Subject: HRPP Compliance Activities

Definitions:

1. Continuous Quality Improvement (CQI): A methodology employed by the HRPP Teams, when needed, to improve existing processes by identifying the root cause of a problem, developing and implementing an action plan, and evaluating the outcome to assure problem resolution. The PDSA cycle incorporates the following process: Plan, Do, Study, Act.

2. Directed Audit: These audits are conducted by the HRPP Regulatory Compliance Analysts (RCAs) to assess the Investigator’s compliance with federal regulations, state and local laws, and HRPP policies and procedures. These audits of IRB approved research studies are in response to identified concern(s). Concerns may be identified by an IRB Committee, an external source (e.g. OHRP, FDA or Sponsor), or an internal source (e.g. participant, family member, or Institutional personnel).

3. Periodic Compliance Review: Random assessments of the internal HRPP department and external departments or sites involved in the conduct of human subjects research at VU and VUMC conducted by the HRPP Regulatory Compliance Analysts (RCAs). These reviews are used to evaluate proper execution and accurate documentation of an IRB approved research project. Internal compliance reviews monitor the adherence to federal regulations, state and local law, and HRPP policies and procedures as well as accurate documentation in the HRPP database. External compliance reviews monitor the adherence to federal regulations, state and local law, HRPP policies and procedures, adherence to the study protocol, accurate documentation and reporting of study related activities, and evaluation/observation of the informed consent process.

4. Quality Assurance Reviews: Quality Assurance reviews are performed by the HRPP Teams to verify that the electronic database is consistent with HRPP policy and procedure.

Policy:

It is the policy of the Human Research Protection Program to oversee all internal and external compliance reviews and/or auditing efforts in order to assure the protection of human research participants and compliance with federal regulations, state and local law as well as HRPP policies, procedures, and VU and VUMC's Assurance with OHRP.

I. Initiation of Audit/Review. The HRPP Director, the HRPP Medical Director, and/or the Chairpersons of the IRB Committees may direct the HRPP RCAs or designee to initiate periodic compliance reviews and/or directed audits when deemed necessary. The HRPP has the authority to observe or appoint a designee to observe the informed consent process of IRB approved research.

II. External Consultant. The HRPP may engage an external consultant with a specific area of expertise to perform or assist with any of the above-defined auditing and reviewing activities.

III. External Sites. Directed audits and periodic compliance reviews are conducted by the HRPP RCAs at non-VU or VUMC sites where the HRPP's IRBs serves as their IRB of Record.
IV. **Verification of Information.** The HRPP will assure that no material changes in the IRB approved study have occurred since the previous review by performing directed audits and periodic compliance reviews for verification. The HRPP must determine which projects require verification from other sources other than the Investigator to ensure that no unapproved changes have occurred since the previous IRB review.

V. **Reporting of Monitoring and/or Auditing Results.** The results of any monitoring or auditing activity by the HRPP are reported in writing to the HRPP Director, the HRPP Medical Director, and the Chairperson of the IRB Committee responsible for the review of the study. The IRB Chairperson determines the need for full IRB Committee review. If the monitoring or auditing activity finds that a human subject participating in a research project has been exposed to unexpected serious harm, the HRPP RCA will promptly report such findings to the HRPP Director, the HRPP Medical Director, and the Chairperson of the IRB Committee responsible for the review of the study. In addition, the study is placed on the agenda of the next regularly scheduled meeting for discussion.

VI. **IRB May Suspend or Terminate Research.** If the information gained during the monitoring or auditing process indicates that human subjects of a research project were exposed to unexpected serious risk or harm, or that the policies of the HRPP were not met, the IRB may suspend or terminate the research (See HRPP Policies II.B and II.C).

VII. **Safety Monitoring.** The IRB may request additional safety monitoring or the creation of an independent data safety monitor (See HRPP Policy VI.E for reporting requirements).

VIII. **Additional Requirements for Activities Involving Vulnerable Populations.** For activities involving vulnerable populations such as fetuses, pregnant women, human in vitro fertilization, prisoners, children, or the cognitively impaired, the IRB determines if adequate provisions have been made by the Investigator for protection of these vulnerable populations and for monitoring the actual informed consent process.

IX. The HRPP will conduct continuous quality improvement (CQI) and quality assurance (QA) activities to assure the best possible practice is conducted in HRPP operations.

References:
45 CFR 46
21 CFR 50&56
HRPP II.A.1 - Procedure for HRPP Compliance Activities
HRPP II.B - Suspension, or Termination of IRB Approval
HRPP II.C - Investigating Any Non-Compliance, Serious, or Continuing Non-Compliance
HRPP IV.E - Approval and Expiration Dates on Informed Consent Documents