

University of California, San Diego
Human Research Protections Program
Institutional Review Board
Standard Operating Policies and Procedures

Section 3.9
Exemption from IRB Review

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.

The IRB Chair and/or the IRB Chair's designee 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. FDA research except in emergency circumstances
13. Research that requires review by the UCSD Embryonic Stem Cell Research Oversight (ESCRO) Committee.

Procedures

The IRB Chair or the IRB Chair's designee will determine whether a submitted research project meets the requirements for exemption from IRB review. The IRB Chair or the IRB Chair's designee 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 IRB Chair or the IRB Chair's designee, who must review the full set of documents submitted by the investigator in reaching a decision during an exempt review.

The Principal Investigator must submit the following documents to the HRPP for consideration of exempt review: [Cover Sheet for Exempt Status Application](#); [Exempt Status Facesheets](#) 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.

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

The IRB Chair or the IRB Chair's designee will evaluate research determined to be exempt to ensure that it meets University of California, San Diego ethical standards. Such an evaluation might include the following:

1. The research holds out no more than minimal risks to subjects.
2. Selection of subjects is equitable.
3. If there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data.
4. If there are interactions with subjects, there will be a consent process that will disclose such information including a) that the activity involves research; b) a description of the procedures; c) that participation is voluntary; d) name and contact information for the investigator; and e) there are adequate provisions to maintain the privacy interests of the subjects. A sample of a consent document/wording is provided [here](#).

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.

For projects that include "existing" data, documents, records, pathological specimens, or diagnostic specimens, "existing" is defined as data, documents, records, pathological specimens or diagnostic specimens that exist prior to the date the Exempt Status Facesheets are submitted to the HRPP database. The Research Plan for project associated with existing data, documents, records, pathological specimens, or diagnostic specimens projects will include the specific dates of the records to be reviewed. An amendment may not be used to

revise the project to include a later date. If a later date is being requested, a complete “NEW” application must be submitted.

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.

The IRB is informed of exemption determinations in the summary of HRPP letters and actions since the last meeting that is available as part of the IRB agenda.

Applicable Regulations

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

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

Links and References

[OHRP Human Subjects Regulations Decision Charts](#)

[OHRP Guidance on Research Involving Coded Private Information or Biological Specimens Cover Sheet for Exempt Status Application](#)

[Exempt Status Facesheets](#)

[Research Plan for Exempt Categories 1, 2, and 3](#)

[Research Plan for Exempt Category 4](#)

[Sample Informed Consent/Wording for Exempt Project](#)