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.
3.2 **RCQA Managers**

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
- 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**

4.2.1 Each RCQA staff member is required to successfully complete the CITI module training listed below, within the first 30 days 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.
The Training Matrix lists for each RCQA position, all SOPs, policies and guidance documents on which training must be completed.

4.3 Position Specific Training

4.3.1 Auditor Specific Training:
Newly hired QA Auditors, including experienced auditors will be trained on how to conduct audits and write audit reports. A minimum of six (6) audits will be conducted under the supervision of a trainer/mentor.

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

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

4.3.2 CAPA Specific Training:
This has not yet been developed as there is only one CAPA Manager and no additional CAPA staff.

4.3.3 CTD Specific Training:
The CTD specific training is listed in the Training Matrix.

4.4 Additional Training

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

4.4.2 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.
4.5 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.

4.6 Mode of Training

Training may be conducted in the following ways:

4.6.1 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.

4.6.2 One on One Training

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

4.6.3 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.

4.6.4 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 the original training forms/supporting documentation in a central file in paper form. These original training records will be scanned and maintained in electronic format in a central training file on the shared drive.

RCQA will maintain the central training files for a minimum of ten years.

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

8. REVISION HISTORY

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Author</th>
<th>Description of Changes</th>
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<tbody>
<tr>
<td>19 Apr 2017</td>
<td>H. Miletic</td>
<td>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.</td>
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9. SIGNATURES

Prepared by: ____________________________ Date: ______________
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Approved by: ____________________________ Date: ______________
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