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**

CAPA – Corrective and Preventive Action  
CRORS – Clinical Research Operations & Regulatory Support  
CTO – Clinical Trials Office at JHS  
eProst – Electronic Protocol Submission and Tracking  
HIPAA – Health Insurance Portability and Accountability Act  
HSRO – Human Subjects Research Office  
IO – Institutional Official  
IRB – Institutional Review Board  
IRB-8 - Electronic protocol submission and tracking system to replace eProst  
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

3. **RESPONSIBILITY**

3.1 **Institutional Official (IO)**

- Authorizes and may request Quality Reviews of test article storage and handling.  
- Receives notification of Quality Reviews to be scheduled.  
- Receives copies of Quality Review reports.  
- Receives notification of potentially serious non-compliance issues.
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 via the IO.
- Receives and reviews Quality Review reports and PI CAPA Plans.
- Determines the need for required follow-up actions.

3.4 **QA and Compliance Function of RCQA**

- Reports to the Vice Provost for Research.
- 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, IO or RCQA.
4.2 Notification

4.2.1 Notify the IO

The RCQA Executive Director or QA Manager will notify the IO of a Quality Review to be scheduled.

4.2.2 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/or Center Director (if applicable)
- IO
- CRORS Director or designee (if study is monitored by CRORS)
- RCQA Executive Director and QA Manager
- For Quality Reviews at the SCCC, include the SCCC central email address: sccercqa@miami.edu
- For Quality Reviews at Bascom Palmer Eye Institute (BPEI), include the BPEI Vice Chair and Director Clinical research Services.

- Attach the Quality Review Flowchart 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.

4.2.3 Request for IRB Minutes

The QA Auditor will send a request for IRB minutes regarding the study to be reviewed to the Associate Director, Regulatory Affairs at the HSRO.

4.2.4 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 eProst and/or IRB-8 for specific product requirements listed in the study protocol, Investigational Drug Brochure, package inserts, etc.

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
• 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)
• 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 IO, the Executive Director for Human Subject Research, and the office of the Executive Dean for Research and Research Education.

4.6 PI Debriefing

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

4.6 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 aim to issue a Quality Review Report within 5 working days of the completion of a Quality Review. Additional time may be necessary for some reviews. The reason for additional time needed 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.

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 working 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 The PI will be given ten working days to provide responses to the observations using the PI CAPA Plan form.

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.

4.9.2 After ten working days, RCQA should receive the PI’s final CAPA Plan. The 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

After the issuance of the final Quality Review 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.
RESEARCH COMPLIANCE AND QUALITY ASSURANCE
STANDARD OPERATING PROCEDURE

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 and the IO 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 a copy of the final Quality Review Report, PI CAPA Plan and any correspondence concerning the report in the RCQA central file for a minimum of ten years.

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 Box 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 Box drive:
S:/RCQA/Auditing/Auditing Forms/Current Templates & Forms

- Quality Review Flowchart
- Quality Review Report Template
- PI CAPA Plan 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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<tbody>
<tr>
<td>1 Apr 05</td>
<td>30 Mar 05</td>
<td>G. Lapinski</td>
<td>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.</td>
</tr>
<tr>
<td>25 Oct 06</td>
<td>25 Oct 06</td>
<td>K. Roach</td>
<td>Name of Vice Provost for Research changed to Richard Bookman, PhD</td>
</tr>
<tr>
<td>16 Jun 08</td>
<td>16 Jun 08</td>
<td>L. Smith</td>
<td>Name of office from RCA to ORCA</td>
</tr>
<tr>
<td>06 Nov 09</td>
<td>06 Nov 09</td>
<td>J. Stamates</td>
<td>Addition of Associate Director Section 4.2: addition of VP for research and JHS CTO Section 4.3: addition of eProst</td>
</tr>
<tr>
<td>19 Oct 10</td>
<td>11 Oct 10</td>
<td>H. Miletic</td>
<td>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.</td>
</tr>
<tr>
<td>10 Mar 11</td>
<td>10 Mar 11</td>
<td>H. Miletic</td>
<td>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.</td>
</tr>
<tr>
<td>08 Jun 12</td>
<td>01 Jun 12</td>
<td>H. Miletic</td>
<td>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</td>
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<tr>
<td>26 Aug 13</td>
<td>21 Aug 13</td>
<td>H. Miletic</td>
<td>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.</td>
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<tr>
<td>25 Aug 2014</td>
<td></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. 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.</td>
</tr>
<tr>
<td>17 Feb 2016</td>
<td></td>
<td>H. Miletic</td>
<td>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.</td>
</tr>
<tr>
<td>19 Feb 2016</td>
<td></td>
<td>H. Miletic</td>
<td>Added the CEO of UHealth and Senior Vice President of Health Affairs to section 4.2.1.</td>
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### Description of Changes

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<tr>
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<tr>
<td>19 Apr 2017</td>
<td>H. Miletic</td>
<td>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.</td>
</tr>
<tr>
<td>23 Oct 2017</td>
<td>H. Miletic</td>
<td>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.</td>
</tr>
<tr>
<td>30 Mar 2018</td>
<td>H. Miletic</td>
<td>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.</td>
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<tr>
<td>02 Apr 2019</td>
<td>H. Miletic</td>
<td>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.</td>
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9. SIGNATURES

Signature on file

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