

RESEARCH COMPLIANCE AND QUALITY ASSURANCE
STANDARD OPERATING PROCEDURE

Document Number:	RCQA-803-03	Effective Date:	01 Sep 2020
Page No.	Page 1 of 6	Author:	L. Rochel
Title:	CAPA Plan Support and Review after a RCQA Quality Review		

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, Sponsor or HSRO/IRB is requested to provide a written response to the Quality Review.

2. DEFINITIONS

AVP – Associate Vice President, Regulatory Affairs and Assessment

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 issues.

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

RESEARCH COMPLIANCE AND QUALITY ASSURANCE
STANDARD OPERATING PROCEDURE

Document Number:	RCQA-803-03	Effective Date:	01 Sep 2020
Page No.	Page 2 of 6	Author:	L. Rochel
Title:	CAPA Plan Support and Review after a RCQA Quality Review		

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

HSRO – Human Subjects Research Office

IND – Investigational New Drug Application

IDE – Investigational New Device Exemption

IRB – Institutional Review Board

PI - Principal Investigator

QR – Quality Review

RCA – Root Cause Analysis

RCQA – Office of Research Compliance and Quality Assurance

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

Sponsor - A person who initiates, but does not actually conduct, the investigation; that is, the investigational drug device or biologic is administered, dispensed or used under the immediate direction of another individual. For the purpose of this SOP, Sponsor means a University Faculty Member holding an IND/IDE

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

VPR - Vice Provost of Research

3. RESPONSIBILITY

3.1 Vice Provost for Research

- Receives copies of the CAPA Plan

RESEARCH COMPLIANCE AND QUALITY ASSURANCE
STANDARD OPERATING PROCEDURE

Document Number:	RCQA-803-03	Effective Date:	01 Sep 2020
Page No.	Page 3 of 6	Author:	L. Rochel
Title:	CAPA Plan Support and Review after a RCQA Quality Review		

- Receives an email outlining the status of the CAPA Plan after its implementation and effectiveness have been evaluated
- Reviews and approves extensions greater than three (3) months requested by the PI/Sponsor-Investigator/Sponsor/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/Sponsor/HSRO to provide CAPA Plans
- Reviews and approves extensions up to three (3) months requested by the PI to complete the implementation of the CAPA Plan
- Reviews and signs Final CAPA Plans
- Assigns CAPA management tasks to other RCQA members as applicable

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, Sponsor or HSRO/IRB prior to finalization of the CAPA Plan

RESEARCH COMPLIANCE AND QUALITY ASSURANCE
STANDARD OPERATING PROCEDURE

Document Number:	RCQA-803-03	Effective Date:	01 Sep 2020
Page No.	Page 4 of 6	Author:	L. Rochel
Title:	CAPA Plan Support and Review after a RCQA Quality Review		

- Conducts reviews of implementation of the CAPA Plan
- Develops CAPA Plan Implementation Review reports
- Verifies the effectiveness of corrective and preventive actions for high risk observations
- 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 three (3) months requested by the PI/Sponsor-Investigator/Sponsor/HSRO to complete the implementation of the CAPA Plan
- Reviews and signs Final CAPA Plans

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

- Receives request for a CAPA Plan
- Responsible for the creation, documentation and implementation of the CAPA Plan
- Creates RCA for high risk observations (Immediate action required observations)
- Maintains written documentation of RCA
- 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
- If observations related to the HSRO/IRB functions are identified, the HSRO/IRB will be responsible for the creation, documentation and implementation of their own 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
- If observations related to the HSRO/IRB functions are identified, the HSRO/IRB will be responsible for the creation, documentation and implementation of their own CAPA Plan

RESEARCH COMPLIANCE AND QUALITY ASSURANCE
STANDARD OPERATING PROCEDURE

Document Number:	RCQA-803-03	Effective Date:	01 Sep 2020
Page No.	Page 5 of 6	Author:	L. Rochel
Title:	CAPA Plan Support and Review after a RCQA Quality Review		

- For IRB CAPA Plans: Creates RCA for high risk observations (Immediate action required observations and maintains written documentation of RCA

4. CAPA Plan Implementation Process

4.1 RCQA Auditor

- 4.1.1 The RCQA auditor will include the CAPA Manager on the initial Quality Review notification, and on the email when the Draft Quality Review report is sent to the PI, Sponsor-Investigator, Sponsor or HSRO/IBB
- 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, Sponsor or HSRO/IBB

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, Sponsor 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, Sponsor Investigator, Sponsor or HSRO/IRB with the development of corrective and preventive actions to remediate and/or prevent recurrence of existing causes of non-compliance 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, Sponsor or HSRO/IRB.

4.4 CAPA Plan Review

- 4.4.1 The CAPA Manager and/or the RCQA Executive Director will review and provide feedback to ensure that all proposed actions are specific and measurable, have a responsible person, and include appropriate timelines.
- 4.4.2 If the provided CAPA Plan draft does not include adequate and/or sufficient corrective and/or preventive actions, the CAPA Manager and/or the RCQA Executive Director will request changes to the CAPA Plan.
- 4.4.3 The RCQA Executive Director will conduct the final review of the CAPA Plan and communicate any additional request for changes.

RESEARCH COMPLIANCE AND QUALITY ASSURANCE
STANDARD OPERATING PROCEDURE

Document Number:	RCQA-803-03	Effective Date:	01 Sep 2020
Page No.	Page 6 of 6	Author:	L. Rochel
Title:	CAPA Plan Support and Review after a RCQA Quality Review		

- 4.4.4 The PI, Sponsor-Investigator, Sponsor or HSRO/IRB will send the final/signed version of the CAPA Plan to the CAPA Manager.
- 4.4.5 The final/signed CAPA Plan provided by the PI, Sponsor-Investigator, Sponsor or HSRO/IRB will be reviewed and signed by the CAPA Manager and the RCQA Executive Director to indicate agreement. If the reviewers do not agree with the final CAPA Plan, the reasons for the disagreement will be documented in the comment section.
- 4.4.6 The PI, Sponsor-Investigator, Sponsor or HSRO/IRB will be notified of the disagreement.

4.5 Issuance and Filing of CAPA Plan

- 4.5.1 The final/signed version of the CAPA Plan received from the PI, Sponsor-Investigator, Sponsor or HSRO/IRB which includes signatures and comments from the CAPA Manager and the RCQA Executive Director will be sent to the Auditor who conducted the Quality Review. Please refer to SOPs RCQA-206 and RCQA-403.
- 4.5.2 The final/signed version of the CAPA Plan received from the PI, Sponsor-Investigator, Sponsor or HSRO/IRB which includes signatures and comments from the CAPA Manager and the RCQA Executive Director will be saved as a pdf file onto the shared RCQA Box drive in *the* applicable CAPA folder using the following naming conventions:
- PI last name CAPA Plan IRB #_ (for a CAPA Plan issued by a PI)
 - IRB/HSRO_ CAPA Plan IRB #_ (for a CAPA Plan issued by IRB/HSRO and related to observations detected during a QR of a PI's study but applicable to IRB/HSRO).
 - IRB/HSRO_ CAPA Plan "XX topic reviewed during the QR" (for a CAPA Plan issued by IRB/HSRO as a result of observation(s) detected during an IRB/HSRO QR)

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 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, Sponsor or HSRO/IRB.
- 4.6.2 The CAPA Plan review will consist of the following, at a minimum:

RESEARCH COMPLIANCE AND QUALITY ASSURANCE
STANDARD OPERATING PROCEDURE

Document Number:	RCQA-803-03	Effective Date:	01 Sep 2020
Page No.	Page 7 of 6	Author:	L. Rochel
Title:	CAPA Plan Support and Review after a RCQA Quality Review		

- Review and confirmation that corrective and preventive action(s) outlined in the 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 CAPA Plan 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:

- Review of eProst/IRB, Velos, etc.
- Review of CAPA documentation and/or study information provided by the CAPA Team Member(s) electronically.

4.6.4 The CAPA Manager or designee may conduct interviews with the PI, Sponsor-Investigator, Sponsor or HSRO/IRB team members as necessary during the review.

4.6.5 The CAPA Manager or designee will request a debrief meeting with the PI, Sponsor-Investigator, Sponsor 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 **PI CAPA Plans:** 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 (if applicable)
- Provost
- VPR
- AVP
- HSRO Director
- Assistant General Counsel
- Chief Risk Officer, Risk Management

RESEARCH COMPLIANCE AND QUALITY ASSURANCE
STANDARD OPERATING PROCEDURE

Document Number:	RCQA-803-03	Effective Date:	01 Sep 2020
Page No.	Page 8 of 6	Author:	L. Rochel
Title:	CAPA Plan Support and Review after a RCQA Quality Review		

- 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, and applicable Site Disease Group Leader.
- 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

4.7.3 **IRB CAPA Plans:** The CAPA Plan Implementation Review Report will be saved in “pdf” format, in a folder under the HSRO/IRB on the shared RCQA Box drive as : S: \RCQA\CAPA\Internal Audits 2019 (or current year) HSRO/IRB \topic or protocol number\FINAL REPORT. An email outlining the status of the CAPA Plan will be sent to the HSRO Director, and the following leadership personnel will be copied:

- IRB Committee Chairs and Co-Chairs
- Provost
- VPR
- AVP
- Assistant General Counsel
- Chief Risk Officer, Risk Management
- RCQA Executive Director
- 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 VPR.

4.7.4 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.

4.7.5 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.

RESEARCH COMPLIANCE AND QUALITY ASSURANCE
STANDARD OPERATING PROCEDURE

Document Number:	RCQA-803-03	Effective Date:	01 Sep 2020
Page No.	Page 9 of 6	Author:	L. Rochel
Title:	CAPA Plan Support and Review after a RCQA Quality Review		

- The CAPA Manager or designee will review all the applicable study information and/or documentation provided by the PI, sponsor-investigator, Sponsor 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 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 future Quality Review.
- 4.8.5 The CAPA Manager or designee may conduct interviews with the PI, the sponsor-investigator, Sponsor or HSRO/IRB team members as necessary during the review.
- 4.8.6 The CAPA Manager or designee will request a debriefing with the PI, sponsor-investigator, Sponsor 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 **PI CAPA Plans:** 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\Effectiveness check. 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 (if applicable)

RESEARCH COMPLIANCE AND QUALITY ASSURANCE
STANDARD OPERATING PROCEDURE

Document Number:	RCQA-803-03	Effective Date:	01 Sep 2020
Page No.	Page 10 of 6	Author:	L. Rochel
Title:	CAPA Plan Support and Review after a RCQA Quality Review		

- Provost
- Vice Provost for Research
- AVP
- HSRO Director
- Assistant General Counsel
- Chief Risk Officer, Risk Management
- CRORS Director or designee (if study is monitored by CRORS)
- For Quality Reviews at the SCCC, include the SCCC central email address: scrcrcqa@miami.edu, and applicable Site Disease Group Leader.
- 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

4.9.3 **IRB CAPA Plans:** The CAPA Plan Effectiveness Check Report will be saved in “pdf” format, in a folder under the HSRO/IRB on the shared RCQA Box drive as : S:\RCQA\CAPA\Internal Audits 2019 (or current year) HSRO/IRB \topic or protocol number\FINAL REPORT. An email outlining the status of the CAPA Plan will be sent to the HSRO Director, and the following leadership personnel will be copied:

- IRB Committee Chairs and Co-Chairs
- Provost
- VPR
- AVP
- Chief Risk Officer, Risk Management
- Assistant General Counsel
- RCQA Executive Director
- 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 VPR.

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.

RESEARCH COMPLIANCE AND QUALITY ASSURANCE
STANDARD OPERATING PROCEDURE

Document Number:	RCQA-803-03	Effective Date:	01 Sep 2020
Page No.	Page 11 of 6	Author:	L. Rochel
Title:	CAPA Plan Support and Review after a RCQA Quality Review		

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-206: Quality Reviews of the IRB/HSRO
SOP RCQA-403: Issuing and Maintaining Quality Review Reports

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

Effective Date	Revision Date	Author	Description of Changes
25 Sep 19	25 Sep 19	L. Rochel	Revised the version number and effective date in the header. Added the Provost & General Counsel and removed of Dean of the respective school, Chief Compliance Officer of UHealth, Executive Dean for Research, and CEO of Uhealth & 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.

RESEARCH COMPLIANCE AND QUALITY ASSURANCE
STANDARD OPERATING PROCEDURE

Document Number: RCQA-803-03 Effective Date: 01 Sep 2020
Page No. Page 12 of 6 Author: L. Rochel
Title: CAPA Plan Support and Review after a RCQA Quality Review

Effective Date	Revision Date	Author	Description of Changes
31 Aug 20	31 Aug 20	L. Rochel	<p>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</p> <p>In section 4.4 a signature lines for the CAPA Manager and RCQA Executive Director and a section for comments were added to the final CAPA Plan received from the PI, Sponsor-Investigator, or HSRO/IRB.</p> <p>Section 5.4.2 was added to indicate where finalized CAPA Plans are saved.</p> <p>The AVP was added to receive copies of the CAPA Plan Implementation Review Report and CAPA Plan Effectiveness Check Report.</p> <p>In section 4.5.1 SOP referred as RCQA SOP-201 was changed to RCQA SOP 204 and 403.</p> <p>In sections 4.7 and 4.9 PI CAPA Plans and IRB CAPA Plans were listed individually for clarity in who receives copies of those CAPA reports.</p> <p>In section 2, definition of the IND, IDE, and Sponsor were added.</p>

9. SIGNATURES

Prepared by: _____
Luis Rochel, BEc, RN, CCRP, RQAP-GCP
CAPA Manager, RCQA

Approved by: _____
Johanna Stamates, RN, MA, CCRC, CHRC
Executive Director, RCQA