1. **PURPOSE**

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

2. **DEFINITIONS**

PolicyStat – University’s Policy Management System  
RCQA – Research Compliance and Quality Assurance  
SOP – Standard Operating Procedure  
VPR – Vice Provost for Research

3. **RESPONSIBILITY**

3.1 **RCQA**

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

3.2 **Vice Provost for Research**

- Provides final approval of policies

4. **PROCEDURE**

4.1 **SOP Document Numbers**

The system of numbering RCQA SOPs 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.
4.2 SOP Format

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

RESEARCH COMPLIANCE AND QUALITY ASSURANCE
STANDARD OPERATING PROCEDURE

4.2.2 Each SOP will contain a history of revisions at the end of the document as follows:

Revision History

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Author</th>
<th>Description of Changes</th>
</tr>
</thead>
</table>

Note: The effective date is the date the document was approved and signed by the RCQA Executive Director.
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 SOP.

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 SOP.

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

9. **SIGNATURES**: SOPs 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:

1 Primary Heading
   1.1 Secondary Heading
   1.2 Secondary Heading
      1.2.1 Tertiary Heading
4.3 Policy Document Numbers

4.3.1 A document number is automatically assigned to a policy when a policy is created in the University’s Policy Management System called PolicyStat.

4.4 Policy Format

4.4.1 Policies will follow the PolicyStat format and consist of the following sections:

1. **PURPOSE**: A statement to describe the reason for the policy.

2. **SCOPE**: A description of who is covered by this policy.

3. **POLICY**: A written statement to describe the organization’s set of expectations or objectives.

4. **DEFINITIONS**: Define terms or abbreviations in order for the policy to be understood.

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

6. **APPLICABILITY**: A list of who should know this policy.

5. DOCUMENTATION

5.1 Maintenance of SOPs and Policies

The original signed paper SOPs will be maintained in the RCQA central files located in the RCQA office. Electronic copies of the SOPs will be maintained in the shared RCQA drive and posted on the RCQA websites.

Policies will be issued and maintained in the University’s Policy Management System called PolicyStat. Electronic copies of approved policies will also be maintained in the shared RCQA drive and posted on the RCQA websites.
5.2 Annual and Biennial Review of Documents

The SOPs will be reviewed annually and if needed will be revised. Original paper documentation of the annual review will be maintained in the RCQA central files located in the RCQA office. Electronic copies will be maintained in the shared RCQA drive.

Policies will be reviewed every two years and documentation of this review will reside within the PolicyStat system.

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>
</tbody>
</table>
# Standard Operating Procedures and Policies

## Effective Date

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Revision Date</th>
<th>Author</th>
<th>Description of Changes</th>
</tr>
</thead>
<tbody>
<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>

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Author</th>
<th>Description of Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>25 Aug 2014</td>
<td>H. Miletic</td>
<td>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.</td>
</tr>
<tr>
<td>04 Sep 2015</td>
<td>H. Miletic</td>
<td>Updated section 4.1 to specify that a new document is given version 01. Also added RCQA procedures 002-99.</td>
</tr>
<tr>
<td>19 Apr 2017</td>
<td>H. Miletic</td>
<td>Renamed work instructions to SOPs in section 4.1. Added tools to sections 4.2.3 and 7.</td>
</tr>
<tr>
<td>23 Oct 2017</td>
<td>H. Miletic</td>
<td>Removed work instructions from sections 2, 3, 4.1, 5.1 and 5.2 as all procedures are now SOPs.</td>
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</tbody>
</table>
# RESEARCH COMPLIANCE AND QUALITY ASSURANCE
## STANDARD OPERATING PROCEDURE

<table>
<thead>
<tr>
<th>Effective Date</th>
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<tbody>
<tr>
<td>27 Aug 2020</td>
<td>H. Miletic</td>
<td>Updated title to include policies and to remove controlled documents. Added policies to the Purpose. Removed Controlled Documents from Definitions. Added definition of PolicyStat and VPR. Added section 3.2 to state that VPR provides final approval of policies. Changed Controlled Documents to SOPs in step 4.1. Updated “procedure” to “SOP” throughout document. Changed documents 900 - 999 to “to be assigned.” Removed second note from step 4.1. Added steps 4.3 and 4.4 to define Policy Document Numbers and Policy Format. Updated section 5 to include PolicyStat and that SOPs and policies will be posted on RCQA websites.</td>
</tr>
</tbody>
</table>

## SIGNATURES

**Prepared by:** Helen Miletic, MA, CHRC, RQAP-GCP  
**Date:** 2020.08.27 15:36:44 -04'00'  
**Position:** Director GxP Compliance, RCQA

**Approved by:** Johanna Stamates, RN, MA, CCRC, CHRC  
**Date:** 2020.08.27 19:13:28 -04'00'  
**Position:** Executive Director, RCQA