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POLICY FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

SAN FRANCISCO STATE UNIVERSITY

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PREAMBLE

1.0

This document sets forth the policies and procedures for the protection of human subjects in research, development, and related activities conducted at or sponsored by San Francisco State University. It also serves to implement the specific requirements of the United States Department of Health and Human Services (HHS) formerly the Department of Health, Education and Welfare, (45 Code of Federal Regulations Part 46, as revised FR 40, 11854-58, March 13, 1975; FR 40, 33528-30, August 8, 1975; FR 43, 1758, January 11, 1978; and FR 46, 8366-8392, January 26, 1981, FR 48, 9269, March 4, 1983, and FR 48, 9818, March 8, 1983). This statement supersedes all previous university policy statements governing the protection of human subjects.

San Francisco State University presently has an all-university internal review board, the Committee for the Protection of Human Subjects (CPHS), which reports to the Director of Research and Professional Development. The committee meets once a month, or as needed, to review SFSU research proposals which involve human subjects. It has the power to approve, disapprove, or require changes in research proposals with the aim of the protection of human subjects. All university research proposals that involve human subjects and are administered by the San Francisco State University Foundation, Inc. are reviewed by the committee. Student research and unfunded faculty research are also governed by these university regulations.

The initial impetus for creation of the CPHS at SFSU was a set of U.S. DHEW (now HHS) regulations issued in May 1975 which explicitly required that a committee conforming with specified requirements as to its composition, procedures, and decision rules would review all university research involving human subjects as a precondition to receipt of any federal funding.

The University's assurance document was revised in 1983 and again in 1987 to reflect changes in HHS regulations. This general assurance satisfies the laws of the State of California covering human subject research.

Basic Principles

1.1

The CPHS policy gives paramount weight to the protection of human subjects on the basis of ethical considerations. The policy also reflects the legal requirements which apply to some research and serves to protect individual faculty and the university from potential liability.

The basic principles underlying the development of procedures for the review of research involving human subjects were as follows:

The procedures recognize the primary responsibility of the researcher in the review process, and provide the researcher with information on which to make informed and responsible decisions.

1.

To protect both the subject and the researcher, important decisions are to be made in consultation with a colleague familiar with both the type of research involved and with the principles guiding the protection of human subjects.

2.

Whenever it is possible that human subjects may be placed at more than minimal risk, the CPHS must become directly involved in the review and approval of the research.

3.

The procedures follow federal guidelines with two notable exceptions:

Federal guidelines require that CPHS review all non-exempt (i.e., HHS funded) research involving human subjects and make all decisions as to the possibility of more than minimal risk. For non-funded research, the decision as to whether there is a possibility of more than minimal risk is to be made by the researcher in consultation with a knowledgeable colleague.

1.

Federal guidelines exempt all survey and interview research in which the subject cannot be identified with the data whether or not the survey or interview involves sensitive aspects of the subject's own behavior; this position does not meet the ethical standards for the protection of human subjects or, for instance, the American Psychological Association. These standards recognize that the process of obtaining such data may be itself significantly stressful whether or not the subject can be identified. The CPHS procedures incorporate this stronger position.

2.

ETHICAL PRINCIPLES

2.0

San Francisco State University accepts as basic principles the following:

All research, training, development, and related projects will be conducted so as to avoid or to keep to the absolute minimum risk to subjects and investigators.

2.1

Risks to subject should be weighed in relation to the potential benefit to him or her or to the importance of the knowledge to be gained.

2.2

Adequate, appropriate, and legally effective informed consent must be obtained in all cases where human subjects are involved in non-exempt research, development, and related activities.

2.3

The rights and welfare of all subjects who are involved in research, development, and related activities shall be protected.

2.4

Any assurance concerning dissemination of research results that an investigator gives to a human subject is to be carried out.

2.5

No information concerning potential harm or risks to subjects may be withheld from a potential subject in order to increase the willingness of the subject to participate in the project.

2.6

Whenever possible or relevant, any hazard to health conceivably resulting from procedures utilizing human subjects must be first investigated through animal research.

2.7

Whenever medicines, surgical or other medical procedures, or exposures to hazardous environmental conditions are used or are likely to occur, the activity must be performed in conformity with the accepted standards of clinical medical practice.

2.8

If, in the course of activity, an investigator discovers unanticipated risks to a subject, the investigator must suspend the project until obtaining the advice of the Committee for the Protection of Human Subjects on how to deal with such risks.

2.9

If, in the course of a biomedical activity, the investigator discovers in a subject an unanticipated symptom or disorder requiring treatment that derives from factors unrelated to the activity, the investigator must inform the subject of the condition and advise the subject to seek medical assistance.

2.10

When subjects are being compensated for their participation, compensation shall not be of such magnitude that the participants' ability to weigh the risks of the research against advantages is impaired.

2.11

The subject's personal privacy must be respected, and the investigator must take steps to ensure the confidentiality of research data.

2.12

Research involving vulnerable populations -- the mentally or physically infirm, children, prisoners, parolees, addicts, and others in conditions of dependency, helplessness, or deprivation -- requires extra scrutiny and may call for additional precautions to assure protection of the rights of human subjects.

2.13

In addition to the principles listed above, the investigator must respect the ethical principles of the culture in which the research takes place.

2.14

Investigators in various disciplines should adhere to the ethical codes adopted by their professional associations.

2.15

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

3.0

The Committee for the Protection of Human Subjects (CPHS) is a standing administrative committee of the university. The CPHS is administratively responsible to the Director of Research and Professional Development who serves as the director of university research.

Membership and Appointment

3.1

The committee's membership shall include at least seven (7) persons. These persons shall have varying backgrounds including consideration of both race and culture, and shall include persons with knowledge of applicable law and of appropriate professional standards. Both sexes should be represented. At least one member will have non-scientific areas as a primary concern. One member of the committee must be a community representative and, as such, may not be an employee or related to an employee of the CSU. No member shall be involved in either the initial or continuing review of an activity in which the member has a conflicting interest, except to provide information to the committee. When considering certain types of activities, e.g., investigation of new drugs on prisoners, the Director of Research and Professional Development shall appoint additional members as required by HHS regulations. All changes in membership will be reported to HHS. Where the subject of research is a fetus, a pregnant woman, a prisoner, or involves human in vitro fertilization, the additional requirements of 45 CFR 46, subparts B and C will apply.

Representatives of the Office of the President, the San Francisco State University Foundation, Inc., and the executive secretary shall be ex-officio members without vote.

The Director of Research and Professional Development shall appoint committee members with the concurrence of the Executive Committee of the Academic Senate for three year terms. In the case of faculty appointments, the Director of Research and Professional Development will consult with the faculty member's department chair regarding his/her qualifications to serve on the Committee for the Protection of Human Subjects.

Committee Rules

3.2

The committee will elect a chair annually.

The CPHS meets at least once a month, or more often if necessary. If an emergency meeting is necessary in order that the CPHS's actions conform to any aspect of HHS policy, such a meeting will be called by the chair.

A quorum of the CPHS is defined as a majority of the total voting membership. In order for official committee business to be conducted, a quorum must be present. In order to review proposed research, the quorum must include at least one member whose principal concerns are in non-scientific areas. Research must be approved by a majority of those members present at the meeting.

DEFINITIONS (See 46.102, Federal Register, v. 46, no. 16, 1981)

4.0

Research and Related Activities

4.1

"Research" means a systematic investigation designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute "research" for purposes of these regulations, whether or not they are supported or funded under a program which is considered research for other purposes. For example, some "demonstration" and "service" programs may include research activities.

NOTE: Classroom instructional activities normally do not constitute research as defined above and are not covered by these regulations. An instructor having any questions as to whether any particular activities conducted as part of instruction might constitute research should consult with the department chair or a colleague designated by the chair.

Human Subject Involvement

4.2

"Human subject" means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. "Intervention" includes both physical procedures by which data 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 that no observation or recording is 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. Private information obtained from existing records must be individually identifiable in order for obtaining the information to constitute research involving human subjects. All research activities in which human subjects are involved are subject to the CPHS review process.

University Responsibility

4.3

The university is responsible for all research activities not otherwise exempt involving human subjects conducted at the university or using university funds or facilities, sponsored by the university as part of the university's program or activities, or engaged in by university investigators in the course of their employment. The university is not responsible for privately conducted research activities, not using university facilities, not part of the university program, and which are outside the scope of employment of the investigators. Faculty members engaging in such non-university sponsored activities must avoid suggesting by use of their university titles, or in any other way, that their activities are sponsored by the university.

Research activities conducted as an integral part of approved courses and seminars and which meet departmental standards for the protection of human subjects approved by the CPHS are exempt from further review.

Designated Colleague

4.4

Once the researcher has decided that human subjects are involved, the further decisions as to (1) whether the research falls within an exempt category, and (2) for non-funded research whether subjects will possibly be placed at more than minimal risk, must be made in consultation with either the department chair or a colleague designated by the chair. Chair or designated colleague share with the researcher in responsibility for these decisions.

Minimal Risk

4.5

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

Assessment of Risk

4.6

The review process is charged with determining the degree of physical, psychological, or social risk in each case. Physical, psychological, and social risks include the following:

4.6.1

Physical Risks: Physical risks are those present when a substance is injected or ingested into a subject's body or some other physical intervention is performed on the subject's body in any way unduly stressed. Exceptions are only given to categories defined in Appendix A:1 through 10. A physical risk may involve unusual physical activity or strong aversive stimulation. Engaging a subject in a social situation which could

a) involve violence may also create a physical risk.

Psychological Risks: Psychological risks are those present when there is the possibility that a subject will undergo a significant degree of psychological stress or discomfort directly or indirectly as a consequence of participating in an experiment or project.

b)

Social Risk: Social risk exists when there is the possibility that the research may cause the subject to suffer a loss of personal reputation or material possessions, be put in legal jeopardy, or suffer personal degradation in the eyes of other persons. Ordinarily, such risks can be minimized if the researcher safeguards the confidentiality of his/her files and conceals the identities of subjects in published findings.

c) some cases, additional safeguards may be necessary.

Exempt Categories (See 45 CFR 46.101)

4.7

Research activities in which the only involvement of human subjects is in total compliance with the following categories are exempt from application of the remainder of these regulations:

4.7.1 Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (1) research on regular and special education instructional strategies, or (2) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

4.7.2 Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

4.7.3 Research involving survey or interview procedures, except where one of the following conditions exist: (1) responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, and the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, or (2) the research deals with sensitive aspects of subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. All research involving survey or interview procedure is exempt, without exception, when the respondents are elected or appointed public officials or candidates for public office.

4.7.4 Research involving the observation (including observation by participants) of public behavior, except where the following conditions exist: (1) observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, (2) the observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or being damaging to the subject's financial standing or employability, and (3) the research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.

4.7.5 Research involving the collection or study of existing data, documents records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects.

4.7.6 Research for which review is not initially required, either due to lack of intent to involve human subjects or because it is a part of a larger funded proposal involving activities not fully specified at the time of submission must be presented to the CPHS for review and certification prior to the commencement of such activities. If the research involves a change in a grant submitted to HHS where the original proposal indicated no human subject involvement, approval by the CPHS and the HHS must be received prior to initiation of the research.

4.7.7 Research which is designed to examine or evaluate (i) federal, state, or local benefit or service programs which are not themselves research programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible services under those programs. If, following a review of proposed research activities as described in this section, it is determined that a danger is presented to the physical, mental, or emotional well-being of a research participant, then a written informed consent must be obtained from each participant.

Expedited Review (Funded Research) (See 45 CFR 46.110)

4.8

The CPHS may review some or all of the funded research appearing on the following list through an expedited review procedure, if the research involves no more than minimal risk. The CPHS may also use the expedited review procedure to review minor changes in previously approved research during the period for which approval is authorized. Under an expedited review procedure, the review may be carried out by the CPHS chairperson or by one or more experienced reviewers designated by the chairperson from among members of the CPHS. In reviewing the research, the reviewers may exercise all of the authorities of the CPHS except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in section 5.

All research reviewed and approved under the expedited process will be reported to the CPHS at the next regularly scheduled meeting, and will be included in the minutes of that meeting.

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 categories listed in Appendix A may be reviewed through the expedited review procedure.

Informed consent (See 45 CFR 46.116)

4.9

No investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative (exceptions stated in 4.9.4).

Consent may only be sought under circumstances which provide the prospective subject or representative sufficient opportunity to consider whether or not to participate, and which minimize the possibility of coercion or undue influence.

The presentation of the consent shall be in language understandable to the subject or representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative would appear to waive any of the subject's legal rights or which releases or appears to release SFSU or any of its agents from liability for negligence.

Basic elements of informed consent:

4.9.1

A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

a)

A description of any reasonably foreseeable risks or discomforts to the subject;

b)

A description of any benefits to the subject or to others which may reasonably be expected from the research;

c)

A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

d)

A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

e)

For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

f)

An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

g)

A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

h)

Additional guidelines can be obtained through Federal Register, v. 46, no. 16, 1981, section 46.116.

Except as provided in 4.9.4 of this section, informed consent shall be documented by the use of a written consent form approved by the CPHS and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing.

4.9.2

A "short form" written consent document stating that the elements of informed consent required have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the CPHS shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both a copy of the short form and the summary. A copy of the summary shall be given to the subject or representative, together with a copy of the short form. The person actually obtaining the consent shall sign a copy of the summary.

4.9.3

CPHS may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

4.9.4

The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

a)

That the research presents no more than minimal risk or harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

b)

In cases where the documentation requirement is waived, the CPHS may require the investigator to provide subjects with a written statement regarding the research.

SCOPE OF THE REVIEW

5.0

The CPHS review process applies to all biomedical and behavioral research involving human subjects (see sections 4.1 and 4.2) conducted at or sponsored by the university, in order to protect the rights of human subjects. No research activity involving human subjects may be initiated prior to review and approval by a researcher and designated colleague or the CPHS.

Faculty/Administration Research

5.1

Funded/Non-funded Research

5.1.1

Principal investigators and/or sponsoring faculty members are responsible for anticipating human subject involvement in research for which they are responsible. Protocols describing all research involving human subjects must be submitted to the Office of Research and Professional Development along with the Protocol Approval Forms and the Informed Consent Form.

Student Research Activities

5.2

5.2.1 Research activities conducted as part of the approved content of a regular course or seminar and that meet CPHS approved departmental criteria for such activities are exempt from further CPHS review. All student research that does not otherwise meet departmental criteria for exemption are subject to the regular CPHS review process.

5.2.2 Sponsoring faculty are responsible for informing student investigators of human subjects procedures and of the ethical codes adopted by their professional associations.

Non-SFSU Affiliated Research Activities

5.3

Non-SFSU affiliated researchers who wish to conduct research activities that involve human subjects at SFSU must adhere to the terms of this document. Protocols submitted to the SFSU CPHS must include documentation that human subjects' approval has been obtained at their institution.

CPHS Review Procedures

5.4

For all research activities involving human subjects, researchers are required to submit a research protocol and Protocol Approval Form to the Office of Research and Professional Development at the point at which the proposal is completed and before any involvement of human subjects begins. The protocols are subject to the following review procedure:

Determination/Sequence of Review Procedures

5.4.1

The review process involves four substantive (1 through 4) and two routing (R1 and R2) questions:

Do the activities involve research with human subjects? This question is normally considered during the initial screening process and is the responsibility of the researcher and/or sponsoring faculty member. Research not involving human subjects is not subject to further review. For all research involving human subjects, a research protocol (see 7.0) and Protocol Approval Form must be forwarded to the Office of

- 1) Research and Professional Development.

Does the research activity fall within an exempt category (see 4.7)? This determination is made by the researcher and/or sponsoring faculty member AND the designated colleague. If yes, facts supporting the decision must be included in the Protocol Approval Form. Exempt research is not subject to further CPHS review.

- 2)

R1 -- Is the research funded? Funded, non-exempt research is routed directly to CPHS via the Office of Research and Professional Development at this point, and questions 3) and 4) are considered by the CPHS.

Are the human subjects in non-exempt research likely to be placed at more than minimal risk? For funded research, this decision is made by the CPHS. All protocols involving funded research must be routed directly to the CPHS via the Office of Research and Professional Development, and the research may not begin until it receives CPHS approval. For nonfunded research, this question is considered by the researcher and/or sponsoring faculty member, and designated colleague. If it is their decision that subjects are NOT placed at more than minimal risk, facts supporting the decision must be included on the signed Protocol Approval Form and the research may proceed. Non-funded research that does not place human subjects at more than minimal risk is not subject to further CPHS review.

- 3)

R2 -- Is the research subject to expedited review? (See 4.8) This decision is made by the Office of Research and Professional Development. Funded research meeting the criteria for an expedited review is reviewed either by the chair of CPHS or an experienced member of the CPHS designated by the chair. The individual CPHS member may approve the research; research not approved by the expedited review process must be reviewed by the CPHS.

Does the research meet CPHS criteria for approval? (See 5.4.5) This decision must be made by CPHS in all cases. Research meeting CPHS criteria for approval may proceed; any protocol not approved is returned to the researcher and/or sponsoring faculty member for revision, and the research may not proceed until brought into compliance with CPHS criteria and approved by CPHS.

- 4)

Review of Research Protocols and Protocol Approval Forms by the Office of Research and Professional Development

5.4.2

The Office of Research and Professional Development will conduct a preliminary review of each protocol and related documents to determine whether the materials submitted are adequate to conduct the appropriate review. Inadequate protocols are returned to the researcher and/or sponsoring faculty member for revision.

Monitoring of Decisions by the Office of Research and Professional Development

5.4.3

The Office of Research and Professional Development will conduct periodic reviews of the decisions made by the researcher (and/or sponsoring faculty member, and, when appropriate, the designated colleague) concerning the exemption of the research or, for non-funded research, the possibility of more than minimal risk. When there is clear reason to question the decision(s) made, this question will be communicated both to the researcher and/or sponsoring faculty member, and to the CPHS for further action.

CPHS Review of Research

5.4.4

The CPHS shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by these regulations.

a)

The CPHS shall require that information given to subjects as part of informed consent is in accordance with 4.9. The CPHS may require that information, in addition to that specifically mentioned in 4.9, be given to the subjects when in the CPHS's judgement the information would meaningfully add to the protection of the rights and welfare of subjects.

b)

The CPHS shall require documentation of informed consent or may waive documentation in accordance with 4.9.4.

c)

The CPHS shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure CPHS approval of the research activity. If the CPHS decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

d)

The CPHS shall conduct continuing review of research covered by these regulations at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

e)

Criteria for CPHS Approval of Research

5.4.5

In order to approve research covered by these regulations the CPHS shall determine that all of the following requirements are satisfied:

a)

Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

1)

Risks to subjects are reasonable in reaction to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the CPHS should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the

2) research).

Selection of subjects is equitable. In making this assessment the CPHS should take into account the purposes of the research and the setting in which the research will be conducted.

3)

Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by 4.9.

4)

Informed consent will be appropriately documented, in accordance with and to the extent required by 4.9.

5)

Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

6)

Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

7)

Where 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 illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.

b)

Research involving children as subjects must conform to requirements providing additional protection, as detailed in HHS Code of Federal Regulations, 45 CFR 46, Subpart D.

c)

Review by the University

5.5

Research covered by these regulations that has been approved by the CPHS may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by the CPHS.

Research which is part of a proposal submitted for funding to HHS will be reviewed and appropriate certification will be forwarded to HHS within 60 days.

Continuing Review

5.6

Projects extending beyond a period of one year require annual review by the CPHS. If the research protocol remains unchanged, investigators are required to provide the CPHS a copy of the protocol which they are currently following and to assure the CPHS, in writing, that the actual use of human subjects has been conducted in accordance with the approved protocol and conditions, if any, imposed by the CPHS, and that no changes are intended. If changes are planned, investigators are required to specify them in a revised protocol. Continuing review may also involve the establishment of ad hoc committees to conduct project site visits. In rare, although conceivable, instances it may involve the appointment of an independent ad hoc committee which would have the sole function of protecting the subjects' interests.

Unanticipated Problems or Non-Compliance

5.7

Any unanticipated problems involving risk to subjects or others must be reported immediately to the CPHS by the researcher.

Any serious or continuing non-compliance by research investigators will be reported to the Director of Research and Professional Development, as will any information concerning possible injuries to subjects or unanticipated problems involving risks to subjects. It is the responsibility of the Director to forward to OPRR-HHS appropriate reports on such matters.

Suspension or Termination of the CPHS Approval of Research

5.8

The CPHS shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the CPHS's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the action and shall be reported promptly to the investigator, appropriate officials, the funding agency, and to OPRR-HHS.

Research Involving New or Experimental Drugs

5.9

Any project involving new or experimental drugs shall be subject to the 30-day delay requirements contained in Federal Regulations 45 CFR 46, Section 46.121 or appropriate successor regulations.

CPHS Records

5.10

CPHS records shall include:

5.10.1

Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

a)

Minutes of CPHS meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the CPHS, the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

b)

Records of continuing review activities.

c)

Copies of all correspondence between the CPHS and the investigators.

d)

A list of CPHS members as required by the Code of Federal Regulations 45 CFR 46, Section 46.103 (b)(3).

e)

- f) Written procedures which the CPHS will follow (1) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (2) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous CPHS review; (3) for ensuring prompt reporting to the CPHS of proposed changes in a research activity, and for ensuring that changes in approved research, during the period for which CPHS approval has already been given, may not be initiated without CPHS review and approval except where necessary to eliminate apparent immediate hazards to the subject; and (4) for ensuring prompt reporting to the CPHS and to the university and for funded research, the OPRR, or unanticipated problems involving risks to subjects or others.

Statements of significant new findings provided to subjects which may relate to the subject's willingness to continue participation in the research.

g)

The records required by this regulation shall be retained for at least three years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the HHS at reasonable times and in a reasonable manner.

5.10.2

DOCUMENTATION OF INFORMED CONSENT

6.0

Any investigator must obtain and document a legal and effective informed consent. No such informed consent, oral or written, shall include any exculpatory language through which the subject waives or appears to waive any legal rights, including any release or appearance of release of the institution or its agents from liability or negligence.

The investigator must provide a written consent document embodying all of the basic elements of informed consent (see section 4.9). This may be read to the subject or to the subject's legally authorized representative, but in any event, the subject or the subject's legally authorized representative must be given adequate opportunity to read it. This document must be signed by the subject or the subject's legally authorized representative. A copy of the consent form as approved by the CPHS will be retained in its records.

The consent form should be written in lay language understandable to the subject and using the first person, and should include all of the basic elements listed in section 4.9.1.

Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

a)

A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

1)

Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

2)

Any additional costs to the subject that may result from participation in the research;

3)

The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

4)

A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

5)

The approximate number of subjects involved in the study.

6)

The CPHS may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the CPHS finds and documents that:

b)

The research is to be conducted for the purpose of demonstrating or evaluating (i) federal, state, or local benefit of service programs which are not themselves research programs, (ii) procedures for obtaining benefits or services under these programs, or (iii) possible changes in or alternatives to these programs or procedures; (iv) possible changes in methods or levels of payment for benefits or services under

1) those programs; and

The research could not practicably be carried out without the waiver or alteration.

2)

The CPHS may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent provided the CPHS finds and documents that:

c)

The research involves no more than minimal risk to the subjects;

1)

The waiver or alteration will not adversely affect the rights and welfare of the subjects;

2)

The research could not practicably be carried out without the waiver or alteration; and

3)

Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

4)

PROTOCOLS

7.0

A protocol is a statement which must be prepared by the investigator for all research, development, or related activities in which human subjects are involved or in which there is a question of involvement. It should provide the Committee for the Protection of Human Subjects with an understanding of the nature and purpose of the proposal activity, and should permit the committee to make a properly informed judgement in those areas required by the federal guidelines for the protection of human subjects.

Specifically, the protocol should enable the Committee for the Protection of Human Subjects to determine:

The nature of the project, its significance, and relationship to on-going work in the field.

1)

The rationale for human subject involvement.

2)

The explicit details of what will happen to the subjects, and what the subjects will do.

3)

- The manner in which subjects will be selected and whether any of the subjects are likely to be subject to coercion or undue influence, such as San Francisco State University students, persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged; and if so, that appropriate additional safeguards have been included to protect the rights and welfare of these subjects.
- 4)

- That procedures to ensure an equitable selection of human subjects and to provide appropriate informed consent are included.
- 5)

- That the risks to subjects are reasonable in relation to anticipated benefits, if any, to the subjects and the importance of the knowledge that may reasonably be expected to result.
- 6)

- The provisions are adequate to ensure privacy of subjects and confidentiality of data.
- 7)

- That research design and methodology are consistent with current sound research practice.
- 8)

Research activities for which Expedited Review Procedures May Be Used:

Appendix
A:

- Collection of hair and nail clippings, in a nondisfiguring manner, deciduous teeth, and permanent teeth if patient care indicates a need for extraction.
- 1)

Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

2)

Recording of data from subjects 18 years of age or older using non-invasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, xrays, microwaves).

3)

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.

4)

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.

5)

Voice recordings made for research purposes such as investigations of speech defects.

6)

Moderate exercise by healthy volunteers.

7)

The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

8)

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.

9)

Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

10)
