

RESEARCH COMPLIANCE AND QUALITY ASSURANCE  
STANDARD OPERATING PROCEDURE

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## 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.

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<b>Number Range</b>	<b>Document Description</b>
001	SOP on SOPs and policies
002 – 99	RCQA SOPs
200 – 499	Quality Assurance SOPs
700-799	Clinical Trial Disclosure SOPs
800-899	Corrective Action and Preventive Action (CAPA) SOPs
900-999	[to be assigned]

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

#### 4.2 SOP Format

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

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

#### Revision History

Effective Date	Author	Description of Changes

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

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**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

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### 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.

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## 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

Effective Date	Revision Date	Author	Description of Changes
1 Apr 05	30 Mar 05	G. Lapinski	Name of office from ORC to RCA; Added "Guidance Documents" to numbered controlled documents
25 Oct 06	25 Oct 06	K. Roach	Vice Provost for Research changed to Richard Bookman, PhD
16 Jun 08	16 Jun 08	L. Smith	Name of office change from RCA to ORCA.
05 Nov 09	21 Oct 09	J. Stamates	Section 5: annual review of policies added
19 Oct 10	08 Oct 10	H. Miletic	Changed numbering format of documents and added version number 01. Removed policies, ORCA forms and guidance documents from list of controlled documents. Removed section on Policy Format. Updated SOP sections. Revised text throughout. Changed approval signature from Vice Provost for Research to ORCA Associate Director. Moved revision history to end of document. Added author signature.

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Effective Date	Revision Date	Author	Description of Changes
18 Apr 12	18 Oct 11	H. Miletic	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.
26 Aug 13	21 Aug 13	H. Miletic	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.

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.

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Effective Date	Author	Description of Changes
30 Mar 2018	H. Miletic	Renamed Audit Procedures in section 4.1 to Quality Assurance Procedures. Minor text revisions made throughout.
27 Aug 2020	H. Miletic	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.

**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