INSTITUTIONAL REVIEW BOARD (IRB)

CALIFORNIA STATE UNIVERSITY, SAN BERNARDINO

Policies and Procedures for Review of Research Involving Human Participants

Introduction:

In compliance with federal regulations, California State University, San Bernardino (CSUSB) has established an Institutional Review Board (IRB) to oversee its obligations with respect to human subjects research. When people are involved as subjects in research or related activities conducted under university auspices, both the institution and individual researchers are responsible for assuring that the rights and welfare of subjects are adequately protected. Such activities include any mode of research conducted either on or off campus. These principles have been accepted and established by the University in accordance with federal regulations 45 CFR 46 and professional ethical codes of conduct. The CSUSB IRB filed for a Federalwide Assurance with the Office of Human Research Protections (OHRP) as CSUSB received federal funding. Our Federawide Assurance number is FWA# 00004865.

All projects involving human participants must be reviewed by the IRB **before** initiation. This applies to both faculty and student research.

Categories of Review:

Administrative (Exempt) Review: Federal regulations provide that certain kinds of research (e.g., some surveys, field interviews, observations, evaluations of standard educational practices or tests) involving no more than minimal risk to subjects can be exempt from full IRB review and record keeping. Categories of exempt review are located later in this document. Final determination of exempt status is the responsibility of the IRB Chair, IRB Vice-Chair, and Research Compliance Officer.

Expedited Review: Federal regulations also provide that certain kinds of research may receive expedited review.

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

IRB Submission Procedure:

The CSUSB IRB has moved from a hard copy IRB application submission process to an IRB online submission system called Cayuse IRB. The Cayuse IRB software provides a web-based user platform that simplifies management of your entire human subjects research portfolio with best-practice workflows that improve productivity, mitigate risk and ensure compliance. A modern, user-friendly interface guides users through the complexities of protocol completion, submission, approval and closure. Automated routing with data transparency reduces IRB review and approval times, and easy, cloud-based access is secured with ISO 27001 certified information security and data privacy.

Source: https://evisions.com/products/research-administration/cayuse-irb/

Cayuse IRB Online Submission System:

For a research proposal to receive full board or expedited review by the IRB, the investigators must login and fill out the online Cayuse IRB submission website at noted on the CSUSB IRB application submission website at

Website:
https://www.csusb.edu/institutional-review-board/irb-application-forms-and-submission-system

Responsibilities of Investigators:

The investigator is responsible for:

a) Obtaining IRB review and approval of any research involving human participants covered under the regulations, or registering their research with the IRE if it falls into one of the exempt categories;

b) Obtaining the legally effective informed consent of all subjects to be included in the research study, unless any or all requirements for obtaining consent have been waived by the IRE during its review;

c) Performance of the protocol as approved by the IRB; and

d) Adherence to ethical principles and professional codes of conduct in research

Basic Principles for Research with Human Subjects:

a) Participation of human participants in any research project or other regulated activity (e.g, experimental demonstration, training program, interview, or questionnaire) must be voluntary.

b) Any risks to subjects must be outweighed by the sum of the benefits to subjects plus the knowledge gained by the study.

c) Informed consent to participate in a project must be obtained upon satisfactory presentation of information to potential subjects about the purposes, procedures, risks, and benefits of participation.

d) The privacy of subjects must be safeguarded by protecting **confidentiality** of information from or about subjects and/or by maintaining their **anonymity.**

The Belmont Report Basic Ethical Principles for Research with Human Subjects:

The expression "basic ethical principles" refers to those general judgments that serve as a basic justification for the many particular ethical prescriptions and evaluations of human actions. Three basic principles, among those generally accepted in our cultural tradition, are particularly relevant to the ethics of research involving human subjects: the principles of respect of persons, beneficence and justice.

1) Respect for Persons. -- Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.

2) Beneficence. -- Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms.

3) Justice. -- Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally. However, this statement requires explication. Who is equal and who is unequal? What considerations justify departure from equal distribution? Almost all commentators allow that distinctions based on experience, age, deprivation, competence, merit and position do sometimes constitute criteria justifying differential treatment for certain purposes. It is necessary, then, to explain in what respects people should be treated equally. There are several widely accepted formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are (1) to each person an equal share, (2) to each person according to individual need, (3) to each person according to individual effort, (4) to each person according to societal contribution, and (5) to each person according to merit.

The full definitions as described by The Belmont Report can be found at website below.

Source:
https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html#xbound

The Office of Human Research Protections Regulations (45 CFR 46)

§46.102 Definitions:

a) *Department or agency head* means the head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated.

b) *Institution* means any public or private entity or agency (including federal, state, and other agencies).

c) *Legally authorized representative* means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

d) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

e) *Research subject to regulation*, and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).

f) *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 (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

g) *IRB* means an institutional review board established in accord with and for the purposes expressed in this policy.

h) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

i) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

j) *Certification* means the official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

Source: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/regulatory-text/index.html#46.102

§46.107 IRB Membership:

a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

b) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

c) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

d) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

e) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

Source: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/regulatory-text/index.html#46.107

§46.109 IRB Review of Research:

a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.

b) An IRB shall require that information given to subjects as part of informed consent is in accordance with §46.116. The IRB may require that information, in addition to that specifically mentioned in §46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

c) An IRB shall require documentation of informed consent or may waive documentation in accordance with §46.117.

d) An IRB 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 IRB approval of the research activity. If the IRB 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.

e) An IRB shall conduct continuing review of research covered by this policy 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.

Source: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/regulatory-text/index.html#46.109

Categories of Exempt Research:

Research activities involving human subjects that are exempt from IRB review are identified in 45CFR 46.101(b) (1)-(6). (Institutions and IRBs may not create new categories of exempt research under 45 CFR Part 46.) Institutions should have a clear policy in place on who shall determine what research is exempt under .46.101(b). Those persons who have authority to make a determination of what research is exempt are expected to be well-acquainted with interpretation of the regulations and the exemptions. In addition, the institution should be prepared to reinforce and review, as necessary, the method of determining what is exempt. OPRR (OHRP) advises that investigators should not have the authority to make an independent determination that research involving human subjects is exempt and should be cautioned to check with the IRB or other designated authorities concerning the status of proposed research or changes in ongoing research.

Institutions may elect to review all research under the auspices of the institution even if the research qualifies for exemption under 45.46.101(b). It is incumbent on the institution to advise investigators and others involved in the conduct and administration of research involving human subjects of the institutional policies for reviewing exempt research.

The CSUSB IRB has formerly adopted a policy derived from OHRP guidance of IRB responsibility in determining a project and/or study as exempt. OHRP guidance recommends that because of the potential for conflict of interest, investigators not be given the authority to make an independent determination that human subjects research is exempt. Institutions should implement exemption policies that most effectively address the local setting and programs of research. OHRP recognizes that this may result in a variety of configurations of exemption authority, any of which are acceptable assuming compliance with applicable regulations.

Source: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/exempt-research-determination/

§46.111 Criteria for IRB Approval of Research:

a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

   1) 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.

   2) Risks to subjects are reasonable in relation 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 IRB 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 research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

   3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

   4) 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 §46.116.

   5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

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

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

b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

§46.112 Review by Institution:

Research covered by this policy that has been approved by an IRB 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 an IRB.

Source: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/regulatory-text/index.html#46.112

§46.113 Suspension or Termination of IRB Approval of Research:

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB'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 IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

Source: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/regulatory-text/index.html#46.113

§46.116 Informed Consent:

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

    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;

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

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

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

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

    6) 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;
    7) 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; and

    8) 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.

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

1) 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;

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

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

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

5) 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

6) The approximate number of subjects involved in the study.

c) An IRB 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 IRB finds and documents that:

1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

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

d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

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

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

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

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

e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

Source: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/regulatory-text/index.html#46.116

§46.101 Exempt Review Categories:

a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States.

1) Research that is conducted or supported by a federal department or agency, whether or not it is regulated as defined in §46.102, must comply with all sections of this policy.

2) Research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in §46.102(e) must be reviewed and approved, in compliance with §46.101, §46.102, and §46.107 through §46.117 of this policy, by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.

b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

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

2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(ii) (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

   (i) the human subjects are elected or appointed public officials or candidates for public office; or

   (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

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

5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

   i) public benefit or service programs;

   ii) procedures for obtaining benefits or services under those programs;

   iii) possible changes in or alternatives to those programs or procedures; or \

   iv) possible changes in methods or levels of payment for benefits or services under those programs.

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

c) Department or agency heads retain final judgment as to whether a particular activity is covered by this policy.

d) Department or agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the department or agency but not otherwise covered by this policy, comply with some or all of the requirements of this policy.

e) Compliance with this policy requires compliance with pertinent federal laws or regulations which provide additional protections for human subjects.

f) This policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.

g) This policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.

h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the FEDERAL REGISTER or will be otherwise published as provided in department or agency procedures.

i) Unless otherwise required by law, department or agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes or research activities otherwise covered by this policy. Except when otherwise required by statute or Executive Order, the department or agency head shall forward advance notices of these actions to the Office for Human Research Protections, Department of Health and Human Services (HHS), or any successor office, and shall also publish them in the FEDERAL REGISTER or in such other manner as provided in department or agency procedures.1

1 Institutions with HHS-approved assurances on file will abide by provisions of Title 45 CFR part 46 subparts A-D. Some of the other departments and agencies have incorporated all provisions of Title 45 CFR part 46 into their policies and procedures as well. However, the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, subpart C. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

Examples of Exempt Review:

Exempt Category 1: Educational Setting

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as

- research on regular and special education instructional strategies, or
- research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods

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Exempt Category 2: Public behavior or anonymous questionnaires

Research involving the use of:

- educational tests (cognitive, diagnostic, aptitude, achievement)
- survey procedures
- interview procedures, or
- observation of public behavior may be exempt

unless the information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; **and** any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Exempt Category 3: Public Officials

Research involving the use of:

- Educational tests (cognitive, diagnostic, aptitude, achievement)
- Survey procedures
- Interview procedures, or
- Observation of public behavior

Research under this category applies when research activities involve the following:

1. The human subjects are elected or appointed public officials or candidates for public office; or
2. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

NOTE: This exemption does not apply to research with children except for research involving observation of public behavior where the investigator(s) do not participate in the activities being observed.

NOTE: This exemption does not apply if it involves human subjects who are elected or appointed public officials or candidates for public office or, Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Exempt Category 4: Existing Data: Records Review, Pathological Specimens

- Research involving the collection or study of **existing** data, documents, records, pathological specimens, or diagnostic specimens may be exempt if they are being:
    - being obtained from publicly available sources **or**
    - if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

NOTE: To qualify for Exemption 4, data, documents, records or specimens must already exist at the time research is proposed.

Exempt Category 5: Public Service Programs

Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

- public benefit or service programs
- procedures for obtaining benefits or services under those programs
- possible changes in or alternatives to those programs or procedures; **or**

- possible changes in methods or levels of payment for benefits or services under those programs.

NOTE: To qualify for Exemption 5 for Public Benefit Projects, which is for projects conducted by or subject to approval of federal agencies, the following criteria must be satisfied:

- The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive or nutrition services as provided under the Older Americans Act)
- The research or demonstration project must be conducted pursuant to specific federal statutory authority o There must be no statutory requirement that the project be reviewed by an IRB
- The project must not involve significant physical invasions or intrusions upon the privacy of participants
- Authorization or concurrence by funding agency

Exempt Category 6: Taste Tests

Taste and food quality evaluation and consumer acceptance studies if:

- Wholesome foods without additives are consumed; **or**
- If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

NOTE 1: This category may be applied to research involving children; however, written parental consent to include children in taste testing studies will be required.

NOTE 2: While not explicitly prohibited in the regulations, inclusion of children in Food Quality and Consumer Acceptance Studies may pose greater than minimal risk to participants and may require IRB review.

CATEGORIES OF EXPEDITED REVIEW

Applicability:

A. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

B. The categories in this list apply regardless of the age of subjects, except as noted.

C. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects= financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

D. The expedited review procedure may not be used for classified research involving human subjects.

E. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

F. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories:

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

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

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

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

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

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

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

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

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

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

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:
    a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains

active only for long-term follow-up of subjects; or

b. where no subjects have been enrolled and no additional risks have been identified; or
c. where the remaining research activities are limited to data analysis.

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

[1] An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

[2] Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a).
Source: 63 FR 60364-60367, November 9, 1998.