

**Revised 10/07**

(Answer each question, using the template below. **Include headings.** Delete all instructions in italics, like these.)

**San Francisco State University**  
*(Title of Research)*

**Researcher's Name:**

**Department:**

**1. STUDY AIM, BACKGROUND AND DESIGN**

- a. State the research question(s) concisely.
- b. Include a brief (1 – 2 paragraphs), current, scholarly review of relevant literature that supports the purpose of the research study.  
*(Include the citations in the literature review and list the references under Section 14, below.)*
- c. Provide a **brief** overview of the research, including
  - research design
  - number and description of participants
  - data collection methods
  - data analysis methods *(describe the specific quantitative or qualitative analyses to be performed. If the data will serve as anecdotal evidence to support the research theory, state that here.)*
  - describe how the data you collect will answer your research question.
- d. What is the anticipated significance of this research to the field?  
*(If the researcher is trying to replicate results of an earlier experiment, state this.)*
- e. If using deception as a procedure, follow the APA guidelines: *(if not, delete this section).*
  - justify the use of this method (explain why it is would fulfill the research purpose better than non-deceptive methods) in terms of the study's prospective scientific, educational, or applied value.
  - researchers may not deceive prospective participants about methods that might reasonably be expected to cause physical pain or severe emotional distress
  - explain the deception to participants as early as possible, preferably at the end of their participation but no later than the conclusion of data collection. Permit participants to withdraw their data at this time.
  - Attach the de-briefing script you will use to explain the deception to participants.

## **2. PARTICIPANT POPULATION**

- a. Participants: Describe the participant pool (e.g., *children in a class, undergraduates in a particular department, random shoppers at a mall.*)
- State the number of participants.  
*(20 or 200? Round numbers off. Researcher may estimate the number of participants that may respond to recruiting efforts.*
  - State the age of participants.  
*This can be specific (8-10 year olds) or general (18 or over).*
  - Are the participants considered a vulnerable population (e.g., prisoners, children, pregnant women, cognitively impaired)?  
*Do they have other special needs, will they require translations?*
  - Are the participants already known to the researcher? (For instance, students in a class, personal contacts). *These will still require a recruiting process—a cover letter, script, flyer, email, or talk.*
- b. State any inclusion/exclusion criteria used to select participants.
- c. Describe the recruiting process clearly. *(Researcher will deliver a brief speech in a classroom, make a phone call, send an email or a letter, post flyers—state location. Describe any sampling methods you will use, such as snowball, purposive, convenience, etc.)*
- d. Attach all recruiting materials—telephone or speech script, email or letter text, or copy of ad or flyer.  
*(Recruiting should be a simple invitation to participate. Make it as business-like as possible. Do not try to “market” the research as a great opportunity for the participants, do not plead for their help in completing a thesis, and do not offer too much money or incentives to participate.)*
- e.** State how researcher will gain access to the participants.  
*(Permission letters are needed to recruit and/or conduct research at schools, agencies, hospitals, institutions, classes, etc. before beginning the recruiting process in these places. )*
- (Even if a researcher has access to the data to be used (medical, academic, test scores) because of a job, permission must be obtained from the participants to use information for research purposes that has individual identifiers attached (e.g., name, Social Security number, demographic information).*

## **3. STUDY PROCEDURES**

- a. Describe the details of the procedures and methodology.  
*(State how information will be obtained from the subjects (e.g., chart reviews, document reviews, interviews, surveys, experiments, observations, reviewing*

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*participants' work, accessing assessment results, using pre and post test results as data.)*

b. List procedures in which the participants will take part in a step-by-step, chronological manner.

*(Include only those research procedures that involve the participants. Do not include procedures that the researcher will be doing (e.g., transcribing tapes, literature review,, or usual classroom procedures that will take place anyway. Use a numbered or bulleted format.)*

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c. Research details

- State *where* the research will take place.
- State *how long* the research will take for the participant.
- State what *time of day* the research will take place (after school, evening, weekend)
- State the *time* for each procedure and the *total time* commitment.  
*(Again, state only the time the participants will be involved in the research activities.)*

- If participants will miss class, how will they make up the work?
- What will non-participants do while the others are participating?

d. State how data collection and analysis will answer the research question.

- *Make sure the related instruments—surveys, questionnaires, or interviews—include questions that will provide data to answer the research question.*
- *Include all rubrics or analytical instruments used to measure the effectiveness of the method or theory tested.*
- If you are conducting qualitative research, describe your methods of data collection and analysis, and define those methods clearly.
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#### **4. RESEARCH RISKS**

a. State the risk(s), and then state how the researcher will lessen each particular risk. *(Sample: A risk may be potential loss of privacy. The risk will be minimized by keeping all research data in a locked cabinet/desk in a secure location, /or/ the risk will be lessened by keeping the research data in a password-protected program. )*

b. Physical risks may include physical injury, aggravation of an existing condition, allergies to materials used in the research, etc.

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c. Risks also include the potential loss of privacy, as well as possible psychological risk (anxiety, stress, depression), and uncomfortable emotions (anger, fear, sadness, discomfort).

*(Sample: A risk may be potential loss of privacy. The risk will be minimized by keeping all research data in a locked cabinet/desk in a secure location, /or/ the risk will be lessened by keeping the research data in a password-protected program. )*

*If the discomfort risk is high, provide the subjects with a list of referrals for counseling and attach to the informed consent document.*

d. Focus groups, use of real names, videotapes and photographs require extra measures to protect against loss of privacy. *(See our website for focus group consent form addition and photo/video release forms at [Forms and Templates \(http://www.sfsu.edu/~protocol/human/forms.htm\)](http://www.sfsu.edu/~protocol/human/forms.htm) )*

e. For sensitive research where loss of confidentiality may expose participants to excessive risk, **such as prison, etc.**, a federal [Certificate of Confidentiality](http://www.hhs.gov/ohrp/humansubjects/guidance/certconf.htm) <http://www.hhs.gov/ohrp/humansubjects/guidance/certconf.htm> may be required.

f. Teachers conducting research on their own classes should consider the power imbalance between themselves and their students to avoid coercion in recruiting students for their study. To do this:

-- make sure the recruiting script or letter to parents and children is an invitation to **participate**. Parents and the child must both have the opportunity to refuse.

--Also, tell parents and children that the child's grade will not be affected whether they participate or not. If the researcher is assessing the results of a curricular model that would be taught anyway, he/she should ask permission of parents and children to use the data collected from the pre and post test scores. Then all students would participate in the assessments, but the researcher would use data only from those students who agree and who have permission to participate.

g. Research in the workplace also offers risk if management has access to the raw data, or data, if identified, could result in loss of employment, rank or salary. Data should be presented to supervisors only in the aggregate, as a finished report.

h. If researcher is using deception, add a line to the risks section:

“Research designs often require that the full intent of the study not be explained prior to participation. When the study is completed, you will receive a full debriefing on the purpose and the procedures of the research.” **Justify the deception and include a short debriefing script, per 1.e, above.**

## **5. CONFIDENTIALITY**

Confidentiality refers to the security of the data.

- a. Describe any coding systems that will be used to protect the privacy of the participants and the security of the data.
- b) For some sensitive research where loss of confidentiality may expose participants to excessive risk, a federal **Certificate of Confidentiality** may be required.
- c) Describe how the confidentiality of the data will be protected. Describe the storage location, storage methods and final disposition of the data. Describe methods of maintaining security.

*If the researcher plans to retain the data and use it in the future for further analysis, all identifiers must be removed for the data to not require human subjects review as existing data. If the data retains identifiers or codes, participants must be assured in the informed consent that the data will be used only for studies that are consistent with the original research purpose, and the researcher will need to obtain IRB approval to re-use the data.*

*Original audio and videotapes are usually destroyed after transcripts have been made, unless the materials include linguistic/behavioral data and future research will be analysis of the actual content of the tapes/digital data.*

*If the material is sensitive, state whether the participants can review and edit the tape(s) or transcripts prior to publication.*

## **6. BENEFITS**

- a. If there are no direct/guaranteed benefits, state this:

**There are no direct benefits to participants.**

*( Usually, there are no direct benefits, which are defined by NIH as universal (curing cancer) or immediate (specific drug therapy for participants.) Direct benefits do not include contributing to a body of knowledge, or any other potential altruistic reward or remote possibilities.)*

- b. In discussing anticipated benefits (optional), use the conditional tense:

**Subjects may learn more about the research subject.**

*The research has not been performed yet, so it cannot be said that the subject will learn more about the subject or whatever the potential benefit may be.*

## **7. PAYMENT**

If there will be no compensation, state this.

**There will be no payment for participant.**

*Payment includes cash payments, gift certificates, food, "goodie bags," etc. that a researcher might provide participants for their voluntary participation in a research study. Excessive payment (as determined by the Committee on a case by case basis, when necessary) may be considered coercive.*

*How will payment be received—cash or check? Handed out or mailed? How does this affect the confidentiality of the data—for instance, if administering an anonymous survey, how will compensation be distributed to the participants?*

**8. COSTS**

If there will be no costs, state this.

**There are no costs to participants.**

*Costs include transportation to the research location, parking expenses, lunch, and child care. If the researcher will arrange to cover any of these expenses, mention this here.*

**9. ACADEMIC CREDIT**

a. If the study does not offer academic or extra credit, *delete this category.*

b. If participants will receive academic credit or extra credit for participating in the research study, state that here. Also state that alternative methods of earning extra credit must be made available to those who do not wish to participate in the research study.

**10. ALTERNATIVES**

a. Usually, the alternative in social/behavioral/educational research is not to participate in the research.

**The alternative is not to participate in the research.**

b. However, if the researcher is proposing a biomedical treatment or therapy, a disclosure of appropriate alternative courses or treatments that might be advantageous to the participant, if any, is required here.

**11. CONSENT/ASSENT PROCESS AND DOCUMENTATION OF CONSENT/ASSENT**

a. The consent/assent process begins with the recruitment of participants, which was described in Section 2.

*In this section, describe the rest of the informed consent process. This includes plans to*

- *inform the participants about the study procedures,*
- *give them an opportunity to ask questions and have their questions answered, and to*
- *give them as much time as they need to make a decision whether or not to participate.*
- *Signing an informed consent or assent document form is the final step in this process.*

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*State where the process will take place, how it will take place (in person or by mail, etc.) who will answer the participant's questions, who will obtain the signatures, and where the informed consent documents will be kept.*

b. State that the participants will receive a signed copy of the consent/assent form.

*California state law requires a separate Bill of Rights for all participants in medical experimentation only.*

*Please note:*

*Special procedures need to be defined for research where there will be no signed or written consent/assent, e.g.,*

- *where participants are not fluent in English or cannot read the consent/assent document;*
- *where cultural conditions preclude written consent;*
- *or where subjects may be cognitively impaired.*

*These situations may require a translator or a witness.*

*The researcher is responsible for requesting and providing a rationale for any waiver of written or signed consent in the protocol, and for detailing the consent process that will occur. Appropriate witness/translator statements are available under Forms and Templates..*

For information on what conditions must be met to waive or alter elements of informed consent, see 46.116 (c) at

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116>

For information on what conditions must be met to waive documentation of signed consent see 46.117 (d).

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.117>

c. Because of HIPAA (Health Insurance Portability and Accountability Act) regulations protecting private health information, researchers must receive permission from participants to review their medical charts or histories. Please include a HIPAA release form if necessary. (We will accept other institutions' standard HIPAA authorization or release forms.)

*For assistance in writing the informed consent or minor assent document:*

*Go to "Forms and Templates" for*

*a) informed consent templates.*

*b) parental consent templates.*

*c) minor assent templates.*

*d) added protections for focus group participants.*

## **12. INVESTIGATOR'S QUALIFICATIONS**

a. State the researcher's qualifications to conduct this specific research project. *Include professional or life experience, previous research, class work, previous experience with this particular population, or volunteer work.*

*For instance, if employed as a social worker to conduct intake interviews for an agency, state that to support the intention to interview subjects. If the researcher has worked with a professor as a research assistant, state that as a qualification to conduct an experiment in that field. If the student investigator has taken a research methods class in which interviewing was practiced and data collected and analyzed, state that.*

b. *For students:* Briefly add (one paragraph) advisor's areas of research expertise or relevant courses taught.

c. *For faculty:* State how any research assistants have been trained, and include their NIH course completion certificates.

## **13. FUNDING SOURCES**

If receiving funding for this research, please identify the funding agency. If this is contract work, please clarify what part of the contract project is research. If not funded, state "No funding."

If the project is funded, do any of the researchers have a financial conflict of interest? Please inform the committee and the prospective participants in the informed consent documents.

## **14. REFERENCES**

Provide the full citation (including title) for any references cited in this protocol.

*All researchers—faculty, staff and students—must attach a copy of the [NIH course completion certificate](#) (course is at <http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>) or the [CITI course completion report](#) (<http://www.citiprogram.org/>)*

*The certificate is valid for three years. Equivalent courses from other institutions may be accepted in place of the NIH or CITI course.*