University
of Miami

Corrective Action Preventive Action (CAPA) Plan

Policy Sections

- **Policy Statement**
- **Reason for Policy**
- **Who Should Know This Policy**
- **Definitions**
- **Procedures**
- **Approval**

Effective Date: 10 April 2015

Revision History (dates of amendments): N/A

Responsible University Officers: Vice Provost for Research

Responsible Offices: Office of Research Compliance and Quality Assurance (RCQA)

Policy Statement

This policy applies to researchers and units conducting human subject research at the University of Miami who are required to create and implement a Corrective Action Preventive Action (CAPA) plan. A CAPA plan may be requested by an external and/or internal entity. Such entities include government agencies (FDA, NIH, DOD, EMA, OHRP, USDA), industry sponsors, Institutional Review Boards (IRB), Vice Provost for Research/Institutional Official (VPR/IO), Data Monitoring Committees (DMC), Office of Clinical Research Operations and Regulatory Support (CRORS), University leadership, and/or departmental leadership.

The Office of Research Compliance and Quality Assurance (RCQA) will provide support to researchers and units in the creation and implementation of a CAPA plan. Researchers and units must notify RCQA of all human subject-related CAPA plans determined to be needed and/or required by an external and/or internal entity.

Reason for Policy

Human subject research conducted at the University is routinely audited and monitored by internal entities, such as the Office of Research Compliance and Quality Assurance (RCQA; Office of the Vice Provost for Research) and the Office of Clinical Research Operations and Regulatory Support (CRORS; Miller Research Office), as well as external entities, such as the FDA and the NIH. As part of these visits, issues/deficiencies that are not in compliance with federal, state, local, or institutional regulations may be identified. Depending on the severity of these issues, it may be required that a CAPA plan be created and implemented. The RCQA CAPA Manager or designee in RCQA will provide guidance and support to University researchers and units on strategies for corrective and/or preventive actions and for CAPA plan formulation and implementation, including the identification of gaps/deficiencies and the implementation of appropriate corrective and/or preventive actions.

This policy is necessary to ensure that University, school, and departmental leadership are informed of and agree with the CAPA plans, and that researchers and units are aware of their responsibilities in the creation, implementation, and oversight of such plans.

Who Should Know This Policy

Center and Institution Directors

Chief Compliance Officer
Deans
Department Chairs
General Counsel
Human Subjects Research Office
Institutional Review Board
Office of Clinical Research Operations and Regulatory Support
Office of Research Administration
Office of Research Compliance and Quality Assurance
Principal Investigators
Provost
Research Administrators
Research Professionals
Sponsor-Investigators
Vice Provosts

History

Amended: N/A

Effective: 10 April 2015

Definitions

CAPA	Corrective Action Preventive Action
CAPA Manager	A member of RCQA who provides CAPA plan assistance and support, including education, as well as verifies CAPA plan implementation and effectiveness
CRORS	Office of Clinical Research Operations and Regulatory Support
Departmental Leadership	Members may include Department Chairperson and Division Chief
DOD	US Department of Defense
DMC	Data Monitoring Committee (also known as Data Safety Monitoring Board (DSMB) or Data Safety Monitoring Committee (DSMC))
Effectiveness Check	Review performed to verify corrective and/or preventive action plan was effective
EMA	European Medicines Agency
FDA	US Department of Food and Drug Administration
HSRO	Human Subjects Research Office
IRB	Institutional Review Board

NIH	National Institutes of Health
OHRP	Office for Human Research Protections
Researcher	An individual who initiates and/or conducts human subject research
RCQA	Office of Research Compliance and Quality Assurance
University Leadership	Members may include School Dean, Executive Dean for Research, Research Education & Innovative Medicine, Chief Compliance Officer, General Counsel, Provost, Institutional Official/Vice Provost for Research, and Associate Vice Provost for Human Subject Research
USDA	United States Department of Agriculture
VPR	Vice Provost for Research

Procedures

To facilitate coordination, researchers and units will:

- notify RCQA immediately upon determination of need, notification and/or receipt of the request of a CAPA plan
- provide RCQA a copy of the notification and associated documentation, as applicable

For all federally required CAPA plans, RCQA will provide support and assistance to researchers and units in the creation and implementation of the CAPA plan. For all other required CAPA plans (industry sponsor, IRB, VPR/IO, DMC, etc.), RCQA will provide support at the request of the researcher and/or unit. Support may include education, guidance and assistance to the researcher/research site personnel/unit personnel from the RCQA CAPA Manager or designee.

Upon completion, CAPA plans requested by a federal agency, industry sponsor, IRB, IO/VPR, DMC, CRORS, and/or University leadership must be submitted to RCQA for review. CAPA plans requested by departmental leadership are not required to be submitted to RCQA. Once finalized, the CAPA plan will be provided to relevant University leadership. Upon acceptance by University leadership, the final CAPA plan can be provided to the external and/or internal entity that requested the CAPA plan.

It is the responsibility of the researcher and unit/department leadership to perform CAPA plan follow-up, maintenance and effectiveness checks as required per CAPA plan requirements and associated timelines. RCQA CAPA Manager or designee will perform CAPA plan effectiveness checks as needed.

Approval

John Bixby, Ph.D._____ Vice Provost for Research_____
Printed Name of Final Approver Job Title

Signature on file	*04/28/2015*
Signature for Final Approval	Date of Final Approval
Omaida Velazquez, M.D.	Executive Dean for Research & Innovative Medicine
Printed Name of Final Approver	Job Title
Signature on file	*04/21/2015*
Signature for Final Approval	Date of Final Approval