

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) conducts Quality Reviews of human subject research at the University of Miami. These reviews are intended to assess the research team's level of compliance with Federal and State regulations and guidelines, and University policies and procedures, as well as to provide guidance and recommendations for good research practices.

2. DEFINITIONS

AVP – Associate Vice President, Regulatory Affairs and Assessment
CAPA – Corrective and Preventative Action
CRF – Case Report Form
CRORS – Clinical Research Operations and Regulatory Support
CTO – Clinical Trials Office at JHS
DSMC – Data Safety Monitoring Committee at the SCCC
FDA – Food and Drug Administration
HIPAA – Health Insurance Portability and Accountability Act
HSRO – Human Subjects Research Office
ICH-GCP- International Conference on Harmonization Guidelines for Good Clinical Practice
IDE – Investigational Device Exemption
IND – Investigational New Drug (Application)
IRB – Institutional Review Board
IRB system - Electronic protocol submission and tracking system
JHS – Jackson Health System
NIH – National Institutes of Health
OHRP – Office for Human Research Protections
PI – Principal Investigator
PRMC – Protocol Review and Monitoring Committee
QA – Quality Assurance
QA Auditor- A member of RCQA that performs Quality Reviews
RCQA – Research Compliance and Quality Assurance
SCCC – Sylvester Comprehensive Cancer Center
UM - University of Miami
University – University of Miami
Velos – Clinical Trial Management System
VPR – Vice Provost for Research

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3. RESPONSIBILITY

3.1 VPR and AVP

- The VPR may request Quality Reviews of human subject research protocols
- Both receive copies of Quality Review reports
- Both receive notification of potentially serious non-compliance issues

3.2 Sylvester Comprehensive Cancer Center (SCCC)

- Provides RCQA with an annual list of studies to be reviewed at SCCC
- Receives Quality Review reports

3.3 Human Subjects Research Office (HSRO)

- HSRO Director receives notification of potentially serious non-compliance issues
- Receives Quality Review reports and PI CAPA Plans and distributes them to the appropriate IRB committee
- Notifies RCQA of required follow-up actions requested by the IRBs
- Notifies RCQA of Quality Review closures and IRB determination letters

3.4 Institutional Review Boards (IRBs)

- May request a Quality Review of a human subject research protocol
- Receive and review Quality Review reports and PI CAPA Plans
- Determine the need for additional required follow-up actions

3.5 QA Function of RCQA

- Assigns QA Auditors to conduct Quality Reviews
- Notifies investigators of planned Quality Reviews and schedules Quality Reviews
- Performs Quality Reviews
- Issues Quality Review reports and facility observation reports

3.6 Principal Investigator (PI)

- Schedules Quality Review with RCQA QA Auditor
- Is available for meetings during the Quality Review
- Provides all study-related documents
- Allows study staff to be available to answer questions
- Responds to Quality Review observations

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4. QUALITY REVIEW PROCESS

4.1 Quality Review Assignment

The RCQA Executive Director or designee prioritizes the schedule of Quality Reviews based on several factors such as the expected level of risk to subjects and the University, and the availability of resources. Directed Quality Reviews have priority over previously scheduled routine reviews.

4.2 Quality Review Notification

4.2.1 Notify the PI

The QA auditor will email a Quality Review Notification Memo to the PI of the selected study and copy the following leadership personnel:

- Departmental Chairperson, Division Chief and Center Director (if applicable)
 - AVP
 - VPR
 - CRORS Director or designee (if study is monitored by CRORS)
 - RCQA Executive Director and QA Manager
 - RCQA CAPA Manager
 - For audits at the SCCC, include the SCCC central email address: sccrcqa@miami.edu, and the applicable Site Disease Group Leader
 - For Quality Reviews at Bascom Palmer Eye Institute (BPEI), include the BPEI Vice Chair and Director Clinical Research Services
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- The following documents will be attached to this notification email:
 - Essential Documents Checklist for Quality Review
 - RCQA Electronic Quality Review Process Flow
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- The Quality Review will be scheduled for **three (3)** days; however, less time may be needed if subject enrollment is low.

4.2.1.1 Focused Quality Reviews

- Notify the PI as stated in step 4.2.1
- Attach the following to the email notification:
 - Essential Documents Checklist for Quality Review
 - RCQA Electronic Quality Review Process Flow
- The Quality Review will be scheduled for **one (1)** day

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4.2.2 Notify JHS CTO

If the study to be reviewed is also conducted at JHS and/or includes JHS patients, the QA Auditor will email the JHS Quality Review Notification memo to the JHS CTO, stating the scheduled review dates.

4.3 Quality Review Preparation

4.3.1 To prepare for the Quality Review, the QA Auditor will review the study documentation found in the IRB and Velos systems, prior to conducting the Quality Review.

4.4 Initial Meeting with PI and Study Team

The QA Auditor will conduct an initial meeting with the PI and study team at the beginning of the Quality Review to discuss the scope of the review, the process, and what to expect from the auditors. The PI will be asked to describe the protocol, and the roles and responsibilities of the team during the conduct of the study.

4.5 Quality Review Conduct

4.5.1 The standards used to conduct Quality Reviews of human subject protocols will include:

- Applicable Federal and State regulations (FDA, OHRP, NIH, HIPAA, etc.)
- ICH-Guidelines for Good Clinical Practice
- University of Miami Policies and Procedures
- External IRB Policies and Procedures (if applicable)
- Research Site-specific Standard Operating Procedures

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4.5.2 Quality Reviews will consist of the following, at a minimum:

- Review of 100% of all consent documentation, up to a maximum of 50 signed consent forms.
 - For studies with high enrollment (> 50 subjects), a percentage of the consent forms may be selected by the auditor in conjunction with the RCQA Executive Director and QA Manager.
 - Confirm that all eight required elements of consent are included in the consent form. Verify that the six additional elements are included, as applicable.
 - Verify that the ClinicalTrials.gov statement is included verbatim, where applicable.
- Confirm the number of study subjects.
- For Screen Failures, review informed consent and documentation supporting the reason for screen failure.
- Review of correspondence records and meeting minutes for IRB, PRMC, DSMC, etc., where applicable.
- Review of key regulatory documents, such as Form FDA 1572, financial disclosures, delegation of authority logs.
- Review of protocol training and human subject research training records for all key study staff.
- Review of study team members' qualifications.
- Records of receipt, storage, usage, and return of, as well as subject compliance with investigational product, if applicable.
- Review of other study-related materials, equipment and/or documentation will be done at the discretion of the QA Auditor.
- A review of subject records:
 - A sampling of subject records to be reviewed will be determined by $(\sqrt{n})+1$, where n is the total number of subjects that started study procedures (except screen failures); or 5 subject records, whichever is the larger number of subject records.
 - This review will include adherence to the protocol and protocol required procedures, verification of source data against data entered in CRFs or electronic data capture systems, review of the identification, PI review and assessment, recording and reporting of serious adverse events, adverse events, and unanticipated problems, review of PI oversight, etc. as outlined in the Quality Review report template.
- For studies where University faculty members are holding an IND or IDE; compliance with sponsor responsibilities in addition to PI responsibilities will be reviewed and assessed.

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Note: Focused Quality Reviews will focus on a particular topic such as informed consent where only related documentation will be reviewed.

4.5.3 The QA Auditor may also conduct interviews of current or past study staff.

4.5.4 During the course of the Quality Review, the QA Auditor will notify the RCQA Executive Director of any issues that may jeopardize the safety and welfare of human subjects or data integrity, as well as of any potential observations related to JHS. The Executive Director will then immediately notify the VPR, AVP, Director for Human Subject Research, and the office of the Executive Dean for Research, as applicable.

4.6 PI Debriefing

At the conclusion of the Quality Review, if possible **on the last day** of the review, the QA Auditor will review the main observations with the PI and study team at a debrief meeting.

4.7 HSRO Debriefing

If observations relating to the review and approval of research are identified, the QA Auditor will summarize the observation in an email to the Director for Human Subject Research and schedule a debrief meeting. The following will be copied on this email:

- RCQA Executive Director
- QA Manager
- CAPA Manager

4.8 Quality Review Report

4.8.1 Observations will be reported in a standardized format as defined in SOP RCQA-402.

4.8.2 RCQA will issue a Draft Quality Review Report within **ten (10) business days** of the completion of a full Quality Review and within **five (5) business days** for focused Quality Reviews. If additional time is needed, it will be discussed with the RCQA Executive Director and QA Manager and will be documented in the RCQA database.

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4.8.3 The Draft Quality Review Report will be reviewed within RCQA prior to issuance.

4.8.4 The Draft Quality Review Report will be issued to the PI and main study team members via email with instructions to review it for factual content.

4.9 Exit Meeting

4.9.1 The QA Auditor will aim to schedule an exit meeting with the PI and study team within **three (3) business days** of issuing the draft report to review the draft report for accuracy and to clarify any issues.

4.9.2 Based on discussions at the exit meeting, the QA Auditor will finalize the Quality Review report and issue the Final Report as per SOP RCQA-403.

4.10 Quality Review Response (CAPA Plan)

4.10.1 Responses to the Quality Review observations should be submitted to the RCQA CAPA Manager within **ten (10) business days**.

4.10.1.1 Additional time to provide responses may be granted, if requested. Additional time must be approved by the RCQA Executive Director and CAPA Manager.

4.10.1.2 The CAPA Manager will offer assistance in the creation of the CAPA Plan.

4.10.1.3 The CAPA Manager will review the draft CAPA Plan and provide feedback in order to obtain responses that are specific and measurable.

4.10.1.4 The RCQA Executive Director will conduct the final review of CAPA Plans.

4.10.2 After **ten (10) business days**, RCQA should receive the final CAPA Plan. The Final Quality Review Report and CAPA Plan will be submitted to the HSRO via email and leadership personnel will be copied on the email as per SOP RCQA-403.

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4.11 Post Quality Review Customer Satisfaction Survey

Within **two (2) business days** after issuing the Final Quality Review Report, the QA Auditor will email the RCQA administrative assistant to request that a customer satisfaction survey be sent to the PI and study team.

4.12 IRB Determination Letter

The IRB will review the Final Quality Review Report and PI CAPA Plan and issue an IRB determination letter. This letter will notify RCQA, the VPR and AVP if a follow up Quality Review is requested by the IRB, or if this Quality Review is considered closed. If the Quality Review did not identify any observations, an IRB determination letter will not be issued.

5. DOCUMENTATION

RCQA will maintain electronic copies of the Final Quality Review Report, CAPA Plan, and any correspondence concerning the report in the RCQA shared drive indefinitely.

6. REFERENCES

- SOP RCQA-402: Quality Review Report Generation
- SOP RCQA-403: Issuing and Maintaining Quality Review Reports

7. TEMPLATES / FORMS / TOOLS

**These templates and forms can be found on the RCQA shared drive:
S:/RCQA/Auditing/Auditing Forms/Audit Email Templates & Memos**

- PI Quality Review Notification Memo
- JHS Quality Review Notification
- Draft Quality Review Report Submission Memo

**The following templates and forms can be found on the RCQA shared drive:
S:/RCQA/Auditing/Auditing Forms/Current Templates & Forms**

- Essential Documents Checklist for Quality Review
- RCQA Electronic Quality Review Process Flow
- Quality Review Report Template

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8. REVISION HISTORY

Effective Date	Revision Date	Author	Description of Changes
1 Apr 05	30 Mar 05	G. Lapinski	Name of office from ORC to RCA; Deletion of text “according to the HSRO Standard Operating Procedures Request to Access Protocol Files dated 26 Dec 2002” in section 4.3; Reports for investigators in the Department of Medicine; Deleted reference to HSRO Standard Operating Procedures Request to Access Protocol Files dated 26 Dec 2002 in section 6; Updated flow sheet attachment.
25 Oct 06	25 Oct 06	K. Roach	Name of Vice Provost for Research changed to Richard Bookman, PhD. Procedure to request directed audit clarified in section 4.1, last paragraph.
16 Jun 08	16 Jun 08	L. Smith	Name of office from RCA to ORCA, scope of policy to include directed audits of SCCC protocol, and new language in section 4.5 allowing ORCA to report findings to HSRO prior to scheduled distribution when warranted by findings.
05 Nov 09	21 Oct 09	J. Stamates	Section 4.2: addition of VP for research and JHS CTO Section 4.3.: addition of eProst Section 4.4: review details added; number of subjects for close review determined to be 5 Addition of Associate Director Attachment: Revised Flow Sheet
01 Aug 10	02 Feb 10	S. Mackey	Section 2: added definitions Section 4.5: added facility finding requirements
19 Oct 10	08 Oct 10	H. Miletic	Changed numbering format of document and added version number 01. Minor changes to text throughout. Updated references. Changed approval signature from Vice Provost for Research to ORCA Associate Director. Moved revision history to end of document. Added author signature.

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Effective Date	Revision Date	Author	Description of Changes
10 Mar 11	10 Mar 11	H. Miletic	Revised the version number and effective date in the header. Added the Dean of the respective school to the list of individuals who will receive audit notifications and audit reports in sections 4.2 and 4.5. The ORCA Associate Director was removed throughout the document.
08 Jun 12	01 Jun 12	H. Miletic	Changed the name of the department from Office of Research Compliance Assessment (ORCA) to Regulatory Support and Quality Assurance (RSQA) throughout the document. Revised the Purpose section such that routine audits requested by the SCCC DSMC are conducted according to this SOP. Changed Compliance Officer to QA Auditor throughout the document. Added the Institutional Official (IO) and removed the OR and Research Administration Office from section 3. Added focused, follow-up, and investigator-requested audits to section 4.1. Changed the hotline number to CaneWatch in section 4.1. Changed the Vice Provost for Research to the IO throughout the document. Changed section 4.4 to remove the requirement for the PI to sign a Conflict of Interest Statement. Changed section 4.5 to state that PIs and facilities have 10 working days to respond to audit findings. Modified section 4.6.3 to state that Facility Findings reports will be sent to the facility and leadership will be copied on the email. Removed the attachment. Deleted the JMH Referral Form from sections 4.6 and 7. Added forms to section 7 and additional references to section 6. Reformatted the entire document. Updated the ORCA Director to the RSQA Executive Director.
26 Aug 13	21Aug 13	H. Miletic	Changed CRRC to ORA in sections 2, 4.6 and 7. Updated section 3.5 to state that QA and Compliance function of RSQA reports to Vice Provost for Research. Removed the requirement to specify a date range for the audit in the PI notification in section 4.2.1. Replaced QA Director with QA Manager in sections 4.2.1 and

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			<p>4.2.3. Modified section 4.2.3 to state that RSQA Executive Director or QA Manager will notify IO of audits to be scheduled. Changed section 4.4.2 to state that audits will generally be scheduled for 3 to 5 days. Modified sections 4.5.4, 4.5.6 and 4.5.6.1 to refer to SOP RSQA-403. Added the Chief Medical Compliance Officer and Assistant VP, Research Support Operations to section 4.6.1.</p> <p>Removed QA Director and Senior Associate Dean for Clinical Research throughout document. Updated section 7 to reflect location of templates and forms.</p>

Effective Date	Author	Description of Changes
25 Aug 2014	H. Miletic	<p>Changed the name of the office from Regulatory Support and Quality Assurance (RSQA) to Research Compliance and Quality Assurance (RCQA) throughout the document. Added IRB-7 to sections 2 and 4.3. A request for IRB minutes was added to section 4.2.2. Updated section 4.4.3 to include a review of the required elements in the ICF. Updated section 4.5.5 and 4.5.6 to state that RCQA will offer assistance to the PI to create a complete audit response and that RCQA Executive Director will review responses prior to sending to IRB. Modified section 4.5.6.1 to state that the audit report and responses will be sent to both the DSMC and HSRO simultaneously for DSMC- requested audits. Removed the Chief Medical Compliance Officer from section 4.6.1. Updated section 5 to state that audit reports, PI responses, etc. will be kept for a minimum of ten years. Updated section 6 to remove the document retention policy. Modified the revision history table.</p>
13 Feb 2015	H. Miletic	<p>Revised section 4.2 to include notifying the CTD Compliance Officer of all audits of investigator-initiated trials. Updated section 4.4.3 to include verification of CTD statement.</p>
17 Feb 2016	H. Miletic	<p>Updated section 3.2 to remove the statement saying that the DSMC will notify the HSRO of audit findings. Updated section 4.2.1 to remove the Provost from the list of leadership</p>

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		personnel. Added the SCCC central email to section 4.2.1. Updated section 4.5.6.1 to refer to SOP RCQA-403. Deleted 4.2.4 requiring a separate notification to SCCC. Added section 4.8 to state that post audit survey will be sent to PI and study team. Minor modifications made to text throughout document.
19 Feb 2016	H. Miletic	Added the CEO of UHealth and Senior Vice President of Health Affairs to section 4.2.1.
19 Apr 2017	H. Miletic	Removed the notification of the CTD Manager in section 4.2. Added Center Director, Chief Compliance Officer of Medical School, CRORS, BPEI Vice Chair and BPEI central mailbox to section 4.2.1. Updated section 4.2.2 to specify who will receive the HSRO Audit Notification. Added that RCQA will aim to issue audit reports within 5 and 10 working days for focused and full audits, respectively. Sections were renumbered as the following processes were added: debriefing meeting with PI, debriefing with HSRO, and issuing a draft audit report to PI. Added the creation of a separate audit report issued to the IRB/HSRO for findings pertaining to IRB/HSRO. Deleted the section on Report of Findings to Other Parties. Minor modifications to the text were made throughout SOP.
23 Oct 2017	H. Miletic	Modified section 4.2.1 to remove the following leadership personnel from the initial audit notification, as per their request: Dean of medical school, Chief Compliance Officer, and CEO of UHealth. Added a step to include the Audit Flowchart and Review Categories documents to the initial PI Audit Notification. Updated section 4.5.2 to reduce the number of ICFs reviewed to a maximum of 50 and modified the text to clarify that only a sampling of subject records will be reviewed. Added Audit Flowchart and Review Categories documents to section 7.
30 Mar 2018	H. Miletic	Changed the term “audits” to “Quality Reviews” throughout the document and title of the SOP. “Audit responses” was changed to “CAPA Plan” throughout the document. Removed the Dean and Executive Dean for Research from section 4.2.1. Added the Essential Documents for Quality Review document to sections 4.2.1 and 7. Replaced HSRO personnel with the HSRO mailbox in section 4.2.2. Minor edits were made throughout.

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02 Apr 2019	H. Miletic	<p>Removed Audit and Advisory Services from section 2. Modified section 4.2 to add the Director Clinical research Services and remove the BPEI mailbox when notifying the PI. Step 4.2.2.1 was added for Focused Quality Reviews. Steps within section 4.2 were renumbered. Removed the HSRO notification and the Quality.Determination@miami.edu mailbox in step 4.2.3. Changed the Associate Vice Provost for Human Subject Research to the Executive Director for Human Subject Research, throughout the SOP. Updated step 4.3 to remove reference to studies initiated prior to 2008. Clarified step 4.5.2 regarding focused reviews and the calculation for sampling of subjects. Updated step 4.7 to notify the Executive Director for Human Subject Research of IRB observations. Updated step 4.12 to clarify that an IRB determination letter will not be issued if no observations were identified. Removed the HSRO Quality Review Notification from section 7. Minor revisions to text were made throughout.</p>
27 Aug 2020	H. Miletic	<p>Added VPR and removed eProst from definitions. Replaced IO with VPR throughout. Changed IO to AVP in step 4.1. Removed IO/VPR notification of Quality Reviews prior to conduct. Added CAPA Manager to step 4.2.1. Added AVP to steps 3.1, 4.2.1, 4.5.4 and 4.12. Updated flow and checklist documents in steps 4.2.1, 4.2.1.1 and 7. Removed step 4.3.2 to review grant against protocol, as no longer done. Removed the request for IRB minutes as Auditors now have access to these. Updated IRB-8 to IRB system throughout SOP. Updated step 4.5.2 with more detail regarding review of documents. Updated office name of Executive Dean for Research in step 4.5.4. Updated Executive Director to Director Human Subjects Research in steps 4.5.4 and 4.7. Removed note in step 4.9.2 as observations related to the IRB and HSRO will be included in the Quality Review Report issued to the PI. Added 4.10.1.4 where the RCQA Executive Director conducts the final review of CAPA Plans. Updated 4.11 to add 2 business day timeline to request survey to be sent. Updated section 5 to clarify that electronic copies of reports, CAPA Plans and correspondence will be maintained in the RCQA shared drive indefinitely. Box drive was changed to shared drive in section 7. Minor edits made throughout SOP.</p>

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9. SIGNATURES

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