University of Vermont

Research Protections Office
Institutional Review Boards

In working with investigators, the IRB staff have noticed common areas that tend to delay progress when moving protocols throughout the IRB process. Based on these observations, we have outlined a list of questions for you to consider while working your way through the IRB submission process. The goal is to assist you in ensuring the submission is complete and facilitate a smooth IRB process. Please refer to the IRB Policies & Procedures as well as our IRB Forms Library for templates to help you during study development. Keep in mind that no recruitment or research can begin until you receive your IRB approval letter.

Protocol	
Have you clearly stated the hypothesis, objectives or aims?	
Is the study designed to test your hypothesis?	
Have you included your statistical justification for the sample size?	
Participant Population	
Have you included study justification for population and size?	
Have you included the criteria for inclusion and exclusion of participants clearly in the protocol?	
Ensured your screening procedures are well described?	
If vulnerable populations are included, are safeguards for the protection of the rights and welfare of these participants appropriate to include undue influence and coercion?	
For protocols using an investigational drug, appropriate justification must be given to ensure children and women of childbearing potential are included. Consider pregnancy testing and contraception requirements as needed.	
Recruitment of Participants	
Is the process of recruiting participants equitable for the protocol? Have appropriate efforts been made to include women, children, and minorities?	
Does the recruitment material provide enough information about the protocol? Ensure the word “research” is included in the participant facing materials.	
Methods and Procedures	
Have you included all the research procedures for the study such as, blood draws, scans, and survey instruments?	
Have you described all the research procedures? Ensure the consent form distinguishes between procedures that are for research only vs. standard practice.	
If deception is used, ensure you have included a debriefing consent and reviewed the IRB guidelines.	
Risk and Minimization of risks	
Make sure you describe the risks (physical, psychological, and social risks) in both the protocol & consent form.	

Have adequate safeguards been adopted to reduce risk exposure as much as possible? (i.e., frequent monitoring, qualified personnel, handling of incidental findings, debriefing procedures, procedures for response to emergency situations including suicidality, mandated reporting, referral resources provided)	
Can you confirm the risks associated with research participation are reasonable in relation to the benefits?	
Have you taken adequate measures to ensure the occurrence of illness or injury will be detected and treated?	
Ensure alternative procedures that might be advantageous to potential research participants have been described.	
If applicable, are reproductive risks adequately described and is appropriate birth control language included? If pregnant participants or partners are to be followed, include a separate consent form	
Anticipated Benefits	
Describe all potential benefits in the consent including knowledge to help others in the future.	
Data Management and Security Plan	
Ensure your research plan adequately provides for monitoring the data collected, ensuring the confidentiality of the participants.	
Include a plan for deidentifying or coding data.	
Will research data be shared outside of the study team? A data use agreement may be needed.	
Make sure the protocol includes information on how long data will be kept and who will have access to it. Describe your plans for the destruction of data and when this will occur.	
Are measures adequately described if harmful information or illegal behavior is discovered? Include your plan.	
If your data (video/audio tapes) will be kept for future, unspecified research, ensure this is appropriately disclosed in the protocol and consent form	
Consent Alteration or Waiver or Waiver of Consent Documentation	
Have you included adequate justifications for requesting an alteration of consent? (phone screening, deception, waiving PI signature, next of kin consent)	
Attach a script of the verbal phone consent (waiver of documentation) for IRB review, this must contain all the elements of consent	
Have you included adequate justification for not obtaining written consent? (waiver of written documentation)	
Have you included adequate justification for why obtaining consent is not practical or possible? (waiver of consent)	
Consent Form	

Is the description of procedures adequate and have you distinguished between research-only procedures vs. standard practice?	
Risks – Is a complete and clear description with expected frequency provided?	
Are there clear descriptions of the precautions taken to minimize risks?	
Are reproductive risks adequately described and is appropriate birth control language included?	
Discomfort: Adequate plan of action to address support and/or referrals as needed?	
Benefits – Is the description fair and complete?	
Are alternative treatments available? If so, are they listed?	
Are additional costs to participants addressed? Is the templated procurement language included if participant compensation is provided?	
Have you included all of the elements of consent required by the Common Rule per the UVM IRB Consent templates? (i.e. Concise summary section, applicable statements about biospecimens, etc.).	
Have you ensured a 6-8th grade reading level, using lay terminology and avoiding acronyms and complex sentences when possible?	
Is the length of the consent as short as possible to convey the information adequately?	
Have you avoided repetition between UVM and Sponsor template language, when applicable (i.e. HIPAA authorization, confidentiality sections, etc.)?	

Other considerations:

- ✓ Have you completed CITI training? This required online program consists of ethics training modules for research with human participants. LCOM researchers are required to complete both the IRB and GCP training.
- ✓ Students – Have you contacted and worked with your faculty advisor and has the protocol been approved by your advisor? Please note, your Faculty Sponsor will be designated within your Click submission, and they must complete their assigned Ancillary Review prior to the IRB's review of your study materials.
- ✓ Are you requesting reliance on another IRB? Please review our Single IRB page prior to submission.
- ✓ Any potential conflicts of interest? Please ensure you have completed a COI disclosure with UVM.
- ✓ Do you plan to share, receive, or transfer research materials outside of UVM, such as tissues, cell lines or devices? A Material Transfer Agreement may be needed.

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- ✓ Need an agreement, contract, or data use agreement? UVM Sponsored Programs can help.
- ✓ Data use agreements and contracts through the hospital can contact The Office of Clinical Trials.

Prior to submitting through UVMClick ensure you have collected all of the following documents and they are ready to upload if applicable. Please see our Guidance Material and Forms page for each submission to ensure you are using the most up-to-date template versions for protocols and consent forms.

- ✓ protocol
- ✓ consents
- ✓ consent process documentation
- ✓ research instruments (questionnaires, diaries, etc.)
- ✓ all recruitment materials
- ✓ investigator drug or device brochures
- ✓ letters of support from external entities
- ✓ research data management and security plan

All protocols need to be submitted online through the UVMClick system. Please see our Click tip sheets page for help and FAQ's on how to submit electronically.

Have more questions?
Find your assigned Regulatory Research Analyst by UVM department.