

Application for the Use of Human Subjects - Part II

Please address each numbered item in the order given. Incomplete applications will be returned to the principal investigator. If there are sections that are not applicable to your research, please explain why. Use the following as your guide:

1. Name the principal investigator. Describe his/her qualifications and any relevant experiences; ***attach a copy of the vitae of the principal investigator and faculty sponsor, if appropriate.*** If a student has been identified as the principal investigator, the role of the faculty sponsor(s) in guaranteeing compliance with the procedures outlined in this application as well as compliance with the regulations governing the use of human subjects must be mentioned.

Faculty sponsors should meet with student researchers to review human subjects protection and to monitor data collection.

2. Explain the procedures involved to carry out your ***in detail.*** What is the overall goal of your study and what are your specific objectives? What will you do? What will the subjects do? A list of the steps in your study is often helpful. It is important that you describe your research protocol in enough detail that an uninformed reader can understand what is involved in your research project.
3. Describe the individuals who will participate in your study, noting their age (or age ranges), gender, ethnic background, and health status (if known). Mention other characteristics that make your subjects identifiable (for example, “elderly males living in supervised living arrangements in rural Chautauqua County”). There are protected classes of subjects (i.e., pregnant women, children under the age of 18 years, individuals with disabilities, prisoners, and any individual viewed as vulnerable). If your subject pool includes members of these protected classes or has the potential for inclusion of these protected classes, full Human Subjects Review Committee review will be necessary and the more complete your Request for Review, the more likely a timely approval will be issued.
4. Identify the data you hope to collect and how you will collect those data. Mention all instruments you will use and ***attach a copy of these instruments to your application.*** Please note that if you are using a piece of equipment, you just need to describe that equipment. Describe how you will use the information you collect; that is, to further research on your topic, to further research, to provide some form of treatment, to improve student performance, etc. Describe what will happen to the data/videotapes/audiotapes you collect upon the completion of the study.
5. Describe how you will recruit subjects for your study and how you will handle obtaining their informed consent for participation. Informed consent is one of the most important components of conducting research that involves living human subjects. State who will obtain consent and what information on your study will be provided to potential subjects. Federal regulations mandate that if a research study involves subjects under 18 years of age, consent must be obtained from the parent or legal guardian **AND** the minor child. You must have two separate forms when minor children are involved in your research: a parent form and a child consent form. Here at *Fredonia*, a child’s consent form must be included in research protocol involving children ages 5 to 17 years. The language used in a minor child consent form must be appropriate to the age of the child. ***You must attach a copy of all consent forms to your application.***

To ensure that your consent forms meet federal standards, please include

- a. a statement that this is research
- b. the purpose of your study
- c. a description of your procedures
- d. how long subjects will be involved in your study
- e. both the potential benefits and the risks and/or discomforts of participants
- f. any alternatives to the treatment you provide, if appropriate
- g. how confidentiality of subjects and their data will be maintained
- h. a statement that participation is voluntary and that the subjects can withdraw at any time without penalty; and
- i. the names and phone numbers of contact people for your study.

6. This component contains four parts:
 - a. Identify any potential risks: physical, psychological, social, legal, or another type of risk. Mention the likelihood of these risks occurring and their seriousness. Describe alternative treatments that might be advantageous to the subjects.
 - b. Where appropriate, state how you will ensure that your subjects receive necessary medical or professional intervention if they have adverse effects to your treatment/research protocol.
 - c. Tell how you will maintain the safety of your subjects during your study.
 - d. If there are risks in your study, tell how the risks are balanced by the benefits to be gained by the subjects from their participation in your study. Also mention the relationship of the risks to the knowledge that will be gained from your study.
7. If your study deals with a sensitive issue and/or the data you collect deals with criminal acts, sexual conduct and behavior, drug and alcohol use, sensitivity and awareness to potential risks, and/or liabilities to your subjects, you will need to clearly state the precautions taken to minimize risks or liabilities.
8. Mention how you will prevent any risk to violating the confidentiality of the subjects involved in your study.

If you have questions about your research project or how this application should be completed, please feel free to contact any of the following individuals:

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