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COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

POLICY AND PROCEDURES FOR RESEARCH WITH HUMAN SUBJECTS AT CALIFORNIA STATE UNIVERSITY, FRESNO

Revised November 2025

POLICY AND PROCEDURES FOR RESEARCH WITH HUMAN SUBJECTS
California State University, Fresno

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California State University, Fresno

1.0 BACKGROUND AND ACKNOWLEDGMENTS

The Committee for the Protection of Human Subjects (CPHS) was first formed at California State University, Fresno in 1971. The policy developed at that time was in force until the adoption of the current **Policy and Procedures** adopted in 1987, and revised in 2018**.**

During the fall and spring of 1986-87 the CPHS surveyed universities within and outside of the CSU system regarding human subjects' policy and procedures. Although the CPHS is not a senate committee, careful consultation with the Research Committee, Academic Policy and Planning, the Executive Committee, and the Senate were undertaken. Open hearings on the present policy and procedures were held as well as consultation with the Vice President for Academic Affairs, the Dean of the Division of Graduate Studies and Research, and the Graduate Council.

The CPHS is grateful for the cooperation of the CPHS at San Diego State University for their advice and consultation. Certain parts of section 2.0 and some example forms are taken (mutatis mutandis) from the **Policy and Procedures** at San Diego State University with their permission.

Revisions of the original document were made by the CPHS in February 2018.

Additional revisions of the document were made by the CPHS in August 2025.

This document is available on the website of the Committee for the Protection of Human Subjects at California State University, Fresno.

For further information, consult the CPHS website
http://fresnostate.edu/academics/humansubjects/ or contact:

The Provost
Division of Academic Affairs
5200 N. Barton Ave., UL54
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The Committee for the Protection of Human Subjects (CPHS) functions as the Institutional Review Board (IRB) at CALIFORNIA STATE UNIVERSITY, FRESNO.

Questions concerning the use of animals in research, radiation, toxic and radioactive substance storage, and use safety are handled by separate committees or officers of the University. For assistance in these matters, please call the Office of Environmental Health & Safety and Risk Management at (559) 278-7422.

2.0 HISTORICAL DEVELOPMENTS LEADING TO INSTITUTIONAL REVIEW OF RESEARCH WITH HUMAN SUBJECTS

The 20th century saw the exponential growth of scientific research with increasing experimentation and data collection on human subjects. Subjects were often involved in studies without any form of informed consent. Sometimes they did not know they were being placed at excessive or inappropriate risk, at times without any compensating benefit.

The Tuskegee study gained notoriety for its ethical violations. Initiated by the United States Public Health Service in the 1930s, the study was a long-term investigation of untreated syphilis. Disadvantaged, rural African American men unknowingly served as subjects of research. During the study, which lasted until 1972, participants with syphilis were examined periodically to follow the natural course of the disease, but treatment was withheld, even after penicillin therapy became available. Measures were even taken to keep subjects from obtaining treatment for syphilis from other sources. The family members of the men also contracted the disease and received no treatment or compensation from the study.

In the 1960s, elderly patients at the Jewish Chronic Disease Hospital in New York were injected with live cancer cells in a study of rejection responses. Subjects were not informed that the injected material contained live cancer cells because the investigators were afraid they would refuse participation. The study was not reviewed by a research committee, nor was approval obtained from several physicians providing care for the subjects.

In 1964, parents attempting to institutionalize their children with mental disabilities at Willowbrook State School in New York were told that admissions were closed. Shortly after, they were advised that there would be vacancies in the hepatitis unit if they were to volunteer their children for a study. They were not informed of the risks to their children. The children were inoculated with infectious hepatitis so that researchers could study the period of infectivity for the disease.

In 1969, child patients with a mental health diagnosis at Milledgeville State Hospital in Georgia were given investigational new drugs without their consent or the consent of their psychiatrist or representative. The practice was only stopped after the governor asked for an investigation.

In the 1970 Tea Room Trade study, a social scientist posed as a “watch queen” for homosexual encounters in public restrooms. He recorded the men’s license plate numbers and located their names and addresses through motor vehicle registration files. The subjects were not told they were being studied. A year later the researcher went to the men’s homes in disguise and interviewed them about their family and social life, supposedly for another type of study. In addition to the ethical questions concerning deception, this study placed subjects at risk of serious legal, social, and economic harm.

In a 1971 study on the side effects of contraceptives, nearly 150 Chicana women seeking birth control in Texas were given placebo-contraceptives without their knowledge. Within four months, ten women had become pregnant but were denied terminations because state laws prohibited abortion.

The most famous and perhaps most controversial studies in regard to the ethics of research with human subjects were conducted by Dr. Stanley Milgram at Yale University in the 1960s. In these studies, which were investigating obedience to authority, subjects were told to administer electroshocks to other persons. First pursued in order to try to understand the participation of the German citizenry in the Jewish holocaust, Dr. Milgram's work found astonishingly high compliance behaviors to authority among U.S. subjects. Although no actual electroshocks were administered to the research confederates, the subjects were deceived into believing that they were administering electroshocks and were witnesses to the feigned reactions to the "shocks." The Milgram studies underline serious issues and conflicts implicit in the area of research with human subjects which are worthy of continuous reflection and debate.

Public disclosure of these studies and many other unacceptable projects contributed to the support for governmental monitoring of research, which resulted in a variety of regulations. One of the first major efforts to deal with unethical biomedical research was the prosecution of Nazis who had conducted medical experiments on inmates in concentration camps. The Nuremberg Military Tribunal established a set of ethical and legal principles for the conduct of experiments as a basis to ascertain the guilt of the defendants and to be used as future standards for research involving human subjects. The "Nuremberg Code," developed in 1947, was refined later by national and international organizations and became a useful guide for evaluation of research activities. According to the Nuremberg Code (https://research.unc.edu/human-research-ethics/resources/ccm3_019064/ & https://ori.hhs.gov/content/chapter-3-The-Protection-of-Human-Subjects-nuremberg-code-directives-human-experimentation), the informed consent of a research subject is essential to ethical research.

In 1962, physician members of the World Medical Association gathered in Helsinki, Finland, to develop standards for clinical research. The standards included respect for the individual, the centrality of informed consent, and recognition of the vulnerability of certain groups of people. These standards were revised in 1964 and became known as the Declaration of Helsinki (https://www.wma.net/policies-post/wma-declaration-of-helsinki/).

United States federal guidelines (https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.401) were established in 1953 when the National Institutes of Health began requiring that research involving human subjects at its clinic in Bethesda, Maryland, be approved by a committee for the protection of human subjects. In 1966, the Surgeon General extended the review requirement to all research and training funded by the United States Public Health Services. In 1971, the Department of Health, Education and Welfare (DHEW) published the Institutional Guide to DHEW Policy on the Protection of Human Subjects

for research funded by the Department. The National Research Act of 1974 combined with the DHEW regulations to extend the need for committee approval of all research involving human subjects at any institution that ever receives federal DHEW (now Department of Health and Human Services [HHS]) support for such work.

The State of California enacted regulations governing research on prisoners in 1977. In 1978, the California Legislature passed the Protection of Human Subjects in Medical Experimentation Act. This bill required, in addition to informed consent, that subjects of medical experiments be given a Bill of Rights (https://www.dhcs.ca.gov/services/Pages/Office-of-Patients-Rights.aspx)

Prompted by revelations of unethical research, such as the examples mentioned above, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research issued “The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research” in 1979 as a result of the Tuskegee Study. The Belmont Report is considered to be the foundational document on research ethics with human subjects. It lays out three fundamental principles for research on human subjects: respect for persons, beneficence, and justice. While federal and state legislation has sought to ensure the legal rights of human subjects, the legacy of the Belmont Report has been to wrestle with the more complex issues of ethical reasoning applied to research with participants.

The purpose of the Committee for the Protection of Human Subjects is to administer institutional review of research. It aims to safeguard the rights and welfare of research participants while promoting a research culture where ethics are valued and the goals of institutional review are honored.

The Committee for the Protection of Human Subjects has worked with the California State University, Fresno research community since 1971.

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS (CPHS)

3.0 POLICY AND PROCEDURES

3.1 PURPOSE

The purpose of establishing policy and procedures on research is to protect the rights, health, and wellbeing of human subjects used in scientific investigations while promoting free inquiry at California State University, Fresno. We seek to assure compliance with governmental regulations by establishing:

A. The appropriate Institutional Review Board (IRB) (i.e., CPHS) and departmental human subjects review committees (herein called “Committees”) as required by federal regulations;

B. Procedures to ensure that the rights and dignity of human subjects are not violated by research projects at California State University, Fresno; and

C. Procedures to protect the principal investigator, the investigative staff, and the University from potential liability in research projects involving human participants.

3.2 APPLICABILITY

All research involving human subjects (defined below) conducted under the auspices of the University, any of its auxiliary organizations, or any cooperative project with researchers outside of the University is covered under this policy.

A specific determination must be made in each instance whether the research is “exempt,” “minimal risk,” or “at risk” (defined below), and thus covered by different aspects of policies and procedures delineated in this document. No research methodology (e.g., survey, questionnaire) is **per se “not at risk.”** Each principal investigator must provide each review committee with sufficient information for an informed judgment about risk level. Each review committee will determine whether the initial risk level is appropriate and if not, may require a change to the risk level.

Instructional activities that take place in the university classroom are generally not governed by this policy. However, research activities that involve classroom groups, students, or individuals are governed by this policy. Should a researcher have questions about whether an activity is covered, the relevant Departmental Human Subjects Review Committee should be consulted first. Questions may also be sent to the CPHS Chair.

Exemptions

Certain kinds of research are “exempt” from review by CPHS. A summary of those is

found in section 3.5.4.

3.2.1 Student Research

Research conducted by students solely for a class project is usually not reviewed by the Committee for the Protection of Human Subjects. However, if such student research may be reasonably foreseen to involve any aspect of the ethical dimensions of this policy or potentially be the subject for future research, then the instructor must submit the project for a Departmental Human Subjects Review Committee review.

3.2.2 Discussion in Research Courses

Although research training activities are not reviewed by the CPHS, it is the policy of the California State University, Fresno, that all graduate and undergraduate courses that deal with research procedures include an appropriate discussion of the ethics and procedures for the protection of human subjects in scientific investigations (APM 516). Helpful information can be found at the US Department of Health and Human Services Office for Human Research Protections https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html and CITI Program https://about.citiprogram.org/

3.3 DEFINITIONS FOR THE PURPOSES OF THIS POLICY

3.3.1 Principal Investigator

A principal investigator is the individual in charge of a research project and must be a California State University, Fresno faculty member (see Sec. 3.3.9) and qualified in the area of the proposed research. The principal investigator must assume the responsibility for compliance with the present policy. No undergraduate, master's level, or doctoral level student may serve as a principal investigator.

3.3.2 Co-Investigator

An investigator is a person working on a research project who is neither a subject nor the principal investigator. A student or collaborator may be an investigator.

3.3.3 Research

Research is investigation or experimentation aimed at the demonstration, discovery or interpretation of new facts, revision of accepted theories or laws in the light of new facts, or practical application of new or revised theories or laws. Research includes, but is not limited to, investigations

conducted by faculty members, University associates, and graduate and undergraduate students, and includes collaboration with researchers outside the University. So-called "pilot studies" are defined as research.

3.3.4 Human Subject

Any person who is studied in any research investigation is considered to be a human subject. Subjects may include, but are not limited to, classroom participants or voluntary participants in behavioral studies or oral or written interviews, donors of fluid and tissues, participants in a clinical setting (the “unborn” are human subjects), or students registered in a course for which academic credit is given for participation in research projects. The use of a departmental pool of subjects does not exempt the principal investigator from compliance with this **Policy and Procedures**.

A human subject also includes any living individual about whom an investigator obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. Intervention includes both physical procedures by which specimens are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect no observation or recording to be taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is known or may readily be ascertained by the investigator) in order to constitute research involving human subjects (or in a format in which the individual can be identified). https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.401

3.3.5 Special Classes of Human Subjects

Research involving pregnant or nursing (breast feeding) women and **in utero or ex utero** fetuses, including nonviable fetuses, must comply with the provisions of the Code of Federal Regulations Title 45, Subpart B section (https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46#subpart-B) of the federal regulations.

Research involving prisoners must comply with Subpart C section (https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46#subpart-C) of the federal regulations.

Research involving children must comply with Subpart D section (https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46#subpart-D) of the federal regulations.

3.3.6 Subject “At Risk”

“A subject is considered to be ‘at risk’ if he or she is exposed to the possibility of harm - physical, psychological, sociological, or other - as a consequence of any activity which goes beyond established and accepted methods for meeting his needs. The determination of when an individual is at ‘risk’ requires sound professional judgment of the circumstances of the activity in question and the ethical principles contained herein. Responsibility for this determination resides at all levels of institutional and departmental review.” (**The Institutional Guide to DHEW Policy on Protection of Human Subjects**, Washington, D.C., 1971, p. 2.)

An illustrative, but not inclusive, list of “at risk” procedures would include experiments involving any aspect, degree, quality, or amount of any of the following:

Deception, mental stress, including subjection to public embarrassment, humiliation, discomfort, irritation, or harassment, hypnosis, sensory deprivation, sleep deprivation, normally ingested or inhaled materials in excess of or less than normal amounts, injection, ingestion or inhalation of toxic materials, including all drugs, alcohol or placebos; strenuous physical exertion; use of physical stimuli in abnormal amounts (e.g., noise, vibration, shock, heat, magnetic fields, radiation); violation of anonymity or confidentiality of subjects and data; observations recorded about the individual which, if they became known outside the research, could make the subject liable to criminal or civil action or damage the subject’s financial or employment status; or abrogation of any civil right.

3.3.7 “Minimal Risk” Research

Research in which the risks of harm anticipated are not greater in terms of probability and magnitude than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. No research utilizing any procedure listed in paragraph 3.3.6 can be determined to be minimal risk. A research proposal submitted as “minimal risk”' in the judgment of the principal investigator, may be determined “at risk” in the department’s and/or CPHS’s judgment.

3.3.8 Certification

Certification means a written signed statement to a funding source by the CPHS that the proposed research has been reviewed and approved by the CPHS in accordance with the present **Policy and Procedures**.

3.3.9 Department, Chair, Faculty

Department means any current organizational unit of the University or first level review echelon (in some cases “school” review). Non-academic units are expressly included.

The term Chair refers to the supervisor of any department, program, or non-academic unit of the University. Departmental Human Subjects Review Committees may also designate a chair other than the Department Chair.

Faculty refers to any principal investigator in any unit of the University. Faculty must be listed as the PI for all graduate and undergraduate research projects and or theses.

3.3.10 “Funded” refers to grants, contracts, or other funding obtained from outside the university (e.g., county, state, federal government, or private agencies) and California State University system.

Externally funded research must have two levels of review; department and university (CPHS) and is not considered “exempt.”

3.3.11 Types of Review (Expedited and Full Board)

Review type refers to how protocols are reviewed and who will review.

A. “Expedited” - Within a department, expedited reviews are only permitted for “Exempt” protocols and some “Minimal Risk” protocols. Expedited reviews of “Exempt” protocols can be reviewed and approved by the Chair of the Departmental Human Subjects Review Committee, or by a small group of reviewers the Chair has assigned to review. “Minimal Risk” protocols may also be expedited but reviews must be completed by a group of three or more.
B. “Full Board” - Within a department, a full board review refers to the entire Departmental Human Subjects Review Committee, and may be assigned to some “minimal risk” protocols. All “at risk” protocols require a full board review. The chair of the Departmental Human Subjects Review Committee may assign a full board review for any protocols regardless of risk level.
C. CPHS reviews protocol as expedited for any protocols receiving external funding. The timeline for expedited reviews by CPHS is five business days. Full board reviews are completed for all “at risk” protocols and some “minimal risk” protocols that are unfunded. The timeline for unfunded, full board reviews by CPHS is ten business days.

3.4 ETHICAL GUIDELINES FOR RESEARCH PROJECTS WITH HUMAN SUBJECTS

3.4.1 Decision for or against Conducting a Research Investigation

It is the personal responsibility of the principal investigator to evaluate the ethical acceptability of each study and to ensure that no one is subjected to unreasonable risk to health, well-being, or dignity. Responsibility for this

determination resides at the departmental and CPHS levels. No assumption exists that “at risk” research is more or less ethical. The standards of care and review are stringent for each class of research proposal.

3.4.2 Individual Informed Consent

The investigator must obtain the informed consent of the prospective subject, or in the case of an individual who is not capable of giving informed consent, the proxy consent of a properly authorized guardian or representative. (See the Informed Consent Template on the CPHS website.)

3.4.3 Essential Information for Prospective Research Subjects

Certification of CITI Human Subjects Assurance Training: All investigators and student collaborators included as study personnel for the protocol must complete the CITI (Collaborative Institutional Training Initiative) Human Subject Assurance Training. A current and dated copy of the completion certificate for each researcher should be uploaded in the study personnel section of the protocol. This certificate ensures researchers are knowledgeable about the subjects they wish to study.

When looking to obtain and sustain informed consent from an individual as written in section 3.4.4, the investigator must adhere to the requirements set forth in the following subsections:

3.4.3.1 Obtaining Informed Consent

Before involving an individual in research, the investigator shall obtain the legally informed consent of the individual as outlined in section 3.4.4 in language that the individual is capable of understanding. If there are material changes in the conditions or procedures of the research, the investigator shall renew the informed consent of each subject.

3.4.3.2 Documentation of Informed Consent

The investigator shall obtain from each prospective subject a signed form as evidence of informed consent in the appropriate language of the participant; and if written consent is unfeasible due to illiteracy or reasonable fear of the authorities due to issues such as undocumented status or active substance abuse, a properly conducted oral informed consent process is engaged.

3.4.3.3 Assuring Freedom From Coercion to Participate

The investigator shall respect the individual subject’s freedom to choose to participate and to discontinue participation at any time. Refusal to participate must not carry a penalty; conversely, participation must not carry

a reward, such as monetary awards, excessive gifts, or special privileges, other than reasonable and context appropriate compensation.

3.4.3.4 Fairness and Freedom from Exploitation in the Research Relationship

The investigator has an obligation to honor all commitments made, including before, during, and after the period of the subject's participation in the research. Before research begins, all subjects must have a clear understanding of the procedures to be used, including, but not limited to, the amount of time involved, potential risks and benefits, what to expect as a subject in the study, and the purpose of the study itself. The investigator should give the prospective subject full opportunity and encouragement to ask questions.

3.4.3.5 Confidentiality of the Data and Anonymity of the Individual Participant

The investigator should keep confidential all personal information obtained. If any possibility exists that the anonymity of the subject will not be protected, this possibility must be explained to the subjects or their parents or legal guardians as part of the Informed Consent procedure. (See section 3.7.4). If the investigator needs to identify the subject for research reasons, such disclosure should be made clearly and explicitly.

3.4.4 Obligations of Investigators Regarding Informed Consent

The investigator has a duty to provide the following information to participants when looking to obtain informed consent:

A. That each individual is invited to participate as a subject in research, and the aims and methods of the research;
B. The expected duration of the subject's participation;
C. The benefits that might reasonably be expected to result to the subject or to others as an outcome of the research;
D. Any foreseeable risks or discomfort to the subject associated with participation in the research;
E. Any alternative procedures or courses of treatment that might be as advantageous to the subject as the procedure or treatment being tested;
F. The extent to which the confidentiality of records, in which the subject is identified, will be maintained;
G. How records will be kept and if they will be destroyed;
H. The extent of the investigator's responsibility, if any, to provide medical, therapeutic or other applicable services to the subject;
I. What resources will be provided free of charge for specified types of research-related distress or discomfort;

J. Whether the subject or the subject's family or dependents will be compensated for disability or death resulting from research-related injury; and
K. That the individual is free to refuse to participate and will be free to withdraw from the research at any time without penalty or loss of benefits to which he or she would otherwise be entitled.

3.4.5 Research Involving Children as Research Subjects

Before undertaking research that involves children, the investigator must ensure that:

A. Children will not be involved in research that might equally well be carried out with adults;
B. The purpose of the research is to obtain knowledge relevant to the educational, social, and health needs of children;
C. A parent or legal guardian of each child has given Informed Consent; https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-D/section-46.408
D. The assent of each child has been obtained to the extent of the child's capabilities; https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-D/section-46.408
E. All materials used with children and parents or guardians such as recruitment script, Informed Consent, and child's assent, are linguistically and culturally appropriate;
F. The child's refusal to participate in research must always be respected unless, according to the research protocol, the child would receive therapy for which there is no medically acceptable alternative;
G. The risk presented by interventions not intended to benefit the individual child-subject is low and commensurate with the importance of the knowledge to be gained; and
H. Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child-subject as any available alternative.
I. In educational/classroom settings some research may be "exempt." The investigator should consult the Departmental Human Subjects Review Committee Chair and/or CPHS Chair. Federal guidelines can be found at https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104 and https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c3

3.4.6 Research Involving Persons with Mental or Behavioral Challenges or Disabilities

Before undertaking research involving individuals who by reason of mental or

behavioral disorders are not capable of giving adequately informed consent, the investigator must ensure that:

A. Such persons will not be subjects of research that might equally well be carried out on persons that do not have mental challenges or disabilities;
B. The purpose of the research is to obtain knowledge relevant to the particular needs of persons with mental or behavioral challenges or disabilities;
C. The consent of each subject has been obtained to the extent of that subject's capabilities, and a prospective subject's refusal to participate in non-clinical research is always respected;
D. In the case of subjects considered not to be competent, Informed Consent is obtained from the legal guardian or other duly authorized person;
E. The degree of risk attached to interventions that are not intended to benefit the individual subject is low and commensurate with the importance of the knowledge to be gained; and
F. Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual subject as any alternative.
   See the Belmont Report
   https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html

3.4.7 Research Involving Prisoners as Research Subjects

Prisoners have constraints due to their incarceration that affects their ability to make a truly voluntary and uncoerced decision about whether to participate as research subjects. Investigators should ensure that the advantages of participating in the research are not of such a magnitude that a prisoner's ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired. Opportunity to participate in research should be fair and immune from arbitrary intervention by prison authorities or prisoners. Parole boards should not use participation in research as a factor when considering decisions and all prisoner subjects should be informed that participation in research has no impact on parole decisions. If there is a need for follow up, then adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact. Prisoners with serious illness or at risk of serious illness should not arbitrarily be denied access to investigational drugs, vaccines, or other agents that show promise of therapeutic or preventive benefit.
Federal guidelines can be found at
https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-C

3.4.8 Selection of Pregnant or Nursing (Breastfeeding) Women as

Research Subjects

Pregnant or nursing women should in no circumstances be the subjects of non-clinical research unless the research carries no more than minimal risk to the fetus or nursing infant and the object of the research is to obtain new knowledge about pregnancy or lactation. As a general rule, pregnant or nursing women should not be subjects of any clinical trials except such trials that are designed to protect or advance the health of pregnant or nursing women or fetuses or nursing infants, and for which women who are not pregnant or nursing would not be suitable subjects.
Federal guidelines regarding the inclusion of pregnant or nursing women can be found at
https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-B

3.4.9 Additional Ethical Principles include:

- The Belmont Report (https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html)
- The American Psychological Association Bill of Rights https://www.apa.org/pubs/videos/4310742-rights.pdf
- The Patient Bill of Rights (https://www.cc.nih.gov/patient-info/legal/bill-of-rights)
- The American Anthropological Association Ethical Guidelines (http://ethics.americananthro.org/category/statement/)
- Principles of the Ethical Practice of Public Health (chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.apha.org/getcontentasset/d5a44514-2dfc-48b0-b1e2-9c0fa4fd5619/7ca0dc9d-611d-46e2-9fd3-26a4c03ddcbb/ethics_brochure.pdf?language=en), among others.

3.5 PROCEDURES FOR APPROVAL OF PROPOSALS IN WHICH HUMAN SUBJECTS WILL PARTICIPATE

All research projects/proposals should be submitted in digital format via Kuali. Researchers should access Kuali via the CPHS website.

Review Sequence. Each researcher shall have access to a review body at the departmental level. (See definition Section 3.3.9.)

3.5.1 Departmental Human Subjects Review Committee Members - Each department shall maintain a review committee for the implementation of this policy or designate an existing committee to comply with the present policy. The departmental review is conducted by at least three faculty who are not involved in the research under consideration. The three faculty may either be the formal Departmental Human Subjects Review Committee, or an ad hoc committee, if no formal committee exists.

3.5.2 Departmental Human Subjects Review Committee Review - Members must complete and submit their review in Kuali. Members may submit comments/requests for revisions which will appear as “action Items”. Action items must be resolved by the researcher before the Committee Chair can approve the proposal.

3.5.3 Departmental Decisions - All decisions by the Departmental Human Subjects Review Committee must be archived in the department where the research originates and is subject to audit by the Committee for the Protection of Human Subjects.

The participation of human subjects in projects and research at California State University, Fresno, is authorized only when approved in advance.

The Departmental Human Subjects Review Committee should use this document as a guide in its deliberations: review submissions for risk, methodology, and adequate consent. Submissions which are externally funded or are judged to be at risk must be forwarded to the California State University, Fresno Committee for the Protection of Human Subjects. If a submission is unfunded and judged to be of minimal risk, the Departmental Human Subjects Review Committee may:

a. Approve with or without modification or disapprove the submission with an explanation of the reasons for disapproval;
b. The Departmental Human Subjects Review Committee may arrange for qualified consultants when needed;
c. Invite the principal investigator to appear before it for clarification and possible modification before disapproving an application; and,

The department should also keep an electronic copy of the protocol and decision on an electronic archival platform.

3.5.4 Exempt Research (less than minimal risk) - Unfunded

**All research, exempt or otherwise, must be entered into Kuali.

If a principal investigator has determined the research to be exempt because it is wholly within one or more of the categories listed below, the researcher shall submit a proposal via Kuali for review by the Departmental Human Subjects Review Committee as exempted by policy, indicating the specific category by number. The principal investigator shall include all required documents that describe the research in full. The Departmental Human Subjects Review Committee shall give the researcher written verification whether the research is exempt or not. Federal regulations flow charts on exempt research can be found here https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c3

The following research projects are exempt from full review by the Committee for the Protection of Human Subjects; however, there are some exceptions for

special populations; research involving children, research involving pregnant or nursing (breastfeeding) women or fetuses, prisoners, or mentally disabled people who are institutionalized. Additionally, some instructional activities may contain an element of risk. If any degree of risk exists, the proposal must be processed as “minimal risk” or “at risk” research.

45 CFR 46 Revised Common Rule Subpart A Exempt Categories

*In 2019, HHS updated an expansion to Exempt Categories of Research with Human Subjects. The following eight categories specify what types of research qualify as “exempt” research. This may mean that a review by the Departmental Human Subjects Review Committee chair would be sufficient and not require further review. The Departmental Human Subjects Review Committee chair may also require a full review at the department level.

**All research, exempt or otherwise, must be entered into Kuali.

§ 46.104 Exempt research.

(a) Unless otherwise required by law or by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the categories in paragraph (d) of this section are exempt from the requirements of this policy, except that such activities must comply with the requirements of this section and as specified in each category.

(b) Use of the exemption categories for research subject to the requirements of subparts B, C, and D: Application of the exemption categories to research subject to the requirements of 45 CFR part 46, subparts B, C, and D, is as follows:

(1) ***Subpart B.*** Each of the exemptions at this section may be applied to research subject to subpart B if the conditions of the exemption are met.

(2) ***Subpart C.*** The exemptions at this section do not apply to research subject to subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

(3) ***Subpart D.*** The exemptions at paragraphs (d)(1), (4), (5), (6), (7), and (8) of this section may be applied to research subject to subpart D if the conditions of the exemption are met. Paragraphs (d)(2)(i) and (ii) of this section only may apply to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph (d)(2)(iii) of this section may not be applied to research subject to subpart D.

(c) [Reserved]

(d) Except as described in paragraph (a) of this section, the following categories of human subjects research are exempt from this policy:

(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7).

(3)

(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part

of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

(5) Research and demonstration projects that are conducted or supported by a federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

(ii) [Reserved]

(6) Taste and food quality evaluation and consumer acceptance studies:

(i) If wholesome foods without additives are consumed, or

(ii) 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.

(7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by § 46.111(a)(8).

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with § 46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § 46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by § 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and

(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

Additional protections for research subjects that fall into subparts B, C, D, and E can be found below.

https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html

Subpart B — Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-b/index.html

Subpart C — Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-c/index.html

Subpart D — Additional Protections for Children Involved as Subjects in Research
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html

Subpart E — Registration of Institutional Review Boards
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-e/index.html

**Any research, exempt or otherwise, receiving external funding must be reviewed by the University Committee for the Protection of Human Subjects (CPHS).

If the exempt research is funded, the Departmental Human Subjects Review Committee shall forward the protocol and memos to the CPHS for review and certification.

3.5.5 Exempt Research and CPHS Chair Purview

Exempt protocols may be reviewed as an expedited review, and approved by the Chair of the Departmental Human Subjects Review Committee. The Chair may also decide to assign specific reviewers or the full departmental committee to review "exempt" protocols.

3.6 "MINIMAL RISK" RESEARCH (UNFUNDED)

No individual researcher can make the determination that a research project is "minimal risk." The principal investigator may state his or her judgment on the application form.

The departmental review is conducted by at least three faculty who are not involved in the research under consideration. If the review by the Departmental Human Subjects Review Committee confirms the judgment that the proposal is of "minimal risk" and written notice to the effect has been given, the principal investigator may consider the professional obligations regarding human subjects to have been satisfied and the research can begin. The Departmental Human Subjects Review Committee Chair shall keep this written decision in an electronic archive for five years.

Some "minimal risk" proposals may be forwarded to the CPHS for a secondary review when there are significant questions about the procedures of the proposal. This decision is within the purview and at the discretion of the CPHS Chair. In this instance, the principal investigator will be notified.

3.7 "AT RISK" RESEARCH (UNFUNDED)

Investigators have an obligation to protect their research subjects from risk conditions. If a potential risk exists, the subject is "at risk," and the investigator must take all possible and reasonable measures to minimize such risk by:

A. Searching for alternative procedures to avoid the risk;
B. Using stringent safety precautions to minimize the risk;
C. Screening out participants who might be particularly susceptible to the risk;
D. Continuous monitoring of the subject during the procedures;
E. Minimizing the level and duration of the risk;
F. Using appropriate measures to detect and correct any consequences of the risk; and,
G. Consulting with colleagues on and off campus for techniques of minimization.

3.7.1 The investigator must inform the subject of all features of the investigation which might influence his or her willingness to participate,

including:

A. All information listed in section 3.4.4 Obligations of Investigators Regarding Informed Consent

Before the research commences, an Informed Consent Form containing the above information must be signed by the subject or, if the subject is a minor or otherwise not legally competent, by his/her parent(s) or legal guardian(s). When possible, written assent should also be obtained from subjects who are minors. The investigator must be sure that the subject, or his/her parent or legal guardian, has understood the explanation and that the consent was obtained without deception or coercion. If the subject is "at risk", the informed consent signature must be witnessed by a member of the research team.

B. A statement that the research procedures have been approved by the Committee for the Protection of Human Subjects at California State University, Fresno.

3.7.2 Questionnaires, recruitment flyers, informed consent forms, and all other materials must be attached to the protocol.

3.7.3 All "at risk" research will undergo a second level of review by the Committee for the Protection of Human Subjects. Once the departmental review is complete and the "at risk" status confirmed, the CPHS will conduct its review.

3.8 FUNDED RESEARCH

All research proposals that are supported by external grants or contracts must be reviewed by the Departmental Human Subjects Review Committee and the University Committee (CPHS). The principal investigator shall first submit the proposal to the Departmental Human Subjects Review Committee. Once it is approved, the proposal will be sent to the University Committee with all documents and materials attached.

3.8.1 The Departmental Human Subjects Review Committee shall consist of three faculty members who are not involved in the research. The Departmental Human Subjects Review Committee should refer to section 3.3.11 and 3.5.1 in reviewing proposals.

A principal investigator, a Chair, or a Departmental Human Subjects Review Committee may request the CPHS to review any decisions made during the Departmental Human Subjects Review Committee process.

4.0 TIMELINE FOR REVIEW

4.1 Department - Each Departmental Human Subjects Review Committee is expected to complete a review in a timely manner. The Chair of the Committee shall

establish an appropriate deadline for committee members to submit their review. If the committee requests revisions, the Chair shall notify the PI by sending the proposal back via the “Request Revisions” button in Kuali. Once the committee and the Chair are satisfied with the revisions, the proposal should be approved and notification sent to PI.

Funded - Externally funded proposals will be sent to the CPHS Chair for the next level of review. Funded proposals will undergo an expedited review and receive a decision in five business days.

Unfunded - “At risk” proposals and some “minimal risk” proposals will be sent to the CPHS Chair for the next level of review. These proposals will undergo a full committee review and receive a decision in ten business days.

4.2 Deadlines - Each department will set deadlines for proposal submissions. The deadline for submission of proposals that require CPHS review can be found on the CPHS website. Protocols submitted after the deadline or during semester breaks will be reviewed when the new semester begins. Externally funded proposals will be reviewed during breaks but must have been approved at the department level first.

5.0 MEMBERSHIPS, PROCEDURES, AND AUTHORITY

5.1 MEMBERSHIP

California State University, Fresno has maintained the Committee for the Protection of Human Subjects (CPHS) since 1971. This Committee functions as the Institutional Review Board (IRB) required by federal regulations. The Committee is always composed of members of all genders, and in the nomination of new members gives consideration to diverse ability, cultural, ethnic, gender, racial, and sexual identity backgrounds, community attitudes, and the promotion of respect for its role in safeguarding the rights and welfare of human subjects. The Committee, an independent committee of the University, reviews proposals submitted pursuant to the **Policy and Procedures** of the University.

The following members are nominated by the Committee to the Provost and Vice President for Academic Affairs for appointment for three-year terms and may serve multiple terms.

At least three faculty members from different schools nominated from a pool of interested faculty maintained by the Committee.

At least one community member with no employment relationship or affiliation to California State University, Fresno, and who is not part of the immediate family of a person who is affiliated with California State University, Fresno.

At least one member of the Committee must be nominated specifically because he or she does not possess a scientific background and primary concerns are in nonscientific areas (e.g., lawyer, activist, ethicist).

A faith advisor from the community, nominated by the Committee.

A health care provider from the community, such as a physician, nurse practitioner or physician's assistant, nominated by the Committee.

A student representative, nominated by the Committee.

The Provost and Vice President for Academic Affairs or designee shall serve as a permanent **ex officio** member.

A member of the Student Health and Counseling Center and a risk manager from Environmental Health, Safety, and Risk Management with California State University, Fresno are permanent, voting members of the Committee.

The Chair of the CPHS is elected by the Committee every three years. The Chair may serve multiple terms.

5.2 PROCEDURES FOR CPHS REVIEW

The Committee has adopted the following procedures.

Upon electronic receipt of a complete proposal to the CPHS Coordinator, the Chair will send electronic copies to each Committee member for independent review. The Chair will write a memo on the decision of the Committee based on the responses. The Chair can request that the principal investigator modify or revise proposals based on the Committee's recommendations.

All decisions of the Committee are confirmed by vote in meetings. During the academic year, the Committee meets monthly. Meeting dates can be found on the CPHS website. The Committee does not meet during the summer. A quorum (defined as 50% of the voting membership plus one), must be present to conduct business, including at least one Committee member who does not possess a scientific background and whose primary concerns are in nonscientific areas.

All decisions require a majority vote of those present. The Chair votes in all cases, except when acting as a principal investigator or when otherwise involved in the research protocol under consideration. The Committee may invite consultants at will. Members may not vote on proposals that they have reviewed at any other level or where they are the principal investigator/co-investigator.

Minutes of meetings, correspondence, and copies of submissions are retained by the CPHS Coordinator and CPHS Chair in a dedicated password-protected drive. Approved proposals that are externally funded are also retained by the Office of Research and

Sponsored Programs for five years.

The Chair of the Committee may grant "expeditious approval" of submissions. (See section 5.3.) The Chair of the Committee for the Protection of Human Subjects, California State University, Fresno is authorized by the Committee to transmit certification of compliance and report any infractions/non-compliance to the Department of Health and Human Services (HHS).

5.3 AUTHORITY

The CPHS has the responsibility for reviewing and the authority to approve, require modification, or disapprove all research and related activities involving human subjects under the auspices of California State University, Fresno, including previously approved activities. The CPHS will approve research after the Committee has determined that the following requirements have been satisfied. (Approval will normally expire, one (1) year from the date of CPHS action.)

A. Risks to subjects are minimized:
    1. By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and
    2. By using procedures already being performed on the subjects for diagnostic or therapeutic purposes.
B. Risks to the subjects are reasonable in relation to anticipated benefits, if any, to the subjects, and the value of information that may reasonably be expected. In evaluating risks and benefits, the CPHS will consider only those risks and benefits that may result from research and not the risks and benefits of therapy the subjects would receive if not participating in the research. The CPHS may consider the long-range benefits of information gained in the research as among the risks or benefits that fall within its purview.
C. Selection of subjects is appropriate. In making this assessment the CPHS will take into account the purpose of the research, the setting in which the research is to be conducted, and the population from which subjects are to be recruited.
D. Informed consent will be obtained from each prospective subject or the subject's legally authorized representative, and will be appropriately documented. If the documentation would impair the validity of the results of the investigation, the CPHS may allow the investigator to provide subjects with only a written statement describing the research.
E. The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
F. The research plan contains adequate provisions for protecting the privacy of subjects and for maintaining the confidentiality of data.
G. If some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, pregnant and nursing women, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, appropriate safeguards have been

included in the study to protect the rights and welfare of these subjects.

5.4 OBSERVATION OF THE CONSENT PROCESS AND THE RESEARCH

The CPHS has the authority to observe or have a third party observe the consent process and the research.

5.5 ANNUAL RENEWAL OF APPROVAL

The CPHS will conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once each year. Principal investigators are responsible for submitting an annual research renewal form in a timely manner.

It is the practice at Fresno State to approve all research proposals for one year. Although exempt protocols are not required by federal law to include an expiration date, it is strongly recommended to set an expiration date. This ensures that principal investigators update materials and forms if the study is ongoing.

5.6 VERIFICATION OF CHANGE

The CPHS can determine that projects require verification from sources other than the investigator, and that no significant changes have occurred since the previous CPHS review.

5.7 SUSPENSION OR TERMINATION OF APPROVAL

The CPHS has the authority to suspend or terminate approval of research that is not being conducted in accordance with the Committee's decisions and requirements, or that has resulted in unexpected injury to subjects.

5.8 INFORMATION DISSEMINATION AND REPORTING

The CPHS has the authority and the responsibility for promptly reporting the following information to the Dean of Graduate Studies, the Provost and Vice President for Academic Affairs, Associate Vice President for Grants and Research, University Risk Manager, and the Department of Health and Human Services (for HHS funded studies):

H. Any noncompliance by research investigators with the requirements of the CPHS
I. Any injury to human subjects
J. Any unanticipated risks to subjects or others
K. Suspension or termination of CPHS approval, including reasons for the Committee's actions

5.9 EXPEDITED REVIEW

Research that involves no more than "minimal risk" will be afforded "expedited" review.

The CPHS Chair will name an ad hoc committee of three CPHS members to perform an expedited review. A member conducting expedited review may exercise all of the authorities of the CPHS except disapproval, which requires action of the full Committee. Reviewers may ask for the opinions of one or more additional CPHS members. Reviewers will refer any research protocols to the full Committee whenever the reviewer considers full committee review to be warranted.

When the expedited review procedure is followed, the CPHS members conducting the review will inform the full CPHS of research protocols that have been approved. At a convened CPHS meeting, any member may request that a proposal that has been expeditiously approved be reviewed by the CPHS. Members will vote on the request and a majority will decide the issue. When research activities initially approved under expedited procedures are subsequently reviewed, the decisions reached at the convened meeting will supersede any decisions made by the expedited review.

Research activities involving no more than minimal risk and in which the only involvement of human subjects will be in one or more of the following categories (carried out through standard methods) may be reviewed by the CPHS through the expedited review procedure authorized in 46.110 of 45 CFR 46 expedited categories. Categories 1-4 must be performed by qualified and/or licensed professionals.

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

   a. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (NOTE: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

   b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

   a. (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

   b. from other adults and children [2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means.
   Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
   Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior)

or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:

   a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

   b. where no subjects have been enrolled and no additional risks have been identified; or

   c. where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

**CPHS may also perform an expedited review of ongoing or previously approved research in which no change is proposed from previous submission to the CPHS.

5.10 APPEAL OF THE CPHS DECISION

If an investigator believes that their proposal has been disapproved as the result of incorrect, unfair, or improper evaluation by the CPHS, and he or she has rebutted the decision with the CPHS, then he or she may appeal to the Vice President for Academic Affairs and to the President (or to the Graduate Dean if the research is a thesis). The CPHS will reconsider any aspect of its decision upon request by the Vice President for Academic Affairs or the President (or the Graduate Dean if the research is a thesis). The records of CPHS are to be made available for such appeal.

No office or officer of the University may reverse the CPHS's decision. (See section 46.112 of the federal regulations.)

5.11 CONSULTATION WITH RESEARCH INVESTIGATORS AND DEPARTMENTS

Investigators and department units may call upon the CPHS for consultation regarding the protection of human subjects in research. The CPHS will maintain a panel of consultants for this purpose. The panel will consist of current and previous members of the CPHS in addition to other individuals approved by the CPHS.

Any researcher may receive a roster of members of the CPHS by consulting its website https://academics.fresnostate.edu/humansubjects/irb/index.html

If the CPHS has questions or concerns regarding a proposal, the investigator may be asked to present additional information to the CPHS in the form of a presentation during one of the regular CPHS meetings.

5.12 FEDERAL MANDATES

THE CPHS SHALL ENSURE THE POLICIES CONFORM WITH FEDERAL REGULATIONS, SHALL NOTIFY THE ACADEMIC SENATE OF ANY CHANGES, AND SHALL PUBLISH REVISION OF THE POLICY & PROCEDURES WHEN NEEDED.

NOTE: THE MOST RECENT GOVERNING REGULATIONS ARE THOSE OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, 45 CFR, SUBTITLE A, Part 46, Subpart A, Oct. 1, 1986, revised in 2018 and implemented in January 2019.

The CPHS complies with and commences implementation of the federal guidelines upon their receipt. The CPHS considers the federal guidelines as superseding California State University, Fresno's Policy and Procedures whenever conflicts in interpretations arise.