PEPPERDINE
UNIVERSITY

IRB TEMPLATE SOCIAL- BEHAVIORAL ADULT PARTICIPANT INFORMED CONSENT

The following instructions and examples are provided to assist in development of the Social-Behavioral Adult Participant Consent Form. Additional templates and information are available from the IRB and website.

The following should be considered when developing the consent form:

- **Consent forms must include clear identification of the responsible institution (Pepperdine University letterhead as shown above can be utilized or Departmental specific letterhead). Consent forms submitted without identification of the responsible institution will result in delay of approval of the project.**

- All forms should be submitted suitable for reproduction (printed single-sided or available electronically) using, at minimum, reasonable 12-point font and 1 inch margins.

- Each page of the consent form should be full without inappropriate divisions: sections can be split (some on one page, some on another page) so that large blank areas do not exist.

- All pages must include page numbers at the bottom and (if applicable), a participant's initial blank.

- The informed consent form must be written in the second person (i.e., use "you" and "your" when appropriate). When combined with conditional language, utilization of the second person personalizes the consent form and reflects the existence of voluntary decision making on the part of the prospective subject.

- The informational content of the elements of informed consent should not be mixed or repeated unless necessary. Information presented under any given element should be reasonably complete and restricted to content appropriate to that element. This helps the prospective subject focus on each individual element of consent thereby increasing the validity of the consent process.

- The consent form must be written in simple enough language so that it is readily understood by the least educated of the subjects to be utilized. Normally, the highest level of language in the consent form should equate to an eighth-grade standard reading level. Scientific terms should be avoided when possible. If scientific terms will be included, the lay term or definition should be provided.

- The following template for informed consent is utilized when interviews are a component of the study procedures.

- Please remember, age of majority in California is 18 years old. Anyone younger than 18 requires parental consent/assent, with few exceptions based on the state law, or a waiver of parental consent must be approved by the IRB.

- ***Before submitting the consent document for IRB approval, delete this page and all comments/instructions/boxes or non-applicable language.***

IRB #:

Participant Study Title:

Optional: If the formal study title is too long or includes technical terminology, you may consider creating a brief title that participants will better understand.

Formal Study Title:

List the title in this section exactly as it appears on the IRB Application.

Authorized Study Personnel

List by name those personnel authorized to document consent as listed in the IRB Application. Use the following personnel labeling: Principal Investigator and Secondary Investigator(s). Include day phone numbers for all listed individuals. For greater than minimal risk studies, consider including night/home phone numbers and/or other direct contact mechanisms. List other study personnel and contact information as appropriate.

Principal Investigator: John Smith, MA Office: (402) 472-1000
Secondary Investigator: Jane Doe, Ph.D. Office (402) 472-2000

Key Information:

The 2018 changes to the Common Rule (45 CFR 46) require that consent forms "must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research." This key information is only required to be included for non-exempt research (i.e., Expedited or Full Board review).

If you agree to participate in this study, the project will involve:

- (Males/Females) between the ages of (Age range)
- Procedures will include (Summary of study procedures)
- (X) number of visits are required
- These visits will take a (X) amount of hours total
- There are/are no risks associated with this study
- You will be paid (X) amount for your participation
- You will be provided a copy of this consent form

Invitation

> ***Invite the prospective subject to participate in the study using the following standard invitation to participate.***

You are invited to take part in this research study. The information in this form is meant to help you decide whether or not to participate. If you have any questions, please ask.

Why are you being asked to be in this research study?

> ***Explain succinctly and simplistically why the prospective subject is eligible to participate. As appropriate, major eligibility criteria may be included in this section.***

Example: You are being asked to be in this study because you are either an employee or a supervisor working a night shift. You must be 19 years of age or older to participate.

What is the reason for doing this research study?

> ***This section should state the scientific purpose of the study. If appropriate, brief background material may be provided to help the potential subject understand why the research is being done. The information should be provided in simplistic language without reference to the subject.***

Example: People who work at night employ different strategies for staying awake during their shifts. These methods are likely to be different between employees and supervisors, because of their different levels of responsibility. This research is designed to (1) better understand these strategies and (2) determine whether 'supervisor strategies' could be successfully used by employees.

What will be done during this research study?

> ***Describe the procedures and their duration chronologically using simplistic language, short sentences, or short paragraphs. The use of subheadings may help organize this section and increase readability for studies with a large number of procedures.***

Example: You will be asked to complete 5 surveys using an internet-based questionnaire. Each survey will take 1-2 hours to complete, and you may complete them from your home computer, one each week for 5 weeks.

How will my [data/samples/images] be used?

> ***If the research involves collection and/or sharing of data/biospecimens/images to other researchers include the following statements as applicable.***

Please also see the Biomedical Adult Participant Informed Consent Template for further language guidance.

If the research involves collection and/or sharing of de-identified data/biospecimens/images to other researchers include the following statement.

Your [data/samples/images] will be sent to researchers outside of Pepperdine University for [explain why the samples are being sent outside Pepperdine University]. Any personal information that could identify you will be removed before the [data/samples/images] are shared.

If the research involves collection and/or sharing of identifiable data/samples/images to other researchers include the following statement.

Your [data/samples/images] will be sent to researchers outside of Pepperdine University for [explain why the samples are being sent outside Pepperdine University]. The [data/samples/images] that are sent to these researchers will contain identifiable information including [describe the identifiable information that will be associated with the data]. Identifiable information is being sent to these researchers because [explain the purpose of sending identifiable data to researchers outside Pepperdine University].

What are the possible risks of being in this research study?

Identify each procedure with a subheading and then state the associated risk(s) using simplistic language. Please indicate the level of the risks as well (i.e., no more than minimal/minimal to moderate/moderate to substantial. The most serious and common risks should be addressed first followed by disclosure of uncommon and less serious risks in a separate paragraph, if warranted. Risks common to social science and behavioral research may include loss of confidentiality and emotional or psychological distress.

Example: This research presents risk of loss of confidentiality, emotional and/or psychological distress because the surveys involve sensitive questions about your work habits.

What are the possible benefits to you?

If direct subject benefits can reasonably be anticipated as a result of participating in the study, then describe these possible benefits. Conclude with the following standard clause.

[Describe benefits]. However, you may not get any benefit from being in this research study.

If direct subject benefits are NOT anticipated, then use the following standard clause.

You are not expected to get any benefit from being in this study.

What are the possible benefits to other people?

State the possible benefits to society in terms of advancement of knowledge and/or ultimate possible benefits to persons in the prospective subjects' position.

Example: The benefits to science and/or society may include better understanding of how to help others working night shifts and their coping strategies.

What are the alternatives to being in this research study?

Describe in reasonable detail, alternatives the prospective subject may have available. If there are no alternatives, this section does not need to be included.

Instead of being in this research study you can [X].

What will being in this research study cost you?

This section should state the financial obligations the subject may incur as a result of participating in the study. If there are no financial obligations to the subject, then use the following standard clause.

There is no cost to you for being a participant in this research study.

Will you be compensated for being in this research study?

If the subject will receive compensation for participating in the research, state the amount of compensation and conditions for payment. A prorated payment system should be used when appropriate and commensurate with the degree of participation required. If no compensation will be provided, state that.

Example: You will receive $5.00 for each survey completed for your participation in this study.

What should you do if you have a problem during this research study?

Your estimation of risk determines what additional information you will include in this section. For studies classified as minimal risk, use the following standard clause.

Your welfare is the major concern of every member of the research team. If you have a problem as a direct result of being in this study, you should immediately contact one of the people listed at the beginning of this consent form.

[Think about also providing resources to participants, dependent on the project parameters. For example, provide them with student health or wellness contact information].

For studies classified as greater than minimal risk, use the following standard clause.

If you have a problem or experience harm as a direct result of being in this study, you should immediately contact one of the people listed at the beginning of this consent form. If needed, seek immediate emergency care for this problem. Please note, it is the policy of Pepperdine University not to pay for any required care. Agreeing to this does not mean you have given up any of your legal rights.

[Think about also providing resources to participants, dependent on the project parameters. For example, provide them with student health or wellness contact information].

How will information about you be protected?

Begin with the following standard clause.

Reasonable steps will be taken to protect your privacy and the confidentiality of your study data.

Next, if the research requires collection of sensitive information (socially, financially, legally, or otherwise) from the prospective subject, follow the introductory standard clause above with a brief description of the precautions which will be utilized to protect the data.

For projects that collect paper-records, use this standard clause.

The data will be stored in a locked cabinet in the investigator's office and will only be seen by the research team during the study and for XX years after the study is complete.

For projects that collect electronic records, use this standard clause. Describe the security in detail so the participant can understand what protections are in place.

The data will be stored electronically through a secure server and will only be seen by the research team during the study and for XX years after the study is complete.

Finally, for all protocols, conclude with the following standard clause.

The only persons who will have access to your research records are the study personnel, the Institutional Review Board (IRB) of Pepperdine University, and any other person, agency, or sponsor as required by law. The information from this study may be published in scientific journals or presented at scientific meetings but the data will be reported as group or summarized data and your identity will be kept strictly confidential.

What are your rights as a research subject?

Use the following standard clause

You may ask any questions concerning this research and have those questions answered before agreeing to participate in or during the study.

For study related questions, please contact the investigator(s) listed at the beginning of this form.

For questions concerning your rights or complaints about the research contact the Institutional Review Board (IRB):

Phone: 1(310)568-2305
Email: gpsirb@pepperdine.edu

What will happen if you decide not to be in this research study or decide to stop participating once you start?

Use the following standard clause

You can decide not to be in this research study, or you can stop being in this research study ("withdraw') at any time before, during, or after the research begins for any reason. Deciding not to be in this research study or deciding to withdraw will not affect your relationship with the investigator or with Pepperdine University (list others as applicable).

You will not lose any benefits to which you are entitled.

Documentation of informed consent

Use the following standard clause if you are obtaining signed/written consent

You are voluntarily making a decision whether or not to be in this research study. Signing this form means that (1) you have read and understood this consent form, (2) you have had the consent form explained to you, (3) you have had your questions answered and (4) you have decided to be in the research study. You will be given a copy of this consent form to keep.

Participant Feedback Survey

To meet Pepperdine University's ongoing accreditation efforts and to meet the Accreditation of Human Research Protection Programs (AAHRPP) standards, an online feedback survey is included below:

https://forms.gle/nnRgRwLgajYzBq5t7

As part of Pepperdine University's ongoing accreditation efforts, the Association for the Accreditation of Human Research Protection Programs (AAHRPP) standard I-4: The Organization responds to concerns of research participants, encourages the HRPP to conduct evaluation or research participant satisfaction. In order to meet this standard, we have created an online feedback survey. All investigators are now required to include the following statement and survey link in all written informed consent information documents.

****Only include the survey if the consent process will be completed via a process not conducted via online procedures. Investigators using online/web-based procedures are NOT required to include this information.***

Participant Name:

_____

Name of Participant: Please Print

Participant Signature:

_____ _____

Signature of Research Participant Date

Investigator certification:

If applicable, include the following investigator certification clause (generally utilized for greater than minimal risk studies).

My signature certifies that all elements of informed consent described on this consent form have been explained fully to the subject. In my judgment, the participant possesses the capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate.

_____ _____

Signature of Person Obtaining Consent Date

If applicable, the following may be included under the appropriate elements to meet the additional elements of informed consent per 45 CFR 46. Depending on the project, some, all, or none of the elements below may need to be met.

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;
- Any additional costs to the subject that may result from participation in the research;
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
- The approximate number of subjects involved in the study;
- A statement regarding whether biospecimens may be used for commercial profit and whether the subject will or will not share in the commercial profit.
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
- For research involving biospecimens, whether the research will (if known) or might include whole genomic sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).
- See also, the Biomedical Adult Participant Informed Consent Template for further template guidance and language that satisfies many of the above additional points.