

**Guidance and Procedures Number: 56**  
**Title: HRPP Quality Improvement Program**  
**Date of Last Revision: April 14, 2009**

## **I. Purpose**

This guidance describes the activities of the newly created Quality Improvement Program (QIP) within UCLA's Human Research Protection Program (HRPP).

## **II. Policy**

In an effort to promote HRPP program accountability and optimize processes, the UCLA Office for Protection of Research Subjects (OPRS) monitors and measures the effectiveness and quality of its human research protection program. Based on the results of these measurements, necessary plans and improvements to the program are considered for implementation.

## **III. Overall Description and Goals**

The primary purpose of the Quality Improvement Program (QIP) is to provide post-approval monitoring and internal oversight, education and training to research professionals to assure that all HRPP operations effectively support UCLA's mandate to protect the rights and welfare of research participants. This includes compliance with institutional policies and procedures, and applicable federal, state and local laws pertaining to the protection of human subjects in research. The program consists of the following components:

- On-site Review of Human Research Studies
- Post-Approval Quality Assurance (QA) and Quality Improvement (QI)
- Complaints and Concerns Regarding Human Subjects Research or the HRPP
- Review and Assessment of HRPP Operations and Procedures
- Assessment of IRB Members and HRPP Staff
- Research Participants' Survey of Study Experience

## **IV. Specific Components of the HRPP QI Program**

### **A. On-Site Review of Human Research Studies**

Routine (not for-cause) and for-cause reviews of on-site research records provide measures of investigator understanding and compliance with laws, regulations and policies governing the conduct of human subject research. These reviews also provide a measure of the effectiveness of investigator resources, quality and timeliness of Investigator/IRB communication, and access to and awareness of HRPP policies, education and available training opportunities. Review findings are provided to the IRBs for acceptance and/or determination, which may include a corrective action plan and/or a recommendation for additional education and training: [On-Site Reviews of Human Research Studies](#)

## **B. Post-Approval Quality Assurance and Quality Improvement**

An important element of quality assurance review of clinical research activities is performed by the QIP through the processing and review of all post-approval reports submitted to the IRB. Research study reports include adverse events, protocol violations, deviations and incidents, as well as any updated study safety information. This review enables the IRBs to identify potential significant new risks, re-evaluate the risks and benefits of the research, ensure that adequate safeguards are in place, and determine whether subjects should be informed of new information.

## **C. Complaints and Concerns Regarding Human Subjects Research or the HRPP**

The QIP is responsible for the processing, review and inquiry into all complaints and concerns that are brought to the attention of the IRB/OPRS regarding human subjects research conducted at UCLA and/or by UCLA HRPP personnel. Complainants may include, but are not limited to subjects (past, present or potential), subject family members, investigators, other research staff, or any person with concerns.

## **D. Review and Assessment of HRPP Operations & Procedures**

Review and Assessment is based upon:

1. Feedback from investigators regarding satisfaction with the IRB review process and services.
2. Audits of the IRB files to measure compliance with HRPP and other institutional policies and procedures, as well as applicable federal, state and local laws.
3. Statistics showing IRB activities and timelines
4. Feedback on educational and training programs and materials.

## **E. Assessment of IRB Members and HRPP Staff**

1. IRB Members are assessed on an annual basis based upon meeting participation, preparedness, quality of review, and knowledge of UCLA policies and federal regulations. Individual educational needs are identified and forwarded to the HRPP Education Program.
2. HRPP Staff receive annual evaluations, constructive feedback, and individual educational needs are identified with their supervisor.

## **F. Research Participants' Survey of Study Experience**

Direct feedback from research participants provides an opportunity for the HRPP to review and assess subjects' considered opinions and assessment of their experience at UCLA and whether they believe that their rights and welfare were protected in accordance with federal regulations and institutional policies governing the conduct of human subject research.

## **V. Annual Reporting**

The HRPP QIP will prepare an annual report of its activities. The report will also include an evaluation of the previous year's improvement activities and describe planned improvement initiatives. The report will be forwarded to the Vice Chancellor and AVC for Research, the Human Research Policy Board, IRB Chairs/members and the faculty OPRS Oversight Committee for review and comment.