

RESEARCH COMPLIANCE AND QUALITY ASSURANCE  
STANDARD OPERATING PROCEDURE

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Title:	Selecting and Defining Quality Reviews of Human Subject Protocols		

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## 1. PURPOSE

The purpose of this document is to define the process by which the office of Research Compliance and Quality Assurance (RCQA) selects studies of human subject research protocols to be reviewed and to define the different types of Quality Reviews conducted.

## 2. DEFINITIONS

Audit and Advisory Services – Responsible for providing operational, financial, and investigative audits

AVP – Associate Vice President, Regulatory Affairs and Assessment

CAPA – Corrective and Preventive Action

FDA – Food and Drug Administration

IDE – Investigational Device Exemption

IND – Investigational New Drug (Application)

IRB – Institutional Review Board

PI – Principal Investigator

QA – Quality Assurance

QA Auditor- A member of RCQA that performs Quality Reviews

RCQA – Research Compliance and Quality Assurance

SCCC – Sylvester Comprehensive Cancer Center

VPR – Vice Provost for Research

## 3. RESPONSIBILITY

### 3.1 VPR and AVP

- The VPR may request Quality Reviews of human subject research protocols
- Both receive notification of Quality Reviews to be scheduled

### 3.2 Sylvester Comprehensive Cancer Center (SCCC)

- Provides RCQA with an annual list of studies for Quality Reviews at SCCC

### 3.3 RCQA

- Creates the annual Quality Review Plan
- Conducts Quality Reviews

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#### 4. PROCEDURE

##### 4.1 Selecting Studies of Human Subject Research Protocols

4.1.1 RCQA will create an annual Quality Review Plan which lists the studies selected for routine Quality Reviews during the coming year.

4.1.2 Studies will be selected based on a risk based approach and the following criteria, which include, but are not limited to:

- Investigators who are holding an IND or IDE
- Expected level of risk to subjects
- Investigators with a history of non-compliance
- Investigators who received a Form FDA 483
- Federally-funded studies
- Studies involving vulnerable populations
- Studies with a complex study design/protocol
- Investigators that have not been previously audited
- Investigators who are first time Principal Investigators
- Investigator-initiated studies
- Therapeutic areas/departments/divisions not previously audited or not audited within the last 3 years
- Investigators storing and dispensing investigational product
- Investigators working outside their area of specialty
- Investigators with a high number of studies
- Social-behavioral studies
- Studies affected by revisions to regulations, University policy or procedures

4.1.3 In addition, the Sylvester Comprehensive Cancer Center (SCCC) will provide RCQA with an annual list of research protocols for a Quality Review.

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## 4.2 Types of Quality Reviews

- 1) **Routine Quality Reviews** selected by RCQA using a risk-based approach and by SCCC as per their process.
- 2) **Directed Quality Reviews** are performed based on identified concerns about human subject safety and rights and/or regulatory compliance, and/or data integrity. These may be requested by any of the following:
  - VPR, Office of Executive Dean for Research, Audit and Advisory Services, IRB, and the SCCC.
  - Requests for directed Quality Reviews should be submitted in writing to the VPR, AVP and RCQA outlining the reason(s) for the request.
  - Directed Quality Reviews may also result from an anonymous complaint reported in person or via the Compliance Hotline.
- 3) **Focused** Quality Reviews may be **Routine** or **Directed**. These Quality Reviews are focused on a particular aspect of the clinical research such as the informed consent process, dispensation of investigational product, etc.
- 4) **Investigator-Requested** Quality Reviews fall into three (3) categories as follows:
  - a) **Study Start-Up Review:** This will consist of a review of the study team's processes, forms, etc. prior to enrollment of the first subject. Recommended for inter-departmental/translational research studies and for investigators and study teams who are new to research. Intended for studies that are not monitored.
  - b) **Study Review:** May be requested for studies already in progress with at least one subject enrolled. The study conduct and associated documentation will be reviewed. Intended for studies that are not monitored.
  - c) **Mock FDA Audit:** RCQA will conduct the audit to mimic an FDA inspection. RCQA members will be assigned different roles during the conduct of the Mock FDA Audit. This audit will consist of, but not be limited to, the following processes which typically occur during a true FDA inspection:

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- RCQA will coach the PI and study team on how to interact with FDA investigators
- Initial meeting with PI and study team to begin the audit
- Audit conduct
- Tour of facilities where study was conducted
- Daily debriefing with PI and study team, if requested by PI
- Interviews of PI and study team members
- Request for copies of study documents
- Exit meeting to review any observations
- Summary report with recommendations will be issued to the PI and study team
- Assistance with audit response will be provided by the CAPA Manager, at the PI's request. The PI will not be required to provide a response to the mock audit, but may do so for training purposes.

## 5. DOCUMENTATION

### 5.1 Quality Review Plan

The annual Quality Review Plans will be maintained in the RCQA shared drive.

### 5.2 Quality Review Reports

Quality Review reports will be generated and issued for all Routine, Directed and Focused Quality Reviews as outlined in SOPs RCQA-402 and RCQA-403 and maintained in the electronic RCQA shared drive indefinitely.

### 5.3 Summary Reports for Investigator-Requested Quality Reviews

Summary reports with recommendations will be issued to the PI and study teams for Study Start-Up Reviews, Study Reviews, and Mock FDA Audits and maintained in the electronic RCQA shared drive indefinitely.

## 6. REFERENCES

- SOP RCQA-402: Quality Review Report Generation
- SOP RCQA-403: Issuing and Maintaining Quality Review Reports

## 7. TEMPLATES / FORMS / TOOLS

N/A

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**8. REVISION HISTORY**

<b>Effective Date</b>	<b>Author</b>	<b>Description of Changes</b>
30 Mar 2018	H. Miletic	Changed the term “audits” to “Quality Reviews” throughout the document and title of the SOP. Added Study Start Up and Study Reviews to section 4.2.1. Removed section 4.2.2.2 regarding the conversion of a mock audit into a true audit if potentially serious non-compliance is detected. Expanded section 5 with more detail regarding reports. Added SOP RCQA-402 to sections 5.2 and 6. Minor edits were made throughout.
02 Apr 2019	H. Miletic	Changed the Associate Vice Provost for Human Subject Research to the Executive Director for Human Subject Research in section 4.2.1.
28 Aug 2020	H. Miletic	Changed IO to VPR throughout document. Added AVP and VPR definitions. Added AVP to step 3.1. Updated the office name of the Executive Dean for Research in step 4.2. Removed Executive Director of Human Subjects Research in step 4.2. Changed CaneWatch to Compliance Hotline in step 4.2. Updated section 5 to reflect that electronic files are maintained in the RCQA shared drive indefinitely. Removed reference to the original paper annual quality review plan as only electronic copy will be maintained.

**9. SIGNATURES**

Prepared by: \_\_\_\_\_ Date: \_\_\_\_\_  
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Approved by: \_\_\_\_\_ Date: \_\_\_\_\_  
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