

# INSTITUTIONAL REVIEW BOARD

## CALIFORNIA STATE UNIVERSITY SAN BERNARDINO

### Policies and Procedures for Review of Research Involving Human Participants

#### Introduction:

In compliance with federal regulations, California State University, San Bernardino has established an Institutional Review Board (IRB) to oversee its obligations with respect to human participants. When people are involved as subjects in research or related activities conducted under university auspices, both the institution and individual researchers are responsible for assuring that the rights and welfare of participants are adequately protected. Such activities include any mode of research conducted either on or off campus. These principles have been accepted and established by the University in accordance with federal regulations (Code of Federal Regulations, Title 45, Part 46) and professional ethics (Ethical Principles in the Conduct of Research with Human Participants, American Psychological Association, 1982).

All projects involving human participants must be reviewed by the IRB **before** initiation. This applies to both faculty and student research. Activities that are routine university classroom exercises using accepted practices within a discipline do not require IRB review. This exclusion does not apply to experimental educational or training programs, or to independent study projects and thesis/project research using human participants.

#### Basic Principles:

- a) Participation of human participants in any research project or other regulated activity (e.g, experimental demonstration, training program, interview, or questionnaire) must be voluntary.
- b) Any risks to subjects must be outweighed by the sum of the benefits to subjects plus the knowledge gained by the study.
- c) Informed consent to participate in a project must be obtained upon satisfactory presentation of information to potential subjects about the purposes, procedures, risks, and benefits of participation.
- d) The privacy of subjects must be safeguarded by protecting **confidentiality** of information from or about subjects and/or by maintaining their **anonymity**.

## **Definitions:**

**Research:** is a systematic investigation designed to develop or contribute to knowledge. This includes any mode of research, demonstration, instruction, training or related activity, survey, interview or questionnaire study. Normal university classroom activities are not subject to IRB review unless they constitute "research" as herein described.

**Human subject:** is a living individual about whom an investigator obtains data through intervention or interaction with the individual.

**Risk:** means that the possibility of physical, psychological, or sociological harm may occur as a consequence of participation in a research activity or if such participation would increase the risks beyond those encountered in ordinary, daily life.

**Minimal risk:** means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in the daily life of the subject or during performance of routine physical or psychological examinations or tests.

## **Responsibilities of Investigators:**

The investigator is responsible for:

- (a) obtaining IRB review and approval of any research involving human participants covered under the regulations, or registering their research with the IRE if it falls into one of the exempt categories;
- (b) obtaining the legally effective informed consent of all subjects to be included in the research study, unless any or all requirements for obtaining consent have been waived by the IRE during its review;
- (c) performance of the protocol as approved by the IRB; and
- (d) adherence to ethical principles in the conduct of the research.

## **Review Board Actions:**

The IRB reviews all projects involving human participants and determines whether the project should be approved, disapproved, approved with modifications, or deferred for later actions pending receipt of additional information or further clarification. Investigators are notified writing of the IRB's decision. Active research must be reviewed annually, and the researcher IS required to resubmit a new application form each year to fulfill this requirement.

## **Criteria for IRB Approval:**

In reviewing research activities involving human participants, the IRB seeks to determine that all of the following requirements are met:

- (a) Risks to subjects are minimized and reasonable. Research procedures should be consistent with sound research design, should not expose the subjects to unnecessary risk and, when possible, should be the same as those already being performed on the subjects for diagnostic purposes.
- (b) Risks to subjects are reasonable in relation to anticipated benefits, if any, to the subjects. The IRB also considers the importance of the knowledge to be gained from the research when evaluating risks vs. benefits.
- (c) Selection of subjects is equitable. In making this assessment, the purposes of the research and the setting in which the research is conducted are considered. Indication of coercion or prejudice must be absent, and participation must be clearly voluntary.
- (d) Informed consent is sought and documented from each prospective subject, or from the subject's legally authorized representative.
- (e) Provision is made for collecting, utilizing, and storing data in a manner that protects the safety and privacy of the subjects and the confidentiality or anonymity of the data.
- (f) Appropriate safeguards are included to protect the rights and welfare of the subjects. Categories of Review:

## **Categories of Review:**

**Exempt:** Federal regulations provide that certain kinds of research (e.g., some surveys, field interviews, observations, evaluations of standard educational practices or tests) involving no more than minimal risk to subjects can be exempt from full IRB review and record keeping. Page 7 lists the categories for research considered exempt from review. Final determination of exempt status is the responsibility of the Chair of the IRB.

**Expedited Review:** Federal regulations also provide that certain kinds of research may receive expedited review. Page 8 lists the categories for research appropriate for expedited review. In such cases, only the Chair and one other member of the IRB need evaluate the proposal.

**Full Board Review:** For those projects that do not fit into the above two categories, a full board review by the IRB is required.

## **Review Procedure:**

For a research proposal to receive full board or expedited review by the IRB, the investigators should fill out the form entitled "Application to Use Human Participants in Research." Submit an original and the indicated number of copies (depending on the review category) to the IRB Secretary: (contact information is listed on the application form).

The application forms can be obtained from the Sponsored Programs Office (AD-128) or they are located outside the office during non-business hours. All applications along with any supporting materials should be submitted to the IRB Secretary. The investigator should retain one copy of the submitted materials.

### **Informed Consent:**

An investigator shall not involve a human subject in a research project without first having obtained the legally effective informed consent of the subject or the subject's legally authorized representative. Unless a waiver has been approved by the IRE, this informed consent must be obtained and documented in writing. Both the participant and researcher should retain a copy of the signed consent form.

Legally effective informed consent includes at least the following:

- (a) identification of the researcher(s);
- (b) an explanation of the nature and purpose of the research, the research method, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
- (c) a description of any reasonably foreseeable risks or discomfort to the subject;
- (d) a description of any benefits to the subject or to others which may reasonably be expected from the research;
- (e) a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- (f) for research involving more than minimal risk, an explanation as to whether any compensation and/or an explanation as to whether any medical treatments is/are available if injury occurs and, if so, what they consist of or where further information may be obtained;
- (g) the name of the person to contact for answers to pertinent questions about the project and the subject's rights, and who to contact in the event of a research-related injury;
- (h) a statement that participation is voluntary, that refusal to participate or discontinuation of participation will involve no penalty or loss of benefits to which the subject is otherwise entitled.

Special protections are afforded minors (persons under age 18), including the need to obtain parental consent. In the case of children over seven years old, the child must also give consent. If the research is not of a sensitive nature, and little or no risks are involved, waiver of parental consent may be requested by the investigator. However, waiver of parental consent can only be granted by the IRB. These same general protections also apply to the mentally incapacitated, or other subjects who have legal guardians.

A sample consent form is given on page 6. This form is intended only as a guide. Researchers should present the required information for their particular study in the most appropriate format.

**Waiver of written consent:** The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if either:

(a) 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 he or she wants documentation linking the subject with the research and the subject's wishes will govern.)

--or--

(b) 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.

**Waiver of informed consent:** Some research may be so indirect, innocuous, and innocent of imposition on the rights and welfare of human participants as to make informed consent a moot point. Therefore, any or all of the requirements for obtaining informed consent may be waived by the IRB during its review of the study. However, such action must be based upon clearly defensible grounds, and the principle investigator must include these justifications in the proposal submitted to the IRB. Specifically, waiver of informed consent may be granted if:

- (a) the research involves no more than minimal risk to the subject;
- (b) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (c) the research could not be practicably carried out without the waiver or alteration; and
- (d) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

## **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.

## CATEGORIES OF RESEARCH EXEMPT FROM IRB REVIEW

On January 26, 1981, regulations amending basic Health and Human Services policy for the protection of human participants were published in the *Federal Register* (46 FR 8366). These regulations were revised and became effective March 8, 1983, and contain exemptions for broad categories of research that involve little or no risk to research subjects (see listing below). Responsibility for approving exemptions rests with the IRB, and in order to establish eligibility for exemption, the investigator must complete and submit the "Registration Form for Exempt Research." Note: Research involving minors (less than 18 years of age) is not exempt. Unless the research is covered by other subparts of the *Federal Register*, exemption from general human participants requirements is possible for research activities in which the only involvement of human participants is in one or more of the following categories:

- (1) Research conducted in established or commonly accepted educational settings and involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- (3) Research involving surveyor interview procedures, except where all of the following conditions exist: (i) responses are recorded in such a manner that the human participants can be identified directly or through identifiers linked to the subjects, (ii) the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and (iii) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. (All research involving surveyor interview procedures is exempt, without exception, when the respondents are elected or appointed public officials or candidates for public office.)
- (4) Research involving the observation (including observation by participants) of public behavior, except where all of the following conditions exist: (i) observations are recorded in such a manner that the human participants can be identified, directly or through identifiers linked to the subjects, (ii) observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and (iii) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.
- (5) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

## CATEGORIES OF EXPEDITED REVIEW

Certain research activities involving no more than minimal risk and in which human participants are involved in special ways are approved by federal guidelines (46 FR 8392) for "expedited review." In such cases, only the Chair and one other member of the IRB need evaluate the proposal which, if approved, is then forwarded to the entire IRB for information and records keeping. In such instances, the entire application form must be completed, and requirements for annual review and informed consent apply. The categories acceptable for expedited review are listed below.

- (1) Collection of hair and nail clippings in a non-disfiguring manner; deciduous teeth; or permanent teeth if patient care indicates a need for extraction.
- (2) Collection of excretal or external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.
- (3) Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject 's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (e.g., x-rays, microwaves).
- (4) Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.
- (5) Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
- (6) Voice recordings made for research purposes such as investigations of speech defects.
- (7) Moderate exercise by healthy volunteers.
- (8) The study of existing data, documents, records, pathological specimens, or diagnostic specimens.
- (9) Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not

## Submitting Your Application

- Check to make sure your application is complete and signed by yourself and your advisor. Applications not signed will be returned.
- Check to make sure you have answered and addressed question 9 - 15 in your own words.
- Any research involving children requires full board, no exception.
- Submit informed consent which includes all 8 elements of the informed consent. See sample informed consent and OHRP checklist at [Informed Consent Procedures](#).
- **IMPORTANT NOTE 1:** *EXEMPT APPLICATIONS*: Exempt does NOT mean Exempt from filing an application for review by the Institutional Review Board of CSUSB. Exempt means Exempt from 45CFR46 of documentation of informed consent and continuing review. In applications informed consent is a federal requirement and informing research subjects the nature and purpose of your research is required. Only the IRB Chair can make the final determination that your application follows under the Exempt status category. Should your application not follow under the Exempt category you will be notified through correspondence and your application will need to be re-assigned for Expedited or Full Board review and resubmitted. Please ensure that your application is indeed Exempt by reviewing with your advisor and going through on the IRB website at <http://irb.csusb.edu/>.
- 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.
- 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.
- DO NOT INCLUDE YOUR THESIS WITH APPLICATION: A ONE PAGE ABSTRACT EXECUTIVE SUMMARY IS SUFFICIENT THE REST WOULD BE THROWN OUT.
- **IMPORTANT NOTE 2:** Please note that once you are approved, your research is only good for one year from the date of stamped IRB approval which is indicated on your informed consent (for expedited and full board review only). Once that date passes you may No longer have any enrollment and cease your data collection. You may continue you research if you submit the above renewal form (see IRB Renewal Form above) and submit that to the IRB Board 60 days prior to your research ending.
- 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 - PLEASE CLIP.**