UNIVERSITY OF KENTUCKY
QUALITY IMPROVEMENT PROGRAM for HUMAN RESEARCH PROTECTIONS

The Office of Research Integrity (ORI) and the University of Kentucky (UK) Institutional Review Board (IRB) developed a Quality Improvement Program (QIP) to strengthen human research protections at UK and demonstrate UK's commitment to continuous improvement in compliance. Identifying the strengths and weaknesses of protection efforts is essential to maintaining a quality program and enables the ORI and the IRB to continue UK's tradition of excellence.

Implementation of the QIP at UK serves to evaluate human research protections at varying levels, increase awareness of existing processes, operating procedures, educational programs, and acquire information necessary for enhancing protections. The QIP provides a means to assess UK's level of compliance with federal, state, and institutional regulations, and Good Clinical Practice (GC) guidelines, which is a key element in meeting the highest standards for human subject protections.

Components of the program focus on educating the University's researchers on the mechanisms by which human subjects are protected. It also allows researchers, ORI staff, and IRB members the opportunity to improve human research protections performance. The QIP can provide useful information to identify educational/training initiatives for researchers, their staff, ORI staff, and IRB members.

The QIP consists of three main components which examine the entire research process and may focus on the researcher, the IRB's review process, and/or the IRB records maintained by ORI.

1. Directed on-site reviews are conducted by the ORI QIP Coordinator and are initiated upon request by the Institutional Review Board (IRB), the Vice President for Research, or ORI Director, due to unusual circumstances, significant risks to subjects, routine failure of an investigator to comply with federal and/or institutional requirements, allegations or concerns about the conduct of the study brought to the IRB's attention, or any case requiring further scrutiny as deemed appropriate by the IRB. The ORI QIP Coordinator may be accompanied by a representative of the IRB. A comparison of the IRB's records maintained by ORI with the investigator's research records may also be conducted to determine accuracy and consistency and to verify that no material changes were made to the protocol prior to IRB approval. The findings of the directed review are shared with the Principal Investigator (PI) and his/her research staff and reported to the IRB to make a determination about whether further action is necessary. If in reviewing the results of a directed review, the IRB determines that the exposed deficiencies warrant suspension or termination of the research, the IRB develops a plan for follow-up, which may entail, but is not limited to, another QI review, or monitoring of the informed consent process. If ORI conducts a directed Quality Improvement Review (QIR) on a protocol that falls under the purview of a unit with which ORI has written and approved joint standard operating procedures (e.g., IBC, MCC, VAMC), the appropriate unit representative is given a copy of the final QIR report.

2. Self-Assessment Reviews are voluntarily performed by the PI or his/her research staff. However, a PI may also be prompted by direct invitation at the discretion of the IRB, Vice President for Research, or ORI Director to perform a self-assessment review. The ORI provides a web-based self-assessment form (also available electronically, or in paper copy) to be completed by the PI and/or research staff. The PI self-assessment tool includes questions and information pertaining to federal regulations governing human research protections, local IRB policies and procedures, and International Conference on Harmonisation (ICH) GCP guidelines. The results from a PI self-assessment review can be submitted to a secure database, after which time, the ORI can return suggested corrective actions to the PI for areas in need of improvement. The IRB will not be notified of results from a PI self-assessment review unless the results of the review reveal significant deficiencies in protection of human subjects in research, or the IRB directed a PI to complete the self-assessment. Reports can be generated by the ORI using the data collected from submitted

self-assessment forms and may enable identification of educational initiatives for researchers. These reports are run on an as-needed basis and analyzed accordingly by the QIP Coordinator.

3. Administrative assessment reviews are conducted by the ORI QIP Coordinator and are initiated at the discretion of the Director of ORI, and/or the Vice President for Research. A thorough examination of the IRB records may be conducted for improvement of management or to evaluate the procedures applied and/or issues addressed by the Office of Research Integrity staff and the IRB for protection of human subjects in research. An example of evaluating IRB procedures would be the use of the Consent/Assent Form Checklist. IRB member performance evaluations are periodically conducted to verify qualifications. The results of an administrative assessment are shared with the ORI Director. The results may impact current practices and may require additional educational activities for ORI staff, IRB members, or investigators/study personnel.

   In addition to the above described administrative assessment reviews is the *Program Assessment for Accreditation,* a significant component in support of maintaining AAHRPP accreditation. This assessment focuses on maintenance of applicable documentation representing current policy and procedures; utilization of the AAHRPP Self-Evaluation Instrument; and evaluation of current HRPP practices to ensure appropriate fulfillment of accreditation standards

Educational programs/announcements are developed for investigators, their research staff, ORI staff, and IRB members based on the results of the QIP Reviews. If/when findings from QIP reviews are reported to the IRB, the IRB makes a determination whether to report the findings to FDA, OHRP, the study sponsor, the UK Institutional Official, or other internal departmental faculty/staff.

UK maintains standard operating procedures (SOPs) for each one of the QIP components. See Directed On-site Review; PI Self-assessment Review; and Administrative Assessment Review SOPs for details.

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