RCQA Quality Review Process Flowchart

Quality Review Notification

 PI is notified of upcoming quality review

Initial Meeting

 Auditor meets with PI and study team to explain quality review scope, process and to discuss the protocol

Site Visit

- Auditor at site for 1 to 3 working days
- Daily communication with study team

Facilities Visit

Auditor visits Research
 Pharmacies, Comprehensive
 Treatment Units, Research
 Laboratories, etc.

Debrief Meeting

 On the last day of the onsite visit, auditor meets with the PI and study team for a brief discussion of observations

Draft Report Issued

 Auditor issues the Draft Report to the PI and study team within 10 business days for their review

Exit Meeting

 Auditor meets with PI and study team to review and discuss the Draft Report prior to issuing Final Report

Final Report Issued

 Auditor issues the Final Report to PI

<u>PI Response</u>

 PI provides written response within 10 business days of receiving Final Report

CAPA Support for PI

- RCQA Corrective Action Preventive Action (CAPA) Manager will provide assistance in developing the PI response
- PI submits response to RCQA CAPA Manager

RCQA Submits Final Report & PI Response to the IRB and HSRO

• IRB reviews the report and PI response

IRB Determination

 The PI, Institutional Official, and RCQA will receive an IRB Determination letter outlining any further action required by the PI and/or RCQA