

HSRRC Application Proposal

Applications must be written in at least 12 pt font and must be page numbered.

I. Investigator's Assurance

This form must be filled out completely and accompanied by the proper signatures. (See page 3)

II. Project Title & Prospectus

In 300 words or less, clearly identify the research question and provide a summary of the project and its significance, including a brief description of the methods and procedures to be used. Use neutral language and do not use jargon. Define any acronyms used.

III. Exemption Claim for Waiver of Review

If your research falls into one of the categories of studies exempt from HSRRC review (*see section IV, "Types of Review"*), cite the exemption category and the associated rationale. Please note that *anonymity* means that the subject's/respondent's identity is unknown (in other words, that responses cannot be linked to individuals); *confidentiality* implies that, while the researcher can identify each subject and his/her responses, that the identity of the subject will be kept private, and not revealed to others.

IV. Subject Recruitment

This section should provide a description of the subject population, including the number of participants which the researcher expects to recruit, the characteristics of that population, which can include age, gender, ethnic background and health status, and the methods to be used for their recruitment. A description of how subjects are selected, approached and invited to participate in the research must be included. Criteria for inclusion and exclusion should be detailed; justification is required if the subject population is restricted to one gender, age or ethnic group, as the federal government strongly encourages investigators to include women, children and ethnic minorities in their research. If different subject groups are to be included in the research, recruitment information must be included for each group.

V. Informed Consent

Both federal and university regulations require researchers to obtain informed consent from their subjects before they may be enrolled in a study, unless otherwise permitted by the IRB. Describe both by whom and in what manner consent will be obtained from each appropriate sample category (*see below*) and include a copy of the informed consent form(s) or cover letter (s). If requesting a waiver of signed consent, a justification must be included (*see Informed Consent section on web page for help in preparing an appropriate consent document and for information on altering or waiving the consent process*).

- Adult subjects (includes persons 18 years of age and over)

- Child subjects (includes all persons under 18 years of age) will require written parent/guardian permission/consent, as well as verbal or written assent from the subjects themselves.
- In some cases, institutional subjects, such as prisoners and mental health patients, may require the consent of an appropriate witness in addition to that of the participant him- or herself.
- When the researcher seeks to use a passive consent process, the Committee will determine that research is one in which a waiver of signed consent is appropriate. If the research and passive consent process is being done in an educational setting, the Committee must be assured that the passive consent process has been approved by an appropriate school official. When writing the passive consent form, the researcher should give the subjects (and parent/guardian if subject is a minor) ample time to decline participation and must offer a variety of ways in which the researcher can be contacted to decline participation.

VI. First-Person Scenario

Provide a short paragraph that presents the experience from the subject's point of view (e.g., "I received a letter last week in the mail which described a new research study...Once I decided to participate, I set up an appointment to meet the researcher...I was seated at a table with the investigator and..."). This scenario should begin when the subject is first contacted, whether by letter or in person, should describe each activity in which he or she is required to take part, and should conclude only with the end of the subject's participation. If different subject groups are to be included in the research, a scenario must be included for each group.

VII. Potential Risks and Safeguards

The risk/benefit ratio for subjects is particularly crucial to a human subjects review. Some research cannot be approved unless the possible benefits to participants or to humanity outweigh the possible risks. Please describe any potential physical, social, psychological, employment, legal, economic, risk of coercion, or other risks to subjects, including discomfort or embarrassment (e.g., nature and seriousness of risk, incidence of probability, etc.). Also describe the safeguards which will be adopted to eliminate or manage these risks, and/or the steps to be taken to detect and treat any injury or distress incurred by subjects.

VIII. Potential Benefits

Describe briefly the anticipated benefits of participation in the study. Subjects might benefit directly, such as having an opportunity to share their story, or indirectly, as the results of a study of blood donors leads to a better-marketed blood drive and, therefore, increased blood bank stores. If a form compensation is offered for participation in research, it should be described as a token of appreciation for participating, not as a benefit of the research.

IX. Confidentiality, Records & Distribution

Discuss procedures which will be used to maintain subject confidentiality, including the implementation of any codes or pseudonyms to conceal identities, both during the course of research and in the period thereafter. Regarding confidentiality in a group setting, the researcher must address, both in person and in the consent process, the risk that confidentiality cannot be guaranteed in a group setting. Also, explain records storage and access methods, the description of which must include information regarding where and for what length of time data provided by subjects will be stored. If possible, records should be securely stored at PSU and/or on a secure PSU network. If subjects will be audio- or videotaped during their participation, this must be addressed, as well, both in this section and on the consent document. Federal regulations *require* all data and records to be kept on file for a minimum of three years after the completion of research.

X. Appendices

All survey instruments, telephone and email introductory scripts, focus group guides, interview questions and informed consent documents must be included in your application.