination@miami.edu">Quality.Determination@miami.edu</a> mailbox in step 4.2.3. Changed the Associate Vice Provost for Human Subject Research to the Executive Director for Human Subject Research, throughout the SOP. Updated step 4.3 to remove reference to studies initiated prior to 2008. Updated step 4.11 to clarify that an IRB determination letter will not be issued if no observations were identified. Added the Draft Quality Review Report Submission Memo and the PI CAPA Plan Template to section 7. Minor revisions to text made throughout.
27 Aug 2020	H. Miletic	Added AVP and VPR to definitions and removed eProst from definitions. Replaced IO with VPR throughout. Added CAPA Manager to step 4.2.1. Added AVP to sections 3.1, 3.3, 4.2.1, 4.2.2, 4.5.8 and 4.11. Removed the IO notification prior to conducting Quality Review. Removed step for requesting IRB minutes as Auditors have access to these. Updated office name of Executive Dean for Research

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		in step 4.5.8. Updated Executive Director to Director Human Subjects Research in step 4.5.8. Added 4.9.1.4 where RCQA Executive Director will do final review of CAPA Plans. Updated 4.10 to add 2 business day timeline to request survey to be sent. Updated section 5 to clarify that electronic copies of reports, CAPA Plans and correspondence will be maintained in the RCQA shared drive indefinitely. Box drive was changed to shared drive in section 7. Minor edits made throughout SOP.

**9. SIGNATURES**

Prepared by: \_\_\_\_\_ Date: \_\_\_\_\_  
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