Institutional Review Board
Post Approval Monitoring Policy

Virginia Tech is committed to ensuring the rights and safety of human subjects participating in research by its faculty, staff and students. The Office of Human Research Protections (OHRP) within the Department of Health & Human Services (DHHS) has approved Virginia Tech’s Federal wide Assurance. The University’s Institutional Review Board (IRB) serves as a mandated surrogate for and reports to the OHRP. As such, the IRB has the authority and responsibility to initially approve and subsequently monitor human subject’s research activities to confirm compliance.

Post-approval monitoring of previously approved protocols provides assurance to the IRB and to the institution that researchers, staff, and students are conducting their activities in accordance with their respective IRB approved protocols, and are thus complying with applicable local, state, and federal regulations. In a large, decentralized institution such as Virginia Tech, post approval monitoring of randomly selected or specifically targeted protocols will help the IRB assess Principal Investigator (PI) compliance.

Since non-compliance with federal regulations may result in loss of significant federal research funding, or imposition of more severe penalties, it is the position of this institution that compliance monitoring of approved human subject’s research is mandatory. Investigators who use human subjects in research must cooperate and participate in this process.

The Post-Approval Monitoring (PAM) Officer serves the University as compliance liaison between the research community, the IRB, and the Office of Research Compliance. The PAM Officer will be a primary resource in assessing and facilitating compliance by providing inspections of research records, laboratories, and procedural techniques. These inspections (audits), referred to as “reviews”, will be utilized as a tool to assess and improve our human subject’s research program by identifying areas requiring further attention, and to identify and rectify problem areas which, if left uncorrected, may result in sanctions against the university if identified during federal inspections.
Areas of non-compliance will be identified and remediation will be discussed with the research staff involved on the protocol being assessed. Training will also be made available as needed to rectify deficiencies. Timelines will be established for remediation of action items, and follow-up monitoring and mentoring will be provided in all cases where deficiencies are identified. The IRB will receive monthly reports of the activities and findings of the Post-Approval Monitoring Officer.

Cooperation and active participation in research compliance must be a part of normal business in a research and teaching institution such as Virginia Tech. It is the responsibility of every research staff and faculty member to recognize their role in compliance assurance with applicable Virginia Tech and federal requirements. The Office of Research Compliance and the PAM Officer, have instructional resources to increase the research community’s awareness and understanding of their role in compliance.