UCLA OHRPP
Office of the Human Research Protection Program

# Guidance and Procedure: Level of Review - Certification of Exemption from IRB Review (last updated April 12, 2019)



## Overview

***The 2018 Revised Common Rule does not include any changes to allow researchers to certify their own study as exempt from IRB review.***

The OHRPP is responsible for making the determination and certification of exemption from IRB review.

Research investigators 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.

## Which Studies Involving Human Participants are Exempt

Effective January 21, 2019, the Revised Common Rule ("2018 Rule") includes eight categories, outlined at 45 CFR 46.104(d).

Research activities in which the only involvement of human subjects falls within one or more of the categories outlined at 45 CFR 46.104(d) may qualify for exemption from review by the IRB.

**Click here for a complete list of the exempt categories outlined in the 2018 Rule.**

NOTE: Applications Certified Exempt prior to January 21, 2019 were certified under the six categories outlined in the pre-2018 Rule at 45 CFR 46.101(b). **Click here** for the pre-2018 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 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.

## 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.

- **Continuing Review.** Effective January 1, 2019, human subjects research protocols that are certified by the UCLA OHRPP to be exempt from IRB review no longer have an expiration date. Protocols that were certified exempt ***prior to*** January 1, 2019 that have an expiration date should submit a continuing review if the research is ongoing at the time of expiration. At that time, the continuing review process will result in an updated certification without an expiration date.

- **Closeout**. The principal investigator should submit a closure report ***within 30 days*** of completion of all research activity.

Click here for Materials Required for IRB Review and Approval.

**Investigator responsibilities after certification:**

**Modifications. Only for studies that the OHRPP has certified as exempt,** researchers can make *minor* changes to the study without notifying the OHRPP. However, significant changes must be submitted to the OHRPP. See examples below.

**Examples of significant changes: Submit to the OHRPP**

- Adding a new subject population
- Adding new procedures
- Adding a new funding source
- Adding questions about sensitive aspects of the participants' behavior – such as illegal conduct, drug use, sexual behavior or use of alcohol – to a survey or interview
- Change in Principal Investigator (PI)

- Disclosure of a new financial interest
- Any change that makes the study no longer eligible for Certification of Exemption

**Examples of minor changes: Do not submit to the OHRPP**

- Editorial or administrative revisions to consent documents or other study documents
- Adding non-sensitive questions to a survey or interview or revising current questions
- Adding a new recruitment material that follows IRB guidelines
- Increasing or decreasing the number of participants, unless you are adding a new participant population
- Study team/personnel changes (except a change in PI)

## OHRPP Criteria for Review of Exempt Applications

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

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

**Limited IRB Review (2018 Revised Common Rule)**

The 2018 Revised Common Rule introduced a new requirement for Limited IRB review for certain exemption categories. In limited IRB review, the IRB must determine that certain conditions, specified in the regulations, are met. [45 CFR 46.109(a) and 46.109(f)(1)(ii)]

The webIRB smartform is designed to collect from researchers the information about privacy and confidentiality that is necessary for the OHRPP to perform limited IRB review.

Limited IRB review is performed for all UCLA applications for certification of exemption.

## 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 participants.
  - Any additional documents deemed appropriate on a case-by-case basis.

- Records of certified exempt applications are maintained in the OHRPP office for at least three years after last annual Principal Investigator Assurances are completed.

**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 participant 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 completion of the study, a minimum of six years for studies involving PHI, and any other sponsor requirements. Records of applications submitted in webIRB maintained in electronic webIRB archives remain accessible to the investigator at least three years after last annual Principal Investigator Assurances.

- 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 Certified Exempt webIRB submission.

## 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

Direct requests that the OHRPP reconsider a denied request for Certification of Exemption to:

- (310) 825-5344 or gcirb@research.ucla.edu

## Regulations & References

### *DHHS Regulations & Guidance*

- Revised Common Rule Q & As
- Categories of exempt research: 45 CFR 46.104(d)
- 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)Overview of Changes to Exemptions in the Revised Common Rule (Video)
- Regulatory Options for Secondary Research with Private Information and Biospecimens Part 1 (Including Discussion of Exemptions 4, 7 and 8) (Video)
- Regulatory Options for Secondary Research with Private Information and Biospecimens Part 2 (Video)
- 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)

**Change history:**
7/5/2018: Edited Director contact information.
4/12/2019: Updated to reflect January 1, 2019 procedure change for no expiration date and updated regulatory references to reflect Revised Common Rule (effective January 21, 2019).