13.0 Quality Improvement in the HRPP Program

13.1 Definitions

Quality Improvement: A process initiated to develop/enhance a practice or procedure and to institutionalize the practice or procedure.

Audit: A systematic review, inspection, or verification, typically conducted by an independent individual or group.

Routine (Not-for-Cause) **Review:** An assessment or examination of something (e.g., a practice or procedure) with the possibility or intention of instituting change if necessary.

Directed (For-Cause) **Audit/Review:** An audit of research and/or Investigators initiated at the request of the Institutional Review Board (IRB) or Institutional Official to obtain or verify information necessary to ensure compliance with regulations and Institutional requirements and to inform Institutional Officials and the IRB about decisions on the conduct of human subjects research and/or human subjects protection.

13.2 Scope of QI Program

The QI program focuses primarily on reviewing and monitoring of the activities, policies, procedures, and records for the following groups:

- Investigators and research staff participating in human subjects research
- IRB
- Individuals involved in HRPP education and outreach

13.3 QI Program Goals

The purpose of the HRPP QI program is to verify and promote the following:

- Protection of the rights, welfare, and safety of human subjects participating in research at the Pennington Biomedical Research Center
- Compliance with federal, state, and institutional requirements governing human subjects research
- Integrity of university research and HRPP activities
- Education and training of researchers, including administrators, Investigators, research staff, IRB members and faculty involved in human research
- Evaluation and follow-up of QI initiatives and corrective actions and implementation of new quality improvement activities
- Implement a QI plan that periodically assesses the compliance of the HRPP

13.4 Development and Review of QI Activities

The HRPP Director is responsible for drafting proposals for HRPP QI initiatives after review of the regulations, guidance, and findings from previous HRPP QI projects, in consultation with the IRB Chair.

13.5 Implementation of QI Activities

The HRPP Director is responsible for the implementation and communication of HRPP QI activities. Information and accompanying materials will be posted and made available on the HRPP website, as applicable. The Institutional Official or designee will set an effective date for implementation of new projects. When a HRPP QI initiative represents a significant change to existing processes or practices, the effective date will be set to allow for communication, including education and planning for operational changes.

13.6 QI Program Maintenance

The HRPP Director is responsible for maintaining the HRPP QI program. The IRB Chair will review program findings and ongoing HRPP QI initiatives as needed, at least annually. Specific findings from directed reviews will be forwarded to the IRB Chair, Pennington Biomedical Research Center QI Committee and/or the Institutional Official. Program initiatives will be developed (as described above) and/or updated as HRPP needs are recognized or changed.

13.7 QI Plan

13.7.1 Compliance Monitoring

The HRPP Staff conduct periodic and for-cause compliance audits to evaluate adherence to applicable federal regulations, state and local laws and Pennington Biomedical policies and procedures.

13.7.2 For-Cause Compliance Audits

For-Cause Compliance Audits may be conducted by the HRPP, IRB or other Institutional designees. These designees may be directed to conduct an assessment in response to a particular concern. Concerns that may prompt a for-cause audits include but are not limited to:

- Failure of routine audits
- Complaints or concerns initiated by a research participant, family member or research staff

- Reports of serious or repeated non-compliance
- Results of audits or monitoring conducted by the following sources: internal and external monitoring, NIH, and FDA audits

13.7.3 Periodic Compliance Audit of Protocols

Periodic Compliance Audits are conducted using systematic methods to assess Investigator and IRB compliance with federal regulations, local laws and Pennington Biomedical policies and procedures. A random selection of Investigator's human subject research records and consent forms are reviewed during these audits for compliance. The following information is reviewed and reported to the IRB:

- IRB file review – documentation of consent form modifications, adverse events, deviations, protocol modifications, monitor letters and continuing review documents
- Subject case file review – subject files contain proper documentation of adverse events, inclusion/exclusion criteria, concomitant medications, enrollment/termination, subject history, lab results, progress notes, physical assessments, drug/device information records, case report forms, source documents
- Consent/Assent/HIPAA for subjects – consent form in subject file, consent form signed and dated, IRB approved consent used, informed consent obtained prior to start of procedures, correct signatures obtained
- Protocol Adherence – inclusion/exclusion, study procedures performed as designated in protocol, approved concomitant therapy followed, protocol adherence requirements met
- Safety Monitoring – adverse events recorded appropriately, serious adverse events reported to the IRB
- Drug/Device Accountability – adequate record of receipt, dispensing/return records, drug used as per protocol, all authorized personnel appropriately signed for release of drug, IND drug record, administration of drug records present and appropriate

13.7.4 Reporting of Compliance Monitoring Results

Results of for-cause and periodic monitoring activities are documented and reported to the IRB, the PI and any other units within Pennington Biomedical as appropriate. The Institutional Official or designee are notified, if the results include non-compliance or other findings pertinent to Institutional Officials. The IRB will review these activities and decide the following:

- The periodic or for-cause audit shows only minor concerns, possible action(s) the IRB may consider:
    - The IRB may do nothing other than notify the PI of the findings
    - Ask the PI to formulate an action plan
    - The IRB may ask for re-education of the PI and staff
    - The IRB may mandate the study continued to be monitored to ensure process improvements were made.
- If the for-cause audit shows major concerns, the convened IRB will evaluate the concern to see if it meets the definition of non-compliance (see Policy 10 – Complaints and Compliance) and act according to the policy. Other actions the IRB may consider:
    - Ask the PI to formulate an action plan
    - The IRB may ask for re-education of the PI and staff
    - The IRB may mandate the study continued to be monitored to ensure process improvements were made.
    - Ask for modifications to the protocol/consent

13.7.5 Periodic Compliance Audit of IRB Minutes

Periodically the IRB completes an internal audit of the meeting minutes to ensure that all items listed in Policy 4 - Documentation and Records, are included in the IRB minutes. A quarterly report will be submitted to the convened IRB for discussion. Process improvements based on these audit results will be considered. Actions the IRB may consider:

- Change policies and procedures to address problems not documented in the minutes.
- Re-educate IRB Members and Staff on policies and procedures

13.7.6 Research Community Feedback Tracking

The HRPP office tracks comments, questions and issues received from participants to identify areas for potential improvement in the effectiveness of HRPP policies and procedures and for ensuring the protection of human subject research participants. The IRB staff will bring any serious and continuing complaints to the convened IRB for discussion. The IRB will rely on the policy and procedures defined in HRPP Policy 10 Complaints and Non-Compliance.

13.7.7 IRB Performance Metrics

The HRPP Director produces periodic metrics and analysis of the IRB operations and functions, including measurements of processing times and activity volumes for the IRB and for each protocol event.

13.7.8 Continuous Quality Improvement

Based on the results of the assessments and feedback received from communities served by the IRB, the HRPP office will work in partnership with the IRB and other components of the HRPP to:

- identify root causes of problems
- foster the development of solutions
- implement or recommend appropriate courses of action
- provide education and outreach programs
- evaluate effectiveness of solutions/outcomes