

University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
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Approved By: ORI Director	Signature	Date	Date First Effective: 06-28-05
Approved By: Nonmedical IRB Chair	Signature	Date	
Approved By: Medical IRB Chair	Signature	Date	Revision Date: 08-09-19

OBJECTIVE

To describe the policies and procedures for the principal investigator (PI) self-assessment review component of the University of Kentucky's Quality Assurance/Improvement Program (QA/QIP)

GENERAL DESCRIPTION

The Office of Research Integrity (ORI)/Institutional Review Board (IRB) Quality Assurance/Improvement Program serves to improve human research protections at the University of Kentucky (UK). One of the three primary quality assurance/improvement activities is the PI self-assessment review. The self-assessment component of the QA/QIP provides an opportunity to educate research staff and PIs on federal, state, and University expectations; assist researchers in assessing their own programs; and assist in identifying areas on which additional educational programs may need to focus.

The ORI provides a web-based self-assessment form that PIs and/or research staff complete. The ORI disseminates information about the web-based self-assessment form via listserv messages, the ORI website, and other forums as they become available. The form includes questions and information pertaining to federal regulations governing human research protections, local IRB policies and procedures, and International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) guidelines.

The PI or his/her research staff perform self-assessment reviews voluntarily; however, the IRB, IRB Chair or ORI Director may also direct the PI to perform a self-assessment review. If a PI declines a direct invitation to conduct a self-assessment review with reasonable justification, at the discretion of the IRB, IRB Chair, or ORI Director, the QA/QIP may conduct or assist the investigator/research staff with a directed on-site QA/QI review.

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The self-assessment form utilizes a database, maintained by the QA/QIP, to generate reports which ORI staff run on an as-needed basis. The QA/QIP analyzes the reports. If the findings reveal significant deficiencies in the protection of human subjects in research, or the IRB directs a PI to perform a self-assessment, the QA/QIP notifies the IRB and coordinating offices of the results of the PI self-assessment review.

In cases where the ORI reports findings from QA/QI reviews to the IRB, the IRB determines whether to report the findings to the Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), the study sponsor, the Vice President for Research (VPR), or other internal departmental faculty/staff.

To support efforts for continuous improvement in compliance, the QA/QIP may conduct a follow-up review at the IRB's or ORI Director's discretion on any protocol for which a PI has completed a self-assessment form.

The web-based self-assessment form utilizes standard security features in order to protect and maintain confidentiality of the information provided by the PI/research staff. ORI staff make every effort to prevent unauthorized individuals from gaining access to any information provided. The ORI limits access to the data to the PI/designated research staff, the QA/QIP, and select ORI staff via a password security system. The results from any self-assessment review are kept confidential to the extent allowed by law.

RESPONSIBILITY

Execution of SOP: ORI QA/QIP, ORI Director, IRB Chair/designated IRB Member, IRB, Principal Investigator (PI)/Study Personnel

PROCEDURES

1. The PI/research staff contacts the QA/QIP for information on how to access the web-based self-assessment form, or if a directed self-assessment, the QA/QIP directs the PI to the web based assessment form.
2. The PI/research staff completes a section of the web-based self-assessment review and is able to save responses without having to complete the review in its entirety. The PI/research staff can return to the saved review at any time utilizing the password security system. Up until submission of the completed review, the PI/research staff is able to change his/her responses within previously saved sections.
3. Once complete, the user submits the generated form. Responses are final once the PI/research staff submits the completed form, as the data are then static (locked) for reporting purposes.

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4. After submission to the ORI database, the QA/QIP verifies information provided in specific sections of the form by comparing the user's responses to the ORI's IRB records. The QA/QIP investigates discrepancies and, if applicable, contacts appropriate parties for additional information. The QA/QIP may also analyze the data to determine whether significant deficiencies in human research protections exist and/or what topics may be useful for future educational programs.
5. The QA/QIP acknowledges completion and receipt of the self-assessment form by sending electronic correspondence to the PI and, if appropriate, designated research staff. If applicable, the QA/QIP requests clarification of discrepancies at that time. The correspondence also indicates that the PI/research staff can return to the web-based self-assessment form and retrieve the completed self-assessment form using the password security system. Upon retrieval, the PI/research staff can view regulatory background information and suggestions for corrective actions for applicable items.
6. If the analysis of a submitted self-assessment form suggests that significant deficiencies in human research protections exist, the QA/QIP may share the findings with the ORI Director. If deemed appropriate by the QA/QIP and/or ORI Director, the QA/QIP forwards a report to the IRB Chair for review. The QA/QIP notifies the PI regarding this decision and what the outcome may entail.
7. The IRB Chair may decide to forward the response to the entire IRB for additional review or acknowledge with no further action requested.
8. For any QA/QI findings requiring review by the full committee, the IRB members vote for one of the following actions:
 - Approved – No further action is required. Per the guidelines in the ORI Customer Service Standards, the QA/QIP sends the PI a letter describing the outcome of the IRB review.
 - Revisions/additional information requested - The IRB withholds approval pending submission of revisions/additional information. The IRB may give the individual chairing the meeting the authority to approve the revisions/additional information or require review of the revisions/additional information at a convened meeting. If the IRB request necessitates further QA/QI review, the QA/QIP acts accordingly and processes any additional findings/information for review based on the IRB's determination at the convened meeting (either given to the individual who chaired the IRB meeting or assigned to a convened IRB meeting for review). If the IRB request necessitates a response from the PI, per the guidelines in the ORI Customer Service Standards, the QA/QIP sends the PI a letter describing the IRB's request.

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When the PI responds to the IRB's request, the ORI processes the response based on the IRB's determination at the convened meeting (either given to the individual who chaired the IRB meeting or assigned to a convened IRB meeting for review). If the individual who chaired the meeting is the IRB's designated reviewer, he/she may decide to forward the response to the entire IRB for additional review, request additional information, or approve.

- Suspension or termination of the research - (See the Termination or Suspension of Research by the IRB SOP.) Per the guidelines in the ORI Customer Service Standards, the QA/QIP sends the PI a letter describing the outcome of IRB review.
9. For directed self-assessments, ORI staff store documentation resulting from PI reviews in the corresponding IRB records and retain QA/QI review documentation in the IRB records for a minimum of six (6) years after study closure. (See IRB/ORI Recordkeeping SOP.) The QA/QIP maintains a separate QA/QI review file containing documentation on all QA/QI activity.

REFERENCES

Not applicable