



UNIVERSITY OF CALIFORNIA, SAN DIEGO HUMAN RESEARCH PROTECTIONS PROGRAM

Exemption from IRB Review

A. POLICY

The "Common Rule" (45 CFR 46 subpart A) defines a set of research activities that may be exempt from its purview, unless otherwise required by Department or Agency heads. Exempt research has very little, if any, associated risk.

These research activities, as defined by 45 CFR 46.101(b), include six exempt categories:

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:
 - a. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
 - 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.
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:
 - a. the human subjects are elected or appointed public officials or candidates for public office; or
 - b. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:
 - a. public benefit or service programs;
 - b. procedures for obtaining benefits or services under those programs;
 - c. possible changes in or alternatives to those programs or procedures; or

- d. possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies,
 - a. if wholesome foods without additives are consumed or
 - b. 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.

Policy at UCSD allows the IRB to disallow exemptions that are allowable under federal law. At this time, only exempt categories 1-4 are allowed at UCSD.

Only the IRB Chair or IRB Chair designee, the Director of the Human Research Protections Program, may determine whether a submitted research project meets the requirements for exemption from IRB review. If the research project does not meet criteria for exemption, the PI will be notified and the project will require resubmission for either expedited review or review by the full IRB.

Research that does not qualify for IRB exemption at UCSD if the research includes the following:

1. Prisoners
2. Pregnant women
3. In vitro fertilization
4. Deception
5. Fetuses
6. Decisionally impaired
7. The use of school records of identifiable students or interviewing instructors about specific students
8. Survey or interview procedures with children (participants under the age of 18 years)
9. Observation of public behavior when the investigator(s) participates in the activities being observed
10. Data collected that includes protected health or medical information when there is a direct or indirect link that would identify the participant
11. Sensitive aspects of the participant's own behavior, such as illegal conduct, drug use, sexual behavior or use of alcohol
12. **Review of UCSD/VA San Diego Healthcare System medical records**
13. FDA research except in emergency circumstances

B. EXEMPT REVIEW PROCESS

The IRB Chair or the Director of the HRPP can require expedited or full review of any research at his/her discretion, even if the research would otherwise qualify for exempt review status. The decision to actually grant exempt review status is initially made by the Chair or HRPP Director. The Chair or the HRPP Director must review the full set of documents submitted by the investigator in reaching a decision during an exempt review.

If it is determined that exempt review is appropriate for a study or one of the other activities described above, and the Chair or HRPP Director wishes to utilize this procedure, the IRB Chair or HRPP Director will document his/her determination of risk. The review is then performed by the IRB Chair or Director.

The Principal Investigator must submit the following documents to the HRPP for consideration of exempt review: [Cover Sheet for Exempt Status Application](#); [Biomed Standard Face Sheets](#) or [Social and Behavioral Application Face Sheet](#) including appropriate signatures; [Research Plan for Exempt Categories 1, 2, and 3](#) or [Research Plan for Exempt Category 4](#); additional protocol materials such as consent, survey, interview questions, etc., as needed; and any other information known to be relevant.

When a study has been certified as exempt from IRB review, continuing review and approval is not required. Certification of Exemption is effective for the life of the study. However, all modifications to a study that has been certified exempt must be submitted to the IRB for prospective review and certification of exemption prior to implementation. In some circumstances, changes to the protocol may disqualify the project from exempt status.

If it is determined that the proposed study is exempt, the Principal Investigator will be provided with a Certificate of Exemption that will include under what category of exemption the study was granted. If it is determined that the proposed study is not exempt *or* additional information is needed to determine exempt status *or* certification is granted pending acceptance of requested modifications/clarifications, the Principal Investigator will be notified of this information in written form.

C. Applicable Regulations

[45 CFR 46.101\(b\)](#)

[21 CFR 56.104\(c\)](#)

D. Helpful Links and References

[OHRP Human Subjects Regulations Decision Charts](#)

[OHRP Guidance on Research Involving Coded Private Information or Biological Specimens](#)