

RESEARCH COMPLIANCE AND QUALITY ASSURANCE
STANDARD OPERATING PROCEDURE

Document Number:	RCQA-206-01	Effective Date:	28 Aug 2020
Page No.	Page 1 of 10	Author:	M. McFann
Title:	Quality Reviews of the IRB/HSRO		

1. PURPOSE

The purpose of this document is to define the process by which the office of Research Compliance and Quality Assurance (RCQA) conducts Focused Quality Reviews of the University of Miami (UM)'s Human Subjects Research Office (HSRO) and Institutional Review Board (IRB). These reviews are intended to assess the HSRO and IRB's level of compliance with Federal and State regulations and guidelines, as well as University policies and procedures governing the review and approval of human subject research.

2. DEFINITIONS

AVP – Associate Vice President, Regulatory Affairs and Assessment
CAPA – Corrective and Preventative Action
FDA – Food and Drug Administration
HSRO – Human Subjects Research Office
ICH-GCP- International Conference on Harmonization Guidelines for Good Clinical Practice
IRB – Institutional Review Board
IRB-8 – Electronic protocol submission and tracking system
OHRP – Office for Human Research Protections
QA – Quality Assurance
QA Auditor- A member of RCQA that performs Quality Reviews
RCQA – Research Compliance and Quality Assurance
SOP – Standard Operating Procedure
UM – University of Miami
University – University of Miami
VPR – Vice Provost of Research

3. RESPONSIBILITY

3.1. VPR and AVP

- The VPR may request Quality Reviews of the HSRO and IRB
- Both receive copies of Quality Review reports
- Both receive notification of potentially serious non-compliance issues

3.2. QA Function of RCQA

- Assigns QA Auditors to conduct Quality Reviews
- Notifies HSRO and IRB of planned Quality Reviews and schedules Quality Reviews
- Performs Quality Reviews
- Issues Quality Review reports
- Updates electronic Quality Review files and database

RESEARCH COMPLIANCE AND QUALITY ASSURANCE
STANDARD OPERATING PROCEDURE

Document Number:	RCQA-206-01	Effective Date:	28 Aug 2020
Page No.	Page 2 of 10	Author:	M. McFann
Title:	Quality Reviews of the IRB/HSRO		

3.3 HSRO Director

- Schedules Quality Review with RCQA QA Auditor
- Is available for meetings during the Quality Review
- Provides all related documents
- Responds to Quality Review observations

4. PROCEDURE

4.1 Quality Review Process

4.1.1 Quality Review Assignment

A selected aspect of the HSRO and IRB review process will be chosen at the discretion of the RCQA Executive Director and/or QA Manager.

4.1.2 Quality Review Notification

The QA Auditor will email a Quality Review Notification Memo to the HSRO Director and include the following leadership personnel:

- IRB Committee Chairs and Co-Chairs
 - VPR
 - AVP
 - RCQA Executive Director and QA Manager
 - RCQA CAPA Manager
- The Quality Review will be scheduled for **three (3) days**; however, more time may be needed.

4.1.3 Quality Review Preparation

The QA Auditor will review the documentation in the IRB system prior to conducting the Quality Review.

4.1.4 Initial Meeting with HSRO Director and HSRO Team Members

The QA Auditor will conduct an initial meeting with the HSRO Director and team members at the beginning of the Quality Review to discuss the scope of the review, the process, and what to expect from the auditors. The HSRO Director may be asked to describe the processes, procedures, and the roles and responsibilities of the IRB and HSRO members, committees, and designated reviewers.

RESEARCH COMPLIANCE AND QUALITY ASSURANCE
STANDARD OPERATING PROCEDURE

Document Number:	RCQA-206-01	Effective Date:	28 Aug 2020
Page No.	Page 3 of 10	Author:	M. McFann
Title:	Quality Reviews of the IRB/HSRO		

4.2 Conducting Quality Reviews

4.2.1 The standards used to conduct Quality Reviews of the HSRO and IRB processes and procedures will include:

- Applicable Federal and State regulations
- ICH-Guidelines for Good Clinical Practice
- University of Miami Standard Operating Procedures (SOP), Worksheets, and Checklists

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

- Review of committee meeting minutes
- Review of study submissions in the IRB system
- Review of documentation in the IRB system
- Review of IRB determinations as they apply to applicable Federal and State regulations
- A review of records:
 - A sampling of records to be reviewed will be determined by $(\sqrt{n})+1$, where n is the total number of records, or as determined by the QA Manager and Executive Director.

4.2.3 The QA Auditor may also conduct interviews of current or past HSRO and IRB members.

4.2.4 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. The RCQA Executive Director will then immediately notify the VPR, AVP, and the HSRO Director, as applicable.

4.3 Debrief Meeting with HSRO Director and HSRO Team Members

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 HSRO Director and HSRO team members at a debrief meeting.

4.4 Quality Review Report Writing

4.4.1 Report Writing Timeline

The QA Auditor will issue a draft Quality Review Report within **five (5) business days** of the completion of the Quality Review. If additional time is needed, it will be

RESEARCH COMPLIANCE AND QUALITY ASSURANCE
STANDARD OPERATING PROCEDURE

Document Number:	RCQA-206-01	Effective Date:	28 Aug 2020
Page No.	Page 4 of 10	Author:	M. McFann
Title:	Quality Reviews of the IRB/HSRO		

discussed with the RCQA Executive Director and QA Manager and will be documented in the RCQA database.

4.4.2 HSRO IRB Quality Review Report Template

Always use the template saved on the shared RCQA 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 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.

4.4.2.1 Reporting Categories

Quality Review Reports will consist of the following categories assessed and reviewed during the conduct of a Quality Review.

1. **Regulatory/Institutional Compliance** - Observations in this category would be related, but not limited to:
 - Non-compliance with federal and state regulations/statutes
 - Non-compliance with institutional regulations/policy
 - Non-compliance with HSRO/IRB policies and procedures

2. **Documentation Practices** – Observations in this category would be related, but not limited to:
 - Inconsistencies between source data and meeting minutes in electronic or paper form
 - Inadequate documentation within checklist and worksheets
 - Inadequate documentation of reviewer determinations

4.4.3 Working Draft Reports

- 4.4.3.1 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 “IRB” on the RCQA shared drive as follows:
S:\RCQA\Auditing\Audits\IRB Audits\2020 (or year audit performed)\ focus of the audit.

RESEARCH COMPLIANCE AND QUALITY ASSURANCE
STANDARD OPERATING PROCEDURE

Document Number:	RCQA-206-01	Effective Date:	28 Aug 2020
Page No.	Page 5 of 10	Author:	M. McFann
Title:	Quality Reviews of the IRB/HSRO		

4.4.3.2 Generate a working draft report using the appropriate report template and save it using the name of the IRB, focus of the audit, month and year the audit took place, and version number of the report, as follows:

Example: IRB, Committee review, May 2020, version 1
Save the report as: **IRBCommitteeMay2020v1.doc**

4.4.3.3 Complete the Quality Review Report listing the observations noted.

4.4.3.4 The determination of the significance of an observation, or group of observations ultimately rests with the RCQA Executive Director.

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

4.4.3.6 **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.

4.4.3.7 Each time the draft report is updated, revise the version number of the report to the next version. e.g., IRBCommitteeMay2020v2.doc.

4.4.3.8 **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.

4.4.4 Approved Draft Reports

Within five (5) business days of completing a Quality Review, a report must be ready to be issued where all reviewers' comments and corrections have been addressed.

4.4.4.1 Save the approved draft report using the applicable naming standard as follows:

- **Approved Draft Quality Review Report:**
Save the report as: **IRBCommitteeMay2020DraftIssued.doc**

RESEARCH COMPLIANCE AND QUALITY ASSURANCE
STANDARD OPERATING PROCEDURE

Document Number:	RCQA-206-01	Effective Date:	28 Aug 2020
Page No.	Page 6 of 10	Author:	M. McFann
Title:	Quality Reviews of the IRB/HSRO		

- **Approved Final Quality Review Report:**
Save the report as: **IRBCommitteeMay2020Final.doc**

4.4.4.2 Convert the approved draft report to an Adobe Acrobat format (.pdf) and save it with the same file name as shown in step 4.4.3.2.

4.4.5 Issuing Draft Quality Review Reports

4.4.5.1 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 focus of the IRB review appears in the footer of the report.
- The report has been saved as a “pdf” file.

4.4.5.2 Issue the draft Quality Review Report to the HSRO Director and HSRO team members via email using the draft Quality Review Report Submission Memo. Additional personnel may be copied on the email as requested by the HSRO Director.

Copy the following:

- RCQA CAPA Manager
- RCQA QA Manager and Executive Director

Set the Outlook settings for this email as follows:

- High importance
- Confidential

4.5 Exit Meeting

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

4.5.2 The QA Auditor will finalize the Quality Review Report within one **(1) business day** after the exit meeting

RESEARCH COMPLIANCE AND QUALITY ASSURANCE
STANDARD OPERATING PROCEDURE

Document Number:	RCQA-206-01	Effective Date:	28 Aug 2020
Page No.	Page 7 of 10	Author:	M. McFann
Title:	Quality Reviews of the IRB/HSRO		

4.6 Issuing Final Reports

4.6.1 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.
- The issue date has been entered into the footer and in the signature box of the report.
- The report has been saved as a “pdf” file.

4.6.2 Customize the 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.

4.6.3 Issue the Final Quality Review report and customized CAPA plan, in “pdf” format, as an email attachment to the HSRO Director and copy the following leadership personnel:

- IRB Committee Chairs and Co-Chairs
- VPR and AVP
- RCQA Executive Director and QA Manager
- RCQA CAPA Manager

Set the Outlook settings for this email as follows:

- High importance
- Confidential

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

4.7 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 HSRO Director and HSRO team members.

4.8 HSRO IRB CAPA Plan

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

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

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

RESEARCH COMPLIANCE AND QUALITY ASSURANCE
STANDARD OPERATING PROCEDURE

Document Number:	RCQA-206-01	Effective Date:	28 Aug 2020
Page No.	Page 8 of 10	Author:	M. McFann
Title:	Quality Reviews of the IRB/HSRO		

- 4.8.3** The CAPA Manager will review the draft CAPA Plan and provide feedback in order to obtain responses that are specific and measurable.
- 4.8.4** The RCQA Executive Director will conduct the final review of CAPA Plans.
- 4.8.5** The CAPA Plan should be signed and dated by the HSRO Director and sent to the CAPA Manager via email.
- 4.8.6** The CAPA Plan will be saved as a pdf file onto the shared RCQA drive in the applicable IRB folder, using the following naming convention:

IRB_CAPA Plan_YY_MM_DD
For example: **IRB_CAPA Plan_18_08_20**

4.9 Submitting Quality Review Reports and CAPA Plans to the VPR

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:

- IRB Committee Chairs and Co-Chairs
- AVP
- Provost
- Assistant General Counsel
- Risk Management
- RCQA Executive Director and QA Manager

5. DOCUMENTATION

5.1 Electronic 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.
- 5.1.2** Maintain a copy of the IRB CAPA plans in pdf format.
- 5.1.3** Convert the following email messages into pdf files and save them in the applicable IRB folder.
- Request for Quality Review (if applicable)
 - Quality Review Report Submission email that was sent to the HSRO IRB
 - Email sent to the VPR containing the Quality Review Report and CAPA Plan

RESEARCH COMPLIANCE AND QUALITY ASSURANCE
STANDARD OPERATING PROCEDURE

Document Number:	RCQA-206-01	Effective Date:	28 Aug 2020
Page No.	Page 9 of 10	Author:	M. McFann
Title:	Quality Reviews of the IRB/HSRO		

- Email received from the HSRO Director containing the completed and signed CAPA Plan

5.1.4 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 Database

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

6. REFERENCE

N/A

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

- HSRO Director Quality Review Notification Memo
- Draft Quality Review Report Submission Memo

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

- HSRO IRB Quality Review Report Template
- HSRO IRB CAPA Plan Template

8. REVISION HISTORY

N/A

RESEARCH COMPLIANCE AND QUALITY ASSURANCE
STANDARD OPERATING PROCEDURE

Document Number:	RCQA-206-01	Effective Date:	28 Aug 2020
Page No.	Page 10 of 10	Author:	M. McFann
Title:	Quality Reviews of the IRB/HSRO		

9. SIGNATURES

Prepared by: _____ Date: _____
Miles McFann, BA, CCRP, CIP
Quality Assurance Auditor, RCQA

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