Preparing your IRB Application

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Please review the "Policies and Procedures Manual" available at http://community.pepperdine.edu/irb/policies/ prior to preparing your application packet for the Graduate and Professional Schools Institutional Review Board (GPS IRB). Research activities that involve human subjects may not begin until the researcher has received an Approval or Exemption Notice from the GPS IRB.

The answers to these frequently asked questions may be used as a supplement to "Policies and Procedures Manual" when preparing a new IRB application.

Frequently Asked Questions

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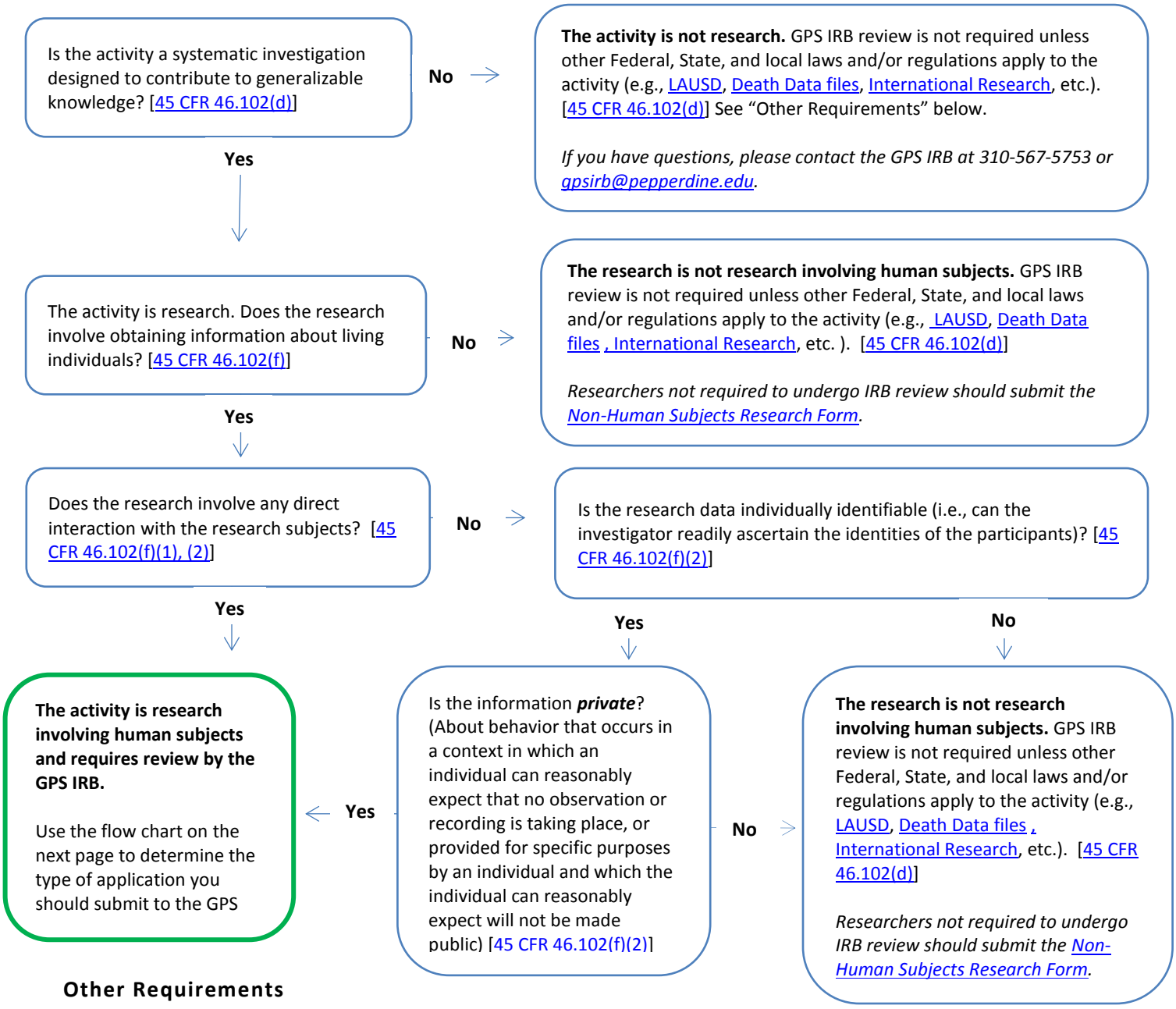
Do I need to submit to the IRB?

The following is a supplement to Section II.B "What Types of Projects Require IRB Review" of the manual. Any activity that is research and involves human subjects requires review by the GPS IRB. To assist you in determining whether your activity requires GPS IRB review, please follow this flow chart:



Other Requirements

- ***Los Angeles Unified School District (LAUSD) Requirements***
  Anyone wishing to access Los Angeles Unified School District (LAUSD) resources to conduct research studies—other than studies conducted by LAUSD—must obtain approval from the Committee for External Research Review (CERR) housed in the Research Unit of the Office of Data and Accountability. For instructions and additional information go to http://notebook.lausd.net/portal/page?_pageid=33,136510&_dad=ptl&_schema=PTL_EP.
- ***CA Health and Safety Code Section 102175-102249 Requirements***
  Section 102231 (a)(5) Death data files containing personal identifying information may be released to persons expressing a valid scientific interest, as determined by the appropriate committee constituted for the protection of human subjects that is approved by the United States Department of Health and Human Services and has a general assurance pursuant to Part 46 (commencing with Section 46.101) of Title 45 of the Code of Federal Regulations.

- ***International Research Requirements***
  Investigators conducting studies internationally should be aware of the laws and regulations governing human research protections in those countries. The Office of Human Research Protections (OHRP) has compiled a list of national policies which can be found on OHRP's website at http://www.hhs.gov/ohrp/international/. Please refer to the "Policies and Procedures Manual" additional information.

Do I apply for Exempt, Expedited, or Full Board Review?

To determine the appropriate level of review of your research study, you must first identify all potential risks involved in the research. Consider your subject population when identifying potential risks (e.g., students, children, etc.). The following are a few examples of potential risks:

Physical risks:
- Physical discomfort
- Pain
- Injury

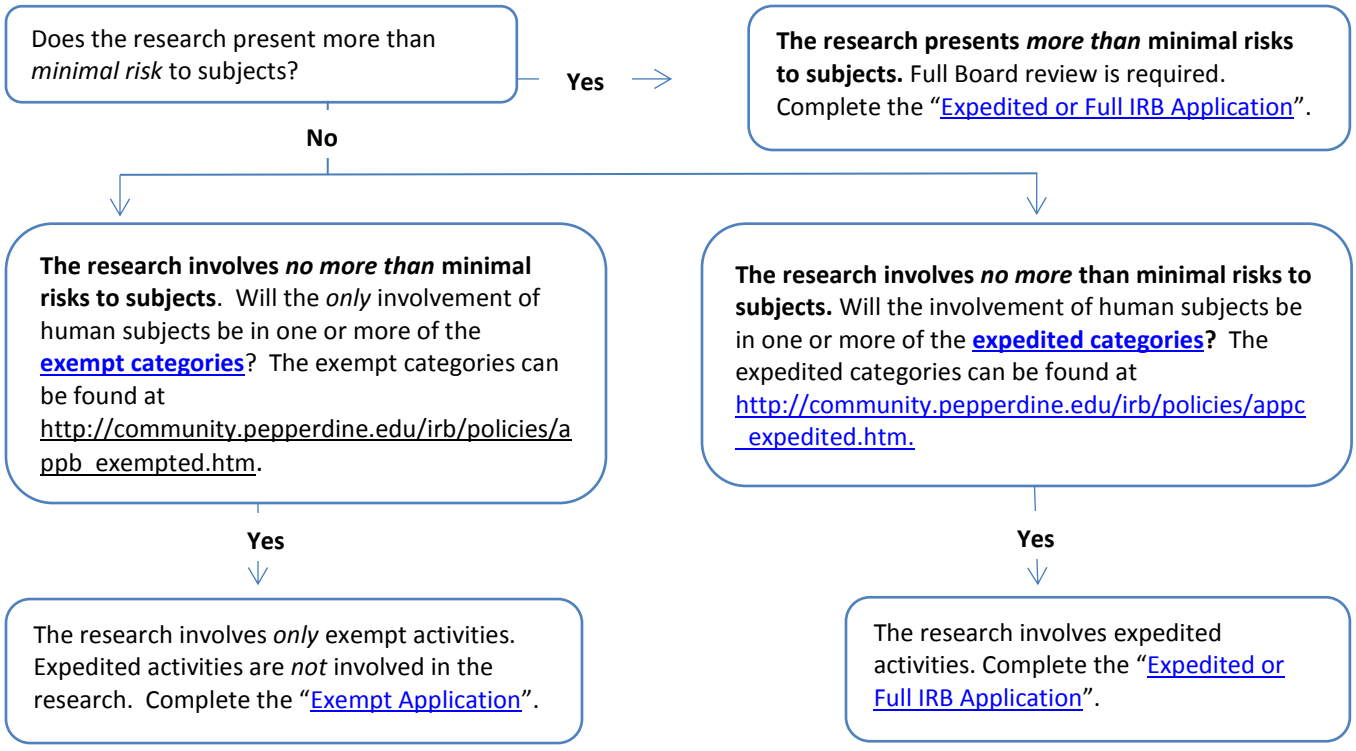
Social risks:
- Loss of wages or other income
- Damage to a subject's financial standing, employability, or reputation
- Perceived coercion

Psychological risks:
- Reactivation of fears
- Occurrences of unhappy thoughts
- Anxiety
- Loss of self-esteem

Other Risks
- Boredom
- Fatigue
- Loss of time
- Inconvenience
- Loss of confidentiality or privacy

Then use the diagram below to help you select the appropriate IRB application for your research study. For detailed information refer to Section III.B "IRB Review Procedures" of the IRB Policy and Procedures Manual.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. [45 CFR 46.102(i)]



What information do I provide in my IRB application?

Your application should include a detailed description of your study design, selection of subjects, potential risks and benefits of the research, informed consent process, how confidentiality of data will be maintained, how privacy of

subjects will be maintained, and your qualifications for conducting the research procedures. You application should contain sufficient information for GPS IRB to confirm the appropriate the level of review for your research study and that all the requirements for approval or exemption are satisfied. Please revise "Section III. The IRB Review Process" of the Policy and Procedures Manual for detailed information on the content of an IRB application.

Your IRB submission packet should contain several documents, in addition to the IRB application. Use the GPS IRB Checklist available at http://community.pepperdine.edu/irb/irbforms/#apps to prepare your IRB application packet.

Do I need to obtain consent from subjects?

Unless the research meets the requirement for altering or waiving the informed consent process (see Section B below), researchers are required to obtain informed consent from potential subjects or subject's legally authorized representative for participation in research, by providing subjects with information outlined below in Section A below. For research involving children, please refer to the requirements described in the Section VIII.B of the "Policies and Procedures Manual" for special instructions on obtaining child assent parental consent/permission for participation in research.

Section A - University Policy & Federal Requirements for Obtaining Informed Consent (45 CFR 46.116 (a)-(b))

When seeking informed consent the following information shall be provided to each subject:

1) An introduction of yourself and your research.
   - Identify yourself by name, affiliation, and your student status.
   - Mention the name of your faculty supervisor.
   - Indicate for whom consent is being requested (e.g., consent is obtained from the parent for a child to participate in research).
   - State that participating in the study is voluntary.
   - State why the participant has been asked to participate.

2) A description of your research, including:
   - A statement that the study involves research
   - An explanation of the purposes of the research
   - The expected duration of the subject's participation
   - A description of the procedures to be followed, and identification of any procedures which are experimental
   - If audio or videotaping will be used in the study, this needs to be noted in the consent form along with the usages of the recorded material and how the material will be handled upon the completion of the study.

3) A description of any reasonably foreseeable risks or discomforts to the subject.

4) A description of any benefits to the subject or to others which may reasonably be expected from the research.

5) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

6) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

7) For research involving ***more than minimal risk***, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

8) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

9) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

When appropriate, one or more of the following elements of information shall also be provided to each subject:

1) 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) which are currently unforeseeable;

2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

3) Any additional costs to the subject that may result from participation in the research;

4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

6) The approximate number of subjects involved in the study.

Section B – Requirements for Altering or Waiving the Consent Process (45 CFR 46.116 (c) – (d))

The following are the requirement for altering or waiving the informed consent process.

45 CFR 46.116 (c)(1-2) Requirements:
An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
   (i) public benefit or service programs;
   (ii) procedures for obtaining benefits or services under those programs;
   (iii) possible changes in or alternatives to those programs or procedures; or
   (iv) possible changes in methods or levels of payment for benefits or services under those programs; **and**

2) The research could not practicably be carried out without the waiver or alteration.

45 CFR 46.116 (d)(1-4) Requirements:
An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

1) The research involves no more than minimal risk to the subjects;

2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

3) The research could not practicably be carried out without the waiver or alteration; **and**

4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Do I need to obtain written/signed consent from subjects?

Unless the research meets the requirements for waiving signed consent (See Section C), informed consent shall be documented by use of a written consent form. The information that is given to the participant or the representative shall be in language understandable to the subject or the representative. (45 CFR 46.116) An example of a consent form for obtaining signed consent is found below (see Example 1).

Section C – Requirements for Waiving Signed Consent (45 CFR 46.117 (c))

The following are the requirement for waiving signing consent.

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

   or

2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

An example of a form for obtaining consent through means other than a signature is found below (see Example 2).

Example 1 – Consent Form for Obtaining Signed Consent

Consent Form for Participation in a Research Study

Instructions for researchers: *You may use this example as a template to assist you with developing a consent form for* ***obtained signed consent*** *from subjects for participation in the research study. Please replace the italicized text with the requested information and undo bold, italicized text, unless necessary.*

[Insert Title of Project]

The following information is provided to help you decide whether you wish to participate in a research study. Please take your time to read the information below and feel free to ask any questions before signing this document.

My name is *(insert name of researcher),* and I am a (*select one: Master's or Doctoral)* student in the *(insert program name)* at Pepperdine University. The professor supervising my work is *[insert faculty supervisor's name]*. The title of my research study is *(insert study title)* and is being done as partial requirement for my *(select on: Master's degree or Doctoral degree).*

Purpose of Research Study: *(Indicate the purpose of the study.)*

Procedures: If you volunteer to participate in this study, you will be asked to *(briefly describe all procedures in chronological order and duration of participation). The following are some suggestions to describing the research procedures:*

- *If several procedures will be used, the use of subheadings may help to organize this section and increase readability.*
- *If survey or questionnaire instrument(s) are used, briefly describe the types of questions asked.*
- *If applicable to the study, clearly state that the subject will be photographed and/or audio/video-recorded. Indicate how recorded material will be used and upon completion of research.*
- *Clarify if the participant can still participate in this research study if they do not wish to be audio/video-recorded or photographed.*

Compensation: *(Describe any compensation/remuneration to be given to the participant. If subjects are not compensated, please delete this section.)*

Potential Risks: *(Provide a complete description of the potential risk(s) to the subjects as result of participation in the study regardless of how minor (e.g., fatigue, boredom, etc.). Describe the precautions that will be taken if participants experience discomfort.)*

Potential Benefit: *(Describe any benefits to the subject or to others which may reasonably be expected from the research. If the subject will not directly benefit from participation please state* "You will not directly benefit from participating in this research study".)

Voluntary/right to deny or withdraw from participation: Your participation in the research study is completely voluntary, and you have the right to deny, withdraw or refuse to participate at any time, with no negative consequences to you.

Confidentiality: Data obtained for this research study, including your responses to the survey will be kept confidential. The confidentiality of my records will be maintained in accordance with applicable state and federal laws. Under California law, there are exceptions to confidentiality, including suspicion that a child, elder, or dependent adult is being abused, or if an individual discloses an intent to harm him/herself or others.

(*Describe how data will be kept confidential and any additional exception to confidentiality. In addition, please state research records will be kept for a minimum of three years as required by the federal regulations)*.

The results of this research study will be summarized as a whole, as so no persons will identify you.

Contact information for questions or concerns: If you have further questions regarding this research, you may contact me, the primary investigator, (*insert your name)* at: *(insert your email address)*, (*provide phone number)* or my faculty supervisor, *(insert supervisor name)* at: *(insert supervisor email), (provide supervisor phone number)*. If you have questions about your rights as a research participant, you may contact Dr. Thema Bryant-Davis, Chairperson of the GPS IRB at Pepperdine University at gpsirb@pepperdine.edu or 310-568-5753.

Consent to participate in research:

I understand that this research study has been reviewed by Graduate and Professional Schools (GPS) Institutional Review Board, Pepperdine University. For research-related problems or questions regarding participants' rights, I may contact Dr. Thema Bryant-Davis, Chairperson of the GPS IRB at Pepperdine University at gpsirb@pepperdine.edu, 310-568-5753.

I have read and understand the explanation provided to me. I have had all my questions answered to my satisfaction, and I voluntarily agree to participate in this study. I have been given a copy of this consent form.

By signing this document, I consent to participate in this study.

_____
Research Participant's Full Name (Print)

_____ _____
Research Participant's Signature Date

I have explained and defined in detail the research procedure in which the subject has consented to participate. Having explained this and answered any questions, I am cosigning this form and accepting this person's consent.

_____
Principal Investigator Full Name (Print)

_____ _____
Principal Investigator Signature Date

Example 2 – Form for Obtaining Verbal, On-line, etc. Consent (not signed)

Research Information Sheet/ Consent Form for Participation in a Research Study

Instructions for researchers: *You may use this example as a template to assist you with developing a consent form or research information sheet for subjects if your* ***research meets the requirements for a waiver of signed consent*** *(i.e., The consent process will not involve written consent. The consent process will involve verbal consent or be obtained through other means). Please replace the italicized text with the requested information and undo italicized text, unless necessary.*

Per federal regulations, an IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; ***or***

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written con-sent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research. 45 CFR 46.117(c)

[Insert Title of Research Study]

The following information is provided to help you decide whether you wish to participate in a research study. Please take your time to read the information below and feel free to ask any questions before signing this document.

(Faculty conducting research should modify the following paragraph as appropriate to remove language pertaining to student researchers)

My name is *(insert name of researcher),* and I am a (*select one: Master's or Doctoral)* student in the *(insert program name)* at Pepperdine University. The professor supervising my work is *[insert faculty supervisor's name]*. The title of my research study is *(insert study title)* and is being done as partial requirement for my *(select on: Master's degree or Doctoral degree).)*

Purpose of Research Study: *(Indicate the purpose of the study.)*

Procedures: If you volunteer to participate in this research study, you will be asked to *(briefly describe all procedures in chronological order and duration of participation). The following are some suggestions to describing the research procedures:*

- *For surveys or questionnaires provide a brief description of the types of questions that subjects will be asked.*
- *If applicable to the study, clearly state that the subject will be photographed and/or audio/video-recorded. Indicate how recorded material will be used and upon completion of research.*

Compensation: *(Describe any compensation/remuneration to be given to the participant. If subjects are not compensated, please delete this section.)*

Potential Risks: *(Provide a complete description of the potential risk(s) to the subjects as result of participation in the study regardless of how minor (e.g., fatigue, boredom, etc.). Describe the precautions that will be taken if participants experience discomfort.)*

Potential Benefit: *(Describe any benefits to the subject or to others which may reasonably be expected from the research. If the subject will not directly benefit from participation please state* "You will not directly benefit from participating in this research study".)

Voluntary/right to deny or withdraw from participation: Your participation in the research study is completely voluntary, and you have the right to deny, withdraw or refuse to participate at any time, with no negative consequences to you.

Confidentiality: Data obtained for this research study, including your responses to the survey will be kept confidential. The confidentiality of my records will be maintained in accordance with applicable state and federal laws. Under California law, there are exceptions to confidentiality, including suspicion that a child, elder, or dependent adult is being abused, or if an individual discloses an intent to harm him/herself or others.

(*Describe how data will be kept confidential and any additional exception to confidentiality. In addition, please state research records will be kept for a minimum of three years as required by the federal regulations)*.

The results of this research study will be summarized as a whole, as so no persons will identify you.

Contact information for questions or concerns: If you have further questions regarding this research, you may contact me, the primary investigator, (*insert your name)* at: *(insert your email address)*, (*provide phone number)* or my faculty supervisor, *(insert supervisor name)* at *(insert supervisor email), (provide supervisor phone number)*. If you have questions about your rights as a research participant, you may contact Dr. Thema Bryant-Davis, Chairperson of the GPS IRB at Pepperdine University at gpsirb@pepperdine.edu, 310-568-5753.

(Create a new section to indicate the means by which consent will be obtained. The following are examples of verbal and on-line consenting:

Verbal consent: Do you have any questions about what participation in this research study involves? Would you like to participate in this research study?

(*If your research meets the requirement for a waiver of singed consent under 45 CF 46.117(c)(1) please add the following and describe how the form will be provided to the subject:* Would you like a copy of this form to document your participation in this research study?

On-line consent: By clicking on the link to the survey, you agree to participation in this research study.

(*If your research meets the requirement for a waiver of singed consent under 45 CF 46.117(c)(1) please add the following:* If you would like documentation of your participation in this research, you may print a copy of this form.)

(You may provide a link to your survey/questionnaire and include the statement: The survey/questionnaire may be accessed at *(insert link).)*

Your consent: By completing the survey and returning it to [insert location], you agree to participation in this research study.

(*If your research meets the requirement for a waiver of singed consent under 45 CF 46.117(c)(1) please add the following:* If you would like documentation of your participation in this research, you may print a copy of this form.)