UCLA Research Administration
Human Research Protection Program

Guidance and Procedure: Level of Review - Certification of Exemption from IRB Review (last updated July 15, 2022)

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 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,
- for research falling under Exempt category 3, the process to wherein participants prospectively agree to the intervention and data collection, and
- when applicable for research that falls under Exempt category 3 and proposes to deceive participants about the nature or purposes of the research, the process by which participants prospectively authorize the deception.

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)]

OHRPP will collect, from researchers, the information about privacy and confidentiality that is necessary 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, 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 the IRB electronic submission system regarding the determination.

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 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 the IRB electronic submission system, 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 the IRB electronic submission system, 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 the IRB electronic submission system 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 the IRB electronic submission system.

- **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 the IRB electronic submission system.

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:
  - IRB electronic submission system application and appended study 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 IRB application, funding proposal,

- 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 the IRB electronic submission system will be maintained as electronic archives, 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 IRB 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).
07/15/2022: Added Appendix I; removed references to webIRB; and updated links.

Appendix I – List of Exemption Categories – 2018 Rule

The UCLA OHRPP will apply these categories to Certify protocols are exempt from IRB review AFTER January 21, 2019.

Exempt status applies to research activities in which the *only* involvement of human subjects will be in one or more of the following categories:

Use of exemption categories for research subject to the requirements of subparts B, C, and D.
Application of the exemption categories to research subject to the requirements of 45 CFR part 46, subparts B, C, and D, is as follows:

1. Subpart B. Each of the exemptions at this section may be applied to research subject to subpart B if the conditions of the exemption are met.

2. Subpart C. The exemptions at this section do not apply to research subject to subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

3. Subpart D. The exemptions at paragraphs (d)(1), (4), (5), (6), (7), and (8) of this section may be applied to research subject to subpart D if the conditions of the exemption are met. Paragraphs (d)(2)(i) and (ii) of this section only may apply to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph (d)(2)(iii) of this section may not be applied to research subject to subpart D.

Exemption Category #1

Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exemption Category #2

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if *at least one* of the following criteria is met:

i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a *limited IRB review*.

Exemption Category #3

Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a *limited IRB review*.

For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which

the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Exemption Category #4

Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

i. The identifiable private information or identifiable biospecimens are publicly available;

ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with applicable federal privacy standards found in the E-Government Act, Privacy Act and the Paperwork Reduction Act.

Exemption Category #5

Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security

Act, as amended. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

Exemption Category #6

Taste and food quality evaluation and consumer acceptance studies: if wholesome foods without additives are consumed, or 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.

Exemption Category #7

Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §__.111(a)(8).

Exemption Category #8

Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

i. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §__.116(a)(1) through (4), (a)(6), and (d);

ii. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §__.117;

iii. An IRB conducts a limited IRB review and makes the determination required by §__.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and 479

iv. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from any legal requirements to return individual research results.