Policy and Procedures for the Protection of Human Subjects

California State University, Dominguez Hills

Institutional Review Board

Rev. 03/2023

PROLOGUE

The Institutional Review Board (IRB) has been established in accordance with federal law to ensure that human subjects participating in research activities sponsored by California State University, Dominguez Hills (CSUDH) and/or CSUDH auxiliaries are protected from undue risks and deprivation of personal rights and dignity.

The following guidelines have been prepared by the CSUDH Office of Graduate Studies and Research to comply with federal regulations and supply investigators with policy directions concerning the submission of research protocols for IRB review.

It is the IRB's charge to facilitate scientific inquiry while preserving the dignity, confidentiality, and safety of individuals and groups participating in research.

GUIDING PRINCIPLES

The CSUDH IRB has adopted the following codes or statements of principle to assist it in the discharge of its responsibilities for protecting the rights and welfare of human subjects:

Belmont Report, April 18, 1979.

45 Code of Federal Regulations Part 46 – Common Rule.

Protection of Human Subjects in Medical Experimentation Act, California Health and Safety Code Section 24170 – 24179.5.

Where other social and medical bodies (such as the AMA, ANA, APA, etc.) have established more stringent principles, those will be applied.

In addition, the IRB will also be guided by the following principles:

1. In considering the participation of human beings as research subjects, the guiding principle is that no one, whether a student or other person, should be exposed to unreasonable risk to health or well-being, whether physical, psychological, or social.

2. Commensurate with the principle of protection of human subjects, the procedures for assessing and minimizing risk to human subjects shall respect and protect the academic freedom of the University's faculty and students in their pursuit of knowledge.

3. In most cases the responsibility is borne solely by the individual investigator, but all persons involved in initiating, approving, or conducting research involving human subjects shall be aware of potential consequences of the investigator's research, or of research done under the investigator's direction. The investigator is expected to be sufficiently knowledgeable of all requirements, including the specific expertise to effectively predict risks.

4. It shall be the responsibility of the individual investigator to decide when they do not have the expertise to predict the consequences of the research done under their direction. When in doubt, the investigator must obtain the advice of others who do have the requisite or relevant knowledge.

5. Any chosen research procedure that carries risk of harm must be justified. At minimum, this requires evidence that alternative research procedures have been considered whenever possible and relevant, as well as the reason(s) for their dismissal from consideration.

6. Whenever medication or operative procedures are used, or there are exposures to hazardous environmental conditions, the research must be performed under medical protection and supervision.

7. The purpose of the research, the procedures to be followed, and the possible risks involved must be explained carefully and fully to the subject; the investigator must be satisfied that the explanation has been understood by the subject; and the consent of the subject must be obtained without duress or deception. With appropriate justification, the IRB may permit the PI to postpone explaining the purpose of the study, ethical considerations, and other aspects of informed consent until after the data have been collected. This is only permissible in a study that poses no unreasonable risks to the subject, in which ethical concerns are not identified, and in which a full account of purpose and procedure in advance might bias the results, such as observation of children in at play or in public opinion research.

8. A research project shall not be represented to potential research subjects as representing the interests of or being sponsored by California State University, Dominguez Hills; any CSUDH auxiliary organization; or by a given department of the University, except by explicit arrangements with appropriate administrative authorities. It is appropriate for the researcher to make known their position at CSUDH. It is the subject's right to know, if they so desire, the source of support for the research in which they are being asked to participate.

9. The risks to a subject must be outweighed by the potential benefit to them. Minimal risk studies can be supported by the importance of the knowledge to be gained.

10. No information concerning a project may be deliberately withheld from a potential subject in order to increase the willingness of the subject to participate in the project.

11. When research takes place in an international setting, the investigator must consider the ethical principles of that setting in addition to the principles listed herein.

12. The subject's personal privacy and the confidentiality of information received from the subject must be protected. Personal health information must be protected under HIPAA/HITECH guidelines. Information pertaining to student educational records must be protected under FERPA requirements.

13. A subject's time should not be taxed to the extent that it creates conflicts with other obligations; whenever possible the research projects should contribute to the subject's knowledge of themselves and/or a knowledge of the topic under investigation.

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A. DEFINITIONS

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California State University, Dominguez Hills

Committee for Protection of Human Subjects

1. APPLICABILITY OF THIS POLICY

All research (funded or not funded) involving human subjects conducted under the auspices of the University or any CSUDH auxiliary is subjected to this policy, including not only the projects of faculty members, staff, and administrators, but those of graduate and undergraduate students. For the purposes of this policy, human subjects research is defined as in 45 CFR §46.102; see also Appendix A, Definitions.

2. INSTITUTIONAL RESPONSIBILITIES WITH REGARD TO HUMAN SUBJECTS

2.1 The administrative authority for the protection of human subjects at CSUDH rests with the university's Institutional Official (IO). This role is typically assigned to the Dean of Graduate Studies and Research. The CSUDH Institutional Review Board (IRB) is appointed by the Institutional Official, in compliance with current federal rules and regulations concerning composition of the review committee.

2.2 The Committee is currently composed of at least nine members, including at least one with expertise in medicine and one who is a member of the community at large and not otherwise affiliated with the University. The Institutional Official will review the composition of the IRB at timely intervals and all changes in membership will be reported to federal authorities as required.

2.3 Campus policies and federal requirements regarding research with human subjects are implemented by the IRB through the Graduate Studies and Research office. Policies are periodically reviewed and updated for compliance with applicable laws and regulations.

2.4 The protection of human subjects from undue risks and deprivation of personal rights and dignity can best be achieved through consideration of three issues: (1) that subject participation is voluntary, indicated by free and informed consent; (2) that the degree, nature and management of risk to the subject and the researcher have been delineated explicitly by the researcher; and (3) that an appropriate balance exists between potential benefits of the research to the subject or to society and the risks assumed by the subjects. The IRB has the ultimate responsibility to determine risk with regard to human subject research, and to approve or not approve such research under the auspices of the University or one of its auxiliaries irrespective of whether funding has been obtained to carry out the research project.

3. PROTOCOL REVIEW REQUIREMENTS

With the exception of the exemptions listed below, the IRB must review research involving human subjects conducted at or sponsored by the University in order to protect the rights of human subjects of such research.

3.1 Per federal regulations, the following categories of research (3.1.1 through 3.1.8) **may** be exempt from this policy on the basis that they consistently involve minimal risk to research subjects. Individual investigators may not self-determine exemption; only the IRB may determine that a particular project is exempt from further review.

3.1.1 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.

3.1.2 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).

3.1.3 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:

(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).

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 expect the subjects will find the interventions offensive, upsetting, 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.

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 they will be unaware of or misled regarding the nature or purposes of the research.

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

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

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

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

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information

that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

3.1.5 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.

Note that 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.

Note also that Federal research guidelines must be adhered to for all Federally sponsored or funded projects.

3.1.6 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.

3.1.7 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).

3.1.8 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.

3.1.9 Written informed consent is not typically required for exempt studies. Continuing review is also typically not required, although the Committee may choose to require an annual review of an exempt study on an individual basis.

3.2 There is human subject involvement when human beings are asked to participate:

3.2.1 physically in an activity or to donate their tissue, organs, fluids, or other bodily material;

3.2.2 when information is sought directly (as through interview, questionnaire) or indirectly (as through observation) from an identifiable person, with the exceptions stated in 3.1 above;

3.2.3 when information concerning specific, individually identifiable human beings is asked for from third parties – whether through access to files, data banks, or other means – or through direct inquiry of third parties concerning the individuals in question, with the exceptions stated in 3.1 above.

3.3 There is no human subject involvement when:

3.3.1 a research project uses already stored (archived) data that are anonymous and not traceable to individuals or well-defined social groups, even if human subjects were involved in the original collection of data; or when

3.3.2 research data are taken from the public domain. This includes data traceable to known individuals or social groups who have clearly made both the information and their

identities available for any forms of scrutiny and analysis within the limitations set by statutes concerning libel.

3.4 Research proposals for which the questions of human subject involvement is itself uncertain or ambiguous must be submitted for review. Data collected for instructional purposes (i.e., a class assignment, data collected directly by students for the class) that is not intended for presentation or publication does not usually need IRB review. Retroactive IRB approval is not available.

3.5 When non-exempt human subject research is conducted and/or sponsored by University employees, auxiliary employees, and/or students under the auspices of the University, a protocol describing the research must be submitted to the IRB for review and approval before any research activities begin.

3.6 For purposes of clarifying the researcher's legal rights and responsibilities, research or related activities conducted under the auspices of the University are defined to be any research or related activity involving human subjects that utilize CSUDH time, facilities, resources, and/or students.

3.6.1 CSUDH affiliated investigators are afforded the normal legal protection by the University, provided their activities have appropriate IRB approval.

3.6.2 The responsibility for resolution of any legal question rests with the CSU Office of the General Counsel. Whenever a legal question arises, the opinion of the CSU Office of the General Counsel will be requested. Protocols involving legal questions that are otherwise capable of being approved will be referred to the General Counsel for comment following their approval.

3.6.3 Activities that are sponsored by an outside agency and that utilize CSUDH resources are considered to be conducted under the auspices of both CSUDH and the outside agency. In this case, approval must be obtained from committees on protection of human subjects at CSUDH and at the outside agency.

3.6.4 All other research or related activities involving human subjects conducted by CSUDH employees or students that do not utilize any CSUDH time, facilities, resources, and/or students are considered to be outside the auspices of the University.

3.7 Researchers requesting support from outside agencies and planning to perform non-exempt activities involving human subjects under the auspices of the University are required to submit a proposal through the Office of Sponsored Research and Programs. Except in extraordinary circumstances, required IRB approval must be secured prior to the acceptance of award funding. In all cases, required IRB approval must be obtained prior to the start of any research activities, even when funding has been accepted.

3.8 Non-CSUDH affiliated researchers planning to conduct non-exempt research activity under the auspices of the University must obtain the following approvals:

3.8.1Non-CSUDH affiliated researchers must document that a human subjects review has been performed by their OHRP-regulated parent institutions (i.e., institutions assigned a Federalwide Assurance (FWA) number and in good standing).

(i) Non-CSUDH affiliated researchers who have not secured human subjects approval from an institution with an approved FWA may not conduct research at CSUDH unless they partner with a CSUDH-affiliated person (faculty, staff, or student) to serve as Principal Investigator. The CSUDH-affiliated PI must then submit the protocol to the CSUDH IRB for review.

(ii) Non-CSUDH affiliated researchers who have secured human subjects approval from an institution with an approved FWA must complete an IRB Authorization Agreement (IAA) with CSUDH, formally designating the researcher's home institution as the IRB of record for the research project.

(iii) Prior approval from outside institutions notwithstanding, IRB reserves the right to disagree with the external IRB's determination and require its own review and determination of the acceptability of research to be conducted under the auspices of CSUDH.

3.8.2 Non-CSUDH affiliated researchers must also document the approval of those other administrative officers from their parent institutions who have jurisdiction over their research.

3.8.3 Non-CSUDH affiliated researchers must obtain the documented approval of the appropriate CSUDH departments and/or facilities wherein the research will be conducted.

3.9 Where federal regulations require a certification and the application or proposal involves an investigational new drug within the meaning of the Food, Drug, and Cosmetic Act, the drug shall be identified in the certification together with a statement that the 30-day delay required by 21 CFR 312.1 (a) (2) has elapsed and the Food and Drug Administration has not, prior to expiration of such 30-day interval, requested that the sponsor continue to withhold or to restrict use of the drug in human subjects; or that the Food and Drug Administration has waived the 30-day delay requirement: except that in those cases in which the 30-day interval has neither expired nor been waived, a statement shall be forwarded to appropriate federal authorities upon such expiration or upon receipt of a waiver.

4. APPLICATION PROCEDURES

4.1 Researchers are required to submit a protocol describing the proposed research activity to the IRB. Under no circumstances may any research activity begin until and unless the IRB has granted approval to conduct the research or determined the research to be

exempt from further review. **If research procedures are begun prior to the granting of approval by the IRB, the research will not be eligible for IRB review or approval.**

4.1.1 The protocol should be submitted to the IRB through the Cayuse Human Ethics (HE) system managed by the Graduate Studies and Research office.

(i) Faculty and staff should automatically have access to the Cayuse HE platform.

(ii) All required information and attachments must be provided in order for the protocol to be submitted.

(iii) The PI must certify the submission in order for the protocol to be submitted.

(iv) PIs must be faculty or staff. Students may serve as research assistants on the protocol, but may not be listed as the Principal Investigator.

4.2 All procedures related to the preparation of appropriate protocols as well as processes leading to their submission to the IRB are the responsibility of the University departments and researchers.

4.3 In preparing the protocol, the Principal Investigator must be aware of ethical principles and general guidelines which apply to research involving human subjects (see Guiding Principles in front of Table of Contents), and of factors that affect their individual legal liability.

4.3.1 Regardless of the acceptability of the research, no research protocol will be approved until the named study personnel have provided sufficient evidence of training in human subjects research (e.g., current CITI Program Human Subjects Research certification IRB review will not begin until the Principal Investigator and all researchers (including students) on the protocol have documentation of completed CITI certification.

4.4 The Protocol is a statement of the researcher's responsibilities toward the human subjects involved in their research, and contains the information described below.

4.4.1 Study personnel: The Principal Investigator is considered to be ultimately responsible for the conduct of the study, including the conduct of other members of the research team. It is the expectation of IRB that all personnel – faculty, students, and staff – who are materially involved in the human subjects research project, whether or not they interact with live human subjects, will be named in the personnel section.

4.4.2 Study populations: Adult volunteers as well as special subject populations and OHRP-defined vulnerable populations who may require additional steps or protections.

4.4.3 Study objectives and background: The protocol should contain a concise review of the proposed research objectives and their significance, including references.

4.4.4 Enrollment and recruitment information: Methods and materials to recruit participants into the study, including information about any compensation provided to subjects.

4.4.5 Study methods and procedures: A detailed description of all procedures to be performed on human subjects for the purposes of research must be included. Observational or interview studies should indicate the type of contacts and interactions with their subjects and the means of observation to be used. Copies of questionnaires to be administered should be included. Standard psychological tests should be identified. Any special procedures involving unusual electrical devices, radioisotopes, or investigational new drugs must also be described. Procedures for storing, accessing, and securing study records and participant information must be described in detail.

4.4.6 Risks and benefits: In the event that the proposed research involves necessary risks to the research subject, those risks should be explicitly identified and justified. The only acceptable justification will yield the conclusion that the risks incurred by the research subject are to be freely and willingly incurred by the research subject, known to the subject and are warranted in light of the gain to be accrued from the research. In cases where information given to subjects as to the procedures and purposes of the study would invalidate the objectives, the investigator should report to the IRB reasons for not informing subjects of the procedures (i.e., deception).

4.4.7 Privacy and confidentiality: Special attention will be given to issues of confidentiality in behavioral studies. Methods of securing informed consent should also be discussed in this section.

4.4.8 Informed consent: See section 4.5 below.

4.4.9 Conflicts of interest: Study personnel must declare any social or financial conflicts of interests, real or apparent, that could potentially alter the risk profile of the research. Particular attention is paid to conflicts that have the potential to create coercive environments, such as faculty recruiting students in their own courses.

4.4.10 Researcher qualifications and other information: IRB has an obligation to ensure that only qualified researchers are permitted to carry out work with human subjects, in order to ensure that risks to subjects are minimized. The investigator must also include any additional information directly pertinent to the proposed use of human subjects that will assist the IRB in considering the application.

4.5 An initial pre-review assessment will be made by a designated member of the committee and/or IRB support staff. The protocol will either be categorized as exempt (per section 3.1), expedited review, or full committee review. If a determination cannot be made, the analyst conducting pre-review will request clarification from the named PI on the protocol.

4.6 Following pre-review, appropriate action will be taken depending on the study categorization:

4.6.1 For exempt studies, support staff will issue an exemption letter to the PI. The study will not be considered further by the IRB unless amended.

4.6.2 For expedited studies, one or more members of the Committee, typically the Chair and/or Vice-Chair(s), will conduct the review. See Section 6, Expedited Review.

4.6.3 For full committee review studies, the Committee will review the protocol at its next convened meeting and take appropriate action regarding approval. The IRB will normally meet at least once per month during the academic year, or more often as necessary; typically the Committee does not meet during the months of January, June, July, and August. See Section 7, Full Committee Review.

5. INFORMED CONSENT

5.1 Any investigator proposing to place any individual at risk is obligated to obtain and document legally effective informed consent. Informed consent means the knowing consent of an individual or their legally authorized representative so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other forms of constraint or coercion.

5.1.1 The Basic Elements of information necessary to consent as specified by the Code of Federal Regulations (45 CFR 46) include, where applicable:

(i) 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. (When elements of purpose cannot be disclosed without biasing the behavior of subjects in a way that would invalidate the objectives of the study, the investigator may request that modified documentation of informed consent be obtained as described under Section 4.4.6);

(ii) a description of any reasonably foreseeable risks or discomforts to the subject;

(iii) a description of any benefits to the subject or to others which may reasonably be expected from the research;

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

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

(vi) 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;

(vii) 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;

(viii) 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;

(ix) a disclosure of the source of support for the research in which they are being asked to participate; and

(x) an instruction that any subject wishing to voice a complaint or a concern about the research may direct their complaint or concern in writing, by phone, or by email to the Graduate Studies and Research office. The IO, in conjunction with the IRB, will investigate the matter and take any necessary corrective action.

5.1.2 Written/documented informed consent may not be required for minimal risk projects or for studies where the only identifying link between the subject and their data is the signed consent form. However, it is the expectation of the IRB that an information form summarizing the basic elements of informed consent will be provided to study participants unless (a) there is a compelling justification not to inform subjects and (b) failing to provide this information would not reasonably place the subjects at greater risk or interfere with their rights as research participants. If a waiver of documentation of informed consent is sought, the information to be conveyed to the potential subjects must be submitted to the IRB with the protocol.

5.1.3 Any agreement, written or oral, entered into by the subject following the informed consent process may not include any exculpatory language through which the subject is made to waive, or appear to waive any of their legal rights, or to release the institution or its agents from liability for negligence.

5.1.4 The explanation of the procedures and purposes must be given in terms comprehensible to the intended subject, e.g., 5 cc = 1 teaspoon. The purpose of the research should be clearly stated to assist the subjects in balancing the risks and benefits for themselves. It is often useful to indicate the larger social purpose of the research as well as the immediate purpose of certain procedures on certain subjects. Ordinarily it is necessary to state the amount of time required to perform the research procedures and the place where they will be performed. Compensation that may be provided should be clearly identified and should be limited to avoid financial coercion.

5.1.5 In the description of the benefits to be expected the distinction should be made between personal benefits and social benefits. Incentives provided solely for research participation do not constitute personal benefits.

5.1.6 In describing the risks and discomforts to the subject, it is appropriate to estimate the degree of risk and to be especially candid about high risk procedures. It should be noted that these effects may be physical, psychological, legal, or social.

5.1.7 Disclosure of alternative procedures is only applicable in certain circumstances, particularly when a new diagnostic or therapeutic procedure is being used. The discussion of the alternatives must be fair and should attempt to balance the alternatives against the experimental therapy or procedures proposed. The risks and benefits of the alternatives should therefore be discussed. Choosing not to participate in the research or to discontinue participation is a viable alternative to participating in the research, and should not carry any penalties or costs to the participant.

5.1.8 When the proposed investigation involves a subject who is a minor, who is uncomprehending, or who is legally incompetent to give consent, the consent form must clearly indicate that procedures are being consented to on behalf of the subject by their legally authorized representative and assent may be required from the participant as well. Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to such subject's participation in the particular activity or procedures (45 CFR, Part 46). For minor children, including CSUDH students under age 18, this is typically but not always a parent or legal guardian.

5.1.9 Informed consent should be secured in the native language of the subject if English is not readily understood. If research is done in cultures where signed statements are mistrusted, or where the concept of experimentation itself is unfamiliar, the investigator's protocol should clearly indicate how the project will be explained, how the consent of the subject will be obtained, and who will validate the act of consent.

5.2 The actual procedure in obtaining documentation of informed consent and the basis for committee determinations that the procedures are adequate and appropriate are to be fully documented. The documentation will follow one of the following three forms (45 CFR, Part 46):

5.2.1 Provision of a written consent document embodying all of the basic elements of informed consent. This may be read to the subject or to the legally authorized representative, but in any event the subject or the legally authorized representative must be given adequate opportunity to read it. This document is to be signed by the subject or the legally authorized representative. Sample copies of the consent form as approved by the IRB are to be retained in its records.

5.2.2 Provision of a “short form” written consent document indicating that the basic elements of informed consent have been presented orally to the subject or the legally

authorized representative. Written summaries of what is to be said to the subject are to be approved by the IRB. The short form is to be signed by the subject or the legally authorized representative and by an auditor witness to the oral presentation and to the subject's signature. A copy of the approved summary, annotated to show any additions, is to be signed by the persons officially obtaining the consent form and of the summaries approved by the IRB are to be retained in its records.

5.2.3 Modification of either of the primary procedures outlined in sections 5.2.1 and 5.2.2 above. Granting of permission to use modified procedures imposes additional responsibility upon the IRB and the institution to establish: (a) that the risk to any subject is minimal, (b) the waiver or alteration will not adversely affect the rights and welfare of the subjects, (c) the research could not practicably be carried out without the waiver or alteration, and (d) whenever appropriate, the subjects will be provided with additional pertinent information after participation. The IRB's reasons for permitting the use of modified procedures are individually and specifically documented in the minutes and in reports of IRB action to the files of the institution.

6. EXPEDITED REVIEW

The protocol will be screened by an IRB Chair or Vice-Chair to determine whether the study represents greater than minimal risk and whether informed consent has been appropriately addressed. If it is clear that the risks inherent in the protocol are no greater than those attendant in the normal course of life and that the Principal Investigator is in full compliance with IRB informed consent requirements, the protocol may be reviewed by the Chair or Vice-Chair without the involvement of the rest of the Committee. The reviewer may request clarifications and/or require that the PI make changes to the protocol before approving the research. If the reviewer determines that the study procedures are minimal risk and the protocol is in compliance with all OHRP and IRB human subjects protection requirements, the protocol will be recorded approved. The reviewer or IRB administrative staff will communicate the terms of the approval, including study expiration date and any necessary documentation (e.g., approved-for-use consent forms), to the PI.

7. FULL COMMITTEE REVIEW

7.1 If it is determined by the Chair or Vice-Chair that the research involves vulnerable populations, has the potential for greater than minimal risk, or presents concerns with the adequacy of informed consent, that protocol will be presented to the full board for review.

7.2 The review performed by the IRB will determine first, whether the research procedures place subjects at greater risk than they would ordinarily experience in everyday life; and second, whether the researchers adequately mitigate the risk to human subjects. The policy criterion for determining "subject at risk" is defined as: any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related

activity which departs from the application of those established and accepted methods necessary to meet their needs or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service. This is defined in contrast to "minimal risk," which is research for which "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" (45 CFR §46.102).

7.3 If greater than minimal risk is involved, the IRB will examine the following three principles in determining the approvability of the research:

7.3.1 The risks to the subject are so outweighed by the sum of the benefits to the subject and the importance of knowledge to be gained as to warrant a decision to allow the subject to accept these risks.

7.3.2 The rights and welfare of any such subjects are adequately protected.

7.3.3 Legally effective informed consent will be obtained by adequate and appropriate methods, in accordance with the provision of the federal regulations.

7.4 Greater than minimal risk studies involving children as research subjects must also meet the requirements of 45 CFR 46 Subpart D, specifically §46.405-407. Although not explicitly required by the CFR, the IRB will generally apply the principles of Subpart D to any other vulnerable populations in determining the acceptability of a greater than minimal risk research protocol.

8. ACTIONS BY THE IRB

Following review and discussion of the protocol and application, the IRB will take one of the following actions:

8.1 Reclassifies the research as exempt. Exempt projects are minimal risk projects meeting one of the federal exemption criteria detailed in Section 3.1 above.

8.2 Approves the research as proposed. The study may be classified as minimal risk or greater than minimal risk. If the research involves greater than minimal risk to the subjects, the IRB finds that this risk is not unreasonable, the potential benefits outweigh the risk, and risk management procedures have been taken to minimize the risks to human subjects.

8.3 Requires minor modifications of some part of the proposed study. The modifications or conditions set by the IRB typically include specific minor revisions to measures or consent forms, restrictions on the use of certain procedures or subject groups or requiring use of specified safeguards, etc., that are necessary for the protection of human subjects. The IRB may request the investigator discuss problems with the full board directly or through a selected member.

8.4 Requires significant modification of the protocol before approval. This occurs when the IRB feels that it has insufficient information to take action, or when it feels that the research design contains inherent dangers and should be revised to minimize risk to human subjects. The IRB may request the investigator discuss problems with the full board directly or through a selected member.

8.5 Disapproves the research. In this case the IRB makes the decision that the potential benefits of the research do not outweigh the risks to the subject, and further revisions to the protocol are unlikely to sufficiently mitigate these risks.

9. DISPOSITION OF THE RECOMMENDATIONS

9.1 Reclassifications, approvals, recommendations, restrictions, conditions, or disapprovals will be communicated to the researcher by a member of the IRB or designated IRB administrative staff.

9.2 If an application is not approved, the IRB shall forward to the researcher a statement setting forth in detail the reasons for not approving the protocol and the recommendations of the Committee for modification of the research proposal. For minor (8.3) or major (8.4) modifications, the IRB may choose whether the modified protocol must be reviewed at a future meeting of the full board, or whether one or more individual IRB members ("Member Review" / "Subcommittee Review") may conduct future review and approval of the modified protocol.

10. RIGHT OF APPEALS

10.1 If the applicant believes that the proposal has been disapproved because of incorrect, unfair, or improper evaluation by the IRB, an appeal may be made directly to the IRB.

10.2 The appeals procedure is as follows:

10.2.1 If an investigator feels that a requested change to their study protocol or materials is unduly burdensome without a clear benefit to participant health and safety, the first step is to engage the reviewer in conversation. The investigator must first use the "Add Comment" feature within Cayuse to provide a clear justification of both the burden presented by the requested change and why participant rights are not potentially affected. There may be some dialogue on these points, and it is important to have this communication exchange preserved in the context of the original IRB application.

Note: further appeals and/or escalation will not be considered until there is evidence of a conversation between the reviewer and the investigator in Cayuse. Investigators will be redirected to Step 1 until complete.

10.2.2 If the conversation is truly at an impasse, the investigator may email a request for subcommittee review to irb@csudh.edu with the study protocol number (e.g., FY-###), a

request for subcommittee review of a reviewer's determination, stipulation, or required change, and the specific proposal item number(s) of the disputed change (e.g., "F3a"). The Research Compliance Officer will respond within two business days confirming receipt of the subcommittee review request.

10.2.3 A subcommittee of three or more IRB committee members, excluding the initial reviewer, will be convened to review the disputed item(s), including all prior conversation and justifications between the initial reviewer and the investigator. Subcommittee members may include alternate members of the IRB, but will not include anyone with a conflict of interest on the specific protocol, such as a co-investigator or faculty advisor. The subcommittee will document their opinions about the disputed item(s) in the appropriate section(s) of Cayuse.

10.2.4 The appeals subcommittee may take one of the following actions:

(i) Uphold appeal: In the event that the subcommittee ultimately agrees with the investigator, the disputed revision will be removed. Investigators are still responsible for revising the application to comply with all non-disputed revisions and re-certifying the application upon resubmission.

(ii) Deny appeal: If the subcommittee ultimately agrees with the initial reviewer, the requirement to revise the protocol accordingly will stand. The investigator may always modify the objectionable items within the proposed research to conform to IRB and federal guidelines.

In either case, the determination and next steps will be sent by email from irb@csudh.edu to the investigator.

10.2.5 If the subcommittee found in favor of the initial reviewer and the investigator still wishes to pursue appeal, the investigator should reply directly to the determination email (from irb@csudh.edu) requesting chair-level review. The IRB chair and vice-chairs will examine the accrued evidence and written opinions to date. If the chairs determine that there is merit to the investigator's dispute, the chairs will bring the question before the full committee at the next convened IRB meeting, and the full committee will vote.

10.2.6 The vote of the full IRB committee is considered final and cannot be overruled by administrative action. The determination of the committee will be communicated to the investigator via email within five business days of the IRB meeting at which the issue was discussed.

10.3 If an appeal is requested, the IO will also investigate the appropriateness of the original determination in conjunction with the CFR, OHRP guidance, and any and all other applicable University, system, local, state, and federal regulations or requirements. If no justification for the initial disapproval or modification request is discovered, the IO may request that the IRB clarify and document its standards related to the disputed item to ensure fair and equitable decision-making going forward.

10.4 The IRB is the final arbiter of whether a research study can be approved. The IO may at any time halt a study and/or revoke approval of a study previously approved by the IRB. However, the IO may not independently approve or authorize a study that has been disapproved by the IRB.

11. RECORDS AND DOCUMENTATION

11.1 Researcher: The Principal Investigator is required to make and keep written records of the study protocol, IRB decisions and approvals for the use of human subjects, and (for studies requiring documented informed consent) to obtain and keep documentary evidence of informed consent of the subjects or their legally authorized representative. Such forms must be retained on file by the PI or their designee for a minimum of three years after termination of the project.

11.2 IRB: The IRB is required to keep copies of all documents presented or required for initial and continuing review by the IRB. Per 45 CFR §46.115, These include:

> (i) Copies of all research proposals reviewed, any scientific evaluations that may accompany the proposals, approved sample consent forms, progress reports submitted by investigators, and reports of injuries to subjects;
>
> (ii) Minutes of committee meetings, in sufficient detail to show attendance at the meetings, actions taken by the IRB, 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;
>
> (iii) Records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review;
>
> (iv) Copies of all correspondence between the IRB and investigators;
>
> (v) A list of IRB committee members identified by name, earned degrees, representative capacity, indications of experience sufficient to describe each member's chief anticipated contributions to committee deliberations, and any employment or other relationship between each member and the institution;
>
> (vi) Written procedures for the IRB in the same detail as described in 45 CFR §46.108(a)(3) and (4), i.e., this Policy;
>
> (vii) Statements of significant new findings provided to subjects; and
>
> (viii) The rationale for an expedited reviewer's determination that research appearing on the expedited review list is more than minimal risk.

11.3 The records of the IRB pertaining to individual research activities are considered confidential and may only be accessed by members of the IRB (including full and alternate members), the IRB administrative staff, and the IO, with the following exceptions:

(i) Records of projects supported by extramural funds, which are subject to inspection by appropriate federal authorities;

(ii) An individual protocol for which the IRB requires additional expertise, which may be viewed by an expert consultant during the determination process for approving or disapproving that protocol; and

(iii) Any and all records of the IRB, including individual protocols and communications between committee members or staff and researchers, subject to an audit by a recognized regulatory authority governing CSUDH and/or its auxiliaries (e.g., CSU Chancellor's Office).

11.4 Except as otherwise provided by law, information acquired in connection with a research, scholarly, or related activity which refers to or can be identified with a particular subject will not be disclosed except: (1) with the consent of the subject or legally authorized representative; or (2) as may be necessary for the University to carry out its responsibilities under federal regulations.

12. DURATION OF APPROVAL, RENEWAL AND MODIFICATION

12.1 Federal policy requires that the Committee conduct at least an annual review of approved research activities. Researchers should indicate the expected overall duration of the research when submitting an initial protocol, but renewal applications should be made annually from the date of IRB approval.

12.2 Research protocols are approved for a maximum of twelve months. Six weeks prior to expiration, the PI must submit an electronic request to renew the protocol (via email or Cayuse, depending on the system used to record the initial study submission). The renewal request must include a summary of the progress of the study thus far. The renewal request must also contain either (a) a statement that the protocol has not changed from that originally proposed by the Principal Investigator, or (b) a full accounting of the intended changes. The submission for renewal request must include the previously approved protocol and all consent and assent forms.

12.3 Approval of a protocol is granted to the Principal Investigator. If the Principal Investigator ceases to be responsible for the study, approval automatically ceases unless a modification request (see Section 12.5) is initiated and approved to change the named PI prior to the initial PI's withdrawal from study activities. Should a new Principal Investigator desire to continue the study after discontinuation or a lapse in renewal, reapplication to the IRB as a new submission is required.

12.4 If, during the course of any research, a change of plans is made so that human subjects are not to be used, that the research methods or techniques are substantially different (including the introduction of new measures), or new risks or hazards are evident, new IRB approval of the protocol is required before the revisions may be implemented. A statement regarding new developments or anticipated changes should be submitted promptly to the IRB. In general, any change which alters the risk/benefit analysis or which modifies the adequacy of the existing informed consent process will require full board approval. Other changes will typically receive expedited review.

12.5 Modification applications require a copy of all modified documents and a description of any proposed modifications to the current or previous protocol. The description and justification should proceed much as outlined for a new application; that is, the background or reason for modification, benefits, risks, etc. When responsible positions are assumed by new personnel in the execution of the protocol (such as change of the Principal Investigator) a description of background of these individuals that qualifies them to perform the work described in the protocol should be provided.

13. UNANTICIPATED PROBLEMS AND ADVERSE EVENTS

13.1 Any unanticipated problems involving risks to subjects or others, or any noncompliance with this policy or the requirements or determinations of the IRB, must be reported to the IRB immediately.

13.1.1 "Risks to subjects or others" includes adverse reactions to study interventions or procedures, including but not limited to biologicals, medications, or medical devices; social and/or behavioral interventions; interview, focus group, or survey questions of a sensitive nature; disclosure of imminent threat of suicide, self-harm, or violence; and situations that may trigger mandated reporting requirements, including disclosure of child abuse or neglect or elder abuse.

13.1.2 "Noncompliance" refers to the conduct of unapproved research activities, including substantive changes to study procedures that were not approved via modification request, continuation of study activities past the study expiration date without an approved renewal, use of unapproved or out-of-date consent documents or other study materials, data access by individuals not named on the protocol, and other deviations from IRB-approved or mandated procedures.

13.1.3 Adverse events not directly related to the research study should still be reported to the IRB, e.g., the death of a patient from an unrelated cause.

13.2 Reports should include:

(i) name of Principal Investigator, title of project and project number;

(ii) identification of the subject(s) involved, including by code or case number when identifying information is not collected;

(iii) a description of the adverse event and any possible association with the study procedures, interventions, activities, etc.;

(iv) any additional relevant information on the subject or context of the adverse event; and

(v) any actions taken by the research team to mitigate the effects of the adverse event and prevent future occurrences.

Review and disposition of adverse event reports shall follow the definitions and procedures set forth in the DHHS Unanticipated Problems Involving Risks & Adverse Events Guidance (2007). See: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html.

14. APPOINTMENT OF COMMITTEE MEMBERS

14.1 Faculty or staff interested in serving on the IRB may self-nominate or be nominated by their Appropriate Administrator. Nominations should describe the qualifications and expertise of the candidate and be submitted in writing to the IO. Appointment to the IRB may only be made by the IO.

14.2 The initial term of service for all newly appointed IRB members shall be one year. Subsequent terms of service on the IRB shall be for three years, with the option for renewal. Officers (Chair and Vice Chairs) should be nominated by Committee members and appointed by the IO, with an expected term of service of five years. After the Chair leaves service, a Vice Chair can be appointed into the Chair position for five years and a new Vice Chair can be selected.

14.3 The Chair and/or Vice Chair(s) should be present at every full board meeting. A quorum of other members should be identified at every full board meeting. It is expected that IRB members will attend at least seven of the nine formal meetings held within an academic year.

14.4 To assist with managing the volume of protocols requiring review, individuals may also be appointed as alternate members of the IRB. Alternate members must also be nominated and selected as in 14.1. Alternate members shall be appointed for one-year terms and must attend at least one full committee meeting during each academic year.

14.5 Individuals with specialty qualifications can be nominated by members of the IRB as well as CSUDH Administrators. Individuals with specialty qualifications include medical professionals, community members, prisoner advocates, attorneys, etc. Additionally, consultants with specific specialty expertise can be invited to participate in reviews of specific protocols as appropriate.

APPENDIX A

DEFINITIONS

From TITLE 45
CODE OF FEDERAL REGULATIONS
PART 46

PROTECTION OF HUMAN SUBJECTS

§46.102 Definitions.

(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 a 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:

(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:

(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 nonresearch 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. Public health authorities have expanded access to personal health information under HIPAA.

(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.

APPENDIX B

RELATED POLICIES

Subcommittees of the IRB will be tasked with developing additional policies to address specific research methods or approaches and organizational needs. The following policies are currently in effect, and additional policies will be appended to this policy manual upon successful completion and ratification by the Committee at a convened meeting.

B1. Mandated Reporting

Appendix B1: Mandated Reporting

California law requires mandatory reporting of known or suspected child abuse and neglect, elder and dependent adult abuse, and domestic violence. Any person who is required by law to report a particular category or type of abuse to the appropriate law enforcement or social service agency is known as a "Mandated Reporter." Mandated reporters are legally responsible to report the incident themselves; however, they are not required to investigate any known or suspected case of abuse.

The California State University (CSU) system further distinguishes between general and limited mandated reporters in accordance with Executive Order 1083, revised July 21, 2017 with California Penal Code § 11165.7(a)(41). "General Reporters" are defined by the CSU as those who are legally required to report child abuse or neglect *no matter where it occurs*. "Limited Reporters" are defined by the CSU as those who are legally required to report child abuse or neglect *only if it occurs on CSU premises or at an official activity of, or program conducted by, the CSU*.

The IRB has determined that <u>all</u> personnel engaged in human subjects research of any kind are, *at minimum*, Limited Reporters. That is, any study personnel who is listed on a human subjects protocol that has not received a "Not HSR" designation is a Limited Reporter, unless for some other reason they are a General Reporter.

The IRB has further determined that personnel who are engaged in <u>research with minors and/or the elderly</u> are considered to be General Reporters. That is, any study personnel is a General Reporter if they are listed on a human subjects protocol for which:
- "Healthy adult volunteers age 65 or older" is checked in the Study Populations section;
- "Minors under 18 years of age" is checked in the Study Populations section; and/or
- participants under 18 years or 65 years or older are listed in the inclusion criteria for enrollment.

In accordance with CSU policy, any employee who satisfies the criteria for both Limited Reporters and General Reporters will be designated as a General Reporter. Therefore, an IRB status of Limited Reporter does not supersede other reporting requirements. For example, if someone is designated as a General Reporter for other reasons (e.g., social worker, physician, athletic coach), they remain a General Reporter even in the context of doing their research.

It is the responsibility of the investigator to know their mandated reporting status and operate accordingly. The "Mandated Reporting" section will be a required component of consent forms unless otherwise determined by a IRB reviewer, regardless of whether a given investigator is a Limited Reporter or General Reporter, to ensure that participants will be informed about the potential disclosure requirements of study team members.