1. PURPOSE

To define the process by which the Office of Research Compliance and Quality Assurance (RCQA) provides support and guidance in the creation and implementation of Corrective Action Preventive Action (CAPA) Plans following internal RCQA Quality Reviews.

As a result of internal Quality Reviews, noncompliance with Federal and/or State regulations and guidelines, and University policies and procedures may be identified. In order to remediate identified noncompliance, the Principal Investigator, Sponsor-Investigator or HSRO/IRB is requested to provide a written response to the Quality Review.

2. DEFINITIONS

**CAPA** – Corrective Action Preventive Action

**CAPA Manager** – A member of RCQA who provides CAPA Plan assistance and support to the CAPA Owner/CAPA Team Member(s), as well as verifies that corrective actions and preventive actions were created, documented, and implemented as specified in the CAPA Plan.

**CAPA Plan** – Plan that is developed and implemented to identify, remediate, and prevent recurrence or occurrence of existing or potential causes of non-conformity or other quality problems

**CAPA Plan Effectiveness Check Report** – A report generated by the CAPA Manager or designee that outlines the effectiveness of the implementation of preventive actions documented in the CAPA Plan to prevent re-occurrence of high-risk observations.

**CAPA Plan Implementation Review Report** – A report generated by the CAPA Manager or designee which outlines the status of the implementation of corrective and/or preventive actions documented in the CAPA Plan.

**CAPA Plan Review** – A review performed by the CAPA Manager or designee, to verify that corrective and/or preventive actions (CAPA) included in the plan were appropriate

**CRORS** – Office of Clinical Research Operations and Regulatory Support

**Departmental Leadership** – Members may include Department Chairperson, Division Chief, and/or Center Directors

**HSRO** – Human Subjects Research Office
IO - Institutional Official

IRB – Institutional Review Board

PI - Principal Investigator

RCQA – Office of Research Compliance and Quality Assurance

RCQA ED - Office of Research Compliance and Quality Assurance Executive Director

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

SOP – Standard Operating Procedure

UM – University of Miami

3. RESPONSIBILITY

3.1 Institutional Official (IO)

- Receives copies of the CAPA Plan
- Receives an email outlining the status of the CAPA Plan after its implementation and effectiveness have been evaluated
- Reviews and approves extensions greater than 3 months requested by the PI/Sponsor-Investigator/HSRO to complete the implementation of the CAPA Plan
- Can defer the decision to grant extensions for implementation of CAPA Plan to others, such as Privacy Office (if such office is the subject matter expert for a particular action)
- Can request actions in addition to the CAPA Plan

3.2 University Leadership

- Receives copies of the CAPA Plan
- Receives an email outlining the status of the CAPA Plan after its implementation and effectiveness have been evaluated
3.3 Departmental Leadership

- Receives copies of the CAPA Plan
- Receives an email outlining the status of the CAPA Plan after its implementation and effectiveness have been evaluated

3.4 RCQA Executive Director (ED)

- Reviews the CAPA Plan
- Provides feedback on the CAPA Plan
- Receives an email outlining the status of the CAPA Plan after its implementation and effectiveness have been evaluated
- Reviews and approves additional time requested by the PI/Sponsor-Investigator/HSRO to provide CAPA Plans
- Reviews and approves extensions up to 3 months requested by the PI to complete the implementation of the CAPA Plan

3.5 CAPA Manager

- Provides guidance and support in the development, organization and implementation of the CAPA Plan
- Reviews and provides feedback to the PI, Sponsor-Investigator, or HSRO/IRB prior to finalization of the CAPA Plan
- Conducts reviews of implementation of the CAPA Plan
- Develops CAPA Plan Implementation Review reports
- Verifies the effectiveness of some corrective and preventive actions included in the CAPA Plan
- Develops CAPA Plan Effectiveness Check reports
- Maintains CAPA Plan review documentation, correspondence and reports
- Reviews and approves extensions in conjunction with the RCQA ED up to 3 months requested by the PI/Sponsor-Investigator/HSRO to complete the implementation of the CAPA Plan

3.6 Principal Investigator (PI), Sponsor-Investigator, or HSRO/IRB

- Receives request for a CAPA Plan
- Responsible for the creation, documentation and implementation of the CAPA Plan
- Signs the CAPA Plan
- Provides supporting documentation of corrective action(s) and/or preventive action(s) implementation
- Maintains CAPA Plan documentation
• Receives an email outlining the status of the CAPA Plan after its implementation and effectiveness have been evaluated

3.7 IRB
• Receives the CAPA Plan
• Can request actions in addition to the CAPA Plan

3.8 HSRO
• Receives the CAPA Plan
• Distributes the CAPA Plan for IRB review
• Receives an email outlining the status of the CAPA Plan after its implementation and effectiveness have been evaluated

4. CAPA Plan Implementation Process

4.1 RCQA Auditor

4.1.1 The RCQA auditor will include the CAPA Manager on the email when the Draft Quality Review report is sent to the PI, Sponsor-Investigator, or HSRO/IRB
4.1.2 The RCQA auditor will notify the CAPA Manager when a Quality Review exit meeting is scheduled
4.1.2 The RCQA auditor will include the CAPA Manager on the email when the final Quality Review report is sent to the PI, Sponsor-Investigator, or HSRO/IRB

4.2 CAPA Manager Support and Follow-up Notification

4.2.1 The CAPA Manager or designee will send a CAPA Plan Support Notification Memo via email to the PI, Sponsor-Investigator, or HSRO/IRB
4.2.2 This Memo will outline the scope of the support, timelines for CAPA Plan development, and communicates the future follow-up for the implementation of actions included in the CAPA Plan

4.3 CAPA Plan Preparation

The CAPA Manager will assist and support the PI or Sponsor Investigator and the study team with the development of corrective and preventive actions to remediate and/or prevent recurrence of existing causes of non-conformity identified during the Quality Review process. This can be done through organized meetings and/or via email according to the preference of the PI, Sponsor-Investigator, or HSRO/IRB.
4.4 **CAPA Plan Review**

4.4.1 The CAPA Manager will review and provide feedback to all CAPA Plan drafts provided by the PI, Sponsor-Investigator, or HSRO/IRB.

4.4.2 The PI, Sponsor-Investigator, or HSRO/IRB will send the final/signed version of the CAPA Plan to the CAPA Manager.

4.4.3 The CAPA Manager will send the final/signed version of the CAPA Plan to the RCQA Executive Director for review.

4.4.4 If the CAPA Plan does not include adequate and/or sufficient corrective and/or preventive actions, the CAPA Manager will send a request for change or modification of the CAPA Plan to the PI, Sponsor-Investigator, or HSRO/IRB.

4.5 **Issuance of CAPA Plan**

The final/signed version of the CAPA Plan received from the PI, Sponsor-Investigator, or HSRO/IRB will be sent to the Auditor who conducted the Quality Review. Please refer to SOP RCQA-201.

4.6 **CAPA Plan Implementation Review**

4.6.1 On-Site CAPA Plan Review

- The CAPA Manager or designee will schedule one day to conduct the on-site review; however, more or less time may be required.
- The CAPA Manager or designee will perform a review of all applicable study information and/or documentation provided by the PI, Sponsor-Investigator, or HSRO/IRB.

4.6.2 The CAPA Plan review will consist of the following, at a minimum:

- Review and confirmation that corrective and preventive action(s) outlined in the PI, Sponsor-Investigator or HSRO CAPA Plan have been documented and implemented.
  - Verification of supporting documentation.
- For PI/Sponsor-Investigator CAPA Plans: As applicable, review and confirmation that additional corrective and/or preventive action(s) required by the IRB have been documented and implemented.
  - Verification of supporting documentation.
- Review and confirmation that designated implementation timeline(s) of corrective and preventive action(s) as outlined in the PI, Sponsor-Investigator, or HSRO/IRB audit response(s) have been adhered to.

4.6.3 Remote CAPA Plan Review

As applicable, the CAPA Manager or designee will perform a remote review of CAPA and applicable study information and/or documentation. Examples of the type of reviews, which may be performed remotely, are as follows:
4.6.4 The CAPA Manager or designee may conduct interviews with PI, Sponsor-Investigator, or HSRO/IRB team members as necessary during the on-site review.

4.6.5 The CAPA Manager or designee will request a debrief meeting with the PI, Sponsor-Investigator, or HSRO/IRB after the CAPA Plan review has been completed as necessary.

4.7 CAPA Plan Implementation Review Report

4.7.1 The CAPA Plan Implementation Review will be documented in a standardized format.

4.7.2 The CAPA Plan Implementation Review Report will be saved in “pdf” format, in a folder under the PI’s last name on the shared RCQA Box drive as: S:\RCQA\CAPA\Internal Audits 2019 (or current year) PI’s last name\FINAL REPORT. An email outlining the status of the CAPA Plan will be sent to the PI, and the following leadership personnel will be copied:

- Departmental Chairperson, Division Chief and/or Center Director
- Institutional Official (IO)
- Provost
- General Counsel
- CRORS Director or designee (if study is monitored by CRORS)
- For Quality Reviews at the SCCC, include the SCCC central email address: sccrcqa@miami.edu
- For Quality Reviews at the Bascom Palmer Eye Institute (BPEI), include the BPEI Vice Chair and Director Clinical Research Services
- RCQA Executive Director and QA Manager

Note: The email summarizing the CAPA Plan Implementation Review Report may be copied to additional leadership personnel as directed by the RCQA Executive Director and/or the IO.

4.7.3 Based on the CAPA Plan review, the CAPA Manager will make the final determination if the CAPA Plan has been documented and implemented as required, and if any further follow-up by the CAPA Manager is necessary.

4.7.4 If any Corrective and/or Preventive Action are in progress or not executed, at the time of the CAPA Implementation Review, new due dates will be established for the pending actions and consequent review by the CAPA Manager or designee.
4.8 CAPA Plan Effectiveness Check

4.8.1 On-site CAPA Plan Effectiveness Check
- The CAPA Manager or designee will schedule one day to conduct the on-site effectiveness check; however, more or less time may be required.
- The CAPA Manager or designee will review all the applicable study information and/or documentation provided by the PI, sponsor-investigator, or HSRO/IRB.

4.8.2 The CAPA Plan Effectiveness Check will consist of the following:
- Reviewing the study documentation that originated after the implementation of the preventive actions included in the CAPA Plan and related only to Quality Review observations indicated as *Immediate Action Required*.
- Assessing the new information to verify that the observations indicated in the Quality Review report as *Immediate Action Required* do not show a recurrence of the non-compliance issue previously noted.

4.8.3 Remote CAPA Plan Effectiveness Check
As applicable, the CAPA Manager or designee will perform a remote review of the study documentation that originated after the implementation of the preventive actions included in the CAPA Plan and related only to Quality Review observations indicated as *Immediate Action Required*, as follows:
- Review of eProst/IRB, Velos, etc.
- Review of CAPA documentation and/or study information provided electronically by the CAPA owner/CAPA Team Member(s).
- Review of the electronic medical records

4.8.4 If, for any reason, sufficient information is not available for making a complete evaluation of the recurrence of the observation (e.g., study is closed to enrollment, the study is closed, the study subjects are in follow up, etc.), other current or future studies of the same PI will be considered for Quality Review.

4.8.5 The CAPA Manager or designee may conduct interviews with the PI, the sponsor-investigator, or HSRO/IRB team members as necessary during the on-site review.

4.8.6 The CAPA Manager or designee will request a debriefing with the PI, sponsor-investigator, or HSRO/IRB after the CAPA Plan Effectiveness Check has been completed.

4.9 CAPA Plan Effectiveness Check Report

4.9.1 The CAPA Plan Effectiveness Check will be reported in a standardized format.

4.9.2 The CAPA Plan Effectiveness Check Report will be saved in “pdf” format, in a folder under the PI’s last name on the shared RCQA Box drive as: S:\RCQA\CAPA\Internal Audits 2019 (or current year) PI’s last name\FINAL
REPORT. An email outlining the status of the CAPA Plan will be sent to the PI, and the following leadership personnel will be copied:

- Departmental Chairperson, Division Chief and/or Center Director
- Institutional Official (IO)
- Provost
- General Counsel
- CRORS Director or designee (if study is monitored by CRORS)
- For Quality Reviews at the SCCC, include the SCCC central email address: sccrcqa@miami.edu
- For Quality Reviews at the Bascom Palmer Eye Institute (BPEI), include the BPEI Vice Chair and Director Clinical Research Services
- RCQA Executive Director and QA Manager

Note: The email summarizing the CAPA Plan Effectiveness Check Report may be copied to additional leadership personnel as directed by the RCQA Executive Director and/or the IO.

4.9.3 Based on the CAPA Plan Effectiveness Check Report, the CAPA Manager and the RCQA Executive Director will make the final determination as to whether the CAPA Plan was effective in correcting the observations included in the Quality Review and indicated as Immediate Action Required or whether a new CAPA Plan for those observations is required.

5. DOCUMENTATION

See SOP RCQA-805, Issuing and Maintaining CAPA Plan Review Reports regarding the maintenance of CAPA Plan study information and/or documentation.

6. REFERENCES

SOP RCQA-805: Issuing and Maintaining CAPA Plan Review Reports
SOP RCQA-201: General Audit Procedure for Human Subject Protocols

7. TEMPLATES / FORMS

This template and form can be found on the RCQA shared drive: S:/RCQA/CAPA/CAPA Templates and Forms

CAPA Plan Review Notification Memo
8. REVISION HISTORY

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Revision Date</th>
<th>Author</th>
<th>Description of Changes</th>
</tr>
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<tbody>
<tr>
<td>25 Sep 19</td>
<td>25 Sep 19</td>
<td>L. Rochel</td>
<td>Revised the version number and effective date in the header. Added the Provost &amp; General Counsel and removed of Dean of the respective school, Chief Compliance Officer of UHealth, Executive Dean for Research, and CEO of UHealth &amp; Senior Vice President Health Affairs to the list of individuals who will receive Implementation Review Reports in section 4.7.3. Revised section 3.1, 3.4, and 3.5 to add responsibilities of the IO, RCQA Executive Director and CAPA Manager related to approval of additional time required by the PIs to complete the implementation of the actions included in the CAPA Plans. Added IRB and HSRO responsibilities. The definition of when the effectiveness of the actions included in the CAPA Plan need to be evaluated and how this evaluation will be communicated were added in 4.8 and 4.9 sections.</td>
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9. SIGNATURES

Prepared by: _________________________________
Signature on file  
Luis Rochel, BEc, RN, CCRP, RQAP-GCP  
CAPA Manager, RCQA

Date: _____________

Approved by: _________________________________
Signature on file  
Johanna Stamates, RN, MA, CCRC, CHRC  
Executive Director, RCQA

Date: _____________