
External Audits For Research

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Effective Date: 29 Aug 2014**Revision History:**

Supersedes HSR-P-002 (effective 24 Sep 2012)
Policy 6.3: External Audits for Research (effective 25 Aug 2010)

Responsible University Officers: Vice Provost for Research**Responsible Offices:** RCQA

Policy Statement

It is the policy of the University of Miami to cooperate with and support external inspectors/investigators conducting audits involving university researchers. External inspectors include but are not limited to the FDA, NIH, OHRP, DOD, EMA, Florida Department of Agriculture, and other governmental agencies at the federal, state, and local levels. Financial audits are the responsibility of the University Controller and are not governed by this policy.

The Office of Research Compliance and Quality Assurance (RCQA) may provide external inspectors/investigators with facilities, support and resources for the duration of the on-site visit. RCQA must be notified of all visits by external inspectors for any clinical research related matter and will be responsible for coordinating notification and activities with General Counsel, UM leadership and the Controller as appropriate. When appropriate, RCQA will provide a secure work environment to the on-site inspectors/investigators for the duration of the Inspection. In such instances, only the on-site inspectors/investigators, RCQA and university security units will have access to the facility provided. RCQA will assist and review all audit response documents.

Reason for Policy

Due to the broad spectrum of research conducted at the university and the number of federal, state, and local agencies authorized under law to inspect/audit the university's research, this policy is necessary to facilitate external audits by providing centralized resources to support the Principal Investigator/university member before, during and after an audit; the external inspectors/investigators while onsite; and to ensure that appropriate university officials are aware of onsite inspectors and potential issues that may arise during or as a result of an audit.

Who Should Know This Policy

Provost, Vice Provosts, Deans, Center Directors, Department Chairs
Chief Compliance Officer
General Counsel
Research Administrators

Principal Investigators
Research Professionals
Office of Research Administration
Office of Research Compliance and Quality Assurance
Office of Clinical Research Operations and Regulatory Support
Office of Research and Research Education
University Controller's Office, Sponsored Programs

History

Amended: 25 Feb 2014

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Definitions

DOD	United States Department of Defense
EMA	European Medicines Agency
FDA	Food and Drug Administration
OHRP	Office for Human Research Protections
RCQA	The Office of Research Compliance & Quality Assurance
USDA	United States Department of Agriculture

Procedures

To facilitate cooperation, Principal Investigators and/or responsible university members are required to:

- Notify RCQA immediately upon contact, notification and/or receipt of a phone call, email or letter from an agency to schedule an audit or visit.
- Designate an escort who will oversee the audit and work with the inspectors/investigators for the duration of the audit (usually the study coordinator or laboratory manager.)
- Coordinate with RCQA for on-site inspector/investigator support.
- Set aside time for the inspectors/investigators as needed and/or requested by the inspectors/investigators.
- In instances of an unannounced inspection, the individual contacted is to escort the inspectors/investigators to the responsible individual (Principal Investigator, unit Director, etc.) for the area being inspected. The responsible individual is responsible for determining and meeting the needs of the inspectors/investigators and notifying RCQA.

All external inspectors/investigators are required to present their credentials at the beginning of the audit.

RCQA will assist study teams in preparation for and response to external audits. A representative from RCQA will attend initial and exit interviews, as well as any scheduled debriefings, and provide input as necessary.

Approval

Name	Title	Signature	Date
Dr. John Bixby	Vice Provost for Research	<i>On File</i>	8/29/2014