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:** IHSR 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 Quality Reviews and write Quality Review reports. A minimum of six (6) Quality Reviews will be conducted under the supervision of a trainer/mentor.

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.

4.3.2 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 Quality Reviews 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 in the shared RCQA Box 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 shared RCQA Box 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>
</tr>
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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</td>
</tr>
<tr>
<td></td>
<td></td>
<td>completion of training in section 4.2.2. Updated sections 4.3.3 and 6 to include CTD</td>
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<tr>
<td></td>
<td></td>
<td>specific training. Updated section 5.1.1 to remove the requirement to document mode of</td>
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<tr>
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<td>training.</td>
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<tr>
<td>30 Mar 2018</td>
<td>H. Miletic</td>
<td>Changed the term “audit” to “Quality Review” throughout document. Changed the RCQA</td>
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<td></td>
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<td>shared drive to Box drive throughout document.</td>
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9. SIGNATURES

Prepared by: _______________________________  Date: ____________
Helen Miletic, MA, CHRC, RQAP-GCP
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Approved by: _______________________________  Date: ____________
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