IRB TEMPLATE
WEB, EMAIL, AND/OR COVER LETTER BASED INFORMED CONSENT
TYPICALLY USED WITH EXEMPT STUDIES

The following instructions and examples are provided to assist in development of the Web, Email and/or Cover Letter Based Consent Form. Additional templates and information are available from the IRB 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. (Note, consent forms administered via email or web may not be able to include letter head but cover letter informed consent should include letterhead.

- 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.

- The informed consent form must be written in the second person. 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.

- Please remember, age of majority in California is 18 years old. Anyone younger than 18 requires parental consent/assent, with few exceptions based on NE 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 Number #

Study Title:

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

Invitation

> ***For Email or Cover Letter based consent forms, utilize the following standard clause.***

Dear [name],

My name is [name]. I am conducting a study on [purpose]. If you are 19 years of age or older [include inclusion criteria], you may participate in this research.

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.***

This is a research project that focuses on [purpose]. In order to participate you must be 19 years of age or older and [include participant criteria].

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.***

Participation in this study will require approximately [amount of time]. You will be asked to [description of procedures]. Participation will take place [include location].

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

> ***Please state the risks associated with your study here and indicate the level of the risks – [No more than minimal/minimal to moderate/moderate to substantial].***

What are the possible benefits to you?

The results of this study will be used to [include benefits].

How will information about you be protected?

Your responses to this survey will be kept [anonymous/confidential]. [Explain how data will be kept 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):
[PI/SI names and contact information].

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

For web-based consent, use the following standard clause.

You are voluntarily making a decision whether or not to participate in this research study. By clicking on the I Agree button below, your consent to participate is implied. You should print a copy of this page for your records.

I agree

I do not agree

For e-mail based consent, use the following standard clause.

You are voluntarily making a decision whether or not to participate in this research study. By completing and submitting your survey responses, you have given your consent to participate in this research. You should print a copy of this page for your records.