Document Number	RCQA-805-02	Effective Date: 21 Apr 2017
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Title:	Issuing and Maintaining CAPA Plan Review Reports	

1. PURPOSE

To define the process by which the Office of Research Compliance and Quality Assurance (RCQA) issues, tracks, and maintains corrective actions and/or preventive actions (CAPA) Plan review reports.

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 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 Plan Implementation Review – A review performed by the CAPA Manager or designee verifying that corrective and/or preventive actions (CAPA) and/or effectiveness of the corrective and preventive actions (CAPA), if applicable, were documented and/or implemented

CAPA Plan Implementation Review Report – A report generated by the CAPA Manager or designee which outlines the CAPA Plan review performed. Reports generated may include CAPA Plan Implementation Review Report, CAPA Plan Effectiveness Check Review Report and/or CAPA Plan Follow-Up Effectiveness Check Review Report

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

HSRO – Human Subject Research Office

IRB – Institutional Review Board

RCQA – Office of Research Compliance and Quality Assurance

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, Vice Provost for Research, and Associate Vice Provost for Human Subject Research

VPR – Vice Provost for Research

3. RESPONSIBILITY

Responsibilities are outlined throughout the document.

4. PROCEDURE

4.1 Issuing Reports

4.1.1 Prior to issuing a CAPA Plan Implementation Review report, the report is printed and the following is verified:

- No comments or corrections are remaining in the report
- The issue date is entered into the footer and the reviewer signature box of the report
- The name of the CAPA Owner, department, and/or the protocol number is indicated in the footer of the report
- The final report will be printed and the CAPA Manager or designee will sign their name in the CAPA Manager signature box
- The final report will be scanned and saved as "pdf" file.

4.1.2 The final report will be issued via email using the CAPA Plan Review Report Submission Memo. The Outlook settings for the email will be set as follows:

- High importance
- Confidential

4.1.3 The final report will be sent to the CAPA Owner in "pdf" format, as an email attachment and the following individuals will be copied:

- VPR
- RCQA Executive Director
- Departmental Leadership, as applicable

- HSRO/IRB, as applicable
- University Leadership, as applicable

Note: The report may be provided to additional University Leadership as directed by the RCQA Executive Director and/or the VPR.

5. DOCUMENTATION

5.1 RCQA Files

The final report and associated CAPA Plan documents and/or correspondence will be maintained in two formats: a word document file and an Adobe Acrobat (pdf) file.

5.2 Electronic Files

All relevant electronic documents and/or correspondence regarding the CAPA Plan review will be converted into pdf files and maintained in a designated electronic RCQA CAPA file.

5.3 Paper Files

All signed original final reports will be maintained in the designated paper RCQA CAPA files for a minimum of ten years from date of signature.

5.4 CAPA Tracking System

5.4.1 CAPA Plan information will be systematically entered, tracked and updated as applicable in the CAPA tracking system.
5.4.2 Upon determination of CAPA Plan closure, the closure date will be entered into the RCQA CAPA tracking system.
5.4.3 All entries into the system will be completed when the information becomes available.

6. REFERENCES

N/A

7. TEMPLATES / FORMS

This template can be found on the RCQA shared drive:

S:/RCQA/CAPA/CAPA Templates and Forms

CAPA Plan Implementation Review Report Submission Memo

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. - Rewording definitions of "CAPA Plan Review" and "CAPA Plan Review Report" in section 2 to include effectiveness review and effectiveness review report as applicable. - Change of "CAPA Document Review Report" for "CAPA Implementation Review Report" to clarify the objective of that report.

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