

INSTITUTIONAL REVIEW BOARD
CALIFORNIA STATE UNIVERSITY, SAN BERNARDINO

Application to Use Human Participants in Research

DEFINITION OF “USE OF HUMAN PARTICIPANTS”

A research project involves human participants when there is an intervention or an interaction with a living person that would not be occurring, or would be occurring in some other fashion, but for this research, or when identifiable private data or information is obtained for the research that can be associated with the identity of an individual participant.

All research involving human participants must be reviewed and approved by the Institutional Review Board (IRB). Information concerning the procedures for review of such research can be obtained from the Office of Academic Research (AD-179) or the IRB website at <http://irb.csusb.edu/>. In addition, assistance is available from any member of the Institutional Review Board (IRB). A listing of current members can also be obtained from the IRB website under the Your IRB website menu.

PROCEDURES FOR REVIEW

Submit the completed application with the appropriate number of copies (as indicated on the application) to:

Office of Academic Research (Administration Building Room AD-179)

Note: Proposals from the Psychology and Social Work departments should be submitted to your departmental Human Subjects Review Board Subcommittee.

Proposals are normally reviewed within two weeks of submission. A letter detailing the Board's decision will be sent to the applicant (or applicant's advisor) via campus mail.

CATEGORIES OF REVIEW

There are three categories of IRB review: administrative review (previously titled exempt review), expedited, or full board review. In order to qualify for either administrative (formerly exempt review) or expedited review, a project must also qualify for waiver of written (signed) informed consent. That is, the research must present no more than minimal risk to participants and involve no procedures for which written consent is normally required outside the research context, or the principal risk to the participant must be the potential harm that would result from breach of confidentiality because of the signature on the consent document. Consult IRB policies and procedures for more detail. Please note that the title for exempt review (now administrative review) was changed due to the improper use and classification of this review title by faculty and students.

Any research involving children (age 17 or younger), or any research in which the participant is asked to sign or to provide an identifying name on any document, is not eligible for exempt or expedited review. In addition, projects involving external grant support are not eligible for exempt or expedited review.

QUESTIONS

Any questions regarding IRB policy, procedures, or application status should be directed to:

Professor Sharon Ward, Ph.D. (IRB Board Chair)
Department of Psychology
CSU San Bernardino
5500 University Parkway
San Bernardino, CA. 92407
sward@csusb.edu
(909) 537-7304
(909) 537-7028

Michael Gillespie (IRB Coordinator/Compliance) B.S, M.P.A., C.I.P.
Administrative Analyst/Specialist
Office of Academic Research AD-179
CSU San Bernardino
5500 University Parkway
San Bernardino, CA. 92407
Email: mgillesp@csusb.edu
Phone: (909) 537- 7588
Fax: (909) 537- 7028

Please include your IRB ID# (if available) in all correspondence.

IRB WEBSITE: <http://irb.csusb.edu>

Includes:

- IRB Applications in PDF and Word format
- Sample Forms
- Research Ethics Sites
- Other items of interest

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1. PROJECT REVIEW

Complete CITI Course in Human Subject's Online Training before submitting IRB application (see IRB website for policy at <http://irb.csusb.edu/>).

New Project (ID# will be assigned by the IRB) _____

Revised Project (Enter IRB ID#) _____

Renewal (Enter IRB ID#) _____

Approximate date of most recent **previous** review of this project _____

2. DATA COLLECTION DATES: From ___/___/___ To ___/___/___

This is required information, must be future dates - after you have received final IRB approval to conduct your research.

3. INVESTIGATOR(S) NAME(S) _____

Department _____ Phone _____

Student(s)/Researcher(s) E-mail Address(s): _____

If you are a **student**, please provide the following information:

This research is for Graduate Thesis & Projects Honors Project
 Independent Study Course _____
 Other _____

4. PROJECT TITLE _____

5. DESCRIPTION OF PARTICIPANTS (Enter approx. no. of participants and categories that apply)

Number _____ Gender: Female Male
 CSUSB Students Children (17 or younger) Child Development Center
 Prisoners Patients in institutions Pregnant Women
 Other _____

6. IS FUNDING BEING SOUGHT FOR THIS RESEARCH?

Yes No

If yes, you must submit one complete copy of that proposal as soon as it is available and respond to the following questions:

Does the funding agency require notification of Institutional Review Board approval? Yes No

(If yes, please provide the IRB Secretary with one copy of all relevant forms, instructions, etc., with your original copy of this application.)

Project period from _____ to _____

7. INDICATE THE REVIEW CATEGORY FOR WHICH YOU ARE APPLYING.

- I am applying for **administrative review (formerly exempt review)**, based on the following category (ies):
(Check all that apply. Submit an original and one copy of all application materials to the IRB.) *Note: Research involving children must be reviewed FULL BOARD.*
- Research conducted in established or commonly accepted educational settings and involving normal educational practices
 - Research involving the use of educational tests, if information from these sources is recorded in such a manner that participants cannot be identified in any way
 - Research involving survey or interview procedures where participants cannot be identified
 - Research involving the observation of public behavior where participants cannot be identified
 - Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, where these sources are publicly available or where participants cannot be identified
- I am applying for **expedited review**, based on the following category(ies):
(Check all that apply. Submit an original and 1 copy of all application materials to the IRB.)
- Collection of hair, nail clippings, teeth in a non-disfiguring manner.
 - Collection of excretal and/or external secretions.
 - Recording of data from adults using noninvasive procedures.
 - Collection of moderate levels of blood samples from adults in good health.
 - Collection of supra- and sub-gingival dental plaque and calculus.
 - Voice recordings made for research purposes.
 - Moderate exercise by healthy volunteers.
 - Study of existing data, documents, records, or pathological or diagnostic specimens.
 - Non-manipulative, non-stressful research on group or individual behavior.
- I am applying for **full board review**.
(Submit an original and 1 copy of all application materials to the IRB.)

8. ATTACHMENTS. I have included copies of all relevant project materials and documents, including (check all that apply):

- Surveys, questionnaires, and/or interview instruments.
- Informed consent forms or statements.
- Letters of approval from cooperative agencies, schools, or education boards.
- Debriefing statements or explanation sheet.
- Participant recruitment materials, including flyers and advertisements.

Please Re-type the headings and answer in your own words (given below in boldface type) for questions 10 through 15 and use as many separate sheets of paper as you need to respond fully. **DO NOT COPY THESE PAGES AS PART OF THE APPLICATION.** Attach the appropriate forms as requested in 14 and 15.

10. PARTICIPANT RECRUITMENT.

Describe the sources of potential participants, how they will be selected and recruited, and how and where you will contact them. Describe all relevant characteristics of the participants with regard to age, ethnic background, sex, institutional status (i.e., patients or prisoners), and their general state of mental and physical health.

11. PROJECT DESCRIPTION.

Briefly describe the methodology and objectives of your research (including hypotheses and/or research questions), the data collection procedures, and any features of the research design that involve procedures or special conditions for participants, including the frequency, duration, and location of their participation.

12. CONFIDENTIALITY OF DATA.

What procedures will be used to safeguard identifiable records of individuals and protect the confidentiality of participants? If this is not possible, state why.

13. RISKS AND BENEFITS.

Describe in detail the immediate or long-range risks to participants, if any, that may arise from the procedures used in this study. Risks may be physical, psychological, social, legal, or economic. They would include side effects, risks of placebo, risks of normal treatment delay, etc. Indicate any precautions that will be taken to minimize these risks. Also describe the anticipated benefits to participants and to society from the knowledge that may be reasonably expected to result from this study.

14. INFORMED CONSENT.

Informed consent can be in either written or oral format. If you request waiver of informed consent, or of written informed consent, please state your justifications (Please note that waiver of informed consent is only granted in limited circumstances and therefore an informed consent should always be prepared and submitted with your application). If an oral consent is planned, attach a copy of the text of the statement. The consent should include identification of 1) the researcher(s), 2) explanation of the nature and purpose of the study and the research method, 2) duration of research participation, 3) a description of how confidentiality/anonymity will be maintained, 4) mention of participants' right to withdraw their participation and their data from the study at any time without penalty, 5) information about the reasonably foreseeable risks and benefits (If there are no foreseeable risks and benefits please state so), 6) the voluntary nature of his or her participation, 7) who to contact regarding questions about participants' rights or injuries, 8) and a statement that the research has been approved by the Institutional Review Board at California State University, San Bernardino (or by the departmental board for exempt proposals). Attach a copy of any written informed consent, or the text of any oral informed consent, with this application. For Non-English speaking subjects please include a translation of the informed consent in their language. (See OHRP Informed Consent checklist and other sample forms at <http://irb.csusb.edu/>)

15. DEBRIEFING STATEMENT.

The two major goals of debriefing are dehoaxing and desensitizing. The participants should be debriefed about any deception that was used in the study. The participants also should be debriefed about their behavioral response(s) to the study. Any undesirable influence that the study may have had on them should be minimized or eliminated. In the debriefing statement describe the reason(s) for conducting the research, the way to obtain the general results of the study, and the person(s) and/or professional resources to contact if the participant has any questions or concerns as a result of his/her participation. (If participants are provided with the predicted results of the study, be sure to state the predictions in a non-directional manner so the participant will not have unnecessary negative feelings as a result of self-identification with one of the predicted outcomes.) Moreover, for methodological purposes, you may wish to include a statement requesting the participants not to reveal the nature of the study to other potential participants. Debriefing statements are required when you use deception to obtain results from research subjects.

IRB APPLICATION CHECKLIST

Submitting the IRB Application

Complete: - CITI Online Course in “The Protection of Human Research Subjects” (see the IRB website main page at <http://irb.csusb.edu/> for mandatory training policy and human subjects online training course).

Signature: - Check to make sure your application is complete and signed by yourself and your advisor. Applications not signed will be returned.

Informed Consent(s): - MUST be on your college department’s letterhead upon submission. Applications will no longer be accepted if informed consent and assent documents are not on department letterhead.

Informed Consent Checklist: - Submit informed consent which includes all 8 elements of the informed consent. See sample informed consent and OHRP checklist (see bottom of IRB Forms page <http://irb.csusb.edu/>).

Questions Addressed: - Check to make sure you have answered and addressed question 9 - 15 in your own words.

Vulnerable Populations: - Any research involving children requires full board, no exception. May also include prisoners, pregnant women, people with impaired decision making capabilities.

ADMINISTRATIVE (FORMERLY EXEMPT) REVIEW CLARIFICATION: - Exempt does NOT mean exempt from filing an application for review by the Institutional Review Board of CSUSB. Exempt, the federal definition, means exempt from 45CFR46 of documentation of informed consent and continuing review. In all applications, informed consent is a federal requirement to inform and notify research subjects the nature and purpose of the research. Only the designated IRB Chair can make the final determination as to your applications Administrative (Exempt) review status. The IRB Chair may determine that your application does not follow under the Administrative (Exempt) review criteria and therefore require Expedited or Full Board review. Should your application not follow under the Administrative (Exempt) review category you will be notified through email correspondence. Please ensure that your application is indeed qualifies for Exempt by reviewing with your advisor

Permission Letters: - to conduct your research must be included - Examples would be permission letter from principle or school district to conduct research at a particular school or school district, district permission to use school and/or student records.

Recruitment and Advertising Materials - Example if you plan on using flyers/advertisements to establish a list of possible research participants, you will need to include the flyer and advertisement materials.

Child Assent: - Written at a child's language level. This informs the child, much like the informed consent, of what research they will be asked to participate in. Should include 8 elements of the informed consent and the assent can be given in writing or orally. You can perform a Google search on Child Assent to find an example of what the IRB is requesting when you submit your IRB application.

DO NOT INCLUDE YOUR THESIS WITH APPLICATION: A ONE PAGE ABSTRACT EXECUTIVE SUMMARY IS SUFFICIENT THE REST WOULD BE THROWN OUT.

IMPORTANT NOTE: Please note that once you are approved, your research is only good for one year from the date of IRB stamp of approval on your informed consent documents (for expedited and full board review only). Once that date passes you may NO longer have any enrollment and you must cease all data collection. You may continue your research if you submit the IRB Renewal Form (see form section at <http://irb.csusb.edu/>) to the IRB Secretary 60 days prior to your research ending.

Application Copies Required: Submitting the application - We require one original and one copy submitted / Single sided copies only. Do not copy on both sides of paper, do not staple, and please paper clip your application.

What If the IRB Requires Changes to my Application?

- Use the changes from the resubmission letter/correspondence and review them one by one with your advisor. As you edit/revise your application highlight or check off the changes on the resubmission letter/correspondence and submit a copy the changes you have made with the revised changes to your application
- Note: You have 60 days to resubmit the IRB's required changes to your application. After 60 days your application will be closed and you will have to resubmit a new application and be assigned a new IRB number for review through the normal IRB submission process.

What do I do after my research has ended?

You must notify the IRB when your research has ended either by email to mgillesp@csusb.edu, or by correspondence to Office of Academic Research Atten: IRB Coordinator Mr. Michael L. Gillespie, 5500 University Parkway, San Bernardino, CA. 92407. Include your IRB# in all correspondence. You may also call the IRB Coordinator at (909) 537-7588 and leave a message. Please include your IRB #.

Informed Consent Checklist from Office of Human Research Protections Website

Following the checklist (Check them off as you go through your informed consent to ensure you have included all required elements of informed consent) appropriately and including all necessary elements of informed consent will facilitate the processing of your application.

Reference: <http://www.hhs.gov/ohrp/humansubjects/assurance/consentckls.htm>

- 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
- Identification of any procedures which are experimental
- A description of any reasonably foreseeable risks or discomforts to the subject
- A description of any benefits to the subject or to others which may reasonably be expected from the research
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- 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
- 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
- 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

Note: Additional elements of informed consent may be required depending upon the nature of your research and the human participants involved. Please refer to the website at the top of this page (Office of Human Research Protections) on when additional elements of informed consent may be required in your research and informed consent form.