Keys to Successful IRB Submissions

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Initial Review

The following materials are required for initial review of all types of research:

- Completed human subjects protocol or Exempt form

Required if Applicable to the Study

Social-Behavioral Research Components

- Investigator-authored or standardized Psychological or Educational M
- Investigator-authored or standardized Surveys, Questionnaires

Biomedical Research Components

- Investigator's Drug Brochure or Package Insert
- Device Brochure and/or other device information

Other

- Recruitment and Screening materials
- Informed Consent Document(s)
- Data Management and Security Plan
- Study surveys/questionnaires
- Letters of support
- Privacy Policies for Apps and Databases
- Participant Study Brochures
- Wallet Cards
- Any other participant-facing material or documentation the Investigat pertinent

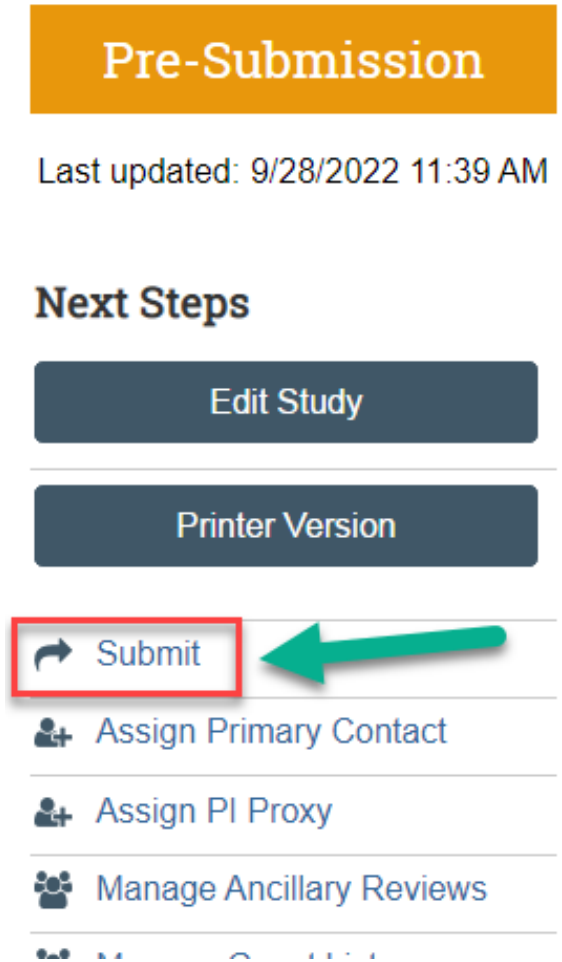
Guidance Materials

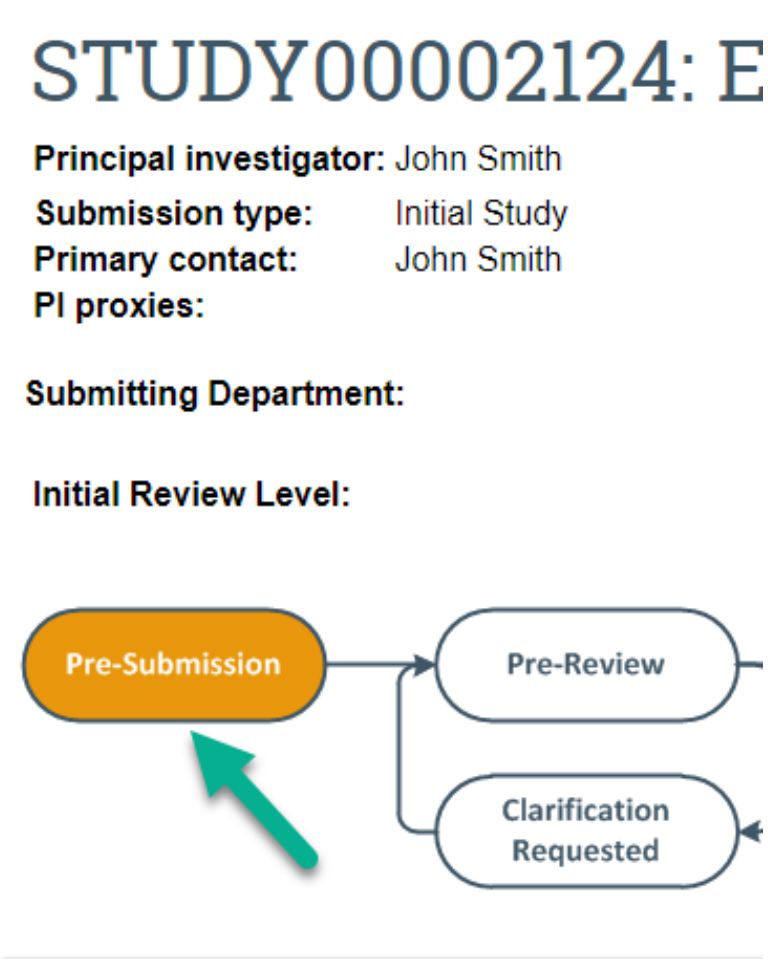
Required for IRB Review and Approval

UVMClick user guides

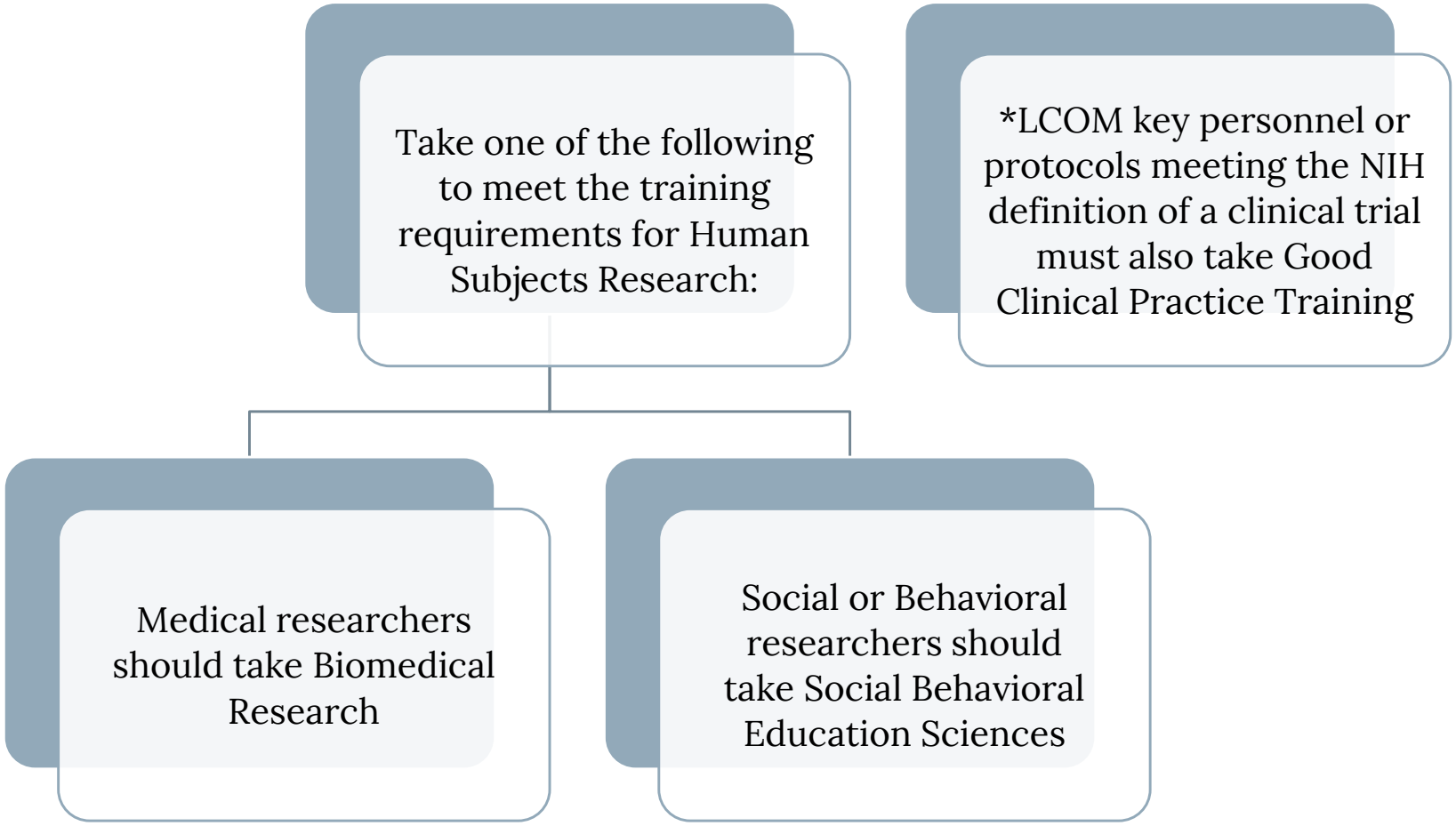
Step-by-Step Documentation for Researchers

UVMClick is where UVM researchers and administrators will manage the lifecycle of IRB Protocols, IACUC Protocols, IBC Registrations, COI Disclosures, Proposal Submissions, Awards and Agreements.





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



Utilize the UVM IRB 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

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

Waiver of Consent - Not obtaining written or verbal consent. Generally used for secondary analysis, i.e., retrospective review of hospital PHI.

Waiver of Documentation - In some very minor risk research, an informational sheet without signature is sufficient. Written signed consent is not necessary.

i.e., research survey/questionnaire is presented with an informational sheet explaining the research, no written signatures are obtained but the participant is still consented verbally.

- 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.

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

Studies frequently propose participant materials written at a reading level much higher than the national reading average (7th–8th 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.

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

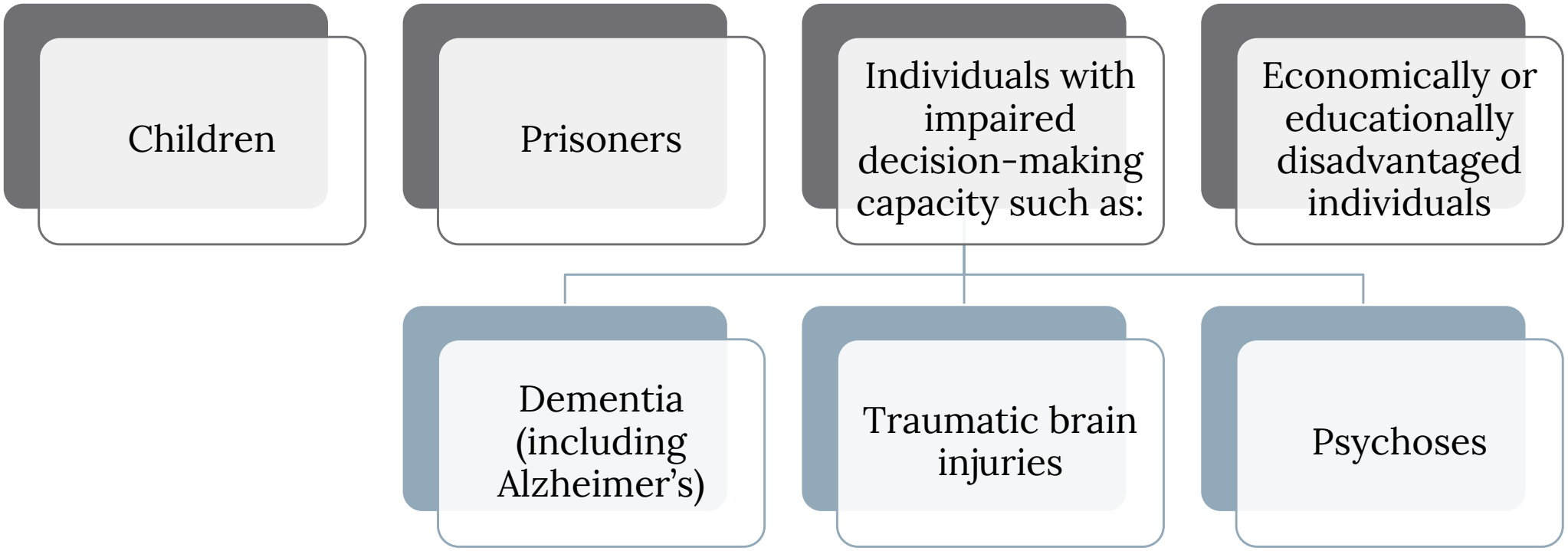
When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.

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



The University of Vermont

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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Checklist for New Studies

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.

Criteria for IRB Approval of Research

To approve research under *45 CFR 46.111* or *21 CFR 56.111*, the UVM convened IRB or designated reviewer using the expedited procedure must determine that the research satisfies all the requirements set forth below. The criteria for review must be used to approve research for initial review, continuing review, and review of modifications.

Risks to Participants

1. Risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk.
2. Risks to participants are minimized whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.
3. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.

Selection of Participants

1. Selection of participants is equitable taking into account the purposes of the research, the setting in which the research will be conducted, the special problems of research involving vulnerable populations, the selection criteria, and the recruitment procedures.

Safety monitoring

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

Privacy

1. When appropriate, there are adequate provisions to protect the privacy of participants.

Confidentiality

1. When appropriate, there are adequate provisions to maintain the confidentiality of data.

Vulnerable populations

1. When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards are included in the study to protect the rights and welfare of these participants. (Note: Subpart B of the DHHS regulations specifies additional protections for pregnant women; Subpart C of the DHHS regulations, for prisoners; and Subpart D of the DHHS and FDA regulations, for children.)

Consent

1. Consent will be sought from each prospective participant or the participant's legally authorized representative in keeping with the criteria outlined below.

General Responsibilities of Principal Investigators

Obtaining and documenting informed consent of subjects or subjects' legally authorized representatives prior to the subjects' participation in the research, unless these requirements have been waived by the IRB (45 CFR 46.116; 45 CFR 46.117);

Obtaining prior approval from the IRB for any modifications of the previously approved research, including modifications to the informed consent process and document, except those necessary to eliminate apparent immediate hazards to subjects (45 CFR 46.103(b)(4)); and

Ensuring progress reports and requests for continuing review are submitted to the IRB in accordance with the policies, procedures, and actions of the IRB as referenced in the institution's OHRP-approved Federal wide assurance (45 CFR 46.103(b)(4), 45 CFR 46.109(e), 45 CFR 46.115(a)(1)).

Educate and Prepare

- Learn how to properly consent a research participate
- Prepare a regulatory binder for protocol compliance documents
- Review IRB education slides on specific topics (children, prisoners, non-English speakers) to can ensure compliance to federal/local regulations
- Attend trainings through OCTR on protocol management or data collection in RedCap
- Consult the UVM IRB Policy and Procedure Manual with questions
- Contact your IRB regulatory analyst with questions