

RESEARCH COMPLIANCE AND QUALITY ASSURANCE
STANDARD OPERATING PROCEDURE

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1. PURPOSE

The purpose of this document is to define the process by which the office of Research Compliance and Quality Assurance (RCQA) escalates Observations identified in human subject research studies conducted by University of Miami (UM) investigators where Jackson Health System (JHS) is a research site or the study involves research participants that signed a combined JHS/UM informed consent form (ICF) or a JHS ICF. Identified JHS observations may relate to JHS research participants, JHS personnel and/or procedures and activities conducted at JHS.

Observations may be identified via an internal Quality Review conducted by RCQA or by the Principal Investigator, study team, UM IRB or by external sources such as the Sponsor, external IRB or federal audit.

2. DEFINITIONS

CTO – Clinical Trial Office
JHS - Jackson Health System
Observation - An identified issue that may pose significant risk to the protection of rights and/or welfare of human research subjects, and/or represents a deviation from or deficiency in compliance with applicable regulations, guidelines, and/or institutional policies
RCQA Auditor - a member of RCQA that performs Quality Reviews
RCQA – Research Compliance and Quality Assurance
UM – University of Miami

3. RESPONSIBILITY

3.1 RCQA Auditors

- Perform Quality Reviews of human subject research studies conducted by UM investigators where JHS is a research site or the study involves research participants that signed a combined JHS/UM ICF or a JHS ICF. The Quality Review may include reviewing records at JHS, visiting sites where research is conducted and interviewing JHS personnel.
- Immediately notify the RCQA Executive Director, or designee, upon identifying a Quality Review Observation related to JHS research participants, JHS personnel and/or procedures and activities conducted at JHS.
- Confirm JHS-related Observations via supporting documentation and/or conversations with the PI and research team.
- Create Quality Review Report.

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3.2 RCQA Executive Director

Immediately notify the following UM leadership group of the identified Observation if the Observation presents a potential risk to subjects, data integrity, billing, etc.:

- Associate Vice President, Regulatory Affairs and Assessment
- Chief Compliance Officer of Medical School
- Assistant General Counsel
- Chief Risk Officer, Risk Management
- Vice Provost for Research

4. PROCEDURE

4.1 Notification of JHS Observation

- 4.1.1 During the conduct of a Quality Review, the RCQA Auditors will immediately notify the RCQA Executive Director or designee of any potential Observation related to JHS research participants, JHS personnel and/or procedures and activities conducted at JHS.
- 4.1.2 Upon receiving notification of an Observation related to JHS research participants, JHS personnel and/or procedures and activities conducted at JHS, RCQA personnel will immediately notify the RCQA Executive Director or designee.

4.2 Escalation to UM Leadership

Upon receiving notification of a potential Observation related to JHS that could present a potential risk to subjects, data integrity, billing, etc., the RCQA Executive Director or designee will notify the following UM leadership members, via email:

- Associate Vice President, Regulatory Affairs and Assessment
- Chief Compliance Officer of Medical School
- Assistant General Counsel
- Chief Risk Officer, Risk Management
- Vice Provost for Research

This notification will include a summary of the potential Observation.

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4.3 Escalation to JHS Leadership

4.3.1 Upon receiving notification of a potential Observation related to JHS that could present a potential risk to subjects, data integrity, or billing, the UM leadership group and the RCQA Executive Director or designee will do the following:

- Determine the JHS department or unit that needs to be notified (e.g. Research Pharmacy, Billing Compliance, Clinical Trials Office, hospital unit, etc.)
- Determine the JHS personnel that need to be notified (e.g. Research Pharmacist, Risk Management, etc.)
- Immediately notify the applicable JHS departments/units, the Chief Compliance Officer, and the Clinical Trials Office of Observations related to subject safety and protection, data integrity, and potential billing issues.
- Include the Chair of the Department that is conducting the human subject research in the notification to JHS leadership.

4.3.2 RCQA will be included in all email communication with JHS.

4.3.2.1 JHS will receive a written summary of any Observations related to research activities occurring at JHS or involving patients recruited at JHS.

In the event of any Observations regarding a research study that occurs at a UM facility, JHS will be notified in the event that (1) the research study also involves study activities at JHS; and (2) the subject of the Observations involves study activities that have occurred or will occur at JHS, or involves JHS personnel that has been involved or will be involved in the study at JHS.

4.3.2.2 For Observations resulting from a Quality Review that are not related to risk to subjects, data integrity, or billing, JHS will be notified at the time of issuing the Final Quality Review Report and will receive a copy of the JHS Observation as it appears in the Final Quality Review Report.

Note that only the JHS Observation will be forwarded to JHS without the remainder of the Quality Review Report.

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5. DOCUMENTATION

5.1 Quality Review Report

All JHS Observations listed in a Quality Review Report will contain instructions to the PI of the study that they must submit a copy of the Observation to the JHS Clinical Trials Office within two (2) business days of receiving the Final Quality Review Report.

5.2 Communication With JHS

All email communication between RCQA, UM leadership and JHS leadership will be saved in the Quality Review file on the shared RCQA drive as follows:

S:\RCQA\Auditing\Audits\Completed Audits\2020 (or current year)\PI's last name

6. REFERENCES

N/A

7. TEMPLATES / FORMS / TOOLS

N/A

8. REVISION HISTORY

N/A – New document

9. SIGNATURES

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Approved by: _____ Date: _____
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