

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: 08-19-09

OBJECTIVE

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

GENERAL DESCRIPTION

The Office of Research Integrity (ORI)/Institutional Review Board (IRB) Quality Improvement Program serves to improve human research protections at the University of Kentucky (UK). One of the three primary quality improvement activities is the PI self-assessment review. The self-assessment component of the 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 (also available electronically or in paper copy) which PIs and/or research staff complete. The ORI disseminates information about the web-based self-assessment tool via listserv messages, the ORI website, and other forums as they become available. The tool 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 QIP Coordinator may conduct or assist the investigator/research staff with a directed on-site QI review.

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The self-assessment tool utilizes a database to generate reports, which ORI staff run on an as-needed basis. The QIP Coordinator analyzes them and notifies the IRB and coordinating offices of results of PI self-assessment reviews only 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 ORI develops educational programs for PIs/research staff based on the results of the PI self-assessment reviews. In cases where the ORI reports findings from 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, or other internal departmental faculty/staff.

To support efforts for continuous improvement in compliance, the QIP Coordinator 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. Follow-up on a PI's self-assessment serves as a means to measure the effectiveness of the self-assessment component of the QIP.

The web-based self-assessment tool 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 via electronic or paper copy of the self-assessment form. The results from any self-assessment review are confidential (internal to UK) to the extent allowed by law.

The QIP Coordinator maintains the self-assessment review database. The ORI limits access to the data via a password security system to the PI/designated research staff, the QIP Coordinator, and select ORI staff.

RESPONSIBILITY

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

PROCEDURES

1. If necessary, the PI/research staff contacts the QIP Coordinator for information on how to access the web-based self-assessment form (alternately, the QIP coordinator e-mails or mails an electronic copy or paper copy of the self-assessment form).

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2. The user completes a section of the web-based self-assessment form and is able to save responses without having to complete the form in its entirety. The user can return to the saved form at any time utilizing the password system. Up until submission of the completed form, the user is able to change his/her responses within previously saved sections.
3. Once complete, the user submits the form (via the web by clicking on “submit completed form,” electronically as an e-mail attachment, or as a paper copy). Responses are final once the PI/research staff submits the completed form, as the data are then static (locked) for reporting purposes.
4. After submission to the ORI database, the QIP Coordinator verifies information provided in specific sections of the form by comparing the user's responses to the ORI's IRB records. The QIP Coordinator investigates discrepancies and, if applicable, contacts appropriate parties for additional information. The QIP Coordinator 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 QIP Coordinator acknowledges completion and receipt of the self-assessment form by sending electronic correspondence to the PI and/or designated research staff. If applicable, the QIP Coordinator requests clarification of discrepancies at that time. Furthermore, the correspondence indicates that the PI/research staff can return to the self-assessment form web site and retrieve (using the password system) the completed self-assessment form. Upon retrieval, the PI/research staff can view regulatory background information and suggestions for corrective actions for applicable items (if submitted as an electronic copy or paper copy, the QIC manually generates a report containing the regulatory background information and corrective actions for applicable items and sends it to the PI/research staff as feedback).
6. If the analysis of a submitted self-assessment form suggests that significant deficiencies in human research protections exist, the QIP Coordinator may share the findings with the ORI Director. If deemed appropriate by the QIC and/or ORI Director, the QIP Coordinator forwards a report to the IRB Chair for review. The QIC notifies the PI in writing and/or by phone call 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.
8. For any QI findings requiring review by the full committee, the IRB members vote for one of the following actions:

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- Approved – No further action is required. Per the guidelines in the ORI Customer Service Standards, the QIP Coordinator 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 QI review, the QIP Coordinator 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 QIP Coordinator sends the PI a letter describing the IRB’s request.

When the PI responds to the IRB’s request in writing, 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 QIP Coordinator sends the PI a letter describing the outcome of IRB review.
9. ORI staff file documentation resulting from PI self-assessment reviews in the corresponding IRB records and retain QI review documentation in the IRB records for a minimum of six years after study closure. (See IRB/ORI Recordkeeping SOP.) The QIP Coordinator maintains a separate QI review notebook containing documentation on all QI activity and periodically reviews the notebook to determine whether to eliminate protocol specific QI materials from the records based on the retention policy for IRB protocol records. The ORI Director determines when to discard materials.

Optional Assessment Tool

1. The PI/research staff may send a link to a subject survey on the web-based self-assessment form (or upon request for those using an electronic or paper copy) to subjects that have

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participated in the study. The survey gives subjects the opportunity to provide feedback to the PI about their experience as a research subject.

2. The PI uses the survey responses as a valuable learning tool regarding strengths and weaknesses in their research program (i.e., informed consent process).