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Title:	Federal 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 Corrective Action Preventive Action (CAPA) Plans requested by a federal agency, group, or organization.

External audits may be conducted by federal agencies such as the FDA, OHRP, NIH, EMA, DOD, or other federal organizations. As a result of such audits, noncompliance with federal regulations and/or requirements may be identified. In order to remediate identified noncompliance, the federal agency, group or organization may request that a CAPA Plan be developed and implemented.

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 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

CRORS – Office of Clinical Research Operations and Regulatory Support

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

DOD –Department of Defense

EMA – European Medicines Agency

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

FDA –Food and Drug Administration

HSRO – Human Subject Research Office

IRB – Institutional Review Board

NIH – National Institutes of Health

OHRP – Office for Human Research Protections

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/or 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
- Provides feedback on the CAPA Plan
- 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
- Provides feedback on the CAPA Plan
- Approves and signs the CAPA Plan

3.4 Human Subjects Research Office (HSRO)/Institutional Review Board (IRB)

- Receives a copy of the CAPA Plan

3.5 CAPA Manager

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

3.6 RCQA ED

- Reviews CAPA Plan
- Provides feedback on the CAPA Plan

3.7 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

3.8 CAPA Team Member(s)

- Assist the CAPA Owner.
- Document and implement the CAPA Plan
- Maintain CAPA Plan documentation

4. PROCEDURE

4.1 CAPA Plan Request

4.1.1 Based on identified noncompliance, a federal agency 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 Form FDA 483, Warning Letter, Untitled Letter, inspection report, audit report, site visit/review report, etc.

4.1.3 A recipient of a CAPA Plan request may be a PI, Sponsor-Investigator, Sponsor, Monitor and/or the IRB.

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 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 the Form FDA 483, Warning Letter, Untitled Letter, audit report, inspection report, site report/review report, etc.

4.2.3 Notification to University Leadership

- CAPA Manager or designee will advise recipient to notify applicable Departmental Leadership and/or applicable UM management.
- University Leadership will be notified of request for CAPA Plan as per SOP RCQA-003.

4.3 CAPA Plan Organization

CAPA Manager or designee will:

- Advise the CAPA Owner to identify CAPA Team Member(s) and to assign associated responsibilities
- Provide CAPA Owner/CAPA Team Member(s) education and training, tools and associated templates, as applicable
- Identify the required timeline for completion of the CAPA Plan, mode of delivery, and all parties who need to receive the CAPA Plan. For example:
    - FDA – 15 business days
    - All other federal agencies as required
- Define CAPA Plan development timelines and provide to Departmental Leadership, CAPA Owner/CAPA Team Member(s), as appropriate

- Advise the CAPA Owner to coordinate reviews and associated discussions as necessary or required with Departmental Leadership and/or CAPA Team Member(s)

4.4 CAPA Plan Draft

CAPA Manager or designee will assist CAPA Owner/CAPA Team Member(s) as follows:

- Guidance and support in the development of the CAPA Plan, utilizing the Form FDA 483 Response Template, CAPA Plan Template or other template as requested
- Guidance in adherence to required CAPA Plan completion timeline
- 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
  Note: An Institutional Response may be requested from a service department, e.g. Research Pharmacy, Billing Compliance, CRORS, IRB/HSRO, etc.
- Guidance and support, as applicable 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 RCQA ED Plan Review

CAPA Manager or designee will provide via e-mail the CAPA Plan to RCQA ED for review and feedback

4.7 University Leadership CAPA Plan Review

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

4.8 Finalization and CAPA Plan Delivery

4.8.1 Finalization of the CAPA Plan

- CAPA Manager or designee will:
  - Provide guidance and support in finalizing the CAPA Plan

- Facilitate obtaining signatures
- Review and facilitate the compilation of the CAPA Plan package, i.e. CAPA Plan, table of contents, exhibits and exhibit cover page(s), as applicable
- Facilitate the creation of paper and electronic copies of the CAPA Plan package, and the maintenance of all associated documentation.

4.8.2 Delivery of the CAPA Plan

- CAPA Manager or designee will:
  - Provide the CAPA Owner/CAPA Team Member(s) guidance and/or support in the delivery of the CAPA Plan package
    - Package will be delivered to the federal agency, organization and/or group contact(s), and any other parties as directed
    - Confirmation of receipt will be obtained
  - Obtain a final copy of the CAPA Plan package
  - Send a notification of delivery, including a copy of the CAPA Plan package to the following, as applicable:
    - VPR
    - Associate Vice Provost for Human Subject Research
    - RCQA
    - Others as applicable

4.9 CAPA Plan Implementation and Maintenance

4.9.1 CAPA Manager or designee will:

- Provide the CAPA Owner/CAPA Team Member(s) guidance in the documentation and implementation of the CAPA Plan, as applicable
- According to CAPA Plan requirements and timelines, advise the CAPA Owner to:
  - Implement the CAPA Plan
  - Perform follow-up and maintenance
  - Maintain documentation

4.9.2 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

4.10 CAPA Plan Review and Report Generation

Based on risk determination/VPR, additional processes or procedures may follow.

5. DOCUMENTATION

RCQA will maintain an electronic copy of the CAPA Plan documentation.

6. REFERENCES

UM Policy: HSR-P-004 Corrective Action Preventive Action (CAPA) Plan
SOP RCQA-003: Hosting Federal Audits

7. TEMPLATES / FORMS

These templates and forms can be found on the RCQA shared drive: S:/RCQA/CAPA/CAPA Templates and Forms

Form FDA 483 Response Template
CAPA Plan Template

8. REVISION HISTORY

Effective Date	Author	Description of Changes
21 Apr 17	L. Rochel	- Updated the Purpose and Definitions sections to: • Remove the specific cooperative groups, as they are captured by NIH • Remove USDA - The definitions of CAPA and CAPA Plan are integrated as CAPA Plan for better understanding. - Added " creation of the CAPA Plan " as a responsibility of the CAPA Owner to section 3.6 - Removed performing and documenting CAPA Plan effectiveness check(s) from 3.6 CAPA Owner responsibility, 3.7 CAPA Team Member(s) responsibility, and 4.8 CAPA Plan Implementation and Maintenance.

9. SIGNATURES

Signature on file *21 Apr 2017*

Prepared by: _____ Date: _____

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

Signature on file *21 Apr 2017*

Approved by: _____ Date: _____

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