1. PURPOSE

The purpose of this document is to outline the process for generating Quality Review Reports and to describe the templates and the content of these reports issued by the office of Research Compliance and Quality Assurance (RCQA).

2. DEFINITIONS

AE – Adverse Event
CTU – Comprehensive Treatment Unit
HIPAA - Health Insurance Portability and Accountability Act
IO – Institutional Official
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 Box drive.

3.2 QA Manager and Executive Director

- Review Quality Review Reports and provide feedback to QA Auditors.
4. **PROCEDURE**

4.1 **Quality Review Report Templates**

There are four Quality Review Report templates located on the shared RCQA Box 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) **IRB Observations Quality Review Report Template:**  
   This template is used to report IRB/HSRO observations to the IRB/HSRO.

4) **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 shared RCQA Box 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 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.

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, IRB observations or facility observations will not contain all the following categories.
1. **Subject Accountability** - Observations in this category would be related to, 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 to, 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-related observations

3. **Training and Regulatory Administration** - Observations in this category would be related to, but not limited to:
   - Missing essential regulatory documentation
   - Discrepancies in regulatory documentation such as Form FDA 1572, study protocol, continuing reports, IRB approval letters
   - Discrepancies between grant and study protocol
   - Lack of documentation of training and in-services
   - Lapses in licensure and certifications
   - Discrepancies in the Delegation of Authority Log

4. **Protocol Compliance** - Observations in this category would be related to, 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 to, but not limited to:
   - Inconsistencies between source data and case report forms in electronic or paper form
   - 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 to, but not limited to:
   - Inadequate adverse event documentation, notification and follow-up
   - Inadequate reporting of SAEs, AEs, UPs
   - Non-compliance with HIPAA regulations
   - 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 to, but not limited to:
   - Lack of chain of custody
   - 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

8. **Sponsor** - Observations in this category would be related to, 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 sponsor-investigators
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 BOX account to include all electronic working files for the Quality Review, including the draft report(s).

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

For IRB Observations Quality Review Report:
- Name the Quality Review Report with “IRB”, IRB number, and version number of the report, as follows:

  Example: PI is Dr. Payne, IRB # 20030001, Quality Review Report, version 1
  Save the report as: IRB20030001v1.doc

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 QA Auditor and RCQA Executive Director.
4.3.6 Send the completed draft report via email to the RCQA QA Manager and Executive Director for review.

4.3.7 The RCQA QA Manager and/or Executive Director will return the draft report with comments, changes, and/or corrections.

4.3.8 If a second review is necessary, repeat the steps described above and update the version number of the report. e.g., Payne20030001v2.doc.

4.4 Approved Quality Review Reports

A report is ready to be issued once all reviewer’s comments and corrections have been addressed.

4.4.1 Create a folder with the PI’s last name on the shared RCQA Box drive and save it as S:\RCQA\Auditing\Audits\Completed Audits\2019 (or current year)\ PI’s last name.

4.4.2 Save the approved Quality Review Report in this folder 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.
4.5 Document Retention

Quality Review Reports and PI CAPA Plans are maintained for a minimum of ten years.

5. DOCUMENTATION

See section 4.4 above.

6. REFERENCES

SOP RCQA-201: General Quality Review Procedure for Human Subject Protocols
SOP RCQA-403: Issuing and Maintaining Quality Review Reports

7. TEMPLATES / FORMS / TOOLS

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

- Quality Review Report Template
- Focused ICF Quality Review Report Template
- IRB Observations Quality Review Report Template
- Facility Observations Report
- Data Management Quality Review Form
8. **REVISION HISTORY**

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Revision Date</th>
<th>Author</th>
<th>Description of Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Apr 05</td>
<td>30 Mar 05</td>
<td>G. Lapinski</td>
<td>Modification of the definition of “Withdrawn” in section 2. Finalized audit reports will be converted to Adobe “.pdf” files for issuing and electronic storage. Conversion instructions are also included.</td>
</tr>
<tr>
<td>15 Jul 05</td>
<td>8 Jul 05</td>
<td>G. Lapinski</td>
<td></td>
</tr>
<tr>
<td>30 Oct 06</td>
<td>30 Oct 06</td>
<td>K. Roach</td>
<td>Section 2. Template is Word 2003 document</td>
</tr>
<tr>
<td>16 Jun 08</td>
<td>16 Jun 08</td>
<td>L. Smith</td>
<td>Name change from RCA to ORCA. Introduction of Data Management Audit Tool. Updated procedure.</td>
</tr>
<tr>
<td>05 Nov 09</td>
<td>22 Oct 09</td>
<td>J. Stamates</td>
<td>New location for audit report template</td>
</tr>
<tr>
<td>01 Aug 10</td>
<td>05 Mar 10</td>
<td>S. Mackey</td>
<td>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</td>
</tr>
<tr>
<td>19 Oct 10</td>
<td>11 Oct 10</td>
<td>H. Miletic</td>
<td>Section 2.11 addition of other facility types. Revised and updated several sections to reflect new facilities findings report and other changes as appropriate.</td>
</tr>
<tr>
<td>17 Mar 11</td>
<td>10 Mar 11</td>
<td>H. Miletic</td>
<td>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.</td>
</tr>
</tbody>
</table>
### Effective Date | Revision Date | Author | Description of Changes
--- | --- | --- | ---
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.

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. 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
### Description of Changes

- 19 Apr 2017: 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: 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: 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.

### 9. SIGNATURES

**Signature on file**

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

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

Date: 02 Apr 2019