Monitoring/Quality Improvement Unit

The Quality Improvement Unit (QIU) unit of the HRPP conducts post-approval monitoring, education/training and other quality improvement activities. The primary role of the QIU is to monitor the conduct of clinical research to assure the rights and welfare of human research participants and to optimize adherence to federal regulations, state laws, institutional policies and research protocols approved by the UCSF IRB.

QIU Activities:

On-site review of clinical research

Given the large number of studies at UCSF, it is not possible for the QIU to review each study. QIU on-site review activities [1] will focus primarily on studies that do not undergo some degree of formal routine on-site monitoring. The QIU selects studies for review or investigation based on either ?Routine [2]? or ?Directed [3]? criteria**.**

Post-approval QA activities

The QIU processes and manages all adverse events [4], protocol violations and incident reports [5] submitted to the IRB.

Research participant complaints

The QIU manages and investigates (as appropriate) all serious, non-routine research participant complaints [6]. Examples include complaints of study-related injury, safety concerns, violations of participants? rights, problems related to past research participation, etc.

Indirect monitoring of clinical research

The QIU compiles and assesses existing monitoring and reporting data that have been

generated via Data Monitoring Committee or DSMB reports, or cooperative/collaborative audits (i.e., NCI, CALBG, VAMC, etc.) The QIU also monitors publications of UCSF investigators to ensure that proper IRB approvals were in place for these studies.

On-site assessment and training for researchers

The QIU conducts on-site assessment and training when requested by a UCSF-affiliated research team member or the IRB.

Internal QA and QI activities

The QIU conducts periodic, routine QA audits of the IRB/HRPP to assess compliance with federal, state and UCSF policies, identify areas for improvement, and to suggest remedies based on existing policies/procedures and current or projected staffing levels.

Informing the IRB of findings

Based on findings from on-site routine reviews and directed investigation activities, the QIU provides the IRB with:

- Documentation, analyses and reporting of investigatory findings
- Recommendations and corrective action plans
- Construction and/or revision of HRPP guidance
- Development and tailoring of educational materials and training program

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Links
[1] http://irb.ucsf.edu/routine-site-visits-and-directed-investigations
[2] http://hrpp.ucsf.edu/routine-site-visits-and-directed-investigations#rsv
[3] http://hrpp.ucsf.edu/routine-site-visits-and-directed-investigations#directed
[4] http://irb.ucsf.edu/adverse-event
[5] http://hrpp.ucsf.edu/protocol-violation-or-incident
[6] http://irb.ucsf.edu/responding-and-reporting-research-related-concerns-and-complaints