The University of Vermont

Top 10 Obstacles to UVM IRB Approval

1. The IRB is paperless! PI's must submit all protocol materials through the UVMClick electronic system. https://www.uvm.edu/ovpr/uvmclick-irb
2. Misunderstanding of a Waiver of Consent vs. Waiver of Documentation of Consent
   - Waiver of Consent - Not obtaining written or verbal consent. This usually applies to a review of 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 that the subject wanted to participate.
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 (7^{th}-8^{th}grade) when recruiting from the general population.
5. Confusing confidentiality vs. anonymization vs. de-identification.
   - Confidentiality means restricting access to information that an individual has disclosed in circumstances that the individual can reasonably expect the information will not be made public. The relationship between a researcher and a study participant is ordinarily one of trust.
   - Anonymization is a process that removes information from data that allows recognition of particular individuals. Common strategies for anonymizing data are deleting or masking personal identifiers, such as name and social security number, and suppressing or generalizing quasi-identifiers, such as date of birth and zip code.
   - 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. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/checklists/index.html
7. Discrepancies between the IRB application form, 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. IRB application uses jargon, highly technical or discipline/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 proof read materials prior to submitting to the Committee.