University of Vermont

Research Protections Office
Institutional Review Boards

Top 10 Obstacles to UVM IRB Approval

1. The IRB is paperless! PI's must submit all protocol materials through the UVMClick system.
2. Misunderstanding of a Waiver of Consent vs. Waiver of Documentation of Consent
   - Waiver of Consent - Not obtaining written or verbal consent. This most often applies to reviewing medical records.
   - Waiver of Documentation - In some research, verbal or implied consent of the subject is sufficient and a signed consent form is not necessary. A typical example would be a mailed survey with a cover letter explaining the research. The receipt of a completed survey implies the participant consented to the research.
3. Not recognizing and explaining common risks and overstating benefits to participants in the consent form.
4. Studies frequently propose participant materials written at a reading level much higher than the national average (7th-8thgrade) when recruiting from the general population.
5. Confusing coded data vs. de-identification.
   - Coded data - Identifying information that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol or combination thereof and a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.
   - De-identification as required by the HIPAA Privacy Rule, involves the removal of the 18 PHI data points from the data.
6. Consent forms missing required elements of informed consent.
7. Discrepancies between the IRB protocol, consent form and other study documents. Lack of consistent document titles or no titles. Missing documents. Discrepant number of subjects. Undefined recruitment plan.
8. When submitting a PI response to a committee review, a point-by-point memo must be submitted along with a revised tracked protocol and consent form.
9. The IRB protocol uses jargon, highly technical or field-specific language, unexplained acronyms or lacks clarity.
10. Not proofreading – typographical errors, disorganized information and lack of attention to detail. Please utilize other key personnel, research coordinators, nurses or faculty sponsors to proofread materials prior to submitting them to the committee.