

RESEARCH COMPLIANCE AND QUALITY ASSURANCE
STANDARD OPERATING PROCEDURE

Document Number:	RCQA-403-13	Effective Date:	11 Sep 2020
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Title:	Issuing and Maintaining Quality Review Reports		

1. PURPOSE

The purpose of this document is to outline the process of issuing, tracking, and maintaining Quality Review Reports of human subject research studies issued by the office of Research Compliance and Quality Assurance. For Quality Reviews of the IRB/HSRO, refer to SOP RCQA-206.

2. DEFINITIONS

AVP – Associate Vice President, Regulatory Affairs and Assessment

CAPA – Corrective Action Preventative Action

CBO – Central Business Office

CTO- Clinical Trials Office at JHS

GCP – Good Clinical Practice

HSRO – Human Subjects Research Office

IRB – Institutional Review Board

JHS – Jackson Health System

JMH - Jackson Memorial Hospital

ORA – Office of Research Administration

PI – Principal Investigator

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

VPR – Vice Provost for Research

3. RESPONSIBILITY

3.1 QA Auditor

- Issues a draft Quality Review Report to the PI at the conclusion of a Quality Review.
- Conducts an exit meeting with the PI and study team to review the draft report.
- Issues a final Quality Review Report to the PI and leadership.
- Receives PI CAPA Plans and saves them in the RCQA shared drive.
- Sends Final Quality Review Reports and CAPA Plans to IRB/HSRO.
- Receives IRB determination letters for each Quality Review and saves them in the RCQA shared drive.
- Updates electronic Quality Review files and database.

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4. PROCEDURE

4.1 Issuing Draft Reports

4.1.1 Prior to issuing a draft Quality Review Report, verify the following:

- The report is watermarked as “DRAFT.”
- No comments or corrections are remaining in the report.
- The issue date has been entered into the footer and in the signature box of the report.
- The name of the PI and the protocol number appear in the footer of the report.
- The report has been saved as a “pdf” file.

4.1.2 Issue the Draft Quality Review Report to the PI and main study personnel via email using the Draft Quality Review Report Submission Memo. Copy the following leadership personnel:

- RCQA CAPA Manager
- RCQA QA Manager and Executive Director
- If the report contains an IRB observation, copy the Director for Human Subject Research
- If study is monitored by CRORS copy the CRORS Director
- For Quality Reviews at the SCCC, include the SCCC central email address: scccrcqa@miami.edu, and the applicable Site Disease Group Leader.
- For Quality Reviews at the Bascom Palmer Eye Institute (BPEI), include the BPEI Vice Chair and Director Clinical Research Services.
- Additional personnel may be copied on the email as requested by the PI.

Set the Outlook settings for this email as follows:

- High importance
- Confidential

4.2 Issuing Final Reports

4.2.1 Prior to issuing the Final Quality Review Report, verify the following:

- “DRAFT” watermark has been removed.
- No comments or corrections are remaining in the report.

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- The issue date has been entered into the footer and in the signature box of the report.
- The name of the PI and the protocol number appear in the footer of the report.
- The report has been saved as a “pdf” file.

4.2.2 Customize the PI CAPA Plan Template to create a dedicated CAPA section for each observation listed in the Final Quality Review Report. For each observation, include the observation number, title and significance onto the template. For Immediate Action Required observations, include a section for Root Cause Analysis.

4.2.3 Issue the Final Quality Review Report and customized PI CAPA Plan Template to the PI and leadership, via email, using the Final Quality Review Report Submission Memo.

Set the Outlook settings for this email as follows:

- High importance
- Confidential

4.2.3.1 Send the Final Quality Review Report in “pdf” format, as an email attachment to the PI and copy the following leadership personnel:

- Departmental chairperson, Division Chief and/or Center Director (if applicable)
- AVP
- VPR
- If the report contains an IRB observation, copy the Director for Human Subject Research
- CRORS Director or designee (if study is monitored by CRORS)
- RCQA Executive Director and QA Manager
- RCQA CAPA Manager
- For Quality Reviews at the SCCC, include the SCCC central email address: scccrcqa@miami.edu, and the applicable Site Disease Group Leader.
- For Quality Reviews at the Bascom Palmer Eye Institute (BPEI), include the BPEI Vice Chair and Director Clinical Research Services.

Note: The report may be copied to additional leadership personnel as directed by the RCQA Executive Director and/or the VPR.

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4.3 Post Quality Review Customer Satisfaction Survey

Within **two (2) business days** of 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.

4.4 Receiving Final PI CAPA Plans

4.4.1 Final CAPA Plans should be signed and dated by the PI and sent to the CAPA Manager via email.

4.4.2 The CAPA Manager will send a copy of the Final CAPA Plan to the Auditors to be saved on the RCQA shared drive in the applicable Quality Review folder, using the naming convention:

PI last name-CAPA Plan-Study Number

For example: **Payne-CAPA Plan-20200123**

4.5 Receiving Final IRB CAPA Plans (*for IRB observations within a PI's Quality Review Report*)

4.5.1 CAPA Plans in response to IRB observations should be signed and dated by the Director for Human Subject Research and sent to the CAPA Manager via email.

4.5.2 The CAPA Manager will send a copy of the Final IRB CAPA Plan to the Auditors to be saved on the RCQA shared drive in the applicable Quality Review folder, using the naming convention:

IRB CAPA Plan-Study Number

4.6 Submitting Quality Review Reports and PI CAPA Plans to the IRB

The PI's CAPA Plan and the Final Quality Review Report will be sent as email attachments to the Director for Human Subject Research, and the following leadership personnel will be copied on the email:

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- Departmental chairperson, Division Chief and/or Center Director (if applicable)
- AVP
- VPR
- Provost
- Assistant General Counsel
- Chief Risk Officer, Risk Management
- RCQA Executive Director and QA Manager
- For Quality Reviews at the SCCC, include the SCCC central email address: sccrcqa@miami.edu, and the applicable Site Disease Group Leader.
- For Quality Reviews at the Bascom Palmer Eye Institute (BPEI), include the BPEI Vice Chair and Director Clinical Research Services.

4.7 Submitting Quality Review Reports and IRB CAPA Plans to the VPR
(IRB CAPA Plan for IRB observations within a PI's Quality Review Report)

The IRB's CAPA Plan and the Final Quality Review Report will be sent as email attachments to the VPR, and the following leadership personnel will be copied on the email:

- AVP
- Provost
- Assistant General Counsel
- Chief Risk Officer, Risk Management
- RCQA Executive Director and QA Manager

4.8 Report of Observations to Other Parties

4.8.1 Subject Enrollment/Tracking and Billing Compliance

- **On a monthly basis**, the QA Manager will report observations in violation of the "Clinical Trial Management (CTM) and Participant Enrollment and Tracking Policy" to the Executive Dean for Research, UHealth Chief Compliance Officer, Executive Director Billing Compliance, and Medical Compliance Specialist. The RCQA Executive Director will be copied on the email.
- Observations in violation of the JHS policy "Notification of Research Participants to the JHS Clinical Trials Office" will be reported to the

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Director of Clinical Research at JHS CTO by the Auditor during the Quality Review. Other research compliance issues related to JMH will be referred to the JHS CTO.

4.8.2 Security of Protected Health Information

- Compliance issues regarding the security of protected health information will be reported to the Privacy Officer by completing the HIPAA Security Incident Report Form.
- Observations regarding HIPAA and Privacy issues will be forwarded to the office of Privacy and Data Security by the Auditor (copy QA Manager and Executive Director) **within 24 hours** of identifying the observation.

4.8.3 Facility Observations

Facility observations will be included in the Final Quality Review Report to the PI. As applicable, a separate “Facility Observations Report” will be forwarded via email to the appropriate authority for the facility identified and the following leadership personnel will be copied on the email:

- VPR
- RCQA Executive Director

For all “Immediate Action Required” observations, the facility authority is required to generate corrective and preventive actions within ten working days and to send them to the RCQA CAPA Manager. RCQA will use the CAPA Plan to assess compliance as appropriate.

5. DOCUMENTATION

5.1 Quality Review Files

5.1.1 Maintain the approved and issued Draft and Final Quality Review Reports in two formats: a word document file and an Adobe Acrobat (pdf) file, as described in SOP RCQA-402.

5.1.2 Maintain a copy of the PI and IRB CAPA Plans in pdf format.

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5.1.3 Convert the following email messages into pdf files and save them in the applicable PI folder.

- Request for Quality Review from the VPR/HSRO/SCCC (if applicable)
- PI Quality Review Notification Memo
- JHS Quality Review Notification (if applicable)
- Quality Review Report Submission email that was sent to the PI
- Facility Observations Report Submission email sent to facility (if applicable)
- Email sent to the HSRO containing the Final Quality Review Report and PI CAPA Plan
- Email indicating approval of Draft and Final Quality Review Reports by the RCQA Executive Director or GxP Compliance Director

5.1.4 Maintain a copy of the IRB determination letter in pdf format.

5.1.5 Any other relevant correspondence with regard to the Quality Review should be converted into a pdf file and maintained in the electronic Quality Review file.

5.2 Quality Review Notes

Unless directed otherwise by the RCQA Executive Director or designee, the following working documents (electronic or paper format) will be retained until the IRB determination letter is received and no follow-up Quality Review is requested:

- Notes taken during the preparation for a Quality Review
- Notes taken during the conduct of a Quality Review
- Copies of source documentation obtained from the research site
- Printouts from the research site's electronic data capture system
- Reports generated from Velos, IRB or other systems

5.3 Quality Review Database

5.3.1 Enter the Quality Review into the database by completing all required fields within **five (5) business days** of issuing the Final Quality Review Report.

5.3.2 The IRB determination letter will state if any further action by RCQA is required. If the letter states that no further action is necessary, then enter the date the letter was received in the "Closed Date" column in the database.

5.3.3 If the letter requests a follow up Quality Review, enter this in the "re-audit yes/no" field of the database, AND into the related field(s) in the database.

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5.3.4 All entries into the database must be completed as soon as the information becomes available.

6. REFERENCES

- SOP RCQA-201: General Quality Review Procedure for Human Subject Protocols
- SOP RCQA-402: Quality Review Report Generation
- SOP RCQA-206: Quality Reviews of the IRB/HSRO
- UM Policy: Clinical Trial Management (CTM) and Participant Enrollment and Tracking Policy
- JHS Policy: Notification of Research Participants to the JHS Clinical Trials Office

7. TEMPLATES / FORMS / TOOLS

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

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

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

- Quality Review Report Template
- Focused ICF Quality Review Report Template
- Facility Observations Report
- PI CAPA Plan Template

Note: The HIPAA Security Incident Report Form can be found on the Office of Privacy and Data Security website.

8. REVISION HISTORY

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Document Number: RCQA-403-13	Effective Date: 11 Sep 2020
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Effective Date	Revision Date	Author	Description of Changes
15 Jul 05	8 Jul 05	G. Lapinski	Finalized audit reports will be converted to Adobe “.pdf” files for issuing and electronic storage.
30 Oct 06	30 Oct 06	K. Roach	Headers in section 2 expanded
16 Jun 08	16 Jun 08	L. Smith	Name of Office change from RCA to ORCA. Updated procedure.
05 Nov 09	23 Oct 09	J. Stamates	Updated procedures.
19 Oct 10	11 Oct 10	H. Miletic	Changed numbering format of document and added version number 01. Added sections for Definitions, Responsibility, Procedure, References and Templates/Forms. Added Vice Provost for Research in Section 4.1. Changed approval signature from Lynn Smith to ORCA Associate Director. Moved revision history to end of document. Added author signature.
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 reports in section 4.1. Revised section 5 to modify how audit reports are signed and to clarify which emails need to be retained in the audit files. The ORCA Associate Director was removed throughout the document.
08 Jun 12	01 Jun 12	H. Miletic	Revised the title of the SOP. Changed the name of the department from Office of Research Compliance Assessment (ORCA) to Regulatory Support and Quality Assurance (RSQA) throughout the document. Changed Compliance Officer to QA Auditor throughout the document. Changed the Vice Provost for Research to the IO throughout the document. Expanded text in section 4.1 and added section 4.2: PI Audit Responses. Added section 4.3: Report of Findings to Other Parties. Reformatted the entire document. Updated references. Added templates to section 7. Updated the ORCA Director to the RSQA Executive Director.

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Effective Date	Revision Date	Author	Description of Changes
26 Aug 13	21 Aug 13	H. Miletic	Changed CRRC to ORA in sections 2, 4.3.1, 5.1.3 and 7. Removed QA Director and Senior Associate Dean for Clinical Research throughout document. Replaced QA Director with IO in note section of step 4.1.3. Replaced QA Director with QA Manager in sections 4.1.3 and 4.2.3. Updated section 4.2.3 to add the Director Regulatory Affairs and Education and to correct the title of the Vice Provost for Human Subject Research to Associate Vice Provost. Updated section 7 to reflect location of templates and forms.

Effective Date	Author	Description of Changes
25 Aug 2014	H. Miletic	Changed the name of the office from Regulatory Support and Quality Assurance (RSQA) to Research Compliance and Quality Assurance (RCQA) throughout the document. Modified section 4.2.3 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 4.3.1. Modified the format of the revision history table. Updated section 5.2.3 to state that reports will be maintained for a minimum of ten years. Updated section 6 to remove the document retention policy.
17 Feb 2016	H. Miletic	Removed CRRC from the Definitions section. Removed the “read receipt” from section 4.1.2. Updated section 4.1.3 to remove the Provost from the list of leadership personnel receiving the audit report. Added the SCCC central email to steps 4.1.3 and 4.2.4. Updated section 4.2 to add a naming convention to the PI audit response file. Added step 4.2.6 to add the customer satisfaction survey. Updated section 5.1.2 to refer to step 4.2.3. Clarified the note in step 4.2.4. Updated section 5.2.2 to include a designated reviewer of audit reports.
19 Feb 2016	H. Miletic	Added the CEO of UHealth and Senior Vice President of Health Affairs to sections 4.1.3 and 4.2.4. Removed the Assistant Provost for IRB Affairs from section 4.2.4.

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Effective Date	Author	Description of Changes
19 Apr 2017	H. Miletic	Expanded Responsibilities section and added the issuance of a draft audit report to PI. Added Center Director, Chief Compliance Officer of Medical School, BPEI Vice Chair and central mailbox to the list of recipients of audit reports. Added CAPA Manager to be copied on final audit report to PI. Added IRB observations report to section 4.5. Added billing compliance representative to section 4.5.2. Added report templates to section 7. Renumbered sections.
23 Oct 2017	H. Miletic	Updated section 4.1.2 to include the CAPA Manager as a recipient of the Draft Audit Report. Updated section 4.2.2.1 to reflect leadership personnel who will be copied on the Final Audit Report at this stage. Removed the dean of medical school from step 4.4, at his request and noted that he will be notified separately as needed. Added the CAPA Manager to step 4.5.1. Added note to 4.5.1 stating that HSRO will be notified if no observations issued to them. Added section 4.5.2.4 for IRB audit responses.
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 sections 4.2.2.1 and 4.4. Removed the Chief Compliance Officer, CEO of UHealth and HSRO personnel from section 4.4. Removed Chief Compliance Officer and Executive Dean for Research from section 4.5.2.4. Replaced the HSRO personnel with the HSRO/IRB mailbox in section 4.4. Removed notes from section 4.4 regarding communication with the Dean and DSMC. Added to section 4.5.4 that HIPAA and Privacy observations will be forwarded to Privacy & Data Security office. Minor edits were made throughout.
02 Apr 2019	H. Miletic	Removed reference to paper files and printing report in sections 3.1, 4.1.1 and 4.2.1. Modified sections 4.1.2, 4.2.2.1 and 4.4 to add the Director Clinical Research Services and remove the BPEI mailbox. Added CAPA Manager to sections 4.3.1 and 4.5.2.1. Changed the Associate Vice Provost for Human Subject Research to the Executive Director for Human Subject Research throughout the SOP. Removed the Quality.Determination@miami.edu mailbox throughout the SOP. Modified section 4.5.1 to add

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		the Provost and to remove the note stating that RCQA will notify the HSRO if no IRB observations were identified. Removed section 4.5.2.4 as the CAPA Manager will be sending the IRB CAPA Plans to leadership. Updated section 4.5.3 to refer to the Clinical Trial Management (CTM) and Participant Enrollment and Tracking Policy and to add the UHealth Chief Compliance Officer and the Director Billing Compliance and to remove the Executive Director Central Business Office for issues identified at UM. For issues identified at JHS, added the Compliance Auditor to be notified. Deleted the HSRO Quality review Notification from sections 5.1.3 and 7. Deleted step 5.2 as paper files of Quality Reviews will no longer be generated. Renumbered step 5.3. Added to step 5.1.3 the emails from the QA Manager & RCQA Executive Director indicating approval of the Quality Review Reports. Updated the title of the UM Policy in section 6.
28 Aug 2020	H. Miletic	Added reference to SOP RCQA-206 in sections 1 and 6 for Quality Reviews of the IRB/HSRO. Removed Executive Dean for Research and IO from definitions. Added AVP and VPR to definitions. Changed IO to VPR throughout. Added AVP to step 4.2.2.1. Changed Box drive to RCQA shared drive throughout. Updated section 4.1.2 to add RCQA Executive Director and QA Manager and to copy CRORS Director if report contains a monitoring observation and CRORS is monitoring study. Added step 4.2.2 to create a custom PI CAPA Plan template. Updated steps 4.1.2 and 4.2.3.1 to add Director of HSRO if report contains IRB observation. Updated naming convention for CAPA Plan in step 4.5. Updated section 4.6 to add AVP and Chief Risk Officer. Updated section 4.7.1 to include the Medical Compliance Specialist and RCQA Executive Director. Converted note in step 5.1 to step 5.2. Removed the ORA/CTO Observation Notification memo, and IRB Quality Review Template from section 7.
11 Sep 2020	H. Miletic	Added section 4.7 to submit IRB CAPA Plans and Quality Review Reports to the VPR and leadership.

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9. SIGNATURES

Prepared by: _____ Date: _____
Helen Miletic, MA, CHRC, RQAP-GCP
Director, GxP Compliance, RCQA

Approved by: _____ Date: _____
Johanna L. Stamates, RN, MA, CCRC, CHRC
Executive Director, RCQA