Human Research Protection Program (HRPP)
Policy Procedures, and Practices:
Human Subjects Institutional Review Board (HSIRB)
April 2022

Background

California State University, Bakersfield ("CSUB") fosters and supports a research environment that ensures the respect of the rights and welfare of individuals participating in research conducted by CSUB faculty, staff, and students. CSUB has established a human research protection program (HRPP) overseen by the CSUB Human Subjects Institutional Review Board (HSIRB). The mission of the HRPP is to: 1) Safeguard and promote the health and welfare of human research participants by ensuring that their rights, safety, and well-being are protected, 2) Provide guidance and support to research investigators in the conduct of research with human subjects, 3) Assist investigators in ensuring compliance with appropriate and relevant regulations as provided by the Federal Code of Regulations and CSUB policy, 4) Provide timely and quality human subjects training, review, and oversight of human research projects, and 5) Facilitate excellence in human subjects research.

Human Research Protection Plan (HRPP)

The authority under which the CSUB HSIRB is established and empowered to act is based upon the following:

- The Belmont Report: Ethical Principles and Guidelines for Research InvolvingHuman Subjects. Report of the National Commission for the Protection ofHuman Subjects of Biomedical and Behavioral Research, April 18,1979. https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html

- The Code of Federal Regulations, Title 45, Public Welfare, Part 46, Protection of Human Subjects (45 CRF 46), Office for Human Research Protections, National Institutes of Health (NIH), Department of Health and Human Services(DHHS), Revised January 19, 2017, and Amended January 22, 2018 and June 19, 2018 with General Compliance date January 21, 2019.

The primary purpose of the CSUB HSIRB is to ensure the protection of the rights and welfare of human subjects for research. In accord with The BelmontReport, the general rule [regarding whether or not an activity requires review] is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects (Belmont Report, Part A: Boundaries Between Practice and Research).

This protection of the rights and welfare of human subjects for research isfounded on three (3) basic ethical principles, as specified in The Belmont Report:

1. **Respect for persons.** This principle incorporates two ethical convictions: (a)

individuals should be treated as autonomous agents; and (b) persons with diminished autonomy are entitled to protection. The application of this principle requires the following:

- Informed Consent- Subjects, to the degree that they are capable, shall be given the opportunity to choose what shall or shall not happen to them (Belmont Report, Part C: Applications, 1.Informed Consent). The consent process shall contain three (3) elements:

    - Information- The extent and nature of information includes, as a minimum, the research procedure, theirpurposes, risks and anticipated benefits, alternative procedures(where "therapy" is involved), and a statement offering thesubject the opportunity to ask questions and to withdraw at anytime from the research .

    - Comprehension- The manner and context in which information is conveyed is as important as the information itself. The researcher has the obligation to adapt the presentation of information to the subject's capacities and to ascertain that the subject has comprehended the information.

    - Voluntariness- This element requires conditions free of coercion and undue influence. Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. Undue influence occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. (Belmont Report, Part C: Applications, 1.Informed Consent).

2. Beneficence. This principle obligates the researcher to make every effort to secure the well-being of the human subject. Two maxims apply that represent beneficent actions: (a) do no harm, and (b) maximize possible benefits and minimize possible harms. The application of this principle involves a thorough assessment of risks and benefits by all parties to the research endeavor—the investigator, the review committee, and the subject. The term "risk" refers to a possibility that harm may occur, and it usually refers both to the chance (probability)of experiencing a harm and the severity (magnitude) of the envisioned harm. The term "benefit" ... refers to something of positive value related to health or welfare [and] is not a term that expresses probabilities. (Belmont Report, Part C: Applications, 1.Informed Consent, 2. The Assessment of Risks and Benefits).

3. Justice. This principle obligates the researcher to ensure that there are fair procedures and outcomes in the selection of research subjects. This principle applies to the selection of subjects at two levels: the individual and the social. Individual justice in the selection of subjects would require that researchers exhibit fairness: thus, they should not offer potentially beneficial research only to some [persons] who are in their favor or select only "undesirable" persons for risky research. Social justice requires that distinction be drawn between classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens and on the

appropriateness of placing further burdens on already burdened persons. Specifically, the selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied (Belmont Report, Part C: Applications, 1.Informed Consent. 3. Selection of Participants).

In accord with 45 CFR 46, the authority of the CSUB HSIRB shall be:

- to define what it will review, including research conducted by CSUB personnel at other institutions or research conducted at CSUB by researchers not affiliated with the university.

- To approve, require modifications (to secure approval), or disapprove protocols based upon human subjects protection including exempt research activities under §46.104 for which limited IRB review is a condition of exemption (under §46.104(d)(2)(iii), (d)(3)(i)(C), (d)(7), and (d)(8)).

- To suspend or terminate a study.

- To require progress reports from investigators and oversee the conduct of the research study.

The relationship of the CSUB HSIRB to other units/agencies is as follows: The CSUB HSIRB reports directly to the Provost and Vice President for Academic Affairs and represents the university on all matters associated with the protection of human subjects for research. The CSUB HSIRB is expected to work cooperatively and constructively, while carrying out its authority regarding the protection of human subjects for research, with the following persons: Research Investigator(s); Thesis chairperson or sponsoring faculty in the case of studentprojects; Department Chair and/or Center /Institute Director; and School/Unit Dean. When required, the CSUB HSIRB will consult, and work directly, with its counterparts at other institutions. The CSUB HSIRB will be responsible for all compliance mattersassociated with the protection of human subjects for research that are specified by Federal and State regulatory agencies. Therefore, after consultation with the Provost and Vice President for Academic Affairs,the CSUB HSIRB is authorized to work directly with the appropriate Federal and/or State regulatory agency.

Membership of the CSUB HSIRB

Membership shall comply with the requirementsspecified in 45 CRF 46. 45 CRF 46 requires a minimum number of five (5) members to the IRB/HSR. The CSUB IRB/HSR shall have at least five (5) members. Membership shall represent a diversity: Gender, Ethnic/Cultural Background, at least one (1) member whose primary concerns are in scientific areas, at least one (1) member whose primary concerns are in nonscientificareas, and at least one (1)

member who is not otherwise affiliated with CSUB andis not part of the immediate family of a person affiliated with CSUB. Qualifications for membership shall include: professional competence necessary to review specific researchactivities., knowledge of standards of professional conduct and practice andreputation for professional compliance, knowledge of institutional commitments and regulations, knowledge of applicable law, and sensitivity to community attitudes.

Management of the CSUB HSIRB

The Chairperson & Vice Chairperson: In consultation with the Assistant Vice President for Grants, Research, and Sponsored Programs, and the Provost and Vice President for Academic Affairs, the HSIRB shall select and appoint the Chairperson and Vice Chairperson of the CSUB HSIRB. The nominal length of service shall be three (3) academic years. By mutual agreement, the Chairperson and Vice Chairperson may be appointed to additional three-year terms. The Chairperson and Vice Chairperson may be removed from office by the Provost and Vice President for Academic Affairs, after consultation with the Assistant Vice President for Grants, Research, and Sponsored Programs, if there are significant and/or repeated "failures" to complywith the policies and procedures outlined in this document by the HSIRB.

The Committee Members

The sitting HSIRB members may select and nominate new members to the board. In consultation with the Assistant Vice President for Grants, Research, and Sponsored Programs, and the Provost and Vice President for Academic Affairs, the HSIRB shall appoint all the committee members of the CSUB HSIRB, in accord with the diversity principles specified above. The nominal length of service shall be three (3) academic years. By mutual agreement, committee members may be appointed to additional three-year terms. Appointments for the first year, the length of service shall be one (1) year. By mutual agreement, a committee member completing a one-year term may be appointed to a full three-year term. All members are expected to attend all meetings convened by the Chairperson. Repeated failure to attend meetings shall be grounds forremoval from the committee. All members are expected to complete the appropriate CITI research ethics training. Any committee member may be removed from HSIRB service by the Provost and Vice President for Academic Affairs, after consultation with the Committee Chair, and the Assistant Vice President for Grants, Research, and Sponsored Programs, if there are significant and/or repeated "failures" to comply with the policies and procedures outlined in this document by the HSIRB.

Orientation and Continuing Education of Committee Members

1. All new members of the CSUB HSIRB shall go through an orientation program regarding the authority, purpose, principles, policies, and procedures of the committee.

2. CSUB shall send HSIRB staff and least one committee member to attend research compliance industry conferences hosted by PRIM&R, the Office for Human Research Protection (OHRP), National Institute of Health (NIH), National Science Foundation (NSF) and/or the Food and Drug Administration (FDA).

3. IRB staff and members of the CSUB HSIRB shall keep their research ethics and human subjects protection training current and up to date.

4. The Assistant Vice President for Grants, Research, and Sponsored Programs shall be responsible for coordinating the terms of training and any travel associated with continuing education for IRB staff and members of the CSUB HSIRB.

The Operations of the CSUB HSIRB

Scheduling of Meetings: Meetings dealing with the review process will be scheduled as deemed necessary bythe Research Ethics Review Coordinator, chairperson, or vice chairperson of the CSUB IRB/HSR, the Assistant Vice President for Grants, Research, and Sponsored Programs, and/or the Provost and Vice President for Academic Affairs. The Office of Grants, Research, and Sponsored Programs, will be responsible for distributing all information and materials in a timely manner before all scheduled meetings. This will include, but not be limited to, the following: (1) date, time, and place of the meeting, (2) meeting agenda, and (3) materials to be reviewed for the meeting.

IRB Membership (45 CFR 46.107)

a) Each HSIRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The HSIRB 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 HSIRB 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 HSIRB shall therefore include persons knowledgeable in these areas. If an HSIRB 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 HSIRB 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 HSIRB 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 HSIRB may have a member participate in the HSIRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested

by the HSIRB.

(e) An HSIRB 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 HSIRB. These individuals may not vote with the HSIRB.

Use of Consultants

In accord with 45 CRF 46, the CSUB HSIRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the committee. Such consultants may not vote with the IRB/HSR.

Support of the HSIRB

The Assistant Vice President for Grants, Research, and Sponsored Programs shall be responsible for identifying, justifying the need for, and providing/acquiring needed resources to support the functions of the CSUB HSIRB. These resources include, but are not limited to, secretarial administrative support, computer access, reproduction/ duplicating, filing space, and meeting area.

Conflict of Interest

No member of the CSUB HSIRB may participate in the initial or continuing review of any project in which the member has a conflicting interest, e.g., the member is the principal investigator, the project director or co-director, is the faculty sponsor, is a consultant or subcontractor.

The Functions of the CSUB HSIRB

1. Conduct initial and continuing review of research involving human subjects.

In accord with 45 CRF 46, the following definitions apply:

- Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

- Human subject means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

- Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

- 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 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.

2. Report findings and actions to the investigator and institution. In accord with 45 CRF 46, the CSUB HSIRB 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 HSIRB approval of the research activity. If the HSIRB 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.

3. Determine which projects require review more often than annually. In accord with 45 CRF 46, the CSUB HSIRB 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.

4. Determine which projects need verification from sources other than the investigators that no material changes have occurred since previous CSUB HSIRB review.

5. Insure prompt reporting to the CSUB HSIRB of proposed changes in research activities.

6. Ensure that changes in approved research are not initiated without CSUB HSIRB review and approval, except when necessary to eliminate apparent immediate hazards to the subject.

7. Ensure prompt reporting to the CSUB HSIRB, appropriate CSUB officials, and Department or Agency heads of unanticipated problems or scientific misconduct involving risks to subjects or others.

8. Ensure prompt reporting to appropriate CSUB officials and Department or Agency heads of any serious or continuing noncompliance with the requirements specified by the CSUB IRB/HSR or any suspension or termination of approval by the CSUB HSIRB.

The HSIRB Review Process (45 CRF 46.109)

CSUB HSIRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy, including exempt research activities under § 46.104 for which limited IRB review is a condition of exemption (under § 46.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7), and (8)).

CSUB HSIRB shall require that information given to subjects (or legally authorized representatives, when appropriate) as part of informed consent is in accordance with § 46.116. The HSIRB 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.

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

The CSUB HSIRB 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 HSIRB approval of the research activity. If the HSIRB 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.

The CSUB HSIRB shall conduct continuing review of research requiring review by the convened HSIRB at intervals appropriate to the degree of risk, not less than once per year, except as described in § 46.109(f). Unless the CSUB HSIRB determines otherwise, continuing review of research is not required in the following circumstances:

(i) Research eligible for expedited review in accordance with § 46.110;

(ii) Research reviewed by the HSIRB in accordance with the limited HSIRB review described in § 46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8);

(iii) Research that has progressed to the point that it involves only one or both of the following, which are part of the HSIRB-approved study:

(A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or

(B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

The CSUB HSIRB shall have authority to observe or have a third party observe the consent process and the research.

Exempt research (45 CFR 46.104)

(a) Unless otherwise required by law or by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the categories in paragraph (d) of this section are exempt from the requirements of this policy, except that such activities must comply with the requirements of this section and as specified in each category.
(b) *Use of the exemption categories for research subject to the requirements of subparts B, C, and D.* Application of the exemption categories to research subject to the requirements of 45

CFR part 46, subparts B, C, and D, is as follows:
(1) *Subpart B*. Each of the exemptions at this section may be applied to research subject to subpart B if the conditions of the exemption are met.
(2) *Subpart C*. The exemptions at this section do not apply to research subject to subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners.
(3) *Subpart D*. The exemptions at paragraphs (d)(1), (4), (5), (6), (7), and (8) of this section may be applied to research subject to subpart D if the conditions of the exemption are met. Paragraphs (d)(2)(i) and (ii) of this section only may apply to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph (d)(2)(iii) of this section may not be applied to research subject to subpart D.
(c) [Reserved.]
(d) Except as described in paragraph (a) of this section, the following categories of human subjects research are exempt from this policy:
(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

1. (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
   (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
   (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(3) (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the

subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

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

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

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

1. (i) The identifiable private information or identifiable biospecimens are publicly available;
   (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
   (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
   (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

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

authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

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

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

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

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

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

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

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

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

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

Expedited Review Procedure (45 CRF 46.110)

Certain research activities which involve no more than minimal risk to human subjects may be approved by the CSUB HSIRB using expedited review procedures.

- Expedited Review: Categories of Research that may be Reviewed Through an Expedited Review Procedure (1998)
- Some or all of the research appearing on the list described in the link above, unless the reviewer determines that the study involves more than minimal risk;
- Minor changes in previously approved research protocols during a period of one year or less may also receive continued approval from the CSUB HSIRB using expedited review procedures.

- Research for which limited HSIRB review is a condition of exemption under §46.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7) and (d)(8).
- Protocol has already gone through another IRB review (e.g., at a hospital, othercampus, etc.).

The expedited review may be carried out by the Research Ethics Review Coordinator, Research Ethics Reviewer (RERC), Chairperson, or Vice Chairperson of the CSUB HSIRB and/or by one or more experienced members of the CSUB HSIRB designated by the Research Ethics Review Coordinator, Chairperson, or Vice Chairperson. The reviewer(s) may exercise the full authority ofthe CSUB HSIRB except disapproval. No research protocol may be disapproved using the expedited review procedures. A research protocol which is judged as "questionable" under expedited review shall be referred for standard review.

Full Convened Board "Full Board" Protocol Review Procedure

Each member of the CSUB HSIRB shall have access to all research protocolsand be apprised of all ongoing reviews. All board members will review the protocols and provide feedback and comments. For each research protocol, one member will be assigned as the "Primary Reviewer" and one member as the "Secondary Reviewer". These members shall report to the CSUB HSIRB at the scheduled meeting and shall lead the discussion on the protocol.

Criteria for CSUB HSIRB Approval (45 CRF 46.111)

(1) Risks to subjects are minimized:

(i) By using procedures that are consistent with sound research design and that 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 HSIRB 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 HSIRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., 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 HSIRB should consider the purposes of the research and the setting in which the research will be conducted. The HSIRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, 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 or appropriately waived in accordance with §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.

(i) The Secretary of HHS will, after consultation with the Office of Management and Budget's privacy office and other Federal departments and agencies that have adopted this policy, issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data.

(8) For purposes of conducting the limited IRB review required by §46.104(d)(7)), the IRB need not make the determinations at paragraphs (a)(1) through (7) of this section, and shall make the following determinations:

(i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of §46.116(a)(1)-(4), (a)(6), and (d);
(ii) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with §46.117; and
(iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, 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, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Voting Requirements for Standard Review Procedure (45 CRF 46.108)

A quorum shall be required for the CSUB HSIRB to take formal action at any convened meeting. At least five (5) members, including at least one member whose primary concerns are in nonscientific areas, must be present for a quorum. Approval or disapproval of a research protocol shall be based upon a majority ofthose members of the CSUB HSIRB present at the meeting. Only members of the CSUB HSIRB in attendance of a convened meeting shall have full voting rights for the approval or disapproval of a research protocol, unless a member has a "conflict-of-interest" with a specific protocol. No proxy votes from non-attending members of the CSUB HSIRB shall be counted in the approval or disapproval of a research protocol. Persons invited by the CSUB HSIRB for assistance or consultation or the investigator(s) for the research activity are prohibited from voting on any research protocol.

Review of Actions Taken by the CSUB IRB/HSR (45 CRF 46.112)

Research covered by this policy that has been approved by the CSUB HSIRB 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 CSUB HSIRB.

Research covered by this policy shall not be initiated prior to receipt of the certification that the research has been reviewed and approved by the CSUB HSIRB.

Suspension or Termination of HSIRB Approval of Research (45 CFR 46.113)

The CSUB HSIRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with its requirements or that has become associated with unexpected serious harm to human subjects (45 CRF 46.113). Any suspension or termination of approval shall include a statement of the reasonsfor the action by the CSUB HSIRB and shall be reported promptly to the investigator(s), appropriate CSUB officials, and the Department or Agency head.

Cooperative Research (45 CRF 46.114)

(a) Cooperative research projects are those projects covered by this policy that involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy.
(b)(1) Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.
(2) The following research is not subject to this provision:

1. (i) Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or
   (ii) Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.

(c) For research not subject to paragraph (b) of this section, an institution participating in a cooperative project may enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangements for avoiding duplication of effort.

Communications from the CSUB HSIRB to the Investigator

Requests for additional information will be made regarding a research protocol needed to clarify the process being proposed to protect the rights and welfare of human subjects. The HSIRB will communicate decisions of the CSUB HSIRB regarding the approval or disapproval of a research protocol or modifications required to secure approval of a research protocol. Specification of any reporting requirements to the CSUB HSIRB will be communicated to the investigator(s), including changes to approved protocols, progress of the research activity, and adverse reactions

from subjects, potential subjects, and/or the public-at-large.

Communications from the CSUB HSIRB to the Provost and Vice President for Academic Affairs

Annual reports summarizing the activities of the CSUB HSIRB shall be submitted through the Office of the Assistant Vice President for Grants, Research, and Sponsored Programs.

Record Requirements for the CSUB HSIRB (45 CRF 46.115)

(a) An institution, or when appropriate the CSUB HSIRB, shall prepare, and maintain adequate documentation of HSIRB activities, including the following:
(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent forms, progress reports submitted by investigators, and reports of injuries to subjects.
(2) Minutes of HSIRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the HSIRB; 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.
(3) Records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review as described in §46.109(f)(1).
(4) Copies of all correspondence between the HSIRB and the investigators.
(5) A list of HSIRB members in the same detail as described in §46.108(a)(2).
(6) Written procedures for the HSIRB in the same detail as described in §46.108(a)(3) and (4).
(7) Statements of significant new findings provided to subjects, as required by §46.116(c)(5).
(8) The rationale for an expedited reviewer's determination under §46.110(b)(1)(i) that research appearing on the expedited review list described in §46.110(a) is more than minimal risk.
(9) Documentation specifying the responsibilities that an institution and an organization operating an HSIRB each will undertake to ensure compliance with the requirements of this policy, as described in §46.103(e).
(b) The records required by this policy shall be retained for at least 3 years, and records relating to research that is conducted shall be retained for at least 3 years after completion of the research. The institution or HSIRB may maintain the records in printed form, or electronically. All records shall be accessible for inspection and copying by authorized representatives of the Federal department or agency at reasonable times and in a reasonable manner.

What Information the Investigator Provides to the CSUB HSIRB for Review

The specific details to be included in the research protocol and supporting documents that are submitted by the investigator(s) for review by the CSUB HSIRB. These supporting documents include the informed consent forms, the interview questions, the survey instrument, evidence of human subjects protection training for the principal investigators and all key personnel, etc.

The Elements of Informed Consent (45 CFR 46.116)

The requirements for informed consent are specified in 45 CRF 46.116.

(a) *General.* General requirements for informed consent, whether written or oral, are set forth in this paragraph and apply to consent obtained in accordance with the requirements set forth in paragraphs (b) through (d) of this section. Broad consent may be obtained in lieu of informed consent obtained in accordance with paragraphs (b) and (c) of this section only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens. Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials is described in paragraph (e) of this section. General waiver or alteration of informed consent is described in paragraph (f) of this section. Except as provided elsewhere in this policy:
(1) Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.
(2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
(3) The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.
(4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
(5) Except for broad consent obtained in accordance with paragraph (d) of this section:

1. (i) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
   (ii) Informed consent as a whole must present information in sufficient detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

(6) No informed consent may include any exculpatory language through which the subject or the legally authorized 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.
(b) *Basic elements of informed consent.* Except as provided in paragraph (d), (e), or (f) of this section, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:
(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 that 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 that 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;
(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; and
(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

1. (i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
   (ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

(c) *Additional elements of informed consent*. Except as provided in paragraph (d), (e), or (f) of this section, one or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:
(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) that are currently unforeseeable;
(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative'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 that may relate to the subject's willingness to continue participation will be provided to the subject;
(6) The approximate number of subjects involved in the study;
(7) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
(8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
(9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).
(d) *Elements of broad consent for the storage, maintenance, and secondary research use of*

identifiable private information or identifiable biospecimens. Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or non-research purposes) is permitted as an alternative to the informed consent requirements in paragraphs (b) and (c) of this section. If the subject or the legally authorized representative is asked to provide broad consent, the following shall be provided to each subject or the subject's legally authorized representative:

(1) The information required in paragraphs (b)(2), (b)(3), (b)(5), and (b)(8) and, when appropriate, (c)(7) and (9) of this section;

(2) A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;

(3) A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;

(4) A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);

(5) Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;

(6) Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and

(7) An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

(e) *Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials.*

(1) *Waiver.* An IRB may waive the requirement to obtain informed consent for research under paragraphs (a) through (c) of this section, provided the IRB satisfies the requirements of paragraph (e)(3) of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at paragraph (d) of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

(2) *Alteration.* An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs (b) and (c) of this section provided the IRB satisfies the requirements of paragraph (e)(3) of this section. An IRB may not omit or alter any of the requirements described in paragraph (a) of this section. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under paragraph (d)

of this section.
(3) *Requirements for waiver and alteration.* In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:
(i) 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:
(A) Public benefit or service programs;
(B) Procedures for obtaining benefits or services under those programs;
(C) Possible changes in or alternatives to those programs or procedures; or
(D) Possible changes in methods or levels of payment for benefits or services under those programs; and
(ii) The research could not practicably be carried out without the waiver or alteration.

General waiver or alteration of consent

(f) General waiver or alteration of consent.
(1) *Waiver.* An IRB may waive the requirement to obtain informed consent for research under paragraphs (a) through (c) of this section, provided the IRB satisfies the requirements of paragraph (f)(3) of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at paragraph (d) of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.
(2) *Alteration.* An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs (b) and (c) of this section provided the IRB satisfies the requirements of paragraph (f)(3) of this section. An IRB may not omit or alter any of the requirements described in paragraph (a) of this section. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under paragraph (d) of this section.
(3) *Requirements for waiver and alteration.* In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:

1. (i) The research involves no more than minimal risk to the subjects;
   (ii) The research could not practicably be carried out without the requested waiver or alteration;
   (iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
   (iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
   (v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

(g) *Screening, recruiting, or determining eligibility.* An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:
(1) The investigator will obtain information through oral or written communication with the

prospective subject or legally authorized representative, or
(2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.
(h) *Posting of clinical trial consent form*
(1) For each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal Web site that will be established as a repository for such informed consent forms.
(2) If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal Web site (e.g. confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.
(3) The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.
(i) *Preemption.* The informed consent requirements in this policy are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in order for informed consent to be legally effective.
(j) *Emergency medical care.* 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 (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe).

Documentation of informed consent (45 CFR 46.117)

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the informed consent form.
(b) Except as provided in paragraph (c) of this section, the informed consent form may be either of the following:
(1) A written informed consent form that meets the requirements of §46.116. The investigator shall give either the subject or the subject's legally authorized representative adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative.
(2) A short form written informed consent form stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative, and that the key information required by §46.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the subject or the subject's legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the subject's legally authorized representative, in addition to a copy of the short form.

(c)(1) An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

1. (i) That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
   (ii) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or
   (iii) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

(2) In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

Research Activities Exempted from Full Convened Board Review (45 CRF 46.101)

(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).
(3) (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).
(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.
(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
(i) The identifiable private information or identifiable biospecimens are publicly available;
(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.
(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under

those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.
(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.
(6) Taste and food quality evaluation and consumer acceptance studies:
(i) If wholesome foods without additives are consumed, or
(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
(7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).
(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);
(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;
(iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and
(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

Applications and proposals lacking definite plans for involvement of human subjects (45 CFR 46.118)

Certain types of applications for grants, cooperative agreements, or contracts are submitted to Federal departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. Except for research waived under §46.101(i) or exempted under §46.104, no human subjects

may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the Federal department or agency component supporting the research.

Research undertaken without the intention of involving human subjects (45 CFR 46.119)

Except for research waived under §46.101(i) or exempted under §46.104, in the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted by the institution to the Federal department or agency component supporting the research, and final approval given to the proposed change by the Federal department or agency component.

Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal department or agency (45 CFR 46.120)

(a) The department or agency head will evaluate all applications and proposals involving human subjects submitted to the Federal department or agency through such officers and employees of the Federal department or agency and such experts and consultants as the department or agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.
(b) On the basis of this evaluation, the department or agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

Use of Federal funds (45 CFR 46.122)

Federal funds administered by a Federal department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

Early termination of research support: Evaluation of applications and proposals (45 CFR 46.123)

(a) The department or agency head may require that Federal department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially failed to comply with the terms of this policy.
(b) In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person or persons who would direct or has/have directed the scientific and technical aspects of an activity has/have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).
§46.124 Conditions.

With respect to any research project or any class of research projects the department or agency head of either the conducting or supporting Federal department or agency may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.

Definitions for purposes of this policy as per 45 CFR 46.102

(a) *Certification* means the official notification by the institution to the supporting Federal department or agency component, 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.
(b) *Clinical trial* means research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.
(c) *Department or agency head* means the head of any Federal department or agency, for example, the Secretary of HHS, and any other officer or employee of any Federal department or agency to whom the authority provided by these regulations to the department or agency head has been delegated.
(d) *Federal department or agency* refers to a federal department or agency (the department or agency itself rather than its bureaus, offices, or divisions) that takes appropriate administrative action to make this policy applicable to the research involving human subjects it conducts, supports, or otherwise regulates (e.g., the U.S. Department of Health and Human Services, the U.S. Department of Defense, or the Central Intelligence Agency).
(e)(1) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research:

1. (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
   (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

(2) *Intervention* includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
(3) *Interaction* includes communication or interpersonal contact between investigator and subject.
(4) *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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
(5) *Identifiable private information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
(6) An *identifiable biospecimen* is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.
(7) Federal departments or agencies implementing this policy shall:

1. (i) Upon consultation with appropriate experts (including experts in data matching and re-identification), reexamine the meaning of "identifiable private information," as defined in paragraph (e)(5) of this section, and "identifiable biospecimen," as defined in paragraph

(e)(6) of this section. This reexamination shall take place within 1 year and regularly thereafter (at least every 4 years). This process will be conducted by collaboration among the Federal departments and agencies implementing this policy. If appropriate and permitted by law, such Federal departments and agencies may alter the interpretation of these terms, including through the use of guidance.

(ii) Upon consultation with appropriate experts, assess whether there are analytic technologies or techniques that should be considered by investigators to generate "identifiable private information," as defined in paragraph (e)(5) of this section, or an "identifiable biospecimen," as defined in paragraph (e)(6) of this section. This assessment shall take place within 1 year and regularly thereafter (at least every 4 years). This process will be conducted by collaboration among the Federal departments and agencies implementing this policy. Any such technologies or techniques will be included on a list of technologies or techniques that produce identifiable private information or identifiable biospecimens. This list will be published in the Federal Register after notice and an opportunity for public comment. The Secretary, HHS, shall maintain the list on a publicly accessible Web site.

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

(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) *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. If there is no applicable law addressing this issue, *legally authorized representative* means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

(j) *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.

(k) *Public health authority* means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

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

(1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is

collected.
(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.
(m) *Written*, or *in writing*, for purposes of this part, refers to writing on a tangible medium (e.g., paper) or in an electronic format.