Exemption Determination	
HSC SOP No:	015
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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 6 (six) categories of research activities that may be considered exempt from the regulations, described below.

3.1.2. The categories in this list apply regardless of the age of subjects, except as noted in section 4.2.

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 6 (six) (45 CFR 46.101(b)) 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.
- Observation of the public behavior of children when investigators interact with the children vis-à-vis Category 2.
- Research involving prisoners.
- Research involving the use of protected health information from UC system covered entities.

3.3. **Federal Exempt Categories** (45 CFR 46.101(b))

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

(i) research on regular and special education instructional strategies; or

(ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

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

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

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

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

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

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

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

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

(i) Public benefit or service programs;

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

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

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

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

(i) if 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 Environ-mental Protection Agency or the Food Safety and Inspection Service of the U.S Department of Agriculture.

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

If upon review, the IRB staff reviewer, who also serving as a voting member, or IRB Chair/Designee determines that the proposed research does not meet the criteria for exempt status, 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 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, a new application must be submitted for either expedited or full board review, as appropriate.

If the modification does not change the status of the protocol to non-exempt research, then the researcher should submit a written summary of the changes to the IRB staff to upload to the document to the corresponding protocol.

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 for IRB review to confirm they are meet exemption criteria. Investigators may not make their own determination as to whether a project 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 exempt review procedures, and will provide IRB members with a list of new applications that met the exemption criteria as set forth in 45 CFR 46.101(b). The list is provided monthly via the meeting minutes.
IRB staff may consult with the IRB Chair/Designee, Research Integrity Director, 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 approval 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

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 reviewer will review the application.

The exempt review process may:

- Approve the exempt status;
- Require modifications to secure approval;
- 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 their 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 status, all approved documents, including the protocol approval letter will be made available to the investigator.

References:

45 CFR 46 Regulations

UC Berkeley Policies and Procedures

The Belmont Report