

RESEARCH COMPLIANCE AND QUALITY ASSURANCE
STANDARD OPERATING PROCEDURE

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1. PURPOSE

The purpose of this document is to outline the process for generating Quality Review Reports of human subject research studies and to describe the templates and the content of these reports issued by the office of Research Compliance and Quality Assurance (RCQA). For Quality Reviews of the IRB/HSRO, refer to SOP RCQA-206.

2. DEFINITIONS

AE – Adverse Event
CTU – Comprehensive Treatment Unit
HIPAA - Health Insurance Portability and Accountability Act
HSRO – Human Subject Research Office
IRB – Institutional Review Board
PI – Principal Investigator
QA – Quality Assurance
QA Auditor - A member of RCQA that performs Quality Reviews
RCQA – Research Compliance and Quality Assurance
SAE- Serious Adverse Event
Systems Review – A Quality Review of a site’s established processes and systems
University – University of Miami
UP – Unanticipated Problems

3. RESPONSIBILITY

3.1 QA Auditor

- Creates a Quality Review Report at the conclusion of each Quality Review conducted.
- Creates Quality Review Reports using the appropriate report template.
- Sends draft Quality Review Reports to the RCQA QA Manager and Executive Director for review.
- Saves approved reports in the shared RCQA shared drive.

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3.2 QA Manager

- Reviews draft Quality Review Reports

3.3 Executive Director

- Conducts the final review of Quality Review Reports
- Makes the final decision regarding significance of observations
- In the absence of the Executive Director, the final review and final decisions will be performed by the GxP Compliance Director

4. PROCEDURE

4.1 Quality Review Report Templates

There are three Quality Review Report templates located on the RCQA shared drive:

1) Quality Review Report Template:

This template is used for all Routine and Directed Quality Reviews.

2) Focused ICF Quality Review Report Template:

This template is used for Focused Quality Reviews of the informed consent process and associated documentation.

3) Facility Observations Report Template:

This template is only used for reporting facility observations from a Quality Review Report to the appropriate facility authority(ies). Examples of a facility are: CTU, Research Pharmacy, laboratories, etc.

Note: There is no template for a Quality Review Report of a Systems Review as the applicable sections will vary with each site reviewed. In this case, the Quality Review Report Template is used and modified as needed.

4.1.1 Always use the templates saved on the RCQA shared drive to ensure that the latest version is used.

Whenever templates are revised, the person making the change(s) is to send an e-mail notifying all RCQA QA Auditors, copy to QA Manager and Executive Director, of the new version, including a description of the change(s) and a reminder of how to access the file. The new version should NOT be sent as an attachment to avoid having multiple copies and incorrect versions available.

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4.2 Reporting Categories

4.2.1 Quality Review Reports will consist of the following categories assessed and reviewed during the conduct of a Quality Review. Some categories may not apply, depending on the type of review conducted. For example, Quality Review Reports for focused ICF reviews or facility observations will not contain all the following categories.

1. Subject Accountability - Observations in this category would be related, but not limited to:

- Non-compliance with the Clinical Trial Management (CTM) and Participant Enrollment and Tracking policy
- Inadequate documentation of subject withdrawals and screen failures

2. Informed Consent/Assent - Observations in this category would be related, but not limited to:

- Use of an expired consent document
- Lack of informed consent and re-consent
- Inadequate documentation of consent/assent
- Missing consent documents
- Informed consent forms missing the required elements or ClinicalTrials.gov statement
- HIPAA and Privacy-related observations

3. Training and Regulatory Administration - Observations in this category would be related, but not limited to:

- Missing essential regulatory documentation
- Discrepancies in regulatory documentation such as Form FDA 1572, financial disclosures, study protocol, continuing reports, IRB approval letters
- Lack of documentation of training and in-services
- Lapses in licensure and certifications
- Lack of evidence of qualification (CV)
- Discrepancies in the Delegation of Authority Log

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4. Protocol Compliance - Observations in this category would be related, but not limited to:

- Non-compliance with protocol requirements (procedures, study medication administration, etc.)
- Study activity during periods of protocol expiration/study suspension

5. Documentation Practices and Data Management – Observations in this category would be related, but not limited to:

- Inconsistencies between source data and case report forms in electronic or paper form
- Missing data
- Inadequate documentation of changes made to research records
- Inadequate study-related source documentation
- Use of pencil and/or correction fluid

6. Subject Protection and Adverse Events – Observations in this category would be related, but not limited to:

- Inadequate adverse event identification, documentation, notification and follow-up
- Inadequate reporting of SAEs, AEs, UPs
- Non-compliance with HIPAA and Privacy requirements
- Inadequate procedures to protect health, safety and rights of subjects
- Lack of PI oversight

7. Test Articles and Facilities – Observations in this category would be related, but not limited to:

- Lack of chain of custody
- Study drug/medication transport, storage, dispensation, expiration, blinding, returns, and destruction
- Device storage, transport, labeling and re-use
- Inadequate documentation of test article management
- Current laboratory inspections/certifications.
- Inadequate specimen handling and storage procedures
- Discrepancies in temperature logs

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8. Sponsor - Observations in this category would be related, but not limited to:

- Sponsor approvals
- Sponsor-investigator responsibilities
- Inadequate monitoring
- Inadequate submissions to the FDA such as missing financial disclosures, missing annual reports, amendments, etc. for sponsors or sponsor-investigators

9. Review and Approval of Research - Observations in this category would be related, but not limited to:

- Inadequate communication with the Investigator
- Inadequate documentation by the approving entity
- Actions of the approving entity do not meet regulatory requirements and/or University policies and procedures for approval

4.3 Working Draft Reports

Follow the procedures outlined below for all types of Quality Review Reports:

4.3.1 Set up a working folder on the RCQA shared drive to include all electronic working files for the Quality Review, including the draft report(s).

Save the working files under the PI's last name on the RCQA shared drive as follows: S:\RCQA\Auditing\Audits\Completed Audits\2020 (or current year)\Electronic Audits\ PI's last name.

4.3.2 Generate a working draft report using the appropriate report template and save it using one of the following naming standards:

For full and focused Quality Reviews:

- Name the Quality Review Report using the PI's last name, IRB number, and version number of the report, as follows:

Example: Dr. Payne, IRB # 20030001, Quality Review Report, version 1
Save the report as: **Payne20030001v1.doc**

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For Facility Observations Report:

- Name the Facility Findings Report using the PI's last name, IRB number, "Facility", and version number of the report, as follows:

Example: Dr. Payne, IRB # 20030001, Facility Report, version 1 of report
Save the facility report as: **Payne20030001Facilityv1.doc**

- 4.3.3 Delete the header of the report containing the revision date of the template.
- 4.3.4 Complete the Quality Review Report listing the observations noted.
- 4.3.5 The determination of the significance of an observation, or group of observations ultimately rests with the RCQA Executive Director.
- 4.3.6 Within **five (5) business days** of completing the Quality Review, email the completed draft report to the QA Manager for review and copy the Executive Director. Draft reports for Focused Quality Reviews or Quality Reviews with minimal issues, will require less time.
- 4.3.7 **Within 24 hours**, the QA Manager will review and return the draft report with comments, changes, and/or corrections, a maximum of two (2) times. At times, the GxP Compliance Director may conduct the review for the QA Manager, as necessary.
- 4.3.8 Each time the draft report is updated, revise the version number of the report to the next version. e.g., Payne20030001v2, Payne20030001v3, etc.
- 4.3.9 **After two (2) review cycles** by the QA Manager, send the draft report to the Executive Director for final review, and copy the QA Manager. The Executive Director will review the draft report and provide comments, changes and/or corrections within 24 hours. At times, the GxP Compliance Director may conduct the review for the Executive Director, as necessary.

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4.4 Approved Quality Review Reports

Within ten (10) business days of completing a Quality Review, a report must be ready to be issued where all reviewers' comments and corrections have been addressed.

4.4.1 Save the approved Quality Review Report (in the same folder created in step 4.3.1): S:\RCQA\Auditing\Audits\Completed Audits\2020 (or current year)\Electronic Audits\ PI's last name

4.4.2 Name the report files using the applicable naming standard as follows:

- **Approved Draft Quality Review Report to be issued to PI:**
Example: Dr. Payne, IRB # 20030001, Draft Report
Save the report as: **Payne20030001DraftIssued.doc**
- **Approved Final Quality Review Report:**
Example: Dr. Payne, IRB # 20030001, Final Report
Save the report as: **Payne20030001Final.doc**
- **Approved Final Facility Observations Report:**
Example: Dr. Payne, IRB # 20030001, Facility Report, Final Report
Save the facility report as: **Payne20030001FacilityFinal.doc**

4.4.3 Convert the approved report to an Adobe Acrobat format (.pdf) and save it with the same file name as shown in step 4.4.2.

4.4.4 Issue the Quality Review Report as described in SOP RCQA-403.

5. DOCUMENTATION

Electronic copies of Quality Review Reports are maintained in the RCQA shared drive indefinitely.

6. REFERENCES

SOP RCQA-201: General Quality Review Procedure for Human Subject Protocols
SOP RCQA-206: Quality Reviews of the IRB/HSRO
SOP RCQA-403: Issuing and Maintaining Quality Review Reports

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7. TEMPLATES / FORMS / TOOLS

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

- Quality Review Report Template
- Focused ICF Quality Review Report Template
- Facility Observations Report
- Data Management Quality Review Form

8. REVISION HISTORY

Effective Date	Revision Date	Author	Description of Changes
1 Apr 05	30 Mar 05	G. Lapinski	Modification of the definition of “Withdrawn” in section 2.
15 Jul 05	8 Jul 05	G. Lapinski	Finalized audit reports will be converted to Adobe “.pdf” files for issuing and electronic storage. Conversion instructions are also included.
30 Oct 06	30 Oct 06	K. Roach	Section 2. Template is Word 2003 document
16 Jun 08	16 Jun 08	L. Smith	Name change from RCA to ORCA. Introduction of Data Management Audit Tool. Updated procedure.
05 Nov 09	22 Oct 09	J. Stamates	New location for audit report template
			Section 2.9: addition of “protection of subjects’ safety and rights Addition of Associate Director Section 3 and 4: change in file name for electronic report
01 Aug 10	05 Mar 10	S. Mackey	Section 2.11 addition of other facility types Revised and updated several sections to reflect new facilities findings report and other changes as appropriate.

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Effective Date	Revision Date	Author	Description of Changes
19 Oct 10	11 Oct 10	H. Miletic	Changed numbering format of document and added version number 01. Added sections for Definitions, Responsibility, Documentation, References, Templates/Forms and Signatures. Changed approval signature from Lynn Smith to ORCA Associate Director. Moved revision history to end of document. Added author signature.
17 Mar 11	10 Mar 11	H. Miletic	Revised the version number and effective date in the header. Revised the naming convention of file folders and audit report filenames in sections 4.3 and 4.4. 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. Deleted text in section 4.4.6 and referred to SOP RSQA-403. Updated the references. Minor changes to text throughout document. Reformatted the entire document. Updated the ORCA Director to the RSQA Executive Director.
26 Aug 13	21 Aug 13	H. Miletic	Updated section 1.1.1 to change the Clinical Research Revenue Cycle to the Office of Research Administration. Removed the QA Director throughout the document. Updated sections 4.4.1 and 7 to reflect the location of the electronic files on the shared drive.

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

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		and Quality Assurance (RCQA) throughout the document. Added screen failure category to table in section 1. Added IRB-7 to sections 2 and 3. Updated section 3.1 to remove the example of a finding related to CTD. Added a separate category for CTD to the audit report. Added section 4.5 on document retention. Updated the References section to add the HSR-P-101 policy and to remove the document retention policy. Modified the format of the revision history table.
13 Feb 2015	H. Miletic	Modified section 2.1.1 to add CTD-related finding. Renumbered section 13 of the report to 14 for CTD findings and changed the “Other” section from 14 to 13. Updated the CTD finding section to add additional examples of CTD findings. Minor changes to text made for consistency.
19 Apr 2017	H. Miletic	Expanded Responsibilities section. Added audit report templates for focused ICF audits and IRB observations to section 4.1. Updated reporting categories in section 4.2. Specified naming convention for IRB audit reports and focused audits in section 4.3.2. Specified the QA Manager in sections 4.3.5 and 4.3.6. Added naming convention for issued Draft Reports. Added report templates to section 7.
30 Mar 2018	H. Miletic	Changed the term “audits” to “Quality Reviews” throughout the document and title of the SOP. Modified the file naming convention of Quality Review Reports in section 4.3. Renamed the RCQA shared drive to Box drive. Minor edits were made throughout.
02 Apr 2019	H. Miletic	Updated the name of the CTM participant enrollment policy in section 4.2.1 (1). Updated step 4.3.1 to clarify that working files are saved in RCQA Box. Removed steps 4.4.4 and 4.4.5 as copies of the reports will not be saved in paper format. Updated step 4.5 to remove the statement that records may be stored on or off site.
28Aug 2020	H. Miletic	Added reference to SOP RCQA-206 in sections 1 and 6 for Quality Reviews of the IRB/HSRO. Removed IO from definitions. Changed Box drive to shared drive throughout document. Expanded responsibilities of QA Manager and Executive Director in steps 3.2. and 3.3. Updated step 4.1 to state that there are 3 types of report templates. Removed

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		reference to IRB observations report from steps 4.1, 4.2.1, 4.3.2 and 7 as these observations will now be included in the main quality review report issued to the PI. Added a category for Review and Approval of Research to step 4.2.1. Added file location to step 4.3.1. Added timelines to steps 4.3.6 and 4.3.7. Added 4.3.9 to specify that the Executive Director conducts the final review of reports. Removed step 4.5 and moved contents regarding document retention to section 5. Removed reference to CAPA Plans. Minor edits to text throughout.

9. SIGNATURES

Prepared by: _____ Date: _____
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Approved by: _____ Date: _____
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