

## Requirements for Research Using Human Subjects

CSU, Chico follows Federal regulations for all research involving human subjects. These regulations require institutional approval for all such research. The following information summarizes Federal regulations, most recently published in the Federal Register on June 18, 1991, and is provided to assist you in developing acceptable research proposals of which human subjects are a part.

All research using human subjects must be approved by the University's Human Subjects in Research Committee (HSRC). Questions, requests for assistance, and all requests for approval (including requests for expedited review or exemption from review by the full HSRC) should be directed to John Mahoney, Ph.D, Chair, HSRC, Sharon Cain, HSRC Assistant, 25 Main St, Suite 103, 530-898-3145, or, [IRB@csuchico.edu](mailto:IRB@csuchico.edu)

### A. Exempt and Expedited Research

#### Exemption from full HSRC Review:

Certain categories of research using human subjects are exempt from Full Board Review by the HSRC. To request exemption, you must submit a "Human Subjects in Research Application" form, available online at <https://www.csuchico.edu/resp/IRB/IRB%20Forms.shtml>. **When completing this form, indicate the category (below) into which your project falls.**

**Note: You must apply for AND RECEIVE notification of exemption from full HSRC review PRIOR to beginning your research.**

#### **Exempt** categories include:

1. Research conducted in **established or commonly accepted educational settings, involving normal educational practices**, such as research on regular or special education instructional strategies, comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of **educational tests** (cognitive, diagnostic, aptitude, achievement), **survey procedures, interview procedures or observation of public behavior**, **UNLESS** information is recorded in such a manner that subjects can be identified and disclosure of data could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation. **Survey research involving minors is normally not exempt, nor is research involving observation of behavior of minors if researchers participate in the activities being observed.**
3. 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 makes identification of the subjects impossible.
4. Research and demonstration projects which are conducted by or subject to the approval of Federal department or agency heads, and which are designed to study, evaluate, or otherwise examine: 1) public benefit or service programs; 2) procedures for obtaining benefits or services under those programs; 3) possible changes in or alternatives to those programs or procedures; or 4) possible changes in methods or levels of payment for benefits or services under those programs.

5. Taste and food quality evaluation and consumer acceptance studies: 1) if wholesome foods without additives are consumed, or 2) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

**Note that if your research population includes children pregnant women, fetuses, prisoners, or mentally incompetent individuals, it is USUALLY NOT exempt and a standard protocol must be prepared for full HSRC review and approval prior to beginning your research.**

### **Expedited Review:**

Some research activities may qualify for **expedited** review. As with exempt research, you must submit an "Application for Human Subjects in Research Clearance" form requesting expedited review and indicating the classification that best describes your project. Again, you must receive approval prior to beginning your research.

**Expedited** review is appropriate for research activities that expose human subjects to **no more than** minimal risk and in which human subjects will only be involved in one or more of the following categories (carried out through standard methods).

1. **Collection of hair and nail clippings**, in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.
2. **Collection of excreta and external secretions** including sweat, uncannulated saliva, placenta or umbilical cord 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 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, and 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 ml 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 sub-gingival 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 investigation 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 manipulate subjects' behavior and the research will not involve stress to subjects.**
10. **Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.**

### **B. Research Involving **Full Board Review** and Approval by the HSRC**

Research involving human subjects that is not eligible for exemption or expedited review must undergo review by the full HSRC. To secure HSRC approval, the researcher must 1) submit a protocol that fully describes (see below) the protection of human subjects, and 2) meet with the HSRC to review the protocol, and incorporate into the research protocol all modifications required by the HSRC.

#### **Requirements and Criteria for Research Using Human Subjects:**

The HSRC will not approve protocols that fail to protect the rights or welfare of human subjects. To insure this protection, the HSRC has adopted a list of criteria that researchers must incorporate into their projects. (A complete copy of the Federal regulations governing the use of human subjects in research may be obtained online at [Health and Human Services Office for Human Research Protections webpage.](#)) These criteria are:

1. **Sound design of protocol and continued use of the procedures initially specified.** Any change in the approach or procedures must be approved by the HSRC before implementation.
2. **Risks the subject will undergo** must be reasonably related to the benefits **the subject will enjoy and/or the knowledge that will be achieved. DO NOT INCLUDE LONG-RANGE EFFECTS OF RESEARCH IN THE ESTIMATE OF RISKS OR BENEFITS** (e.g., anticipated changes in public policy).
3. **Selection of subjects must be equitable.** That is, unless restrictions are specifically required by the research design, subjects of all ages, races, socioeconomic strata, genders, etc., should be included.
4. **Informed consent of each subject**, or if the subject is a minor the subject's parent/guardian, must be obtained and documented.
5. The safety of the subjects must be protected through **adequate monitoring of the subjects and of the data collected.**
6. **Adequate provisions must be taken to protect the privacy and confidentiality** of the subjects and their records.
7. In cases **where any subject is "likely to be vulnerable to coercion or undue influence**, such as children, prisoners, pregnant women, mentally disabled persons, or persons who are economically or educationally disadvantaged, **appropriate additional safeguards [must be] included** in the study to protect the rights and welfare of these subjects".

**Your proposal must explicitly address these criteria. If they apply, discuss them. If they do not apply, explain why.**

The Principal Investigator's responsibilities do not end with the HSRC approval process. Please remember that the Principal Investigator is continually responsible for subjects participating in his/her research and is obligated to inform the HSRC immediately if unanticipated problems involving risks to subjects arise. Likewise significant changes in the protocol as approved by the HSRC must be submitted for HSRC approval before implementing the changes in the research.

In addition to these general criteria, specific requirements apply to the informed consent process. (The Federal regulations provide a more detailed description of these requirements.)

Participants' **consent must be FULLY INFORMED**. To insure a genuinely informed subject, the consent form should use language and structure that the subject can understand. Note, also, that consent of parents or guardians is required if research subjects are minor children.

In general, you must present each subject (or parent or guardian) with a **written informed consent statement**. Although this statement must address numerous issues, the form should be concise; in general, consent forms should not exceed one page.

**Items that must be addressed in the consent form include:**

1. **A statement that the study involves research**
2. **A description of the research** that includes
  - a. Its purpose
  - b. Duration of the subject's participation
  - c. Procedures to be followed
  - d. Which procedures are experimental
3. **A description of the reasonably foreseeable risks or discomforts** to the subject
4. **A description of the reasonably foreseeable benefits** that the subject or others will experience
5. In the case of **therapeutic research, what treatment alternatives exist**
6. **Procedures for insuring the subject's confidentiality**
7. In **research involving more than minimal risk specification of**
  - a. Whether any compensation is available
  - b. Availability of medical treatments for possible injury and where they may be obtained
  - c. Availability of further information
8. **Person to contact**
  - a. For further information about the nature of the research
  - b. For further information about the research subject's rights
  - c. In case of research-related injury
9. **Explicit statements** that
  - a. Participation is voluntary
  - b. There is no penalty for non-participation

c. The subject can withdraw from the research at any time without penalty or reprisal

In addition to 1-9, **particular protocols may require further statements** regarding:

1. The possibility that particular procedures may involve currently unforeseeable/unanticipated risks
2. Anticipated circumstances under which the researcher may terminate the research without the subject's consent
3. Anticipated costs to the subject
4. Procedures for withdrawing from the project
5. Making available to subjects significant findings that arise during the research that may have an effect upon the subject's desire to continue to be a participant
6. The approximate number of subjects involved in the study
7. California law requires that any subject asked to participate in research involving "medical experimentation" must receive a copy of the experimental subjects' Bill of Rights written in the language in which the subject is fluent (see attached). "Medical experiment" is defined as:
  - a. The severance or penetration or damaging of tissues of a human subject or the use of a drug or a device as defined in the California Health and Safety Code, use of electromagnetic radiation, heat or cold, or use of biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of such subject or otherwise directly benefiting such subject
  - b. The investigational use of a drug or device licensed by the Federal Food and Drug Administration or the California Department of Health Services (when the study is conducted under California law)
  - c. Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of such subject

**Informed consent for any type of research activity may not include any waiver of the subjects' legal rights or any release of investigators from liability for negligence.** A copy of the consent shall be given to the subject unless otherwise approved by HSRC. The HSRC may waive or alter some of the consent requirements if, in its opinion,

1. the risks to subjects are minimal;
2. the waiver will not adversely affect subjects (their rights or welfare); or
3. the research is impossible without certain changes.

You should not presume that such waivers will be granted. In the absence of any extenuating circumstances, you should make certain that all of these criteria are explicitly included in the protocol when submitted for approval.

**If you wish to be excused from any of the above criteria, you should specifically request an exemption and explain why it is justified.**

Protocols that do not include these items are incomplete; incomplete protocols will be returned for revision.

Please direct any questions to John Mahoney, Ph.D., HSRC Chair at [jmahoney@csuchico.edu](mailto:jmahoney@csuchico.edu), or Sharon Cain, HSRC Assistant 530-898-3145 or [IRB@csuchico.edu](mailto:IRB@csuchico.edu).

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