

Most Frequent Errors for Full Protocol Human Subjects Research

1. Not reading the instructions on the website for conducting research at USAFA.
2. Submitting a protocol to the USAFA HRPP that has an existing determination from another HRPP/IRB.
3. Not reading the instructions at the end of the HRPP Determination Request form.
4. Not providing a power analysis or other rationale for the sample size requested. Not making clear what the maximum number of participants requested is.
5. Not stating procedures that will be in place to deal with the diminished autonomy of cadet subjects.
6. Not securing resource support before submitting the HRPP Determination Request.
7. Not providing training certificates or resumes for all investigators.
8. Not obtaining required signatures.
9. Numerous errors both typographical and grammatical. Spell check is NOT ENOUGH.
10. Not completing all questions on the HRPP Determination Request form.
11. Not writing out all acronyms before using the abbreviated form (e.g. write out Department of Behavioral Sciences and Leadership before using the abbreviation DFBL).
12. Not describing how the data will be stored and disposed of.
13. Not adequately summarizing what the risks and benefits are, and why the benefits outweigh the risks.
14. Making inquiries to HRPP Support Personnel that are incomplete or inappropriate. Inquiries must include the protocol title and number and must be from a named investigator.

Specific Informed Consent Document (ICD) Errors

1. Not reading the instructions for completion at the end of the ICD.
2. Not removing investigators' ranks in "Who is doing the study?" section.

3. Not including the total number of subjects and total time required to participate in “What is the purpose of the study?” section. Not making clear what the maximum number of participants requested is.
4. Not writing out the procedures in layperson’s terms.
5. Not including the DF subject pool language, when it is appropriate, that is provided in the instructions for the Compensation section.
6. Listing indirect benefits in the “Will You Benefit...” section. The section should only contain direct benefits. If there are no direct benefits, then say, “There are no direct benefits from participation in this study.” Examples of direct benefits are personal fitness information, and genetic medical information. Indirect benefits are advancing scientific knowledge, and positive change at USAFA.
7. Not including the time required to participate as a risk or discomfort in the study.
8. Not proofing the ICD for misspellings, font changes, etc. An ICD is a legal document and will not be accepted with typos or other errors.
9. Inconsistencies between the protocol and the ICD, especially for the protocol Study Methods section and the ICD “What will you be asked to do?” section. Examples are inconsistency in number of subjects and the time for participation.
10. Not adding sections identified at the end of the instructions that apply to the research.