1. PURPOSE

The purpose of this document is to define the process of developing and formatting standard operating procedures for the office of Research Compliance and Quality Assurance (RCQA).

2. DEFINITIONS

Controlled documents – RCQA SOPs and policies
RCQA – Research Compliance and Quality Assurance
SOP – Standard Operating Procedure

3. RESPONSIBILITY

3.1 RCQA

- Determines if new policies or SOPs are needed
- Determines if existing policies and/or SOPs require revision
- Writes and reviews policies and SOPs
- Executive Director approves SOPs

4. PROCEDURE

4.1 Numbering of Controlled Documents

The system of numbering RCQA controlled documents is as follows:

The prefix “RCQA” is followed by a three-digit document number and the version number, each separated by a dash. For example: RCQA-002-03, where 002 is the document number and 03 is the version number. The next revision of this document would be numbered as RCQA-002-04. A new document will be given version 01 as the initial version number.
### Number Range | Document Description
--- | ---
001 | SOP on SOPs and Controlled Documents
002 – 99 | RCQA Procedures
200 – 499 | Quality Assurance Procedures
700-799 | Clinical Trial Disclosure Procedures
800-899 | Corrective Action and Preventive Action (CAPA) Procedures
900-999 | RCQA Policies

**Note:** Document numbers 100 to 199, 300 to 399 and 500 to 699 have been retired and should not be re-issued.

**Note:** Policies have a different format to differentiate them from the SOPs.

## 4.2 Procedure Format

4.2.1 Each procedure will have a heading on each page that contains the following information:

RESEARCH COMPLIANCE AND QUALITY ASSURANCE
STANDARD OPERATING PROCEDURE

<table>
<thead>
<tr>
<th>Document Number:</th>
<th>Effective Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Page No.</td>
<td>Page of</td>
</tr>
<tr>
<td>Title:</td>
<td>Author:</td>
</tr>
</tbody>
</table>

4.2.2 Each procedure will contain a history of revisions at the end of the document as follows:
4.2.3 SOPs will consist of the following sections:

1. **PURPOSE**: A statement of the purpose of the document, such as: “to describe the process for conducting a routine Quality Review of research involving human subjects.”

2. **DEFINITIONS**: The definition of technical terms or abbreviations used in the procedure.

3. **RESPONSIBILITY**: Who is responsible for the actions defined in the SOP.

4. **PROCEDURE**: A description of what is to be done, when and by whom.

5. **DOCUMENTATION**: A description of the associated documentation generated and where it will be stored.

6. **REFERENCES**: A list of regulations, guidances, or other documents used in the development of the SOP.

7. **TEMPLATES / FORMS / TOOLS**: A list of standard forms, templates or tools used in the procedure.

8. **REVISION HISTORY**: A table indicating the history of changes made to the document; who made it and when it was made.

9. **SIGNATURES**: Procedures will be signed by the author and approved by the RCQA Executive Director.

4.2.4 If a section is not applicable, it should not be deleted. Instead, write N/A. Additional sections may be added if necessary. Information may be broken down within sections using the following numbering scheme:
5. DOCUMENTATION

5.1 Maintenance of Controlled Documents

The signed original SOPs and Policies are maintained in the RCQA central files located in the RCQA office. Electronic copies of the policies and procedures are maintained in the shared RCQA Box drive.

5.2 Annual Review of Controlled Documents

The SOPs will be reviewed annually and if necessary will be revised. Documentation of the annual review will be maintained in the RCQA central files located in the RCQA office.

Policies will be reviewed every two years and if necessary will be revised. Documentation of the review will be maintained in the RCQA central files located in the RCQA office.

6. REFERENCES

N/A

7. TEMPLATES / FORMS / TOOLS

N/A
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>Name of office from ORC to RCA; Added “Guidance Documents” to numbered controlled documents</td>
</tr>
<tr>
<td>25 Oct 06</td>
<td>25 Oct 06</td>
<td>K. Roach</td>
<td>Vice Provost for Research changed to Richard Bookman, PhD</td>
</tr>
<tr>
<td>16 Jun 08</td>
<td>16 Jun 08</td>
<td>L. Smith</td>
<td>Name of office change from RCA to ORCA.</td>
</tr>
<tr>
<td>05 Nov 09</td>
<td>21 Oct 09</td>
<td>J. Stamates</td>
<td>Section 5: annual review of policies added</td>
</tr>
<tr>
<td>18 Apr 12</td>
<td>18 Oct 11</td>
<td>H. Miletic</td>
<td>Changed the name of the department from Office of Research Compliance Assessment (ORCA) to Regulatory Support and Quality Assurance (RSQA) throughout the document. Removed OR and Research Strategic Planning responsibilities from section 3. Added office of Research and Research Education responsibilities to section 3. Added monitoring procedures, monitoring work instructions, monitoring templates and forms, and regulatory support procedures to section 4. Minor formatting and text revision throughout.</td>
</tr>
<tr>
<td>26 Aug 13</td>
<td>21 Aug 13</td>
<td>H. Miletic</td>
<td>Updated section 2 to remove Compliance Officer, HSRO, IRB and University, as these terms are not used in this document. Removed the Office of Research and Research Education from section 3.</td>
</tr>
</tbody>
</table>
### Effective Date | Author | Description of Changes
--- | --- | ---
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. Changed RSQA to RCQA in the document numbering system outlined in section 4. Added Clinical Trial Disclosure and CAPA procedures to section 4. Removed and retired document numbers 100-199, 300-399 and 500-699 relating to monitoring and regulatory support procedures and forms. Modified section 4.2.2 to remove the revision date column in the revision history table.
04 Sep 2015 | H. Miletic | Updated section 4.1 to specify that a new document is given version 01. Also added RCQA procedures 002-99.
19 Apr 2017 | H. Miletic | Renamed work instructions to SOPs in section 4.1. Added tools to sections 4.2.3 and 7.
23 Oct 2017 | H. Miletic | Removed work instructions from sections 2, 3, 4.1, 5.1 and 5.2 as all procedures are now SOPs.

### 9. SIGNATURES

**Signature on file**

Prepared by: ____________________________ Date: ____________

Helen Miletic, MA, CHRC, RQAP-GCP
Quality Assurance Manager, RCQA

**Signature on file**

Approved by: ____________________________ Date: ____________

Johanna Stamates, RN, MA, CCRC, CHRC
Executive Director, RCQA