



Guidance and Procedure: Level of Review - Certification of Exemption from IRB Review (last updated March 14, 2014)

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Overview

The OHRPP is responsible for reviewing the preliminary determinations of exemption by investigators and for making the final determination and certification.

Research investigators who intend to involve human research subjects cannot make the final determination of exemption and may not initiate research involving human subjects that the investigator believes is exempt until the investigator has received written documentation of the exempt determination from the OHRPP. Evaluation and certification of exempt status is performed by the OHRPP in consultation with the IRB.

Human subjects research protocols that are certified by the UCLA OHRPP to be exempt from IRB review have a limited 5 year certification period. Researchers are required to request continuing review and certification of exemption for projects that continue after 5 years and to close out the study when research activities are complete.

Which Studies Involving Human Participants are Exempt

Research activities in which the only involvement of human subjects falls within one or more of the categories outlined at [45 CFR 46.101\(b\)](#) may qualify for exemption from review by the IRB.

[Click here](#) for a complete list of the exempt categories.

UCLA policy allows the OHRPP/IRB to disallow exemptions that are allowable under federal policy.

Important Notes:

- **Many social science research projects may fall within the exempt categories, however very few biomedical research projects will be exempt.**
- None of these exemption categories apply to research involving prisoners (45 CFR 46.101(i)(footnote 1)).
- Categories 1-5 do not apply to FDA regulated research.
- Under 45 CFR 46.201(b), the exemption categories apply to research involving pregnant women, human fetuses and neonates.
- None of these exemption categories apply to research that involves derivation and use of human embryonic stem cells, human embryonic germ cells, or human adult stem cells from any source, including somatic cell nuclear transplantation.
- Under FDA regulations at 21 CFR 56.104(c), the emergency use of test articles is exempt from IRB requirements. However, the OHRPP review process described in this guidance is not designed to meet the requirements related to emergency use of test articles. [Click here](#) for more information about the handling of this exemption.

Additional Guidance Regarding Application of Select Exempt Categories

- **45 CFR 46.101(b)(1) - Educational research proposals may qualify for exemption from IRB review if ALL of the following conditions are met:**
 - All of the research is conducted in a commonly accepted educational setting (e.g., private or public school).
 - The research involves normal educational practices (e.g., comparison of instructional techniques).
 - The study procedures do not entail a significant deviation in time or effort from those educational practices already existent in the study site.
 - The study procedures do not involve an increase in the level of risk or discomfort beyond normal, routine educational practices.
 - The study procedures do not involve sensitive topics such as sexual behavior of individual subjects.
 - Provisions are made to ensure the existence of a non-coercive environment for all students, including those who choose not to participate.
 - The school or other institution grants written approval for the research to be conducted.
- **45 CFR 46.101(b)(2) - Based on 45 CFR 46.401(b), the above exemption category applies to research with children ¹ as follows:**
 - Research involving the use of educational tests is exempt
 - Research involving survey or interview procedures is *not* exempt
 - Research involving observations of public behavior is exempt only when the investigator does not participate in the observed activities

¹ In California, a child gains majority at age 18 or upon marriage. Pregnancy does not confer majority status. See [UCLA OHRPP Guidance and Procedure: Research Involving Children and Minors](#) for additional information.

Observational research involving sensitive aspects of subjects' behavior, or in settings where subjects have a reasonable expectation of privacy, does not qualify for exemption from IRB review.

Collection of individually identifiable information qualifies for exemption under this category as long as that information would not cause harm to the individual if it were known (for example, recording observations of everyday public behavior, or interviewing people about non-controversial opinions or preferences).

Research involving deception does not qualify for exemption from IRB review. It may be important in some research to withhold the specific theoretical purpose of the research from subjects, in order not to bias their opinions. If done in a neutral way, withholding such information would not be considered deceptive. If subjects are intentionally led to believe that the research is for a purpose different than the actual purpose, this would be considered deceptive.

- **45 CFR 46.101(b)(4)** - All materials that will be used to conduct the research must already exist at the time the research is proposed, as signified by the date the protocol was submitted for review via webIRB.

How to Request Certification of Exemption

Researchers are required to request review and certification of exemption by using the webIRB application for the following:

- **New projects.** All human subjects research projects must be submitted to the OHRPP for prospective review and certification of exemption prior to implementation.
- **Modifications.** All modifications to a project that has been certified exempt from IRB review must be submitted to the OHRPP for prospective review and certification of exemption prior to implementation. In some circumstances, changes to the protocol may disqualify the project from exempt status.
- **Continuing Review.** For research which is not completed within five years, the principal investigator is responsible for submitting a continuing review application with sufficient time prior to the expiration of the current exemption certification so that there will be no lapse in certification.
- **Closeout.** The principal investigator is responsible for submitting a continuing review application **within 30 days** of completion or termination of all research activity for a study to provide a final report and request that the IRB close its research records.

Click here for [Materials Required for IRB Review and Approval](#).

Investigator responsibilities after certification:

- **Reminder Notices.** As a courtesy, the OHRPP emails the principal investigator a reminder with a link to the webIRB website 90 days prior to the exempt expiration date. Investigators bear ultimate responsibility for making sure that there is no lapse in exempt certification.

- **Expiration of Exempt Status.** If the study expires before a continuing review application is certified, all enrollment, data collection and analysis of private, identifiable information must stop by the day after the study expires.

OHRPP Criteria for Review of Exempt Applications

In reviewing the research, the OHRPP will consider the criteria for exemption of all applicable laws, regulations, codes, and guidance, and will give proper consideration to:

- the risks to the subjects (in particular that the research presents no more than minimal risk),
- the protection of subjects' privacy interests,
- the confidentiality of private identifiable information,
- the anticipated benefits to the subjects and others,
- the importance of the knowledge that may reasonably be expected to result,
- the process of recruitment and selection of subjects, and
- the informed consent process to be employed.

Exempt applications are assessed to ensure the research will be conducted in accordance with [The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research](#) (April 1979).

The criteria for continuing review are the same as those for initial review.

How Certification of Exemption Determinations are Provided

When the protocol is submitted for review via webIRB, it will automatically be assigned a protocol ID number. The application will be reviewed within approximately 5 to 7 business days and the investigator will be promptly notified via webIRB regarding the determination.

Using the [UCLA OHRPP Exempt Reviewers Checklist](#), the IRB Administrators and Exempt Coordinators are authorized to independently review and make one of the following determinations:

- **Certification of Exemption:** The reviewer determines that the protocol qualifies under one or more of the exemption categories; the project is certified exempt from IRB review with no changes required. An exemption notice is issued which specifies the exemption category(ies). The investigator is sent notification via webIRB that their project has been certified as exempt from IRB review.
- **Additional information needed to determine exempt status:** The reviewer will communicate requests for additional information to the investigator via webIRB, email or telephone. Upon receipt of the additional information, the reviewer determines whether the research activities qualify under one or more of the exemption categories.
- **Certification of Exemption, contingent upon the reviewer's acceptance of requested modifications and/or clarifications:** The reviewer will notify the investigator of the requested revisions via webIRB, email or telephone. Upon receipt of the investigator's response, the reviewer determines if the revisions are sufficient. If the reviewer determines the revisions are insufficient, the investigator may be asked to make additional

modifications. This process will repeat until the reviewer determines whether the research activities qualify under one or more of the exemption categories.

- **Referred for IRB Review:** If the reviewer determines that the project does not qualify for exemption from IRB review, the reviewer will notify the investigator in writing (generally via webIRB or email) that the request for exemption from IRB review has been denied. The reviewer will reassign the protocol to the appropriate IRB for either expedited or full committee review.
- **Not Human Subjects Research:** If a reviewer determines that the project does not meet the definition of "research" and/or does not involve "human subjects", the reviewer will provide the investigator with a "Not Human Subjects Research" determination letter via webIRB.
- **Not Engaged in Human Subjects Research:** If a reviewer determines that UCLA is not "engaged" in a human subjects research protocol, the reviewer will provide the investigator with a "UCLA Not Engaged in Human Subjects Research" determination letter via webIRB.

Recordkeeping Responsibilities

UCLA OHRPP:

- The OHRPP maintains record of all exemption determinations, including those that are denied or determined to be Not Human Subjects Research. Records include:
 - webIRB application and appended recruitment and consent documents, data collection materials and instruments, and funding proposal if applicable.
 - Communications between the OHRPP reviewer(s) and the investigator and key personnel.
 - Copies of study-related correspondence between the IRB and other entities, including regulatory authorities, other review committees and study subjects.
 - Any additional documents deemed appropriate on a case-by-case basis.
- Records of applications submitted are maintained in the OHRPP office for at least three years after closure or completion of human research activities.

Investigator: The investigator is responsible for:

- Maintaining records of all certified Exempt documents and correspondence which must include at minimum the webIRB application, funding proposal, screening, recruitment and consent documents, data collection materials and instruments, documentation of subject eligibility and participation and a copy of all signed consent forms unless waived by the IRB.
- Retain records for a minimum of three years past the close of the study, a minimum of six years for studies involving PHI, and any other sponsor requirements. Records of applications submitted in webIRB maintained indefinitely in electronic webIRB archives remain accessible to the investigator.
- Making all research records accessible for review by authorized representatives of the IRB and/or the department or agency supporting or conducting the research to ensure proper performance of the study and compliance with federal regulations and institutional policies

- Maintaining confidentiality of stored records in accordance with the IRB-approved protocol.

Persons Authorized to Make Exemption Determinations

Research investigators who intend to involve human research subjects cannot make the final determination of exemption and may not initiate research involving human subjects that the investigator believes is exempt until the investigator has received written documentation of the exempt determination from the OHRPP.

The OHRPP is responsible for reviewing the preliminary determinations of exemption by investigators and for making the final determination. Evaluation and certification of exempt status is performed by designated OHRPP staff, in consultation with the IRB Chair(s).

OHRPP staff and IRB Chair(s)/designees do not participate in any review of exemption requests in which they have a conflict of interest. (See OHRPP Guidance and Procedure: [IRB Member Conflict of Interest](#)).

Questions

Direct questions about how to submit an application for Certification of Exemption to:

- (310) 825-7122 or gcirb@research.ucla.edu

Contact **one** of the following with requests that the OHRPP reconsider a denied request for Certification of Exemption:

- OHRPP Associate Director Alison Orkin
(310) 206-3969 or aorkin@research.ucla.edu
- OHRPP Director Kip Kantelo
(310) 825-5855 or kip.kantelo@research.ucla.edu

Regulations & References

DHHS Regulations & Guidance

- Categories of exempt research: [45 CFR 46.101\(b\)](#)
- Applicability of exempt categories to research involving pregnant women, human fetuses, and neonates: [45 CFR 46.201\(b\)](#)
- Applicability of exempt categories to research involving children: [45 CFR 46.401\(b\)](#)
- [Guidance on 45 CFR 46.101\(b\)\(5\), Exemption for Research and Demonstration Projects on Public Benefit and Service Programs.](#)
- [Exempt Research and Research That May Undergo Expedited Review.](#)
- [Exempt Research Determination – FAQs](#)

FDA Regulations

- Exemptions from IRB Review: [21 CFR 56.104\(c\) and \(d\)](#)