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# Corrective Action Preventive Action (CAPA) Plan

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**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)

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## Policy Statement

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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.

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## Reason for Policy

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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.

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## Who Should Know This Policy

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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

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## History

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**Amended:** N/A

**Effective:** 10 April 2015

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## Definitions

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

<b>NIH</b>	National Institutes of Health
<b>OHRP</b>	Office for Human Research Protections
<b>Researcher</b>	An individual who initiates and/or conducts human subject research
<b>RCQA</b>	Office of Research Compliance and Quality Assurance
<b>University Leadership</b>	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
<b>USDA</b>	United States Department of Agriculture
<b>VPR</b>	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.  
Printed Name of Final Approver

Vice Provost for Research  
Job Title

Signature on file  
Signature for Final Approval

04/28/2015  
Date of Final Approval

Omaida Velazquez, M.D.  
Printed Name of Final Approver

Executive Dean for Research & Innovative Medicine  
Job Title

Signature on file  
Signature for Final Approval

04/21/2015  
Date of Final Approval