



## Human Research Protection Program Policy

### **QUALITY IMPROVEMENT ACTIVITIES IN HUMAN RESEARCH PROTECTION**

#### **POLICY**

The University of Cincinnati's (UC) Human Research Protection Program (HRPP) will undergo quality assurance and improvement review to measure and improve the effectiveness of and compliance with organizational policies, procedures as well as applicable federal, state, and local laws. These activities are designed to develop a culture of protection of human participants in research by assessing whether the various elements of the HRPP are effective at protecting research participants.

#### **APPLICABILITY**

Quality assurance and improvement activities are applied to all university researchers, departments and units engaged in IRB-approved human subjects' research, including those whose research is conducted at non-university sites. These program activities serve five functions: 1) to assist investigators with improving their research processes by sharing best practices among researchers; 2) to protect the integrity of research by identifying and correcting significant deficiencies in approved research protocols; 3) to promote human subject protection through the ethical conduct of research; 4) to improve the processes of the IRB; 5) to identify topics for research education and training;

The HRPP will: 1) continuously assess active, ongoing IRB approved studies for compliance with approved protocols and with university policy and federal regulations; 2) perform quality assurance reviews of selected studies; 3) monitor the informed consent process for selected studies; 4) monitor the functioning of the IRB for efficiency and compliance with federal regulations and institutional policy; and 5) develop strategies for improving the quality of research through educational and training programs.

#### **QUALITY ASSURANCE MONITORING ACTIVITIES**

HRPP will conduct study reviews which will include but not be limited to:

- a) IRB File Review. This includes a review of the electronic database, study files, meeting minutes and other relevant documentation in order to identify areas for improvement.
- b) On Site Reviews. The focus of the review includes an assessment of the roles, responsibilities and training of research team members, suitability of the facility



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to conduct research including pharmacy operations, regulatory and IRB compliance, recruitment, eligibility and consenting process, case review for protocol adherence through source documentation and data collection, adverse events, file security, and other relevant aspects of the study;

- c) Informed Consent Review. This review helps researchers in assuring that adequate informed consent is provided to participants in studies and can be performed in conjunction with other reviews. Auditors may observe the consenting process; verify that the person consenting the subject is qualified and designated by the PI; verify that the consent document is appropriately signed and dated, and a copy was given to the participant;
  - d) For Cause Review. This type of review is performed at the request of the IRB and/or Compliance Officer. Reasons for this request may include: specific concerns regarding compliance, protocol adherence, or subject safety. The review may be either scheduled or unscheduled and may involve full review or focus on specific concerns.
  - e) Off-Site Reviews. This type of study review utilizes a faxed or emailed survey form for the given research site to complete and return. It is designed to assist the investigators and research staff in maintaining human subject protection, support Good Clinical Practice education, and increase the number of researchers that are able to benefit from the program.
- 2) Selection of Studies to Review. Research studies will be chosen for QA/QI review primarily from among studies meeting one or all of the following characteristics:
- a) Not receiving study monitoring by the study sponsor or another organization;
  - b) Present greater than minimal risk to participants;
  - c) Involve investigator-initiated research;
  - d) Enroll vulnerable populations, including UC employees and students, cognitively-impaired participants, pregnant women/fetuses/neonates, prisoners, and children;
  - e) Have potential for conflict of interest;
  - f) Are requested by the IRB or Compliance Officer or



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g) Have high enrollment.

- 3) Any non-compliance which is identified during the course of review will be reported to the IRB for further procedures in keeping with Institutional Policy VII.03, *Investigating Allegations of Non-Compliance in Human Subjects Research*.

### OTHER QUALITY ASSURANCE ACTIVITIES

The following QA/QI activities will also occur:

- 1) Assess the functioning of the IRB and its compliance with regulations and policy, not less than annually;
- 2) Identify areas where researchers, IRB members, and HRPP staff can benefit from training activities and educational materials;
- 3) Identify research practices, which, if shared among similar researchers could improve the quality of research;
- 4) Have personnel available to assist researchers who request help with research methods, protecting vulnerable subjects, record keeping practices, or research related problems and to direct them to resources that may assist them in designing or conducting research safely.

### QUALITY ASSURANCE OUTCOME

In order to evaluate the effectiveness of the HRPP, the Research Compliance Officer or designee will conduct an annual review.

Evaluation criteria will include:

1. The number of protocols reviewed in the preceding year and the proportion of active IRB protocols that represents.
2. Whether any of these monitoring reports result in regulatory investigations or actions by the IRB.
3. Whether these investigations accomplished the following:
  - a. Assist investigators to improve their research processes
  - b. Protect the integrity of research by identifying and correcting significant deficiencies in approved research protocols.
  - c. Promote human subject protections through the conduct of ethical research.
  - d. Improve IRB or IRB office processes

