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Title:	External Organization Requested CAPA Plan	

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 a Corrective Action Preventive Action (CAPA) Plans requested by an external organization.

External audits and/or reviews may be conducted by external organizations such as an industry sponsor, contract research organization (CRO), or other external organizations. As a result of such audits, noncompliance with federal and/or state regulations, requirements, guidance's, and/or the external organization's required processes or procedures, may be identified. In order to remediate the noncompliance identified, the external organization may request that a CAPA Plan be developed and implemented.

Note: This SOP does not include CAPA Plan requests from federal agencies. See SOP RCQA-800.

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/or preventive actions were created, documented, and implemented as specified in the CAPA Plan

CAPA Owner Individual who is responsible for the development, implementation and oversight of a CAPA Plan for a human subject research study or processes related to human subject research. This individual is typically the individual who has been issued noncompliance observation(s) and is the recipient of the request for a 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 Team Member(s) – Individual(s) who assist and support the CAPA Owner

Contract Research Organization (CRO) – A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions

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

Executive Dean for Research – Abbreviated title for Executive Dean for Research and Research Education & Innovative Medicine

HSRO – Human Subjects Research Office

Industry Sponsor – An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial

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

SOP – Standard Operating Procedure

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

University Leadership – Members may include Dean of respective school, Executive Dean for Research Education & Innovative Medicine, Chief Compliance Officer, General Counsel, Provost, Institutional Official/Vice Provost for Research, and Associate Vice Provost for Human Subject Research

VPR – Vice Provost for Research

3. RESPONSIBILITY

3.1 Vice Provost for Research (VPR)

- Reviews the CAPA Plan, as applicable.
- Provides feedback on the CAPA Plan, as applicable.
- Receives notification of emergent quality and compliance issues

3.2 University Leadership

- Reviews the CAPA Plan, as applicable
- Provides feedback on the CAPA Plan, as applicable

3.3 Departmental Leadership

- Reviews the CAPA Plan, as applicable
- Provides feedback on the CAPA Plan, as applicable
- Approves and signs the CAPA Plan, as applicable

3.4 CAPA Function of RCQA/CAPA Manager

- Provides guidance and support in the development, organization and implementation of the CAPA Plan
- Maintains CAPA Plan documentation and reports(s)

3.5 RCQA ED

- Reviews CAPA Plan
- Provides feedback on the CAPA Plan

3.6 CAPA Owner

- Receives request for a CAPA Plan
- Notifies RCQA of the CAPA Plan request
- Assigns CAPA Team Member(s)
- Develops and signs the CAPA Plan
- Responsible for notifying Departmental Leadership and any relevant UM management, as applicable
- Responsible for the creation, documentation and implementation of the CAPA Plan
- Maintains CAPA Plan documentation

3.7 CAPA Team Member(s)

- Assists the CAPA Owner
- Documents and implements the CAPA Plan
- Maintains CAPA Plan documentation

4. PROCEDURE

4.1 CAPA Plan Request

4.1.1 Based on identified noncompliance, an external organization may request a CAPA Plan

4.1.2 A CAPA Plan requests may be received via various types of communication, e.g. letter, e-mail, verbally; or the request may be indicated in an official report, such as audit report, site visit/review report, etc.

4.1.3 A recipient of a CAPA Plan request may be a PI, Sponsor-Investigator, or a Sponsor

4.2 CAPA Plan Notification

4.2.1 As required per UM Policy, HSR-P-004: RCQA Corrective Action Preventive Action (CAPA) Plan, RCQA must be notified immediately upon receipt of a request for a CAPA Plan.

4.2.2 The recipient of the request needs to provide to RCQA within 24 hours, a copy of the notification or request and associated documentation, as applicable. Documentation may include an audit report, inspection report, site visit/review report, etc.

4.2.3 Notification to University Leadership*****

- CAPA Manager or designee will advise recipient to notify applicable Departmental Leadership and applicable UM management
- RCQA will send a notification to the recipient (CAPA Owner) and the following University Leadership as applicable:
  - Dean of respective school, if applicable
  - VPR
  - Provost
  - Executive Dean for Research, if applicable
  - Chief Compliance Officer
  - General Counsel
  - Associate Vice Provost for Human Subject Research
  - Division Chief
  - Departmental Chairperson
  - Others as applicable
- The RCQA notification will outline the noncompliance identified. Additional information, applicable document(s) and the audit report, inspection report, site visit/review report will be provided, as necessary

*** University Leadership may be notified if the scope of the noncompliance identified affects multiple UM functional areas.**

4.3 CAPA Plan Organization

CAPA Manager or designee will:

- Advise the CAPA Owner to identify CAPA Team Member(s) and assign associated responsibilities

- Provide CAPA Owner/CAPA Team Member(s) education and training, tools and associated templates, as applicable
- Provide guidance in determining CAPA Plan development timelines

4.4 CAPA Plan Draft

As requested by the CAPA Owner, the CAPA Manager or designee will provide:

- Guidance in the development and drafting of the CAPA Plan
- Review and feedback on the CAPA Plan
- If an Institutional Response is required, information from the most appropriate source will be obtained and will be incorporated into the CAPA Plan
- Guidance and support in finalizing the CAPA Plan

4.5 CAPA Plan Departmental Review

4.5.1 CAPA Manager or designee will advise the CAPA Owner to provide the CAPA Plan to respective Departmental Leadership for review and feedback, e.g. Division Chief and/or Departmental Chairperson

4.5.2 If necessary, the CAPA Owner will revise the CAPA Plan

4.6 University Leadership CAPA Plan Review*

If applicable, CAPA Manager or designee will:

- Provide via e-mail, the CAPA Plan to University Leadership and request review and feedback within 48 hours
- Review University Leadership's feedback and/or revisions and provide to the CAPA Owner

*** University Leadership may review the CAPA Plan if the scope of the noncompliance identified affects multiple UM functional areas.**

4.7 Finalization and CAPA Plan Delivery

4.7.1 Finalization of the CAPA Plan

- As requested by the CAPA Owner, the CAPA Manager or designee will:
  - Provide guidance in finalizing the CAPA Plan
  - Provide guidance in obtaining signatures
  - Provide guidance in the compilation of the CAPA Plan package, i.e. plan, table of contents, exhibits and exhibit cover page(s), as applicable
  - Provide guidance in the maintenance of the CAPA Plan package and of all associated documentation

4.7.2 Delivery of the CAPA Plan

- As requested by the CAPA Owner, the CAPA Manager or designee will:
  - Provide guidance in the delivery of the CAPA Plan package
  - Advise the CAPA Owner to provide the CAPA Plan package to Departmental Leadership
- CAPA Manager or designee will:
  - Obtain a final copy of the CAPA Plan package and delivery confirmation
  - Send a notification of delivery, including a copy of the package to the following:
    - RCQA
    - University Leadership, as applicable
  - Send copy of the CAPA Plan to HSRO

4.8 CAPA Plan Implementation and Maintenance

4.8.1 As requested by the CAPA Owner, the CAPA Manager or designee will provide guidance in the documentation and implementation of the CAPA Plan.

4.8.2 The CAPA Manager or designee will maintain CAPA Plan documentation.

- The CAPA Plan package will be converted into a pdf file and maintained in a designated electronic RCQA CAPA file
- All relevant documents and/or correspondence regarding the CAPA Plan from the electronic RCQA CAPA file will be printed and maintained in the designated paper RCQA CAPA file.

4.9 CAPA Plan Review and Report Generation

Based on risk determination, additional process or procedures may follow.

5. DOCUMENTATION

RCQA will maintain an electronic copy of CAPA Plan documentation.

6. REFERENCES

UM Policy: HSR-P-004 Corrective Action Preventive Action (CAPA) Plan
SOP RCQA-800: Federal Organization Requested CAPA Plan

7. TEMPLATES / FORMS

These templates and forms can be found on the RCQA shared drive:

S:/RCQA/CAPA/CAPA Templates and Forms

CAPA Plan Template

8. REVISION HISTORY

Effective Date	Author	Description of Changes
21 Apr 17	L. Rochel	- The definitions of CAPA and CAPA Plan are integrated as CAPA Plan for better understanding. - Updated the Purpose and Definitions sections to remove the IRB and DMC as external organizations conducting audits at UM. - Added " creation of the CAPA Plan " as a responsibility of the CAPA Owner to section 3.6

9. SIGNATURES

Signature on file *21 Apr 2107*

Prepared by: _____ Date: _____

Luis Rochel, BEc, RN, CCRP, RQAP-GCP
CAPA Manager, RCQA

Signature on file *21 Apr 2107*

Approved by: _____ Date: _____

Johanna Stamates, RN, MA, CCRC, CHRC
Executive Director, RCQA