

RESEARCH COMPLIANCE AND QUALITY ASSURANCE  
STANDARD OPERATING PROCEDURE

---

Document Number:	RCQA-002-05	Effective Date:	27 Aug 2020
Page No.	Page 1 of 7	Author:	H. Miletic
Title:	RCQA Staff Training		

---

## 1. PURPOSE

The purpose of this document is to define the staff training requirements for the Office of Research Compliance and Quality Assurance (RCQA).

## 2. DEFINITIONS

CAPA – Corrective Action Preventive Action  
CCRA – Certified Clinical Research Associate  
CCRP – Certified Clinical Research Professional  
CHRC – Certification in Healthcare Research Compliance  
CITI – Collaborative Institutional Training Initiative  
CTD – Clinical Trial Disclosure  
FDA – Food and Drug Administration  
OHRP – Office of Human Research Protection  
QA – Quality Assurance  
RCQA – Office of Research Compliance and Quality Assurance  
RQAP-GCP – Registered Quality Assurance Professional in Good Clinical Practices  
SOP – Standard Operating Procedure  
Trainee – A staff member undergoing training  
Trainer – An experienced staff member who is conducting training  
UM – University of Miami  
VPR – Vice Provost for Research

## 3. RESPONSIBILITY

### 3.1 RCQA Executive Director

- Assigns each staff member to complete the following:
  - RCQA new employee orientation
  - Assigned training as outlined in the Training Matrix
  - Additional training assigned as needed
  - Documentation of training
- Trains RCQA staff on, but not limited to: compliance-related topics such as FDA regulations and guidance documents, RCQA SOPs and policies, and University policies and procedures.
- May delegate any of the above duties to the RCQA Managers/Director.

RESEARCH COMPLIANCE AND QUALITY ASSURANCE  
STANDARD OPERATING PROCEDURE

---

Document Number:	RCQA-002-05	Effective Date: 27 Aug 2020
Page No.	Page 2 of 7	Author: H. Miletic
Title:	RCQA Staff Training	

---

### 3.2 RCQA Managers/Director

Train and mentor RCQA staff on the following, but not limited to:

- RCQA SOPs and policies
- University policies and procedures
- FDA and OHRP regulations and guidance documents

### 3.3 RCQA Staff

Each staff member is responsible for:

- Completing all assigned training upon hire
- Completing CITI refresher training every 2 years
- Completing Matrix refresher training every 3 years
- Documenting that training was completed
- Obtaining at least one professional certification related to human subject research (e.g. CHRC, CCRP, CCRA, RQAP-GCP, etc.) as outlined in job description.

## 4. STAFF TRAINING

### 4.1 New Employee Orientation

New RCQA employees will be given an overview of the following:

- RCQA office and functions
- RCQA shared documents filing structure and location of documents
- Vice Provost for Research (VPR) office
- UM campus and satellite locations
- UM organizational structure

### 4.2 Mandatory Training Upon Hire

4.2.1 Each RCQA staff member is required to successfully complete the CITI module training listed below, within the **first week** of employment and prior to any review of confidential information. This training is valid for a **two-year period**, after which, refresher modules must be successfully completed every two years.

- **Required CITI Course in the Protection of Human Research Subjects: HSR Series for Biomedical Researchers**

4.2.2 Each new RCQA staff member will complete their assigned training as outlined in the Training Matrix within the first **180 days** of their employment.

RESEARCH COMPLIANCE AND QUALITY ASSURANCE  
STANDARD OPERATING PROCEDURE

---

Document Number:	RCQA-002-05	Effective Date: 27 Aug 2020
Page No.	Page 3 of 7	Author: H. Miletic
Title:	RCQA Staff Training	

---

The Training Matrix lists for each RCQA position, all regulations, SOPs, policies and guidance documents for which training must be completed.

### **4.3 Mandatory Refresher Matrix Training Every 3 Years**

4.3.1 RCQA staff members will complete their assigned training as outlined in the Training Matrix **every three (3) years +/- 3 months** from the last completion date.

### **4.4 Position Specific Training**

#### **4.4.1 Auditor Specific Training:**

Newly hired QA Auditors, including experienced auditors will be trained on how to conduct Quality Reviews and write Quality Review reports. Six (6) Quality Reviews will be conducted under the supervision of a trainer/mentor; however, experienced auditors may complete their training with less than 6 supervised Quality Reviews.

The first three (3) Quality Reviews will be led by the trainer with the newly hired auditor (trainee) observing and participating. The last three (3) Quality Reviews will be led by the trainee and supervised by the trainer.

It is possible to have one trainer and two (2) trainees conduct a Quality Review together. The six (6) Quality Reviews will consist of a mix of medical and social-behavioral clinical trials.

#### **4.4.2 CAPA Specific Training:**

This has not yet been developed as there is only one CAPA Manager and no additional CAPA staff. In the event that other RCQA team members need to conduct specific CAPA tasks, they will do so under the direction of the CAPA Manager or Executive Director.

#### **4.4.3. CTD Specific Training:**

The CTD specific training is listed in the Training Matrix.

### **4.5 Additional Training**

#### **4.5.1 On-going Internal Training**

Additional training on SOPs and policies will be assigned as new SOPs and policies are implemented or existing documents are revised, and as new FDA/OHRP regulations and guidance documents become available. Internal

RESEARCH COMPLIANCE AND QUALITY ASSURANCE  
STANDARD OPERATING PROCEDURE

---

Document Number:	RCQA-002-05	Effective Date:	27 Aug 2020
Page No.	Page 4 of 7	Author:	H. Miletic
Title:	RCQA Staff Training		

---

training may also include training offered outside RCQA but within UM. RCQA staff members are responsible for completing assigned training in a timely manner.

#### **4.5.2 External Training**

RCQA staff is encouraged to attend external training related to human research compliance, on an annual basis. This training may be in the form of a webinar, conference, workshop or seminar.

**Note:** Attending external training may be limited due to budgetary reasons.

#### **4.6 Certification**

RCQA staff members are expected to obtain at least one professional certification related to human subject research, such as CHRC, CCRP, CCRA, RQAP-GCP, etc. as outlined in each individual job description.

It is the responsibility of each staff member to maintain or renew their certification by attending human research compliance training on a regular basis and submitting evidence of this to the respective accreditation entities.

#### **4.7 Mode of Training**

Training may be conducted in the following ways:

##### **4.7.1 Group Training**

Training may be offered in a group setting such as a presentation by the designated trainer at a RCQA educational meeting. This method is most often used to present and discuss new or revised SOPs, policies and/or FDA/OHRP regulations and guidance documents with staff.

##### **4.7.2 One on One Training**

Training may be offered individually, with one trainer and one trainee, such as in the conduct of Quality Reviews where the trainee is observing the trainer. It may also be conducted to train someone on new SOPs or policies.

##### **4.7.3 Self -Training**

Self-training is typically reserved for computer-based training, such as CITI training, or reading a simple revision to a SOP or policy.

RESEARCH COMPLIANCE AND QUALITY ASSURANCE  
STANDARD OPERATING PROCEDURE

---

Document Number:	RCQA-002-05	Effective Date:	27 Aug 2020
Page No.	Page 5 of 7	Author:	H. Miletic
Title:	RCQA Staff Training		

---

#### **4.7.4 Webinar/Conference Training**

Training may be obtained by attending a webinar, conference or workshop.

## **5. DOCUMENTATION**

### **5.1 Training Documentation**

#### **5.1.1 Training Forms**

All training must be documented upon completion. The documentation must indicate the following information:

- Date of training
- Training topic, such as SOP or policy number and title
- Name of trainee
- Name of trainer, if applicable

**Note:** For self-training, there will not be a trainer involved.

#### **5.1.2 Supporting Documentation of Training**

Documentation demonstrating completion of a particular training should also be maintained. Examples of such documentation are:

- Copies of attendance certificates issued by a conference organization or webinar
- Copies of slide presentations
- Copies of professional certifications obtained

### **5.2 Central Training Files**

RCQA will maintain a central training file in electronic format in the RCQA shared drive for the following:

- Completed Training Matrix for new hire
- Completed Refresher Training on Training Matrix
- Group Trainings
- Position specific training

RESEARCH COMPLIANCE AND QUALITY ASSURANCE  
STANDARD OPERATING PROCEDURE

---

Document Number: RCQA-002-05	Effective Date: 27 Aug 2020
Page No. Page 6 of 7	Author: H. Miletic
Title: RCQA Staff Training	

---

### 5.3 Individual Training Files

RCQA team members should maintain their own training file with documentation such as, but not limited to:

- copies of attendance certificates from conferences or webinars
- professional certifications
- position-specific training

## 6. REFERENCES

- CITI website
- Training Matrix: UM Policies and SOPs
- Training Matrix: UM Guidance Documents
- Training Matrix: Federal Regulations and Guidelines
- Training Matrix: CTD Specific Training

## 7. TEMPLATES / FORMS / TOOLS

**These templates and forms can be found on the RCQA shared drive:  
S:/RCQA/Training/Training Forms:**

- Group Training Form
- Individual Training Form
- New Auditor Training Form

## 8. REVISION HISTORY

Effective Date	Author	Description of Changes
19 Apr 2017	H. Miletic	Specified the required CITI module in section 4.2.1. Extended timeline to 180 days for completion of training in section 4.2.2. Updated sections 4.3.3 and 6 to include CTD specific training. Updated section 5.1.1 to remove the requirement to document mode of training.
30 Mar 2018	H. Miletic	Changed the term “audit” to “Quality Review” throughout document. Changed the RCQA shared drive to Box drive throughout document.

RESEARCH COMPLIANCE AND QUALITY ASSURANCE  
STANDARD OPERATING PROCEDURE

---

Document Number: RCQA-002-05	Effective Date: 27 Aug 2020
Page No. Page 7 of 7	Author: H. Miletic
Title: RCQA Staff Training	

---

02 Apr 2019	H. Miletic	Added RCQA Director to sections 3.1 and 3.2. The New Auditor Training Form was added to section 7.
27 Aug 2020	H. Miletic	Added refresher training to section 3.3. Updated step 4.2.1 to state that CITI training must be completed within the first week of hire. Added mandatory refresher training on the Training Matrix every 3 years. Updated section on central training files to specify documents maintained. Added section on Individual Training files. Changed Box drive to shared drive. Minor edits throughout.

**9. SIGNATURES**

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

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