UNIVERSITY OF SAN DIEGO

Institutional Review Board (IRB)


PROPOSAL COVER SHEET
To be completed for all research, defined in 45 CFR 46.102(d) involving human subjects, defined in 45 CFR 46.102(f) and conducted at the University of San Diego, by or under the direction of any employee, agent or student of this institution, including research conducted at or in cooperation with another entity.

1. Title of Research: ________________________________

2a. Principal Investigator (PI): ________________________________
   (If student, please circle: UG, Masters, Doctoral; College of Arts & Sciences, School of Business, School of Education, School of Law) If not affiliated with USD, please explain: ______________

2b. Additional Investigators: ________________________________

2c. Faculty Advisor (if applicable): ________________________________

2d. USD Sponsor (if PI is not a USD employee or agent): ________________________________

3. Review Category
   _____ Exempt (Complete Section A) by category _____
   _____ Expedited (Complete Section B) by category _____
   _____ Full (Complete Section C)

4. Anticipated Date on which Data Collection will begin: ______________

5. If this is a funded project, please name funding source(s). ________________________________

6. If this proposed research has been, or will be reviewed by an IRB elsewhere please name the IRB(s). If applicable, attach a copy of each IRB's recommendations and findings, and dated approval.

You must submit this form, all supporting documents and a description of the proposed research, as specified in Section B (for Expedited Review) or in Section C (for Full Review) in paper format. Prior to submission to the Provost’s Office, all proposals require all signatures below as necessary.
The project described above has been approved by the USD Institutional Review Board.

Proposals that are incomplete or lacking signatures will be returned.
SECTION A:
EXEMPT FROM FURTHER, DETAILED REVIEW
(see Federal Law 45 CFR 46.101 a-d)

1. Complete and attach the Cover Sheet with necessary signatures.
2. Indicate on the cover sheet by number into which of the six exempt categories listed in 45 CFR 46.101 (b) you believe this research best falls.
3. Attach a succinct description of the proposed research. Be sure to include the following:
   a. Who are the subjects and how will you recruit them?
   b. What will subjects do or how will you interact with the subjects?
   c. What steps will you take to assure that participation is voluntary?
   d. Attach copies of questionnaires or other materials that will be used (such as interview questions or topics, experimental stimuli or other instruments).
4. Send ONE PAPER copy of the proposal to the Provost’s Office (HC328).

SECTION B:
EXPEDITED REVIEW
(see Federal Law 45 CFR 46.110)

1. Complete and attach the Cover Sheet with necessary signatures.
2. Indicate on the cover sheet by number into which of the nine categories of expedited review (as defined by Federal Law at http://ohrp.osophs.dhhs.gov/humansubjects/guidance/expedited98.htm) you believe this research best falls.
3. Attach a succinct description of the proposed research, using numbered pages. Be sure to address each of the following issues, with particular attention to potential risks to subjects and what will be done to minimize those risks.
   a. Background and purpose of the research.
   b. Who are the subjects and how will you recruit them?
   c. What steps will you take to assure that participation is voluntary?
   d. What will the subjects do or how will you interact with the subjects?
   e. Describe all the equipment you will use or with which the subject will interact.
   f. Note the estimated duration of subject participation.
   g. Will the subjects incur any expenses? If so, please explain.
   h. Name facilities other than USD where research will be conducted.
   i. Attach copies of questionnaires or other materials that will be used (such as interview questions or topics, experimental stimuli or other instruments).
   j. List the foreseeable risk(s) to subjects, describe how you will minimize each risk, and why each risk is justifiable in light of benefits (either directly to the subject or indirectly to generalized knowledge) to be gained by the research.
   k. Describe the procedures you will follow to obtain informed consent. Attach a copy of the consent form(s). Remember that informed consent is a process. The form verifies that the process has occurred and, therefore, the form will be examined closely. See Appendix A for informed consent guidelines.
4. Send ONE PAPER copy of the proposal to the Provost’s Office (HC328).
SECTION C:
FULL REVIEW
(proposed research not eligible for Expedited Review)

1. Complete and attach the Cover Sheet with necessary signatures.
2. Attach a succinct description of the proposed research. Be sure to address each of the following issues, with particular attention to potential risks to subjects and what will be done to minimize those risks.
   a. Background and purpose of the research.
   b. Who are the subjects and how will you recruit them? Specifically, note whether subjects belong to a protected group as defined in 45 CFR 46.111 (b) and see Subparts B and C there for further details.
   c. What steps will you take to assure that participation is voluntary?
   d. What will the subjects do or how will you interact with the subjects (e.g., describe any bodily invasive procedures)?
   e. Describe all the equipment you will use or with which the subject will interact.
   f. Note the estimated duration of subject participation.
   g. Will the subjects incur any expenses? If so, please explain.
   h. Name the facilities other than USD where research will be conducted and provide copies of any letters of permission or support that you have obtained. If you have not obtained any letters, please explain.
   i. Attach copies of questionnaires or other materials that will be used (such as interview questions or topics, experimental stimuli or other instruments).
   j. List the foreseeable risk(s) to subjects, describe how you will minimize each risk, and why each risk is justifiable in light of benefits (either directly to the subject or indirectly to generalized knowledge) to be gained by the research.
   k. Describe the procedures you will follow to obtain informed consent, and/or assent, if applicable. Attach a copy of the consent and/or assent form(s). Remember that informed consent is a process. The form verifies that the process has occurred and, therefore, the form will be examined closely. See for informed consent (and assent) guidelines.
3. Send TWELVE (12) PAPER copies of the proposal to the Provost's Office (HC328).
1. General guidelines for obtaining informed consent or assent, as applicable.
   a. Since informed consent is a PROCESS, a form is used to provide evidence of this important process, which protects all research subjects under the Belmont Report, to ensure that the ethical principles of “Respect for Persons, Beneficence and Justice” are met.
   b. In rare circumstances research may be exempt from use of an informed consent form, however, the circumstances resulting in greater risk than benefit from the use of the form must be rigorously justified, including but not limited to potential loss of anonymity or confidentiality (See 45 CFR 46.117c).
   c. The consent form should be written in everyday language, not in scientific jargon, and should be fully understandable by any specific populations.
   d. Two copies of the consent form should be provided for each research subject: one for the researcher’s files and another for the subject to keep for future reference.
   e. The consent form itself is preferably written in second person; first person should be avoided, except for the phrase, “I have read and understood this form, and consent to the research it describes to me (or similar appropriate phrase to indicate the subject’s consent).”
   f. For research involving individuals for whom the informed consent must be signed by a parent or a legal guardian (e.g., children, mentally disabled persons), assent, including an assent form must be included, which mirrors the consent process and form in its spirit but must be written in more appropriate language.
   g. The researcher should consult http://ohrp.osophs.dhhs.gov/humansubjects/assurance/consentckls.htm for additional guidance.

2. The consent form itself must include the following items, reflecting that the explanation or description of each of these elements to the individual subject has taken place prior to participation:
   a. A statement that the subject is, in fact, participating in a research study, including a statement of the purpose of the research, potential uses of assessment instruments, a complete description of any tasks the subject might need to perform, any audio or videotaping that might occur, and the estimated duration of the subject’s participation.
   b. A description of any foreseeable risks or discomforts.
   c. A description of any benefits which might be expected to be derived from participation in the research, both direct and indirect.
   d. A disclosure of appropriate alternative procedures or courses of treatment, if any.
   e. A statement regarding the confidentiality and/or anonymity of records and the safeguards that will be taken to assure these for a minimum of 5 years.
   f. A statement that although results might be made public, all individual data will remain anonymous and confidential.
   g. For research involving greater than minimal risk, an explanation of whether or not any potential compensation will be available, and, if so, how and where such compensation may be obtained.
   h. A statement that participation is voluntary, refusal to participate in the research will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may withdraw from the research at any time with no penalty.
   i. An explanation of whom to contact with future questions about the research or the subject’s rights, or in the event of a research-related injury. Ideally, two contact persons should be made available to the subject. The subject should understand that he or she is to retain one copy of the consent form for his or her records.
   j. A signature line for the Subject, date of signature, printed name of subject, signature of PI and date of signature should be included; a witness’ signature may be desired if the study task is being performed over long-distance (e.g., use of questionnaires and follow-up phone calls).
UNIVERSITY OF SAN DIEGO

Institutional Review Board (IRB)
Research Project Report Form (Summary/Continuation Form)

PROJECT ID#:

PROJECT TITLE:

TYPE OF REPORT (check one):  Summary  Continuation

LEVEL OF INITIAL APPROVAL:  Exempt  Expedited  Full Review

IF SUMMARY, DATE OF COMPLETION OF DATA COLLECTION:

A. Results/Progress of Research:

B. Human Subjects Problems/Benefits:
   Data were collected for _____ subjects (indicate number).
   Informed Consent Forms are on file.  Yes  No
   Explain: ________________________________

   Changes have been made in the Informed Consent Form.  Yes  No
   (If yes, please provide new copy.)

C. Adverse Events: (See http://www.osp.cornell.edu/Compliance/UCHS/Adverse.htm for a
definition of adverse event.)

__________________________________________  __________________
Researcher (Signature)      Date

__________________________________________  __________________
Researcher (Print)

__________________________________________  __________________
Faculty Advisor (Signature) [If researcher is student]  Date

_____________________________  __________________
Dean or His/Her Representative (signature)  Date

_____________________________  __________________
College or School IRB Representative (signature)  Date

__________________________________________  __________________
Administrative Approval (if “Continuation”)  Date