



POLICY 6.3 – EXTERNAL AUDITS FOR RESEARCH

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Effective Date: 8/25/10**Revision History (list dates of amendments):** NA**Responsible University Officer:** Vice Provost for Research**Responsible Offices:** Office of Research (OR); Office of Research Compliance and Assessment (ORCA)

Policy Statement

It is the policy of the University of Miami to cooperate with and support external inspectors conducting audits involving university researchers. External inspectors include but are not limited to the FDA, NIH, OHRP, USDA, 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 may provide onsite inspectors with facilities, support and resources for the duration of the onsite visit, and is responsible for coordinating notification and activities with General Counsel and the Controller as appropriate. When appropriate, the Office of Research will provide a secure work environment to the onsite inspectors for the duration of the inspection. In such instances, only the on-site inspectors and university security units will have access to the facility provided.

To facilitate cooperation, PI's and/or other responsible university members are required to:

- Notify the Vice Provost for Research (VPR) and the Office of Research (OR) (see contacts below) immediately upon contact, notification and/or receipt of a phone call or letter from the agency to schedule an audit.
- Designate an escort who will oversee the audit and work with the inspectors for the duration of the audit (usually the study coordinator or laboratory manager).
- Coordinate with the Office of Research for on-site inspector support.
- Set aside time for the inspectors as needed and/or requested by the inspectors.
- In instances of an unannounced inspection, the individual contacted is to escort the inspector to the director of the unit responsible for the area being inspected. The unit director is responsible for determining and meeting the needs of the inspector/s and notifying the VPR and OR.

All onsite inspectors are required to present their credentials at the beginning of the audit.

The Office of Research Compliance Assessment (ORCA) is available to assist study teams in preparation for and response to external audits. A representative from the Office of Research may attend exit interviews and provide input as necessary.

Reason for Policy

Because of the broad spectrum of research conducted at the university and the number of federal, state and local agencies authorized under law to inspect and audit the university's research, this policy is necessary to facilitate external audits by providing centralized resources to support the PI before, during and after an audit; the inspectors while onsite; and 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
General Counsel
Research Administrators
Principal Investigators
Office of Research: Clinical Research Initiation Services, Pre-Award Research Administration, Office of Research Compliance Assessment
University Controller's Office, Sponsored Programs

Related Information

FDA final guidance on "Investigator Responsibilities - Protecting the Rights, Safety, and Welfare of Study Subjects." [FDA Guidance Link](#)
USDA Animal Welfare Center: [Animal Welfare Act Link](#) and [Research Facility Inspection Guide](#)
NIH Office of Biotechnology Activities (OBA): [OBA Link](#)
Office of Research: [OR Link](#)
Human Subject Research Office: [HSRO Link](#)
Office of Research Compliance and Assessment: [ORCA Link](#)
Clinical Research Initiation Services: [CRIS Link](#)
Pre-Award Research Administration: [UMPARA Link](#)
University Controller's Office: [Controller's Link](#)
University External Audit Policy B008: [Policy B008 Link](#) (governing financial audits)
Office of Research Guidelines – External Audit and Inspection Support Facility

Contacts

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History

Effective: 8/25/10
Revised: none

Approval

Dr. Richard J. Bookman
Printed Name

Vice Provost for Research
Title

On File
Signature

8/25/10
Date
