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POLICY AND PROCEDURES

FOR RESEARCH WITH HUMAN SUBJECTS AT CALIFORNIA STATE UNIVERSITY, FRESNO

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

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

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1. BACKGROUND AND ACKNOWLEDGEMENTS

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.

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:

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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. 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 1973, 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 couldstudy 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.

In the 1960s, Dr. Stanley Milgram at Yale University conducted studies investigating obedience to authority. Subjects were told to administer electroshocks to others. First pursued in order 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. Developed in 1947, the "Nuremberg Code" was later refined by national and international organizations and became a useful guide for evaluation of research activities. According to the Nuremberg Code, 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.

United States federal guidelines were established in 1953 when the National Institute 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 thatreceives federal DHEW (now Department of Health and Human Services [HHS])support for such work.

The State of California enacted regulations governing research on incarcerated individuals (“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.

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 1971. 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.

In 1981, the U.S. Department of Health and Human Services and the Food and Drug Administration revised their existing human subjects regulations. The Federal Policy for the Protection of Human Subjects or the "Common Rule" was published in 1991 and codified in separate regulations by 15 federal departments and agencies. Significantly revised in July 2018, the Common Rule governs Institutional Review Boards for oversight of biomedical and behavioral research involving human subjects and is the baseline standard of ethics by which any government-funded research is in the United States is held. Fresno State researchers are held to these standards of human subject research rights regardless of funding.

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.

3. POLICY AND PROCEDURES

3.1 PURPOSE

The purpose of establishing policy and procedures on research is to protect the rights, health, and well-being 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 boards (IRBs) (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.

Instructional activities that take place in the classroom are 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.

Exemptions

Certain kinds of research are “exempt” from review. A summary of those is found in section 3.5.2.

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 departmental review.

3.2.2 Discussion in Research Courses

Although research training activities are not reviewed by the CPHS, it is the policy of 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.

3.3 DEFINITIONS

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 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 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. 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.

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).

3.3.5 Special Classes of Human Subjects

Research involving pregnant or nursing (breastfeeding) individuals and in utero or ex utero fetuses, including nonviable fetuses, must comply with subpart B of the provisions of the Code of Federal Regulations Title 45 CFR 46.

Research involving incarcerated individuals (“prisoners”) must comply with subpart C.

Research involving children must comply with subpart D.

3.3.6 Subject “At Risk”

A subject is considered to be “at risk” if they are 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 their 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.

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 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” or “college” 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.

“Faculty” refers to any principal investigator in any unit of the University.

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).

3.4 ETHICAL GUIDELINES

A. 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 proposed.

B. 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.

C. Essential Information for Prospective Research Subjects

Before requesting an individual’s consent to participate in research, the investigator must provide the individual with the following information in language that they are capable of understanding:

1. That each individual is invited to participate as a subject in research;
2. Aims and methods of the research;
3. Expected duration of the subject’s participation;
4. Benefits that might reasonably be expected to result to the subject or to others as an outcome of the research;
5. Any foreseeable risks or discomfort to the subject associated with participation in the research;
6. Any alternative procedures or courses of treatment that might be as advantageous to the subject as the procedure or treatment being tested;
7. The extent to which the confidentiality of records in which the subject isidentified will be maintained;
8. How records will be kept and if they will be destroyed;
9. Extent of the investigator’s responsibility, if any, to provide medical, therapeutic, or other applicable services to the subject;
10. That resources will be provided free of charge for specified types of research-related distress or discomfort;
11. Whether the subject or the subject’s family or dependents will be compensated for disability or death resulting from research-related injury; and
12. 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 they would otherwise be entitled.

D. 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.

E. Fairness and Freedom from Exploitation in the Research Relationship

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 has an obligation to honor all commitments in that understanding.

F. 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 researcher needs to identify the subject for research reasons, such disclosure should be made clearly and explicitly.

G. Obligations of Investigators Regarding Informed Consent

The investigator has a duty to:

1. Communicate to the prospective subject all information necessary for adequately informed consent;
2. Give the prospective subject full opportunity and encouragement to ask questions;
3. Exclude the possibility of unjustified deception, undue influence, and intimidation;
4. Seek consent only after the prospective subject has adequate knowledge of the relevant facts and consequences of participation and has had sufficient opportunity to consider whether to participate;
5. Obtain from each prospective subject a signed form as evidence of informed consent in the appropriate language of the participant; 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, the investigator shall conduct a proper oral informed consent process;
6. Renew the informed consent of each subject if there are material changes in the conditions or procedures of the research.

H. Research Involving Children as Research Subjects

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

1. Children will not be involved in research that might equally well be carried out with adults;
2. The purpose of the research is to obtain knowledge relevant to the educational, social, and health needs of children;
3. A parent or legal guardian of each child has given informed consent;
4. The assent of each child has been obtained to the extent of the child's capabilities;
5. All materials used with children and parents or guardians such as recruitment scripts, informed consent, and child's assent are linguistically and culturally appropriate;
6. 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;
7. The risk presented by interventions not intended to benefit the individual child research subject is low and commensurate with the importance of the knowledge to be gained; and
8. Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child research subject as any available alternative.

I. Research Involving Persons with Mental or Behavioral Challenges or Disabilities

Before undertaking research involving individuals who by reason of mental or behavioral challenges are not capable of giving adequately informed consent, the investigator must ensure that:

1. Such persons will not be subjects of research that might equally well be carried out on people who do not have mental or behavioral challenges or disabilities;
2. The purpose of the research is to obtain knowledge relevant to the particular needs of people with mental or behavioral challenges or disabilities;
3. The consent of each subject has been obtained to the extent of that person's capabilities, and a prospective subject's refusal to participate in non-clinical research is always respected;

4. In the case of subjects considered not to be competent, informed consent is obtained from the legal guardian or other duly authorized person;
5. 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
6. Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual subject as any alternative.

J. Research Involving Incarcerated Individuals ("Prisoners") as Research Subjects

Incarcerated individuals 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:

1. The advantages of participating in the research are not of such a magnitude that an incarcerated individual'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;
2. Opportunity to participate in research should be fair and immune from arbitrary intervention by prison authorities or incarcerated individuals. Parole boards should not use participation in research as a factor when considering decisions, and all incarcerated subjects should be informed that participation in research has no impact on parole decisions.
3. 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 individuals' sentences, and for informing participants of this fact.
4. Incarcerated individuals 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.

K. Selection of Pregnant or Nursing (Breastfeeding) Individuals as Research Subjects

Pregnant or nursing individuals 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 individuals should not be subjects of any clinical trials except such trials as are designed to protect or advance the health of pregnant or nursing

individuals or fetuses or nursing infants, and for which individuals who are not pregnant or nursing would not be suitable subjects.

Additional Ethical Principles include:

- Belmont Report
- American Psychological Association Ethical Principles of Psychologists
- Department of Health and Human Services Patient Bill of Rights
- American Anthropological Association Ethical Guidelines
- American Sociological Association Code of Ethics
- Principles of the Ethical Practice of Public Health
- American Medical Association Code of Medical Ethics

3.5 PROCEDURES – REVIEW SEQUENCE

Each researcher shall have access to a review body at the departmental level (see definition Section 3.3.9). As of March 25, 2021, all protocols and supporting documentation requiring departmental IRB review and approval must be submitted through the Kuali IRB electronic submission system, which can be accessed via the CPHS homepage. Please see the Kuali User Guide for submission instructions.

3.5.1 Establishment of Departmental Committees/IRBs

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 Institutional Review Board (IRB) or an ad hoc committee if no formal committee exists. If the review by the Departmental IRB 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. All decisions by the Departmental IRB must be archived in the online Kuali IRB system and are subject to audit by the University Committee for the Protection of Human Subjects.

As indicated in the Flow Guide (see appendix), proposals considered to be “minimal risk” are reviewed at only the departmental level (unless funded). All "funded" research and "at risk" research is reviewed by the appropriate departmental IRB and the University CPHS. The participation of human subjects in projects and research at California State University, Fresno, is authorized only when approved in advance by the appropriate departmental IRB and, if necessary, the CPHS.

Departmental IRBs should:

A. Use this document as a guide in its deliberations;

B. Review submissions for risk, methodology, and adequate consent;
C. Approve with or without modification or disapprove the submission with an explanation of the reasons for disapproval;
D. Arrange for qualified consultants when needed;
E. Invite the principal investigator to appear before it for clarification and possible modification before disapproving an application;
F. Submit reviews and approval/disapproval decisions via Kuali.

A principal investigator, Chair, or departmental IRB may request that the CPHS review any departmental IRB procedures or decisions.

3.5.2 Exempt Research (less than minimal risk)

If a principal investigator has determined research to be exempt because it is wholly within one or more of the categories listed below, the researcher shall indicate this in Kuali, including the specific category (or categories) by letter(s). The principal investigator shall submit a protocol, including supporting documentation (e.g., survey, interview guide, consent document), with sufficient description of the research to allow the Department IRB Chair to assess and confirm the exemption in Kuali. If the researcher's department does not have a standing departmental IRB, the Department Chair shall provide written verification via Kuali of the exempt status to the researcher. If the exempt research is funded, the Departmental IRB shall forward the protocol to the CPHS Chair for confirmation and certification.

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. Category F does not apply to research involving children. Category E is applicable to research involving pregnant or nursing individuals or fetuses, incarcerated individuals, or mentally challenged people who are institutionalized and is not exempt. 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.

A. Research conducted in established or accepted educational settings using standard educational practices, such as comparison among instructional techniques, curricula, or management methods;
B. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that makes identification of the subjects impossible;
C. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are routinely available to the investigator, and are recorded by the investigator in such a manner that makes identification of the subjects impossible;
D. Research involving survey or interview procedures when the

respondents are elected or appointed public officials or candidates for public offices;

E. Research involving the observation (including observation by participants) of public behavior in places where there is no recognized expectation of privacy;
F. Research involving survey or interview procedures that do not produce psychological stress, in which the subjects are legally competent, and where investigators identify themselves and state that they are conducting a research survey or interview.

Categories E and F are not exempt if responses or observations are recorded in such a manner that the subjects can be identified and the information, if it 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, or the research deals with a sensitive aspect of a subject's behavior, such as illegal conduct, sexual behavior, or use of alcohol or controlled substances.

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 their judgment on the protocol form in Kuali. The departmental review is conducted by at least three faculty who are not involved in the research under consideration. If the review confirms the judgment that the proposal is of "minimal risk", the principal investigator may consider the professional obligations regarding human subjects to have been satisfied and the research can begin.

3.6.1 To obtain approval of unfunded minimal risk research, the principal investigator shall submit through the Kuali IRB electronic system the following information and materials for departmental IRB review:

A. The protocol title and research personnel information, including documentation of CITI human subjects research training certification;
B. A protocol detailing the procedures to be employed, potential risks to subjects, and precautions taken to deal with the risks and to protect the welfare and civil and human rights of research subjects (See detailed application procedures on the CPHS website);
C. The informed consent document (written in a way that is linguistically, culturally, educationally, and age appropriate to subjects, as well as in English) to be provided to the subjects, which describes in detail the procedures to be performed and potential risks, or a detailed explanation and justification of an oral informed consent process.
D. Recruitment materials;
E. Study instruments, such as surveys or interview guides; and
F. Letters of support from participating institutions.

The investigator must inform the subject of features of the research that might influence

their willingness to participate, including: a complete explanation of the procedures to be followed; description of possible discomforts and risks; an offer to answer any questions about procedures; instruction that the subject is free to withdraw their consent and to discontinue participation in the investigation at any time without prejudice or penalty; and a statement that the research procedures have been approved by the Committee for the Protection of Human Subjects at California State University, Fresno.

Before research commences, an informed consent form with the above information must be signed by the subject or, if the subject is a minor or otherwise not legally competent, by their 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 their parent or legal guardian has understood the explanation and that consent was obtained without deception or coercion. If the subject is "at risk" the informed consent signature must be witnessed.

3.7 "AT RISK" RESEARCH (UNFUNDED)

If the departmental IRB approves the research as “at risk,” the departmental IRB Chair should note departmental approval in Kuali and notify the University Committee for the Protection of Human Subjects (cphs@mail.fresnostate.edu) that the protocol and supporting documentation are ready for CPHS review.

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 may be particularly susceptible to 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 risk consequences;
G. Consulting with colleagues for minimization techniques.

3.8 FUNDED RESEARCH

All research proposals that are supported by external grants or contracts must be reviewed and approved by the University CPHS after departmental IRB review and approval in Kuali. If the subjects are deemed "at risk," the principal investigator must include in the protocol a discussion of all measures listed above.

4.0 COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS MEMBERSHIP, PROCEDURES, AND AUTHORITY

4.1 MEMBERSHIP

The CPHS functions as the Institutional Review Board (IRB) required by federal regulations. The Committee always is 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:

A. At least three faculty members from different colleges/schools nominated from a pool of interested faculty maintained by the Committee;
B. A community member with no employment relationship to California State University, Fresno;
C. A faith advisor from the community;
D. A health care provider from the community, such as a physician, nurse practitioner or physician's assistant;
E. A Fresno State graduate or undergraduate student representative.

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

A member of the University Health and Psychological Services and a risk manager with California State University, Fresno, are permanent voting members of the Committee.

One member of the Committee must be nominated specifically because they do not possess a scientific background (e.g., lawyer, activist, ethicist). No action of the CPHS can be official without the participation of this member.

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

4.2 PROCEDURES

Upon receipt of a complete protocol via the electronic Kuali IRB submission system, the CPHS Chair will assign the requisite number of reviewers to the protocol. The CPHS Chair will write a memo on the decision of the CPHS 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 with the

exception of January and August. 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.

All decisions require a majority vote of those present and the participation of the Committee member with a non-scientific background. 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. Minutes of meetings and correspondence are maintained by the CPHS Coordinator of the Office of the Dean of Undergraduate Studies for five years.

The Chair of the Committee may grant "expeditious approval" of submissions and is authorized by the Committee to transmit the Certification to the Department of Health and Human Services (HHS), unless the Committee has denied approval.

4.3 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:

A. Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and by using procedures already being performed on the subjects for diagnostic or therapeutic purposes;
B. Risks to subjects are reasonable in relation to anticipated benefits 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 persons with acute or severe physical or mental challenges or disabilities, or persons who are economically or educationally disadvantaged, appropriate safeguards have been included in the study to protect the rights and welfare of these subjects.

Approval of protocols will normally expire one year from the date of CPHS action.

4.4 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.

4.5 CONTINUING REVIEW – ANNUAL RENEWAL

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 renewal request via Kuali at least two weeks prior to the approval expiration.

4.6 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.

4.7 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.

4.8 INFORMATION DISSEMINATION AND REPORTING

The CPHS has the authority and the responsibility for promptly reporting the following information to the Dean of Research and Graduate Studies, the Provost and Vice President for Academic Affairs, the University Risk Manager, and, if any, external funding agencies.

A. Any noncompliance by research investigators with CPHS requirements;
B. Any injury to human subjects;
C. Any unanticipated risks to subjects or others;
D. Suspension or termination of CPHS approval, including reasons for the
E. Committee's actions;

4.9 EXPEDITED REVIEW

Research that involves no more than “minimal risk” will be afforded “expedited” review. The 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. Categories C, D, E,and F must be performed by qualified and/or licensed professionals.

A. Ongoing or previously approved research, in which no change is proposed from previous submission to the CPHS;
B. Collection of hair and nail clippings, in a non-disfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction;
C. Collection of excreta and external secretions including sweat, uncannulated saliva, and placenta removed at the time of rupture of the membrane prior to or during labor;
D. 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 to either 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 (for example, x-rays, microwaves);
E. 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;
F. 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;

G. Voice recording made for research purposes, such as investigations of speech defects;
H. Moderate exercise by healthy volunteers;
I. The study of existing data, documents, records, pathological specimens, or diagnostic specimens;
J. 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;
K. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

4.10 APPEAL PROCEDURES

If an investigator believes that their proposal has been disapproved as the result of incorrect, unfair, or improper evaluation by the CPHS, and they have rebutted the decision with the CPHS, then they 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). CPHS records 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).

4.11 CONSULTATION

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 CPHS members by consulting its website.

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.

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 when needed.

4.12 FEDERAL MANDATES

The CPHS complies with and commences implementation of federal guidelines. The CPHS considers the federal guidelines as superseding these policies and procedures whenever conflicts in interpretations arise.

Appendix: Review Sequence Flow Chart