

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 policies and procedures for the administrative assessment component of the University of Kentucky (UK) Quality Assurance/Improvement Program (QA/QIP)

GENERAL DESCRIPTION

The Office of Research Integrity (ORI)/Institutional Review Board (IRB) QA/QIP serves to improve human research protections at UK. One of the primary quality assurance/improvement activities is the administrative assessment review.

The ORI QA/QIP conducts administrative assessment reviews at his/her discretion or at the request of the ORI Director and/or the Vice President for Research (VPR). These reviews measure the effectiveness and/or efficiency of the ORI/IRB procedures for protection of human subjects in research. Examples of areas in which the QA/QIP may periodically conduct a thorough examination of the IRB records, the ORI files/submissions, and/or other materials to evaluate performance include, but are not limited to:

- IRB member performance;
- Proper use of expedited and exemption categories;
- Timeliness of ORI staff responses to investigators/study personnel and/or of IRB review;
- Volume of the ORI's outreach activity for investigators and research subjects (i.e., web page "visitors" report);
- Major versus minor revisions at initial review;
- Appropriate consideration and documentation for protecting vulnerable or potentially vulnerable populations;
- Timeliness of continuation review of approved research;
- Documentation for and approval of waivers of informed consent and/or alteration of elements of informed consent;

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- Inclusion of all the elements of informed consent as required by the UK IRB;
- IRB consideration for data and safety monitoring;
- Completeness of IRB minutes;
- Quality of UK's human research protection program (HRPP) and IRB system as measured by accreditation assessment tools.

Any performance evaluation topic described under this SOP may be incorporated into a directed on-site review at the discretion of the ORI Director, the QA/QIP, the VPR, and/or the IRB Chair. The QA/QIP shares the results of an administrative assessment with the ORI Director. The results may impact current practices and may require additional educational activities for ORI staff and IRB members.

In addition, the QA/QIP coordinates the *Human Research Protection Program Evaluation*. This assessment focuses on maintenance of applicable documentation representing current policy and procedures, utilization of the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) Self-Evaluation Instrument, and evaluation of current human research protection practices to ensure appropriate fulfillment of accreditation and HRPP standards. The program assessment serves to determine whether the institution's HRPP is effective in achieving its intended outcomes and provides the opportunity to develop improvement plans as deemed necessary.

RESPONSIBILITY

Execution of SOP: ORI QA/QIP, ORI Director, ORI Staff, ORI Professional Associate (PA), VPR, IRB

PROCEDURES

Administrative Assessment

1. An administrative assessment may require selection of specific protocols for examination of a variety of topics including, but not limited to: review type, funding source, off-site research, event types, special research categories, specific IRB committee, and/or assigned ORI staff. Generally, the QA/QIP chooses protocols that meet the criteria for the particular administrative assessment randomly; however, the QA/QIP, ORI Director, and/or VPR have the discretion to identify specific studies for assessment. If identifying specific protocols is not necessary for the administrative assessment conducted (e.g., review of meeting minutes, review of a committee's workload, evaluation of the performance of IRB members), the QA/QIP obtains and reviews other related materials.

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2. After identifying the protocols and/or related materials for examination, the QA/QIP or designee conducts an in-depth review of either the IRB records for each identified protocol or related materials. This may entail review of the ORI computerized tracking system, electronic or physical IRB records maintained by ORI, and/or the IRB meeting minutes. The QA/QIP may conduct a comparison to verify that the events listed in the ORI computerized tracking system are in alignment.
3. The QA/QIP shares the results of the review with the ORI Director. Based on results, the ORI Director or designee takes measures to strengthen applicable areas of the HRPP.
4. The QA/QIP or designee educates ORI staff and/or the IRB in areas in need of strengthening as identified by analysis of the results, as appropriate (e.g., QA/QI presentation at an IRB meeting, staff meeting, in-service presentations, etc.). The QA/QIP informs the IRB and the VPR of specific findings only if the findings reveal significant or numerous deficiencies in protection of human subjects in research.
5. If significant deficiencies necessitate reporting to the IRB and the VPR, the IRB determines whether to report the findings to the FDA, OHRP, or the study sponsor, and/or other applicable internal departmental faculty/staff. (See Mandated Reporting SOP.)
6. To support continuous improvement when policy or procedure change as a result of QA/QI review findings, the QA/QIP may perform a follow-up QA/QI review to determine whether the processes are effective.

Assessment of Expedited Review

1. If the QA/QIP conducts an assessment for protocols reviewed using expedited procedures, he/she verifies conformance with policies and procedures, which may include but are not limited to:
 - Assignment to appropriate expedited reviewer;
 - Notification of IRB members of expedited reviews;
 - Review of protocols using expedited procedures according to the eligibility requirements for expedited review;
 - Documentation for the basis of allowing expedited review;
 - Performance of expedited reviewer;
 - Timely processing of applications by ORI staff and/or the IRB reviewer.

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Assessment of Exempt Review

1. If the QA/QIP conducts an assessment for protocols reviewed for exemption certification, he/she verifies conformance with policies and procedures which may include, but are not limited to:
 - Appropriate category of exempted research chosen;
 - Assignment to appropriate exempt reviewer;
 - Documentation for the basis (allowable category) of making the exempt determination;
 - Timely processing of applications by ORI staff and/or IRB.

Assessment of Risks and Benefits

1. If the QA/QIP conducts an assessment of the IRB's determination of risk versus potential benefit for a protocol, including designation of minimal risk when appropriate, he/she verifies documentation in the research records which includes, but is not limited to:
 - Documentation in the meeting minutes or IRB records of the IRB's evaluation of risks of the research;
 - Provisions for safety monitoring;
 - Determination that risks to participants are minimized by using procedures that are consistent with sound research design and do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes;
 - Determination of the level of risk;
 - Determination of the risk level of investigational device, if applicable;
 - Appropriate disclosure of risks and benefits in the informed consent process.

Elements of Informed Consent Evaluation

1. When the QA/QIP conducts a review to evaluate appropriate inclusion of the elements of informed consent, he/she verifies adherence to the required elements of informed consent according to UK IRB policy using the Consent/Assent Checklist as a guide. Protocols selected for directed on-site review may include this informed consent evaluation.
2. The nature of the research dictates whether additional elements of informed consent are necessary, but for required additional elements which have been excluded (e.g., significant new findings statement), the QA/QIP confirms the IRB records contain appropriate documentation of the IRB's determination.

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3. Upon completion of the informed consent evaluation, the QA/QIP shares the results with the ORI Director and, if appropriate, the IRB Chair(s).
4. If the informed consent evaluation identifies deficiencies, the ORI Director, designated ORI staff, and/or IRB Chair(s) provide follow-up training to IRB members, and/or education to researchers on best practices.

Assessment for Appropriate Representation and Expertise for Vulnerable Population Protocol Reviews

1. If the QA/QIP conducts an assessment for appropriate representation and expertise for full review research involving vulnerable populations (e.g., children, prisoners), he/she verifies the appropriate IRB representative(s) was/were either present at the convened meeting or available via teleconference at the convened meeting. If research involving vulnerable populations is eligible for expedited review, the QA/QIP verifies the Expedited Reviewer had appropriate expertise or a consultant review was obtained.
2. The QA/QIP or ORI Director may decide to focus an assessment on a specific vulnerable population during a particular time period.

Evaluation of IRB Member Performance

1. Approximately once each academic year, the QA/QIP or designee sends the ORI PAs and IRB members an IRB Performance Questionnaire to assess representation of appropriate knowledge, skills, and abilities respective to the roles of the IRB member and IRB Chair. Questions intend to collect information including, but not limited to:
 - IRB Member participation/service;
 - Individual members' ability to apply knowledge of the federal regulations and ethical principles that serve as guidelines for responsible research and whether additional training is necessary to facilitate appropriate reviews;
 - Committee competence in relation to appropriate review (e.g., expertise, representation); and
 - IRB Chairperson leadership (e.g., efficiency and promotion of discussion).
2. The ORI PAs evaluate the IRB Chair, IRB Vice Chair, and IRB members serving on the PA's assigned committee in a confidential survey.
3. The QA/QIP and/or the ORI Associate Director analyze the responses and notify the ORI Director if any of the responses appear to reveal issues with membership qualifications. If the

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results identify problems with membership qualifications, the ORI Director or Associate Director discusses the issues with the VPR. The VPR may direct the ORI Director or ORI Associate Director to ask an IRB member to resign and to appoint an appropriate replacement. (See the Membership of the IRB SOP.)

4. The QA/QIP provides aggregated evaluation responses (to maintain anonymity of responders) to the IRB members.

Human Research Protection Program Evaluation

1. UK's HRPP is assessed at least once every five (5) years. The QA/QIP, with input from the ORI Director and/or designee, conducts the assessment using the AAHRPP Evaluation Instrument and feedback from AAHRPP.
2. ORI staff, the IRB, investigators, other administrative units, and the VPR may participate in the assessment process.
3. Throughout the course of the assessment, the ORI Director, QA/QIP, and/or designees may determine the need for revisions to current HRPP policies, procedures, and/or practices in order to ensure appropriate fulfillment of accreditation standards. Based on the nature of the revisions to the HRPP, the Research Education Specialist (RES), the ORI Director, the QA/QIP, and/or designee develop appropriate education plans for ORI staff, IRB members, investigators, and other affected units, if applicable.
4. The QA/QIP and/or designee(s) incorporates the outcome of this ongoing evaluation in the AAHRPP re-accreditation application (or AAHRPP Annual Report, if applicable).

REFERENCES

Not applicable