



Describing Your Research to the IRB

The principal component of your *Application for Approval to Use Human Subjects in Research* is your description of the research that you plan to conduct. The application form includes a set of 8 specific requests for information that require investigators to describe 1) the goals of their research; 2) the source of subjects and the selection criteria; 3) the procedure; 4) the potential risks and benefits for subjects; 5) the methods by which confidentiality and anonymity will be protected; 6) the debriefing process and the actions that will be taken in adverse situations; 7) the consent form; and 8) any other information that might be relevant to the approval decision.

What follows is a brief discussion of each of the 8 requests for information delineated on the application form. Common mistakes, misconceptions, and omissions are described for each one in turn. At the end of this discussion, an example of an exemplary graduate student submission from last year is included as a general model to follow.

*1. State the purpose of the research. Include major hypotheses and research design. If the study is part of a larger study, briefly describe that larger study and indicate whether it has received IRB approval from another institution. **Please keep in mind that the IRB is composed of individuals from many disciplines and thus the description of your research should be written in terms readily comprehensible by non-experts.***

What are the major research questions that you are trying to answer? Are you trying to assess the effectiveness of a particular software program, technological device, pedagogical method, etc. on subject's performance on a certain task? Are you merely trying to collect opinions about an existing program or treatment method? Are you using a case study to illustrate a particular strength or weakness of some program or treatment? Whatever the goals of your research, state them as clearly and precisely as possible. When you are describing your hypothesis, try not to describe it in a biased manner (e.g., "I intend to show that this new method is clearly more effective than the old method."), but describe it as a something to be tested (e.g., "I intend to statistically test the hypothesis that the new method is significantly better than the old method.").

The main problem that occurs in response to this request is already bolded in the request itself. Applicants frequently employ highly technical terms as if everyone on the IRB, which consists of people from very diverse disciplines, will be familiar with these terms. Don't just say things like, "I intend to use the Sonteim Technique of Audio Interference Assessment", without previously, or immediately thereafter, explaining exactly what this assessment technique is.

*2. Describe the source(s) of subjects and the selection criteria. Selection of subjects must be equitable and, in the case of protected populations such as children, prisoners, pregnant women, the mentally disabled, etc. should address their special needs. The text of any advertisement, letter, flier, oral script or brochure used to solicit potential subjects **must be attached.***

Your subjects must be described in detail to the IRB. Don't just say things like, "Participants will be Hispanic women residing in the Bronx", when you should be saying, "Participants will be 20 Hispanic woman currently enrolled in an Introduction to Psychology class at Bronx Community College." Just as importantly, **include not only a description of your subjects, but also a separate description of the selection criteria.** How are the 20 students described above going to be selected? Is the total number of Hispanic women in this class 20, or will they be selected randomly from a larger class? Will an announcement be made at the end of class, and will everyone who signs up be included as subjects? Is this a class that the investigator herself teaches? If not, has the instructor given permission to announce the experiment during or at the end of class time?

Keep in mind that the goal of the IRB is to ensure that subjects are treated fairly and adequately protected from research risks. This includes the right to a fair and equitable opportunity to be a participant in research studies. You cannot just say

that you are going to select 8 of your own students to serve as subjects in your research. This allows for the possibility that you are selecting only students of one gender or ethnic group because you are more comfortable working with people from these groups. The selection process must not be biased in any way. Unless gender or ethnicity is a focus of the research, as it would be in a study on women's attitudes toward child-care, the method of selection should be nonbiased. Random selection of subjects from a larger available sample, for example, is a good nonbiased selection method.

3. Provide a description of the procedures to be followed. If available, include copies of questionnaires and/or interview protocol, or a sufficiently detailed description of the measures to allow the IRB to understand the nature of subjects' involvement.

The goal here is to make the procedure that you intend to follow clear to the members of the IRB. When a subject shows up for this study, exactly what are they asked to do? Whenever possible, **provide a complete list of the questions you will be asking or the tasks you will be asking subjects to perform.** Make it clear where the study will take place and how long it will take. Will subjects be run individually or in groups?

Also, keep in mind that the primary job of the IRB is to weigh the risks and benefits of your research for participants, and this means that in some cases the validity of your design can become an issue for the IRB to address. If a study has no validity, then even minimal risks are not justified. Try not to design a study in which you are virtually guaranteed to get whatever results you are looking for. For example, if you are testing the effectiveness of a particular workshop in reducing classroom violence, don't construct a questionnaire in which every question asks respondents to describe positive ways in which the workshop helped to reduce violence. Also, try to control for obvious confounds in the design. For example, of course a large group of students who performed at the bottom 10% on some test will perform better upon retesting after being given your remedial lecture. Regression to the mean would ensure that this group will show improvement even if your technique is completely worthless.

4. Describe any potential harms or benefits to be derived by subjects, with a discussion of the risk/benefit ratio. For approval of any study with more than minimal risk, the benefits must clearly be shown to outweigh the risk. Describe how the study may expose participants to stress, physical, psychological or interpersonal hazard, including the possibility of pain, injury, disease, discomfort, embarrassment, worry or anxiety.

The most important point to make here is that you should be honest about any risks your study poses and not try to mislead the IRB. Studies with limited risks are frequently approved, as long as adequate precautions are taken and the benefits outweigh the risks. Thus, instead of trying to say that your study, which asks subjects to describe traumatic autobiographical experiences, has no risks, indicate that there is some potential for this study to upset some subjects. Then go on to say that the sign up sheet will describe the procedure ahead of time to prospective subjects, the consent form will do the same, and you will have a referral source at the counseling center available just in case any subjects need some one to talk to after the study.

5. Describe the specific methods by which confidentiality and anonymity will be protected, including the use of data coding systems, how and where data will be stored and who will have access to it, and what will happen to data after the study has been completed.

Keep in mind that confidentiality and anonymity are two different things. Confidentiality refers to the fact that personal information will never be revealed by the researchers. Anonymity refers to the fact that even the researchers themselves will have no way of identifying any of the participants in the study from their data. Make it clear whether your study provides confidentiality or anonymity and describe the procedure by which these are achieved. Also, as indicated in the question itself, provide a clear detailed description of how the data will be stored and who will have access to it.

6. If applicable, provide the following: 1) a description of the debriefing procedures to be used in cases where deception has occurred; 2) a statement describing what actions you will take should the research reveal the possibility of a medical or other potentially troubling condition.

In cases in which a debriefing seems warranted, indicate what it is that the subjects will be told and whether the debriefing be verbal or written. Also, describe what will happen if a subject's data indicate that he or she might have a serious health problem or might be the victim of abuse etc. Of course, most procedures will probably not produce data that could reveal such information.

*7. Describe the oral and written consent processes and attach all consent documents, including scripts for oral consent and assent form for research involving minors under the age of 12. When the consent form to be used will be in a language other than English, an English translation must be provided. **Unless one or more of the required elements described below is explicitly waived by the IRB, informed consent documents should contain:***

- A. A fair explanation of the procedures to be followed and their purposes, including any procedures that are experimental.*
- B. A description of any possible attendant discomforts and risks reasonably expected. This includes any potential financial risks that could ensue.*
- C. A description of any benefits reasonably expected.*
- D. A disclosure of any appropriate alternative procedures.*
- E. An offer to answer any inquiries concerning the goals of the research or the research procedures and to provide a summary of results upon request. A contact person and phone number should be provided.*
- F. An instruction that the subject is free to withdraw or discontinue participation at any time without prejudice.*
- G. A statement that the data are confidential and that the subject will not be identified by name in writing or orally.*
- H. Provisions for parent or guardian approval for participation of minors or for subjects from vulnerable populations when appropriate.*

This request for consent forms is especially important. The federal agencies that oversee the IRB insist that all subjects be adequately informed about the exact nature of the procedure they are volunteering to participate in, including any potential risks or discomforts the procedure might create. In composing your consent form, pay attention to all of the required elements listed in the request itself (lettered A through H).

8. Please provide any other information that might be pertinent to the IRB's decision.

Most research designs will not require any further elaboration given that all of the prior requests were appropriately answered. However, if your design requires additional explanation include it here. Provide information about your qualifications to conduct the proposed study. If you will be working with subjects from a vulnerable population, please describe your background and experience working with this population.

SAMPLE STUDENT SUBMISSION FOR APPROVAL TO USE HUMAN SUBJECTS

1. The purpose of this study is to evaluate the use of assistive technology, more specifically the use of a computer and a single switch, to enhance the communication and mobility of a child with Cerebral Palsy. A “switch” is simply an alternative to a computer mouse. It is larger than a mouse and easier to employ. It only needs to be touched and allows for easy control. The null hypothesis is that the use of assistive technology will not enhance the communication and mobility of a child with Cerebral Palsy.

Two students will first use a computer without a switch and a pre-test will be given to assess their current computer skills (see attached pre/post test). Then a switch will be added and the children will use various computer programs (choice of Living Books, Jump*Start Toddler and Little People Farm), and the researcher will look at whether or not child A or B used the switch to activate the program and whether there was communication directly between the two children or through the computer. Upon completion of this study the children will be given a post-test (same as pre-test) to evaluate their computer skills.

2. The source of the subjects is the children in my special education preschool classroom. They range in age from 3-4 years old and are male. Their disabilities include Cerebral Palsy (spastic quadriplegia), speech language delays and cognitive delays. One child was chosen because he alone has Cerebral Palsy and the other child was chosen randomly from a hat, which contained the names of all the students in my class.
3. The students will be given a pre-test (as described above and attached). Then, the students will play with a computer using a single action switch that is attached to the computer for 20 minutes a day, 3 days per week (Monday, Wednesday and Friday) for a period of six weeks. The session will take place in the morning and occur at the same time each day. Data will be taken on each child separately by the principal investigator. The children will be known as Child A and Child B. The data will include information on whether or not they used the switch to activate the program and if communication occurred from either one of the children. Upon conclusion of this study, the children will be given a post-test (same as a pre-test).
4. This study poses no risk of physical harm to the children. The children’s names will not be used and only the principal investigator will know their identity. The benefit to the children will be improving their computer skills and expansion of their communication skills while working in a small group setting. Stress should be limited in this study because the switch is a large single switch activator and just needs to be touched (pointing or precision movement is not required).
5. The study names will not be used, they will be known as Child A and Child B. The principal investigator will be the only person who knows their identities. The pre/post test and data sheets will be coded with Child A and Child B and will be stored in a binder in a locked filing cabinet in my classroom (only I have the key). Upon completion of this study, the paperwork will be stored in my home in a locked filing cabinet.
6. NA.
7. See attached Consent Form.
8. NA.