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## **1. PURPOSE**

1.1. Federal regulations applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency. There are several categories of research that are exempt from federal regulations, however the IRB makes the final determination as to whether research activities involving human subjects fall under the categories as defined by 45 CFR 46.

## **2. DEFINITIONS**

2.1. *Exempt research*, is a term used to describe human subjects research that may be considered exempt from the Federal Policy for the Protection of Human Subjects (45 CFR 46).

## **3. POLICY and PROCEDURE**

### **3.1. Applicability**

- 3.1.1. There are 8 (eight) categories of research activities that may be considered exempt from the regulations, described below. At this time, the UC Santa Barbara Human Subjects Committee will not be implementing the use of exempt categories 7 and 8.
- 3.1.2. The categories in this list apply regardless of the age of subjects, except as noted in section 3.2.
- 3.1.3. Individual investigators do not have the final authority to determine if a research project qualifies as exempt research. This final assessment must be made by the IRB Chair/Designee or IRB staff member appointed as a voting committee member upon review of an application for exempt status submitted by an investigator.
- 3.1.4. Although studies that qualify for exempt status do not fall under the same federal requirements for research involving human subjects as non-exempt studies, investigators still have a responsibility to protect the rights and welfare of their subjects. Investigators are expected to adhere to UCSB policies and conduct their research in accordance with the ethical principles of Justice, Beneficence, and Respect for Persons as described in the Belmont Report.

### **3.2. Research that is Not Exempt**

- 3.2.1. The federal exemption categories 1 (one) through 8 (eight) (45 CFR 46.104(d)) listed in section 3.3 do not apply to the following:
- Research that involves greater than minimal risk.
  - Survey or interview of children vis-à-vis Category 2 (i) and (ii) unless educational tests are employed.

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- Observation of the public behavior of children when investigators interact with the children vis-à-vis Category 2.
- Research involving children vis-à-vis Category 3.
- Research involving prisoners, except for research aimed at involving a broader subject population that only incidentally includes prisoners.
- Research involving the use of protected health information from UC system covered entities, except in cases where a limited data set is being used.
- Research regulated by the Food and Drug Administration (FDA), with exception of Category 6.

### 3.3. **Federal Exempt Categories** (45 CFR 46.104(d))

(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 research, such as:

- (i) Research on regular and special education instructional strategies; and
- (ii) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research that **only** include 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 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 be readily ascertained**, directly or indirectly or through identifiers linked to the subjects, and the IRB conducts a limited IRB review to make the determination required by 45 CFR46.111(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:

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- A. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects **cannot be readily ascertained**, directly or indirectly or through identifiers linked to the subjects;
- B. Any disclosure of the human subjects' 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 the IRB conducts a limited IRB review to make the determination required by 45 CFR46.111(a)(7).

(ii) 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. Examples of benign behavioral interventions include:

- Subjects playing an online game
- Subjects solving puzzles under various noise conditions
- Subjects deciding how to allocate a nominal amount of received cash between themselves and someone else (e.g., prisoner's dilemma game)

(iii) If the research involves deceiving the subjects regarding the nature or purpose of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research, meaning that the subject is informed that s/he 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 be readily ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify the 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 CFR164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

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(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. 522a, 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, and that are designed to study, evaluate, 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 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 the Federal Register prior to commencing the research involving human subjects.

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

(i) if whole-some 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

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secondary research use if an IRB conducts a limited IRB review and makes the determinations required by 45 CFR 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 biospecimen was obtained in accordance with 45 CFR 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 45 CFR 46.117;
- (iii) An IRB conducts a limited IRB review 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 the 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.

3.3.1. For purposes of conducting a limited review as required under 45 CFR 46.111(a)(7) for exempt categories 2(ii) and 3(C), the IRB will assess if the research plan makes adequate provisions for protecting the privacy of subjects and maintaining the confidentiality of the data.

#### **3.4. Action Taken if Proposed Research Does Not Meet Criteria for Exemption**

If upon review, the IRB staff reviewer, who also serves as a voting member, or IRB Chair/Designee determines that the proposed research does not meet the criteria for exemption, the investigator will be notified in writing of the reason why the project does not qualify for exemption and they will be asked to submit the appropriate application for non-exempt review (Expedited or Full Board review).

#### **3.5. Modifications to an Exempt Protocol**

Any request for modification to a project previously determined to be exempt from IRB review must be submitted to the IRB staff for a prospective review and determination that the proposed modification does not change the status of the protocol to non-exempt research. In some circumstances, a proposed change to the protocol may disqualify the project from exempt status. In instances such as these, the IRB staff will contact the investigator informing them of the change in exemption and switch the protocol to a full application for the investigator to complete and submit for either expedited or full board review, as appropriate.

If the modification does not change the status of the protocol to non-exempt research, the it will be reviewed under the appropriate exemption category(s).

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### 3.6. **Authority of the IRB Chair and/or Designee**

The IRB Chair may exercise all of the authorities of the IRB, except they may not disapprove of a research application. A research application may only be disapproved after review by the convened IRB. The Designee may exercise authority as permitted and specified by the IRB Chair.

### 3.7. **Notification of the IRB**

The IRB staff notify the investigator in writing as to whether the project qualifies for exemption or the reasons for rejection of exemption status.

### 3.8. **Documentation**

Research applications must be submitted to the IRB for confirmation that the application meets exemption criteria. Investigators may not make their own determination as to whether a project or modification qualifies as exempt research. The IRB Chair/Designee has the final authority to determine if a project qualifies as exempt research and make revoke or revise determinations granted by the IRB staff.

## 4. **SCOPE**

These policies and procedure apply to all exempt human subjects' research.

## 5. **RESPONSIBILITY**

The IRB staff are responsible for facilitating the review of exempt applications and pre-reviewing submission to ensure they qualify for exemption, and will provide IRB members with a list of new applications that met the exemption criteria as set forth in 45 CFR 46.104(d). The list is provided monthly via the meeting minutes.

IRB staff may consult with the IRB Chair/Designee and/or the Research Integrity Director, or others as appropriate, as needed, in order to determine if an application may qualify for exempt review.

The IRB Chair/Designee and/or assigned IRB member is responsible for the review and assessment of all applications eligible for exempt review.

Other IRB members may be consulted and/or conduct reviews as needed or requested by the IRB Chair or assigned IRB member based on their specific expertise. Ad hoc consultants may also be asked to review the research, if needed, if the research activities involve issues that necessitate the additional consultation of someone with relevant expertise outside the realm of the IRB members. An ad hoc consultant does not have the authority to vote or take action on a research application.

## 6. **EXEMPT REVIEW PROCESS OVERVIEW**

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The IRB staff will coordinate the review process and perform a preliminary check of applications (new or amendments) that appear to qualify for exempt status. If additional information or clarification is necessary, the responsible staff member initiates correspondence, which may include requests for revisions, with the investigator. After the investigator responds to the requested information, the staff member verifies that all items have been addressed and the application is complete.

6.1 The IRB staff member will set-up the application for review at the next regularly scheduled expedited review meeting. Exempt applications are typically reviewed at the same meeting as projects that qualify for expedited review.

6.2 During this meeting, the IRB Chair/Designee and/or IRB member will review the application.

The exempt review process may:

- Confirm the exempt status;
- Require modifications to secure confirmation of exempt status;
- Require the investigator to submit a non-exempt application for review

6.3 If revisions are requested, following the scheduled review, the IRB staff member will follow-up with the investigator in writing. The IRB staff member may review the revised protocol once the investigator has submitted revisions. The IRB staff member who also serves as a voting member may verify that all items have been completed, and consult with the IRB Chair/Designee if needed, and approve the protocol for exemption status.

6.4 If there are no revisions, concerns, or clarifications, the IRB Chair/Designee and IRB member will approve the research application for exemption status.

6.5 After the application has been approved for exemption, all approved documents, including the protocol exemption determination letter will be made available to the investigator.

6.6 Exempt Categories of Research Table:

<p><b>Exempt Category 1 - Educational Practices</b></p> <p>Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:</p> <p>a) research on regular and special education instructional strategies; or</p> <p>b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.</p>	<p>This category does not apply to surveys, interviews, questionnaires, or focus groups which are covered under exempt category 2.</p> <p>The study cannot adversely impact the students' opportunity to learn required curriculum.</p> <p><b>Examples include:</b></p>
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<p>(45 CFR 46 104 (d)(1))</p>	<p>A study comparing two curricula being implemented at a school with observation and analysis of class evaluations.</p> <p>A study about professional development workshops.</p> <p>A study evaluating the effectiveness of a commonly accepted math curriculum.</p> <p>A study involving a cooking class in a grocery store.</p>
<p><b>Exempt Category 2 - Educational Tests, Interviews, Surveys, Observation of Public Behavior</b></p> <p>Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, if at least one of the following is met:</p> <p>a) information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects;</p> <p>b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation; or</p> <p>c) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects and if the IRB conducts a limited review for provisions for protecting privacy and maintaining confidentiality</p> <p>(45 CFR 46 104 (d)(2))</p>	<p>This category does not apply to interviews or surveys with minors.</p> <p>This category only applies to observation of public behavior involving children if the study team does not participate in the activities being observed.</p> <p>Observations must be of public behavior in a public setting (i.e., park, intersection, parking lot, lobby, etc.)</p> <p><b>Examples include:</b></p> <p>An observational study of a pedestrian street crossing where the researcher takes notes of age, gender, clothing of pedestrians.</p> <p>A focus group involving college students and their STEM experiences.</p> <p>An online anonymous survey studying various types of social media use.</p>



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<p><b>Exempt Category 3 - Benign Behavioral Interventions with Adults</b></p> <p>Research involving benign behavioral interventions in conjunction with the collection of information through verbal or written responses or audiovisual recordings if at least one of the following criteria is met:</p> <p>a) information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects;</p> <p>b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation; or</p> <p>c) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects and if the IRB conducts a limited review for provisions for protecting privacy and maintaining confidentiality.</p> <p>(45 CFR 46 104 (d)(3))</p>	<p>This category does not include minors.</p> <p>Benign behavioral interventions must be brief in duration, harmless, painless and not physically invasive and there is no reason to think the interventions will be offensive or embarrassing.</p> <p>Interventions should not have a last significant adverse impact on the participants.</p> <p>Research involving deception is allowed if the participant is prospectively informed, and agrees to, that they will be unaware of, or misled regarding the nature or purpose of the research.</p> <p><b>Examples include:</b></p> <p>A random assignment of participants to take a test under various noise conditions.</p> <p>A study involving randomly assigning participants to various experimental conditions where they decide how to allocate cash between themselves and others.</p>
<p><b>Exempt Category 4 - Secondary Uses of Identifiable Private Information or Identifiable Biospecimens</b></p> <p>Secondary research for which consent is not required if at least one of the following criteria is met:</p> <p>a) The sources are publicly available; or</p> <p>b) the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to</p>	<p>Many projects involving the secondary use of data/specimens do not meet the definition of a "human subject".</p> <p>This category does not apply to data protected under HIPAA due to UC's hybrid entity status.</p> <p>This category covers re-using identifiable data collected for some other primary purpose or initial activity, or in other words the data must not be collected for the purpose of the specific proposed study.</p>

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<p>the subjects and the investigator does not contact or re-identify the subjects; or</p> <p>c) the research is collected by or on behalf of the federal government using government generated or collected information obtained for non-research activities.</p> <p>(45 CFR 46 104 (d)(4))</p>	<p>If access to the data is “limited” or “restricted” then the data set is not likely publicly available.</p> <p>This category covers data analysis from online repositories where users may pay a “user fee” or needs to register to access the data.</p> <p><b>Examples include:</b></p> <p>A study involving secondary research of audio archives in a public library.</p> <p>An analysis of biospecimens from an IRB-approved biorepository.</p> <p>A study involving review of national census data that contains zip codes.</p>
<p><b>Exempt Category 5 - Public Service Projects</b></p> <p>Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine the following:</p> <p>a) public benefit or service programs; or</p> <p>b) procedures for obtaining benefits or services under those programs;</p> <p>c) possible changes in or alternatives to those programs or procedures; or</p> <p>d) possible changes in methods or levels of payment for benefits or services under those programs.</p> <p>(45 CFR 46 104 (d)(5))</p>	<p>This category is limited to programs designated by a federal department head, such as the Secretary of Health and Human Services.</p> <p>The federal entity conducting or sponsoring the research must publish a list of projects that are covered under this exemption on a publically available website prior to commencing the research involving human subjects.</p> <p>This category is rarely applicable to research at UC Santa Barbara.</p> <p><b>Examples include:</b></p> <p>The US Department of Social Security Administration is charged by Congress with providing periodic reports about the effectiveness of access to benefits under the program and SSA contracts with a researcher to collect data for the report.</p>

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<p><b>Exempt Category 6 - Taste and Food Quality Evaluation and Consumer Acceptance Studies</b></p> <p>Taste and food quality evaluation and consumer acceptance studies, if:</p> <p>a) wholesome foods without additives are consumed; or</p> <p>b) 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.</p> <p>(45 CFR 46 104 (d)(6))</p>	<p>This category is rarely applicable to research at UC Santa Barbara.</p> <p><b>Examples include:</b></p> <p>A study involving consumer acceptance of various brands of frozen meals.</p> <p>A study involving a taste-testing of fruit varieties that do not contain additives to determine consumer preference.</p> <p>A study involving taste-testing of various pork products that have been given feed with a chemical additive, if the researcher can document the additive was at or below the levels approved by the USDA.</p>
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**References:**

45 CFR 46 Regulations

UC Berkeley Policies and Procedures – P&P: FO 302

The Belmont Report