Keys to Successful IRB Submissions

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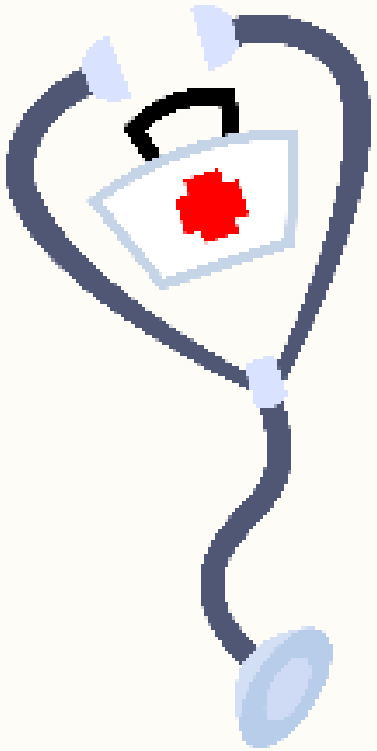
Misunderstanding of a Waiver of Consent vs. Waiver of Documentation of Consent

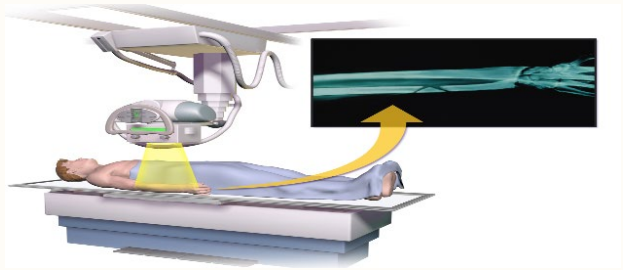
- Waiver of Consent - Not obtaining written or verbal consent. This usually applies to a review of records.
- Waiver of Documentation - In some research, verbal or implied consent of the subject is sufficient and a signed consent form is not necessary. A typical example would be a mailed survey with a cover letter explaining the research. The receipt of a completed survey implies that the subject wanted to participate.

Not recognizing and explaining common risks and overstating benefits to participants in the consent form.

- Risks to participants are minimized whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.
- Some studies will provide no direct benefit and that should be clearly stated.
- If the research study involves a placebo-controlled arm, state clearly that individuals assigned to the placebo group are expected to receive no direct benefit from study participation.

Studies frequently propose participant materials written at a reading level much higher than the national reading average (7^{th}-8^{th} grade) when recruiting from the general population.





- A low level of literacy is independently associated with poor health outcomes
- Consents must be written in clear, direct language. Plain language requires honesty and a good understanding of what to convey
- Use our Plain Language Medical Dictionary to help you craft your consent
- Improve research subject comprehension by using:
  - ✓ Headings
  - ✓ **Bolded type**
  - ✓ Pictures
  - ✓ Tables
  - ✓ Consider using bulleted points to highlight key information.
  - ✓ Keep sentences short and simple.
  - ✓ Do not use fractions or %. Instead, state “1 out of 10 people will…”

Confusing coded data vs. de-identified data

De-identified data - Information that was previously recorded or collected without any of the 18 identifiers as defined by HIPAA, and no code is assigned that would allow data to be traced to an individual.

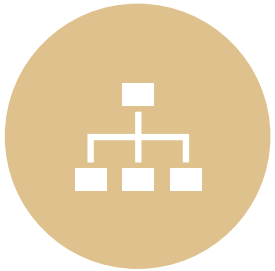
Coded data - Identifying information that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol or combination thereof and a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

Omitting safety monitoring from the protocol

When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.

Does the protocol require a Data Safety Monitoring Board or Plan?

Could the protocol benefit from a Clinical Trial Steering Committee?



Does the protocol have an outside monitoring team?

Not considering special protections for vulnerable populations

Children

Prisoners

Individuals with impaired decision-making capacity such as:

- Dementia (including Alzheimer's)
- Traumatic brain injuries
- Psychoses

Economically or educationally disadvantaged individuals

Utilize the UVM generated Forms

The UVM IRB has created many templated forms to assist researchers in their work.

Consents, protocols, consent documentation

These forms will aide PI's in ensuring federal/state/local regulation language has been submitted.

Forms are frequently updated with new regulations and questions – use the most recent forms from our form's library

No need to reinvent the wheel

Omissions in the IRB submission

- protocol
- consents
- consent process documentation
- research instruments (questionnaires, diaries, surveys etc.)
- all recruitment materials (flyers, newspaper ads, social media recruitment etc.)
- investigator drug or device brochures
- letters of support (LOS) from external entities (schools, prisons, listserv)
- research data management and security plan

Work with Faculty Sponsors prior to submitting to the IRB

All research conducted by students/trainees, including postdoctoral fellows, must include a faculty sponsor as a member of the study team.

In addition to the expectation that the faculty sponsor offer active mentorship to the student during the conduct of the research, the faculty sponsor shares responsibility with the student/trainee researcher for the ethical conduct of the research and is institutionally accountable for the study.

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Institutional Review Board for Human Subject Research

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?	
Subject Population	
Have you included study justification for population and size?	
Have you included the criteria for inclusion and exclusion of subjects 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 subjects appropriate to include undue influence and coercion?	
For protocols using an investigational drug, appropriate justification must be givento ensure children and women of childbearing potential are included. Consider pregnancy testing and contraception requirements as needed.	
Recruitment of Subjects	
Is the process of recruiting subjects 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 subject facing materials.	
Methods and Procedures	
Have you included all the research procedures for the study such 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 described 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 that alternative procedures that might be advantageous to the potential research subject have been described	

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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 sepearte consent form	
Anticipated Benefits	
Describe all potential benefits in the consent including knowledge to help others in the future.	
Data Management Plan/Confidentiality	
Ensure your research plan adequately provides for monitoring the data collected, ensuring the confidentiality of the subjects.	
Don't forget to include a plan for deidentifying or coding data.	
Make sure your protocol includes information on how long data will be kept and who will have access to it. Describe your plans for destruction of data and when will this 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 for IRB review, this must contain all the elements of consent	
Have you included adequate justification for not obtaining a 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 subjects addressed? Is the templated procurement language included if subject 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. Key Information 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.)?	

Consent summaries are not always concise……

What is considered “key information”?

- The fact that consent is being sought for research and that participation is voluntary
- The purposes of the research, the expected duration of the prospective subject’s participation, and the procedures to be followed in the research.
- The reasonably foreseeable risks or discomforts to the prospective subject
- The benefits to the prospective subject or to others that may reasonably be expected from the research
- Appropriate alternative procedures or courses of treatments, if any, that might be advantageous to the prospective subject.

All faculty involved in the conduct of research with human subjects, regardless of funding source, must complete training through CITI for non-exempt research.

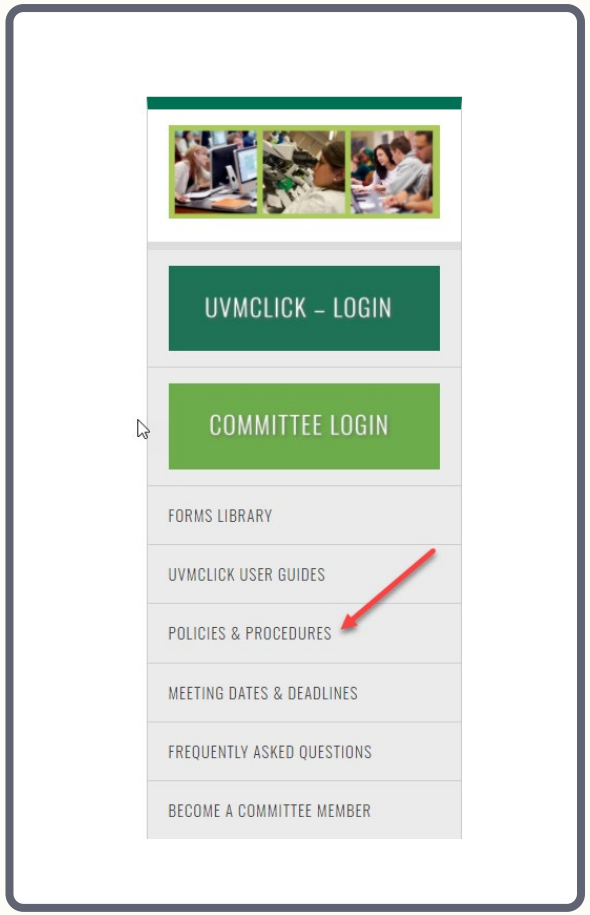
Take one of the following to meet the training requirements for Human Subjects Research:

- Medical researchers should take Biomedical Research
- Social or Behavioral researchers should take Social Behavioral Education Sciences

*LCOM key personnel or protocols meeting the NIH definition of a clinical trial must also take Good Clinical Practice Training

Policies and Procedures Manuals

The IRB has an extensive P&P manual containing guidance on protocol submissions to the institutional boards.



Criteria for IRB Approval of Research

Name	Position	Email	Phone
Clas, Aubrie	Assistant Director for Administrative Operations, IRB, IACUC, IBC	Aubrie.Clas@uvm.edu	802-656-1282
Crain, Karen	Research Review Analyst, IRB	Karen.Crain@uvm.edu	802-656-5025
Dulin, Jennifer	Research Review Analyst, IRB	Jennifer.Dulin@uvm.edu	802-656-4179
Guayasamin, Ryann	Research Review Analyst, IRB	Ryann.Guayasamin@uvm.edu	802-656-8162
Locher, Melanie	Assistant Director for Monitoring and Education, IRB, IACUC, IBC	Melanie.Locher@uvm.edu	802-656-5249
Silver, Donna	Director	Donna.Silver@uvm.edu	802-656-8804
Wright, Sarah	Research Review Analyst, IRB	Sarah.Wright@uvm.edu	802-656-8144

Contact the RPO staff with questions prior to submitting to the IRB