

**UCSD Human Research Protections Program  
New Social and Behavioral Sciences Application  
RESEARCH PLAN INSTRUCTIONS**

These are instructions for filling out the Research Plan that is available in MS Word format from the HRPP website: <http://irb.ucsd.edu>.

The headings on this set of instructions correspond to the headings of the Research Plan .

General Instructions: Enter a response in for all topic headings.

Enter "Not Applicable" rather than leaving sections blank if the section does not apply to this project.

**Research Plans, excluding attachments such as surveys and consent/assent forms, should be no more than 8-10 pages. Longer protocols must be explicitly justified.**

Version date: 10/01/09

### **1. PROJECT TITLE**

Enter the project title. It should match the title entered on the face page.

### **2. PRINCIPAL INVESTIGATOR**

Include Principal Investigator's title and department. This is for identification purposes, to match the Research Plan to the project application face page. The **complete list** of investigators should be entered on the face page.

### **3. FACILITIES**

List all locations where the project will be done.

### **4. ESTIMATED DURATION OF THE STUDY**

Include time from opening of study for participant accrual through the end of data analysis.

### **5. SPECIFIC AIMS (2 paragraphs maximum)**

Provide a precise statement of the specific aims (goals) for this protocol. Emphasize those aspects that justify the use of human subjects.

### **6. BACKGROUND AND SIGNIFICANCE (2-3 paragraphs maximum)**

Provide a succinct discussion of relevant background information and the rationale for the current study.

### **7. PROGRESS REPORT/PRELIMINARY STUDIES**

If this is a **renewal application**, a brief **summary of past experience to date** with this protocol must be provided including any untoward effects on the subjects. List any publications that have emanated from this protocol. Renewal applications must be revised from the original application to reflect any changes in the research design and other areas and must describe the progress made since the original application.

### **8. RESEARCH DESIGN AND METHODS (1 page maximum)**

Describe the research design and the procedures to be used to accomplish the specific aims of the project. Define in clear terms exactly what will be done to the human subjects and how long they will be involved in the study. Where appropriate, identify the sources of research material obtained from individually identifiable living human subjects in the form of records or data. Indicate whether new data will be obtained specifically for the purposes of this research, or if existing records or data will be used.

In addition, this item of the Research Plan should include a precise, but brief, description of the methods for data collection, data analysis and data interpretation. If video and/or audio recording will be done as part of the study, a description of the study procedures associated with the taping should be provided including how the tapes will be used, who will have access to the tapes, and the final disposition of the recordings.

If questionnaires/surveys will be completed as part of the research, please provide the name and reference for questionnaires/surveys that are standard. If the questionnaire/survey is not a standard assessment tool, please provide a copy of the questionnaire/survey.

### **9. HUMAN SUBJECTS (2 paragraphs maximum)**

Describe the characteristics of the proposed subject population, including number of subjects to be enrolled and their age, **gender**, **ethnic background** and health status. Identify the criteria for inclusion/exclusion of subjects to be enrolled in the study. Explain the rationale for using special subjects, if any, such as pregnant women, children, or institutionalized individuals who are likely to be vulnerable.

**Please note: Inclusion of women and minorities** must be addressed in all research protocols. For example, what is the study population? What percentages of women and minorities make up the demographic area under study and what percentage will be enrolled in the study? If women or minorities will not be included in the research, the scientific rationale for their exclusion must be explained and justified. Moreover, equitable subject selection holds that the benefits and risks of the research must be equally shared across the population regardless of language or socioeconomic status. Specifically, individuals cannot be excluded from participation solely because they are not speakers of English. Justification for excluding individuals from research due to inability to speak or comprehend English language must be based on sound scientific rationale or the PI must document that excluding such individuals will not deprive them (individually or as a group) of potential benefits of the research.

#### 10. RECRUITMENT

Describe how human subjects will be contacted in the first instance and by whom, what they will be told, and how they will be selected for participation including how the PI will ensure the recruitment/selection of subjects is equitable. The text of all communications with prospective subjects (advertisements, flyers, letters, etc.) must be submitted for review and approval by the IRB **prior** to their use in the study.

In addition, students (undergraduate, graduate, and medical students), and employees of UCSD (administrative, clerical, etc.) are considered vulnerable to undue influence. Such individuals may feel some pressure to participate in a researcher's study, especially if the requesting researcher is their supervisor, instructor, or someone who might be in a position to influence their future. Researchers must exercise great caution to avoid even the appearance of pressuring such individuals into enrollment or continued participation. If such individuals will be potential subjects in the study, describe the study procedures that will be used to address this issue.

Further, if children are to be enrolled in the study, describe how possible undue influence for their participation will be addressed. For more information, please see [here](#).

#### 11. COMPENSATION FOR PARTICIPATION

Describe all plans to pay subjects, either in cash, a gift or gift certificate. The PI should pay special attention to conditions under which compensation could be coercive: for example, giving a lump sum at the end of a study instead of prorating the compensation throughout the life of the study, or giving a large sum to socio-economically vulnerable subjects. The amount of payment must be justified. This item should also clarify if subjects will be reimbursed for travel or other expenses.

Please note when students participate in research studies for class credit they should be provided alternative methods of getting that credit that do not include participating in an experiment, and it is the investigator's responsibility to determine that those alternative methods exist. Wherever possible, students should be provided with a choice of research opportunities, including some not associated with the investigator. The IRB currently requires the informed consent form to state that alternatives are available and what those alternatives are.

#### 12. INFORMED CONSENT

Describe the **consent procedures** to be followed, including the circumstances under which consent/assent will be obtained, who will seek it, and the methods of documenting consent/assent. A sample SBS informed consent document can be found [here](#).

If the PI will be seeking a waiver of consent or waiver of informed consent, justification for such a waiver must be provided in this item of the Research Plan. The requirements for waiver of consent that need to be satisfied include that the research is minimal risk; the waiver or alteration will not adversely affect the rights and welfare of the subjects; the research could not practicably be carried out without the waiver or alteration; and whenever appropriate, the subjects will be provided with additional pertinent information after participation. The requirements for waiver of documented consent are described [here](#).

For research that involves video and/or audio recording, procedures for obtaining consent for such recording must also be stated and the consent must indicate that the recordings may be stopped at any time, and that portions and/or the entire audio/video may be erased at the subject's request. The consent should also state how the audio/video recording will be used by the researchers. A sample video recording consent can be obtained [here](#). A sample audio recording consent can be obtained [here](#).

For research that involves subjects under the age of 18 years, both a parent permission/consent form and adolescent assent (for children aged 13-17 years) and/or child assent (children 7-12 years of age) must be used. Please note that both parent permission/consent and adolescent/child assent must be obtained before adolescent/children can be involved in a research study.

### 13. ALTERNATIVES TO PARTICIPATION

Describe the alternatives that are reasonably available that may be of benefit to the potential subject. In most cases, the alternative to participation is not to participate. However, procedures for special cases, such as how classroom students may choose not to participate in a study organized by the professor should be included in this item of the Research Plan as well as the informed consent/assent documents.

### 14. POTENTIAL RISKS

Describe and assess any potential or known risks - psychological, physical, social, legal or other, and assess their likelihood and seriousness.

For example, is there potential for emotional stress, boredom, or fatigue? If there is a potential for subjects to become upset, and thus require psychological or medical attention as a result of the research procedures, then a means of supplying this attention must be addressed. Is there potential for a loss of confidentiality about the information given by the subjects and how serious would loss of confidentiality be for the subject? Does the research create potential social stigmatization, physical harm to subjects such as potential abuse, legal action by authorities if subject information, responses to survey questions, etc., become known outside of research? Are there potential risks to the subject related to the political, social, or economic context in which they live?

### 15. RISK MANAGEMENT

Describe the procedures for protecting against or minimizing any potential risks, including **risks to confidentiality**, and assess their likely effectiveness. Specify steps to be taken to guard the anonymity of subjects and/or the confidentiality of their responses, and who will have access to the data including the UCSD Institutional Review Board. If there will be a key to coded information, describe the means of protecting the key. Indicate what personal identifying indicators, if any, will be kept on subjects. Specify procedures for storage and ultimate disposal of personal information.

The IRB does not require that researchers destroy their human subjects data at the completion of their research. If the project is funded, researchers should contact their funding agency which may have specific requirements for retention or disposal of records. For information regarding retention of research records, please see the HRPP fact sheet, "Study Withdrawal/Closure" that is available [here](#).

If the research includes video and/or audio recording, this item should state that the taping may be stopped at any time and that portions and/or the entire tape may be erased at the subject's request. In addition, this item should also describe how the tape recording will be used, when/whether the tape will be destroyed by the researchers, and any risk and risk management procedures associated with this taping including loss of confidentiality. This information should also be included in the informed consent/assent documents and a separate video and/or audio consent/assent document may also be required.

For research that could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's

financial standing or employability or the research deals with sensitive aspects of the subject's own behavior, the IRB suggests that the PI apply for a "Certificate of Confidentiality" from the U.S. Department of Health and Human Services. For more information about obtaining such a certificate, please see [here](#) and [here](#).

#### 16. POTENTIAL BENEFITS

Discuss those benefits, if any, to be gained by the individual subject, as well as those benefits that may accrue to society in general. If there is no direct benefit to the subject, this must be stated in this item of the Research Plan as well as in the informed consent/assent documents.

**Note: Overly optimistic statements of benefit should be avoided. Reimbursement/compensation and class credit do not fall under the benefits section.**

#### 17. RISK/BENEFIT ASSESSMENT

Discuss why the risks to subjects are so outweighed by the sum of the benefit to the subject and/or the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks.

#### 18. QUALIFICATIONS, TRAINING, CULTURAL LITERACY AND ROLES OF THE PI AND RESEARCH TEAM

This section should provide a detailed explanation that specifically outlines *each* member of the research team's responsibilities as well as specifies each members qualifications, training, cultural literacy, etc. as they relate to this study.

#### 19. FUNDING FOR THIS PROJECT

Indicate whether this project is supported by federal, state, or another source. Provide the UCSD grant number and inclusive dates of support, as appropriate. **If you have indicated on the face sheet that there is NO funding support for this project, you will need to explain how the project is to be supported.**

#### 20. CONFLICT OF INTEREST

The Principal Investigator, co-investigators **or any other individual** who is responsible for the design, conduct or reporting of research or educational activities, will be required to disclose financial interests related to the research. This section should be filled out by all investigators involved with "non-government" research or research funded by monies in any form from private sources.

In this section, put a narrative description of what this relationship is for all investigators and other key personnel on the project. Examples of financial relationships include consulting, participation in speakers bureaus, stock or stock option ownership, or service on advisory boards or the board of directors of a company, or service as a company officer.

In addition, where there is a commercial sponsor for a project, a Form 700U form "PRINCIPAL INVESTIGATOR'S STATEMENT OF ECONOMIC INTEREST" should be completed by the PI and all co-investigators on the study and submitted to the UCSD Conflict of Interest Office. Disclosure forms (for private and federally sponsored studies) and instructions for completing them are available on the UCSD Conflict of Interest Office website <http://coi.ucsd.edu/>. The disclosure forms should be sent only to the COI office and not included in the IRB application, making it essential that financial relationships be described as a narrative in this section.

#### 21. BIBLIOGRAPHY (1 page maximum)

List several relevant articles, if applicable, that the IRB Committee can use to provide necessary background for the protocol.

## **Additional Information for Completing the SBS Application**

### **RESEARCH INVOLVING QUESTIONNAIRES/SURVEYS/INTERVIEWS**

Consents should state that subjects have the right to refuse to answer any question or skip any question they chose not to answer. The PI should also state what procedures will be used to protect the confidentiality of the subject's responses. The investigator should provide copies of the questionnaire if they are not standard clinical assessment tools.

Where the investigator does not have specific questions, a listing of topics and generic questions should be provided for review and approval by the IRB.

### **RESEARCH INVOLVING PSYCHOLOGICAL INTERVENTION**

If the subject(s) of the proposed research will be exposed to any psychological intervention such as contrived social situations, manipulation of the subject's attitudes, opinions or self-esteem, psychotherapeutic procedures, or other psychological influences, the following must be provided in the appropriate item of the Research Plan:

1. Identify and describe *in detail* the psychological intervention.
2. Identify and describe *in detail* the behavior expected of subject(s) and the context of the behavior during the psychological intervention.
3. Describe how data resulting from this procedure will be gathered and recorded.
4. Identify anticipated and possible psychological, or social consequences of this procedure for the subject(s).
5. Indicate the investigator's competence and identify her/his qualifications, by training and experience, to conduct this procedure. *If the PI lacks these qualifications, a qualified co-investigator must be named.*

### **RESEARCH INVOLVING DECEPTION**

If the protocol involves **deception** (false information given to subjects, false impressions created, or information relating to the subjects' participation is withheld from subjects) a detailed description as to how subjects will be *debriefed* must be provided.

The researcher must provide the participant with information about the nature of the study and attempt to remove any misconceptions that may have arisen. Where scientific or humane values justify delaying or withholding this information, the researcher incurs a special responsibility to monitor the research and to ensure that there are no damaging consequences for the participant.

Where research procedures result in undesirable consequences for the individual participant, the researcher has the responsibility to detect and remove or correct these consequences, including long-term effects.

In research involving deception, debriefing is required to compensate the research subjects for having been denied at least some powers of self-determination and for having been deliberately misinformed; debriefing procedures thus should be designed to provide subjects with (1) satisfaction from having contributed to science or society, and (2) new knowledge that will be of educational or therapeutic value to them. In addition, subjects should receive other benefits or reparations: (3) dehoaxing - entails giving the subject whatever explanation or evidence is necessary to convey the truth about the research and to clear up any misunderstandings. (4) desensitizing - involves the detection and removal of any undesirable emotional consequences of research participation. Desensitizing should be designed to “alter subjects’ feelings concerning the way they behaved or were treated in the study so that they are restored to a state of emotional well-being.” (5) restoration of confidence in science, (6) information on ways risk was anticipated and circumvented, (7) an opportunity to ask questions, and (8) an opportunity to withdraw one's own data.

If the proposed research involves deception, the following must be provided in the appropriate item of the Research Plan:

1. Describe **in detail** the deception involved, including any instructions to subjects or false impressions created.
2. Justification. Explain **in detail** why deception is necessary to accomplish the goals of the research. Care should be taken to distinguish cases in which disclosure would invalidate the research from cases in which disclosure would simply inconvenience the PI.
3. Describe **in detail** the plan for debriefing subjects. Clarify when and how subjects will be debriefed? Attach a copy of any debriefing statement.
4. Justify why the proposed subject population is suitable for such a study.

### **RESEARCH INVOLVING SCHOOL PERMISSION**

Schools do not have the authority to give consent for children to participate in research; ***only parents or legal guardians have that authority***. Permission from the school district, however, must be obtained before conducting research in schools within the district.

In most cases, Principals and teachers do not have the authority to grant permission for research to be conducted in a school; such permission must come from the school district. Although this permission will usually come from the superintendent, in some districts another individual or committee has been given the authority to grant permission. *Investigators should check with the district office to determine the appropriate procedure for obtaining permission.*

Proof of that permission in the form of a letter from the school district must be submitted to the IRB in writing, and whenever possible, the permission should be on school district

letterhead. Provisional approval of the research project can be given by the IRB pending receipt of permission by the school district. The research cannot begin, however, until written proof is received by the IRB.

### **RESEARCH IN A FOREIGN COUNTRY**

The political or social climate in a foreign country may be such that normal methods for protecting the confidentiality of research data and the identity of subjects are not adequate. Researchers should address this problem in their protocols. The procedures employed may not be any less stringent than those required by the UCSD Institutional Review Board for research in this country, even if those customary in the foreign country are less restrictive.

*Should a situation arise that the PI is not at UCSD when conducting the research at the time continued approval of resubmission of a protocol is due, it is **still incumbent upon the PI** to see that all materials are submitted to the Human Subjects Program Office in a timely manner.*

**The continuation of research after expiration of IRB approval is a violation of regulation 21 CFR 56.103(a). “If the IRB has not reviewed *and approved* a research study by the study's current expiration date, i.e., IRB approval has expired, research activities should stop. No new subjects may be enrolled in the study.”**

### **OBSERVATIONAL STUDIES**

This usually involves fieldwork, or ethnographic research, involving observation of and interaction with persons or groups being studied in the group's own environment, often for long periods of time. Because field work is a research process that gains shape and substance as the study progresses, it is difficult, if not impossible, to specify detailed contents and objectives in a protocol. Often a waiver of informed consent is given for this type of research. However, the investigator should supply the IRB with *a copy of the types of questions or issues that will be discussed with the subjects.*

Researchers should discuss the following in the appropriate item(s) of the Research Plan:

1. What types of activities will be observed.
2. Whether or not the Researcher will participate in the activities observed.
3. Describe the public locations where the researcher will conduct these observations.
4. Whether or not the research will have any direct contact or interaction with subjects. If yes, this should be described.
5. Whether the data will be recorded anonymously. If not, will a key code be used and who will have access to the data.
6. If video and/or audio taping be done or photographs be taken, then describe the confidentiality measures to be taken including storage, safeguarding measures.

If the research involves observation (including observation by participants) of public behavior, the Researcher must also make clear whether the responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects. In addition, could the subject's responses, if they became known outside the research, reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability; or does the research deal with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.

### **INVOLVEMENT OF PUBLIC OFFICIALS AS SUBJECTS IN RESEARCH**

If the research involves public officials, then Researchers should discuss whether the individual is appointed, elected, or is a candidate for public office; what is their public official title(s), and/or role(s); how many subjects will be recruited; what procedures will they be involved in such as public observations, survey/interviews, etc. For surveys/interviews, a copy of the survey/interview schedule or list of questions should be attached. If the subjects will be surveyed or interviewed, then Researchers should indicate whether the subjects responses will be recorded; type of recording (video or audio or both); whether identified on tape or anonymous; whether a key code be used to protect the identifiable data; whether follow-ups be conducted; who will have access to the data, etc. The Research should also describe the confidentiality measures (including storage/safeguarding measures) and whether the subject's identity will be disclosed in final reports or publications. *A copy of the proposed consent form or consent script should be provided for review and approval by the IRB.*

### **RESEARCH INVOLVING CHILDREN/ADOLESCENTS**

If working with children and/or adolescents as subjects, an “assent” will be needed in addition to a parent permission form/consent. This assent should be written in wording appropriate to that age group. Consideration must also be given to the maturity and psychological state of the child.

Federal regulations define assent to mean “a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.” [45 CFR 46.202(b)]

In research conducted in schools, the Researcher must indicate in the “Informed Consent” item of the Research Plan that this research is not part of the child's regular school program, is not being conducted under the auspices of the school, and the child's grade or continued enrollment will not be affected by her/his decision to participate.

**Both** the permission/consent of the parent(s) and the assent of the child/adolescent must be affirmatively received and documented for a child/adolescent to participate in the study. Children should also be informed as to what to do if their parents did not give permission from them to participate.

## MINIMIZING COERCION INVOLVING CHILDREN

In conducting research on children, every attempt must be made to minimize coercion to participate. Researchers must remember that children are in a dependent relationship with adults and special care must be taken to ensure that the decision to participate as research subjects made by children is truly voluntary. The following factors should be taken into account when developing research procedures:

1. Rewards. Concrete rewards for participation may be used, but should not be so valuable within the value system of the child, as to outweigh legitimate reluctance to participate.
2. Peer Pressure. Care must be taken to minimize social pressure to participate, particularly peer pressure and fear of ridicule for not participating.
3. Coercion/Undue Influence. Care must be taken to minimize the coercion implicit in requests to participate from parents, teachers, or other adult authorities.

In general, researchers should refrain from having teachers or parents request children to participate in research.

Researchers should avoid using phrases such as “will you help me?” or “we would like your help with this” because children are not likely to refuse to help an adult. Rather, children should simply be asked if they want to participate.

## ORAL CONSENT

Regulations state that an “informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.”

However, regulations also allow the IRB to grant waiver of documented consent (oral consent). Listed below are situations when an *oral consent* may be used:

- (a) A short form written consent document, reviewed and approved by the IRB, stating that the elements of informed consent have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

An oral consent may also be used under the following circumstances:

- (b) 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

- (c) 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.

*While documentation may be waived, all investigators must provide subjects with a written statement regarding the research. A copy of the oral script must be submitted to the IRB for review and approval.*

***THE INVESTIGATOR IS REQUIRED TO PROVIDE THE APPROPRIATE CONDITION FOR ITS USE AS WELL AS THE JUSTIFICATION.***

### **CERTIFICATE OF CONFIDENTIALITY**

Some research involving human subjects could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability; or the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. In such cases, the IRB suggests that the investigator apply for a "Certificate of Confidentiality" from the Department of Health and Human Services (DHHS). The certificate protects researchers against being *compelled* to disclose the identity of their subjects in any legal proceeding.

Where appropriate, discuss provisions for ensuring medical or professional intervention in the event of adverse effects to the subject. Also, where appropriate, discuss the provisions for monitoring the data collected to ensure the safety of subjects.