IRB Category II Research Form

**INSTRUCTIONS:** Please complete this form and submit it online at <https://www.depauw.edu/offices/academic-affairs/grants-and-research/irb/>. Two or more members of the IRB will review the proposal and respond, generally within two working weeks.

**Proposal Evaluation Checklist**

*Check all boxes*

**Does my proposal have all required elements?**

[ ]  Description of project?  An adequate and clear description in lay terms of:

[ ]  Purpose and goals—could someone without specific training understand why I am doing this research?  What I am trying to investigate? Why the issue is important?

[ ]  Methods and measures—Have I made it clear how I will conduct my research, and what participants will experience?  Have I made it clear how my methods/measures address my research question?

[ ]  Recruitment—Have I described and provided documentation for how I will contact and recruit participants?

[ ]  Procedures for confidentiality (or anonymity) in short and long term—

[ ]  Have I described and made clear how my procedure will protect confidentiality (or anonymity)?

[ ]  Have I described how and where and in what form I will store the data, and for how long?

[ ]  Have I described how the data may be used or shared?

[ ]  Detail about purpose, methods and aims—

[ ]  Have I provided enough information to allow IRB to judge whether the inconvenience/cost/risks to participants are balanced by what study may learn or accomplish, and made a case (explicit or implicit) that the benefits outweigh costs?

[ ]  Have I provided copies of, or adequate descriptions of, relevant research materials and procedures (surveys, stimuli, interview questions, interview procedures, etc.)?

[ ]  Have I provided a copy of informed consent sheet (or consent information for anonymous surveys)?

[ ]  If not, have I made a case for exemption from informed consent?  Have I provided consent information for all needed parties (in some cases this might include parents/guardians, school or organization officials with authority to provide consent, etc.)?

***Project title:***  *[Click to enter text.]*

***Investigator name(s), phone number(s) and email address(es):***
*[Click to enter text.]*

## Questions

1. **Will any of your participants be under 18 years of age?**
Answer: *[Yes or No]*

*If so, you will need to describe how you will obtain approval from parents or guardians in the study description section below. If you will be gathering data in a school or institutional setting, include your procedure for obtaining authorization from school officials and teachers.*

1. **Will any of your participants fall under "protected" categories (e.g., prison inmates, mentally ill, pregnant women)?**
Answer: *[Yes or No]*

*If so, you will need to describe the population, and how you will obtain consent/authorization in the study description section below.*

1. **Will you be obtaining data from private records?**
Answer: *[Yes or No]*

*If so, you will need to describe the records you will be using and how you will obtain them in the study description section below.*

1. **Will you be collecting data from participants concerning sensitive personal information?**
Answer: *[Yes or No]*

*If so, you will need to give a description of the sensitive information, including an explanation of why you need to obtain it and how you will obtain/record it in the study description section below.*

1. **Will your study collect information on medical conditions and/or disease/disorder/disability status?**
Answer: *[Yes or No]*

*If so, you will need to describe why this is necessary and how you will preserve confidentiality and/or anonymity in the study description section below.*

1. **Will your participants receive inducements (e.g., money, course credit, or extra credit) for participation?**
Answer: *[Yes or No]*

*If so, you will need to describe the inducements in the study description section below.*

1. **Will your experimental manipulations and/or measurement techniques intentionally produce stress/discomfort beyond everyday levels, or might your manipulations and/or measurements reasonably be expected to induce more than everyday stress?**
Answer: *[Yes or No]*

*If so, you will need to describe why and how in the study description section below. (Note: Procedures that result in high stress/discomfort require at least some level of immediate debriefing, where such debriefing would be expected to reduce stress or discomfort, and a full debriefing at some point in time.)*

1. **Will your study involve any risks/discomfort in addition to those asked about in this form?**
Answer: *[Yes or No]*

*If so, you will need to describe those risks/discomforts in the study description section below.*

1. **Will your study manipulate feelings of self-esteem and/or competence, or involve manipulations that might reasonably be expected to affect feelings of self-esteem and/or competence?**
Answer: *[Yes or No]*

*If so, you will need to explain the level and nature of the manipulation, why it is necessary, and how it will be accomplished in the study description section below. (Note: Procedures that reduce feelings of self-esteem and/or competence require at least some level of immediate debriefing (where such debriefing would be expected to ameliorate the reductions in self-esteem/competence), and a full debriefing later in the project.)*

1. **Will your study involve deception (beyond merely not informing participants fully about the full nature of the research)?**
Answer: *[Yes or No]*

*If so, you will need to explain the level and nature of the deception, why it is necessary, and how it will be accomplished in the study description section below.*

1. **Will the data you collect preserve participant anonymity?**
Answer: *[Yes or No]*

*If so, you will need to explain how you will preserve anonymity in the study description section below. (Note: Participant anonymity is preserved when a study is conducted in a manner that does not allow linkage of participant names with individual data; that is, no one, not even the researcher, can link participant identity with individual data.)*

1. **Will the data you collect preserve participant confidentiality?**
Answer: *[Yes or No]*

*If so, you will need to explain how you will preserve confidentiality in the study description section below. (Note: Participant confidentiality is preserved when results are presented in a manner that does not allow identification of individual participants and their data—that is, although the researcher may be able to identify individual participants and link names to data, results are not presented in a manner that allows others to identify individual participants and their data.)*

## Study Description

*Please provide a detailed description of your study below, including specific responses to issues raised in the Questions section above. Include the topic and purpose of your research, and your procedures and measures in lay terms. Be as brief as possible, but include enough information to allow a non-specialist to understand and interpret your research. Click below to enter text.*

## Informed Consent

*Please copy your final informed consent form below. Visit the Topics section of the IRB website for more information on informed consent, including a sample form. This sample form must be edited to fit your study. Click below to enter text.*

DPU IRB Consent Checklist

DPU Informed Consent Requirements Checklist

*Check all boxes*

[ ]  Language and wording used throughout the form is appropriate and accessible for the target participants (comprehensible to participants, age-appropriate, etc.)

[ ]  Statement (in general terms) of research with appropriate description of topic, procedures, experience for participant, and duration

[ ]  Statement of affiliation with DePauw and Department/Program

[ ]  Statement of risks

[ ]  Statement of benefits and compensation (or lack)

[ ]  Statement that participation in the research is voluntary and about the right to withdraw w/o penalty

[ ] Description of confidentiality or anonymity, and brief description as to how confidentiality is protected—e.g., data and participation coding, reporting, data and participation storage method and duration (if appropriate to study), who will have access to data (if appropriate to study)

[ ]  Contact information to address concerns including names, phone/email of researcher and faculty sponsor (in some cases it may be appropriate to list *full* contact only for faculty sponsor—safety concerns, if students will be leaving soon, etc.)

[ ]  Insurance that participants no worse off from participation, and that participants have access to information.  A debriefing procedure appropriate to the nature of the study. More thorough debriefing required with strong deception, or any procedure reducing self esteem, or otherwise “harmful” to participants, but at minimum, how, where and when information will be available to be more informed about the study or see results

[ ]  Notice of copy of consent form given or offered to participant

[ ]  Statement research has been approved by DPU IRB, offer for participant to contact IRB by email (irb@depauw.edu) with any questions or concerns

[ ]  18 years of age or older affirmation (this can be in the signature statement)

[ ]  Signature lines—Written signature space, print signature space, date space.  A statement that indicates participant received, read, and understood IC, understands their rights, and by signing consents to participate.  For online signatures, a statement that the participant acknowledges the above, plus a statement that participants acknowledge that by typing a name and clicking ‘Continue’ (or a step equivalent to that) they are providing the equivalent of a legal signature.

[ ]  For recorded interviews (or other recorded procedures), a separate statement (this can be integrated into the text just before the signatures) that the participant understands the nature of the recording, and agrees to be recorded.  Some forms might allow a participant to note whether they wish the procedure to be recorded or not, and still allow for participation.

[ ]  For focus groups or other procedures that gather data in groups in which participants can observe or interact with other participants,

[ ]  A statement that notes the participant will be seen/heard by other participants.

[ ]  A statement that notes the importance of maintain the confidentiality of others, along with a statement in which participants agree that they will not discuss the responses of other participants outside of the study.

## Debriefing

*Please copy your final debriefing form below. Visit the Topics section of the IRB website for more information. Click below to enter text.*

## Additional Materials

*Please copy any additional materials below (e.g., questionnaires, appendices) here. Materials that cannot be cut and pasted into Word may be attached to your application email instead. Click below to enter text.*