Human Participants Review Board Proposal Form Detailed Field Descriptions

Overall goals

Briefly state the purpose of the research. Some possible questions to answer are: What will be known when the research is finished? What problem(s) will the research address? Example: The main goal of the proposed research is to better understand the relationship between college students’ views of their parents’ discipline practices during childhood and the students’ current attitudes about child discipline. A second goal is to determine whether parent discipline practices and adult child attitudes are related to socioeconomic status.

Specific Aims

Describe the research strategy. What information will be collected and how will it be used to meet the overall goal(s)? Example. Specific Aim #1: Collect information on participants’ childhood backgrounds using the Parent Discipline Questionnaire and the Standard Socioeconomic Measure. Specific Aim #2: Obtain data on participants’ attitudes about how they intend to parent or are currently parenting their own children by using an adapted version of the Parent Discipline Questionnaire. Specific Aim #3: Divide participants into groups depending on their responses on the three measures and compare the groups.

Background and rationale

Describe what is already known about the topic and how it leads up to the proposed project. Describe the gap in knowledge that will be filled by the results of the project. Example: There is substantial research on parents’ discipline practices and their children’s later behavior and mental health. Research shows that professional and working class parents use different discipline practices. There is little research on the attitudes of adult children about how they were disciplined and whether they use or plan to use similar practices as their parents. Results will provide information that may relate to generational changes in child rearing practices.

Methods of investigation

Describe the methods that will be used. Example: This project will use the following method(s): in person semi-structured interview, in-person pencil and paper questionnaire, in-person response to a computer questionnaire after watching a video clip, Internet survey using Survey Monkey, Internet interview using Skype, videotaped group interaction, in-person observation of behavior after exposure to a treatment condition, focus group, recorded reaction time in response to a visual stimulus

Item 1: Level of risk

Minimal risk means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations. There are different types of risks to which human subjects may be exposed that are inherent in various research procedures. Risk is most obvious in medical and behavioral science research projects involving procedures that may induce a potentially harmful state or condition. Some examples are: the requirement of strenuous physical exercise; and/or subjection to deceit, public embarrassment, self-incrimination (the admission of illegal or immoral behavior), or humiliation.
There is a wide range of medical, social, and behavioral projects in which no immediate physical or psychological risk for the participant is involved (e.g., those involving the use of personality inventories, interviews, questionnaires, observations, photographs, tapes, records, and stored data). However, some of these procedures may involve varying degrees of discomfort, harassment, or invasion of privacy, or constitute a threat to the subject's dignity, all of which pose another type of risk.

**Item 2: Deception**

A researcher should never deceive participants about significant aspects that would affect their willingness to participate, such as physical risks, discomfort, or unpleasant emotional experiences. Deception necessary to the study’s design must be explained to participants as early as is feasible, preferably at the conclusion of their participation, but no later than at the conclusion of the research.

**Item 3: Vulnerable participants**

_Vulnerable populations_ are those who may have reduced capacity to consent to voluntary participation, and they include, but are not limited to, children younger than 18, prisoners, the poor, pregnant women, fetuses, clinical populations or individuals who are mentally or psychologically ill or incompetent. Research using vulnerable populations automatically requires full board review.

**Item 5b: General characteristics of participants.**

Examples: Sample recruited from Psychology research pool students, sample recruited from local community college students, sample recruited from among friends and acquaintances, sample recruited from Internet interest group boards, sample recruited at local food bank.

**Item 5c: Sample size and inclusion/exclusion criteria**

Provide the rationale for your sample size because it is desirable to have neither too few nor too many participants (due to the use of their time when unnecessary). Justification is required if the sample is restricted to one gender, ethnic group, or other specific group because of historical underrepresentation of certain groups in research and consequent lack of knowledge about these people. Provide inclusion/exclusion criteria. Some examples are: people younger than 18, students with more than 60 college credits, people with a low level of use of the English language, people with chemical sensitivities, people who are receiving weekly services at the community agency.

**Item 5d: Recruitment**

Describe all strategies for recruiting participants. Be specific and describe how you will make contact and what materials you will use. This may include handing out flyers (provide the flyer with the proposal), using the Psychology Department Research Familiarization Pool, setting up a table in the UC (provide the oral script for inviting prospective participants), creating a Google or Facebook event, posting a notice on an Internet interest board, contacting a small target group and asking them to refer others to your study (snowball method). Submit all written and oral recruitment materials with the proposal.

**Item 7a: Risks**

Expand on your selection of category of risk in Item 1. _Minimal risk_ is “the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily
encountered in daily life or during the performance of routine physical or psychological examinations.” For minimal risk, there may be some physical or psychological discomfort, but it is not an unusual level. If the level of risk is more than minimal, describe your plan for mitigating the possible harm to participants. An example would be psychological distress caused by research materials related to a past experience of violence. A risk mitigation strategy would be to provide sufficient information in the consent form to prevent a participant at particular risk for distress from exposure to the materials. Another strategy would be to distribute to all participants a handout with valid contact information for help in case of psychological distress caused by their exposure to the research materials. Another form of risk would be loss of social status if others overheard or saw the participant’s responses to sensitive questions. A mitigation strategy would be to provide examples of sensitive questions in the consent form so prospective participants can decide not to expose themselves to the risk. Further strategies involve setting up procedures to ensure privacy and anonymity or confidentiality.

Item 7b: Benefits

An implicit benefit of the research is eventual dissemination of the results to a wider community, or the benefit is the educational value to the student investigator of learning to do research. For the purpose of the proposal, benefits are those that directly affect participants. Sometimes there is no direct benefit to people for their participation, and it should be so stated in this section of the proposal. Course credit is a direct benefit as is payment. Forcing participants to reflect on their own characteristics or experiences may or may not be a benefit, and depending on the person, it may be detrimental.

Item 8: Anonymity

To safeguard anonymity, you may use procedures such as avoiding demographic questions that can result in identification of an individual with unique characteristics, issuing writing utensils to participants to avoid unique ink as an identifier, maintaining signed consent forms and completed research materials in separate containers, aggregating completed research materials in random order in a large group before examining them and ensuring that neither you nor anyone else sees participants’ responses during data collection. You can do this by seating participants with sufficient distance between them and by adding a cover sheet to your research materials that can be used as a shield. Example of text for Item 9 (HPRB proposal form): “It will not be possible for anyone, including the investigator, to link individual identifiers with study results. No participant names will be written on research materials except for the consent form which will be kept separate from research materials. No identifying ink will be used on written materials. Completed research materials will be aggregated into groups of no fewer than 10 participants’ materials and will be shuffled in order before examination by the investigator. Participants will be seated with sufficient distance from each other to prevent them from seeing each other’s responses. (and/or “A cover sheet will shield participants’ responses from the view of others”). Note: If demographic data can identify individuals, and the data are not variables but are being used to describe the sample, then demographic questions can be included on a sheet of paper that is kept separate from the consent forms and from the raw data sheets.

Item 8: Confidentiality

If you will be able to link identity with research data, you may nonetheless assure participants that their responses will be held confidential. You must prevent others from gaining access to participants’ personal identifiers and data. This includes assignment of a code to replace the participant’s name on materials, keeping the key to the code in a separate location from the materials (note: keep a code key only if necessary to re-link names with data, otherwise destroy it or do not create one). Maintaining confidentiality also includes keeping the raw data in a secure location and preventing others from seeing a database that you may create and that may contain identifiers such as demographic information that is
linked to research data. Example of HPRB proposal text for Item 9: “The investigator(s) will be able to link individual personal identifiers with their responses. Responses will be kept confidential by keeping all completed research materials in a secure location to which no one but the investigator(s) will have access. No names will appear on any study materials except for the consent form which will be kept separate from other materials and will be unable to be linked to them. A code will be assigned to each individual and will appear on study materials and in the computer database for the study. (If a key is necessary then add the following.) The key to the code will be kept in a secure location separate from the materials. (And if applicable) The database, which will contain demographic information that may allow identification of individuals, will be kept secure and will be seen by only the experimenter(s)” The process for video or audio recordings includes keeping them secure, of course, but also destroying them when they have been transcribed (audio) or coded (video).

Item 9: Informed and Voluntary Consent

Obtaining consent from prospective participants is a process, not simply a form. There should be opportunities for participants’ questions to be answered, and participants should understand that they may decline to continue participation at any point and they may withhold some responses if they so choose. Note that a copy of the consent form is given to all participants to keep. There are certain elements that must be included in the consent process to ensure that participation is both informed and respectful of individual autonomy. The HPRB has a written consent form template that includes the required elements at http://www.plu.edu/hprb/documents-and-forms/home.php. The consent process and the information in the form must match the information in the proposal, and may not include new information that is not in the proposal form. This is especially true for risks and anonymity/confidentiality. A written cover letter may be substituted for the signed consent form if certain conditions are met. The conditions are described in the document “Determining Informed Consent Procedure” at http://www.plu.edu/hprb/documents-and-forms/home.php. The cover letter template is “Anonymous Survey Cover Letter Template” and can be found on the HPRB documents page (link above).

Item 10: Debriefing

Submit a copy of any oral script or written debriefing materials with the proposal. Research ethics require that participants be told about important information that may have had to be withheld during earlier phases of the study. It is ethical to alleviate any concerns or distress caused by the procedures, and it is a courtesy to provide information about the study to which participants contributed their time and effort. A written or oral debriefing should be provided that includes new information about the study beyond what is provided in the consent form (a copy of which they receive to keep) and that is understandable to the participants. If deception is used in the procedure, describe why it is necessary and when and how you will fully inform the participant.