Subject: Procedure for HRPP Compliance Activities

Procedure:
The purpose of this procedure is to outline the processes for conducting compliance reviews and audits by the HRPP.

I. Investigator Responsibilities.
A. Directed Audit.
   1. Investigators will cooperate with the HRPP by making him/herself available for questions, having documents accessible, and responding to any written requests within the time frame designated by the HRPP in association with a directed audit. Written preliminary audit results are provided to the Investigator to facilitate understanding of the process and collaboration in resolving any outstanding issues/concerns. The PI or designee will be present for an exit interview that will occur following each directed audit.
   2. Investigators will abide by all IRB Chairperson or his/her designee and/or full IRB Committee determinations. These determinations may include developing and following a corrective action plan and/or an educational plan and completing it in the time specified by the Committee.
   3. The Investigator may request or may be requested to attend a full IRB Committee meeting to present information addressing any concerns resulting from a directed audit, as well as any determination rendered by the full IRB Committee.

B. Periodic Compliance Review.
   1. Investigators will cooperate with the HRPP by making him/herself available for questions, having documents accessible, and responding to any written requests within the time frame designated by the HRPP in association with a compliance review. The preliminary findings are communicated to the Investigator to facilitate understanding of the process and collaboration in resolving any outstanding issues/concerns. The PI or designee will be present for an exit interview that will occur following each compliance review.
   2. Investigators will address the recommendations suggested by the Process Improvement Team or the IRB and submit responses within a timely manner.

II. IRB Committee Responsibilities.
A. Directed Audit.
   1. Directed audits may be requested to assess compliance with local, state, and federal laws, participant safety, and HRPP policies and procedures.
   2. Determining the need for such additional supervision or participation by the IRB is made by the IRB on a case-by-case basis during the initial and continuing review, or as new information is presented.
3. Upon receipt and review of the directed audit summary, the IRB Committee may:
   a) Accept the audit report with or without revisions to the currently approved study;
   b) Impose additional measures for participant safety;
   c) Create an education plan recommended by the HRPP; or
   d) Accept the audit report and:
      (1) Request for an RCA to gather additional information; and/or
      (2) Refer to the Optimization Committee for consideration of a “Suspension for Cause”, if applicable (See HRPP Policies II.B and II.C).

4. The Committee will outline any recommendations in a letter to the Investigator.

5. At the direction of the HRPP Medical Director and the HRPP Director, or IRB Committee, the HRPP may engage an expert consultant to perform or assist with any of the auditing and reviewing activities.

B. Periodic Compliance Reviews.
   Periodic Compliance Reviews are conducted using a systematic method to review IRB approved research or IRB records/activities on a regular basis. Results of all periodic compliance reviews are reported to the HRPP Director and the Chair of the IRB Committee associated with the study. Results of these activities are placed on the appropriate Committee’s agenda.

III. HRPP Regulatory Compliance Analyst Responsibilities.
   A. Directed Audit.
      1. An RCA will contact the Investigator to schedule the on-site visit.
      2. An RCA will conduct a focused or comprehensive audit contingent upon consideration of the request and preliminary evaluation.
      3. Conclusion of audit activities.
         a) The RCA will document the preliminary findings in writing as well as specific recommendations.
         b) At the conclusion of the directed audit, an exit interview with the Investigator(s) or his/her designee will be conducted to discuss the preliminary findings to facilitate the Investigator’s understanding of the process and collaborate in resolving any outstanding issues or concerns.

   4. Reporting Activities.
      a) Findings will be distributed to the HRPP Director, the HRPP Medical Director, and the Chairperson of the IRB Committee responsible for the study.
      b) All audit summary reports will be placed on an agenda for full Committee review and a determination.

   5. Documentation.
      a) The information will be entered into the database by creating an audit, selecting “directed”, completing relevant information and attaching all pertinent documents electronically.
      b) A review history will be entered into the database and will reflect the type of review required.

B. Periodic Compliance Review.
   1. An RCA will perform random periodic compliance reviews.
   2. An RCA will perform one internal compliance review within the HRPP.
a) The compliance review will be conducted to assure accurate processing of studies, e.g. expedited, exempt and full committee reviews.
b) The RCA may utilize the CQI methodology to conduct the compliance review.
c) The RCA will draft a review summary, which will include a summary of the findings, as well as specific recommendations.
d) The information will be entered into the database by creating an audit, selecting “periodic”, completing relevant information and attaching all pertinent documents electronically.
e) A summary of findings will be distributed to the HRPP Director. The information will be discussed at an HRPP staff meeting and/or Optimization Committee meeting when necessary.
f) Individual teams may also conduct their own compliance reviews utilizing the CQI methodology.

C. Non-VU or VUMC Institutional Directed Audits and Compliance Reviews.
   1. External directed audits and compliance reviews are conducted by the HRPP at Non-VU or VUMC sites where the VUMC IRB serves as the IRB of Record. These reviews will be conducted in accordance with the procedures detailed above. Additionally, assuring proper recruitment, space, facilities, qualified staff, enrollment, and execution of the consenting process will be reviewed.
   2. The on-site visits will also entail review of documentation required when applying for a Memorandum of Understanding including but not limited to:
      a) Verification of up-to-date comprehensive general liability and professional liability for all Investigators and research staff;
      b) Correct titles and degrees for all research staff;
      c) Verification of whether the Investigators or key study personnel have Vanderbilt faculty status;
      d) Verification of the Investigators and key study personnel’s qualifications;
      e) CVs for all Investigators and key study personnel;
      f) Verification that all Investigators and key study personnel have completed the CITI Training program;
      g) Documentation of the local research context;
      h) Names and phone numbers of the local contacts for each non-Vanderbilt site;
      i) Certificates of completion for the 3 OHRP training modules by the Human Subject Protections Administrator and the Institutional Signatory Official. A certificate of completion for each of the 3 sections must be retained.

D. Quality Assurance (QA) Reviews
   1. Each month at least 20 QA reviews will be performed across all IRB teams.
   2. HRPP department files will be selected randomly from all active protocols.
   3. A quality assurance (QA) form will be completed for each file selected and the QA activity will be documented in the database.

IV. General Responsibilities.
A. If while conducting a directed audit or compliance review the auditor finds an issue that potentially places participants at risk, they will report the findings immediately to the HRPP Director, the HRPP Medical Director, and the Chairperson of the IRB Committee responsible for the study.

B. All HRPP activities are reviewed on a monthly basis by the HRPP Director and Manager(s) to assure oversight program objectives are conducted in accordance with policies and procedures and the compliance plan.

C. The HRPP senior leadership team reviews a summary of all HRPP activities and outcomes on a quarterly basis to identify opportunities for improvement. Item reviewed may include:

1. Trends in compliance review/audit findings;
2. Customer (internal/external) feedback;
3. Volume of research and demographics of the studies (where, who, phase, etc.);
4. Participant complaints; and
5. Any other HRPP data relevant to the performance of HRPP activities.

References

HRPP II.A - HRPP Compliance Activities