

**Guidance and Procedures Number: 5**

**Title: HRPP Review Process - Certification of Exemption from IRB Review**

**Date of Last Revision: February 26, 2009**

## **I. Exemption Review Eligibility**

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.

### **Important Notes:**

- 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.<sup>1</sup>
- Under 45 CFR 46.201(b), the exemption categories below apply to research involving pregnant women, human fetuses and neonates.
- The research 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 OPRS review process described in this guidance is not designed to meet the requirements related to emergency use of test articles. For more information about the handling of this exemption, see [HRPP Guidance and Procedure 36: Emergency Use of a Test Article](#).

**45 CFR 46.101(b)(1):** Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

- (1) Research on regular and special education instructional strategies, or
- (2) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Educational research proposals may qualify for exemption from IRB review if all of the following conditions are met:

- (a) All of the research is conducted in a commonly accepted educational setting (e.g., private or public school).
- (b) The research involves normal educational practices (e.g., comparison of instructional techniques).
- (c) The study procedures do not entail a significant deviation in time or effort from those educational practices already existent in the study site.
- (d) The study procedures do not involve an increase in the level of risk or discomfort beyond normal, routine educational practices.

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<sup>1</sup> See [HRPP Guidance and Procedure 34: FDA Requirements](#) for details about whether research is FDA-regulated.

- (e) The study procedures do not involve sensitive topics such as sexual behavior of individual subjects.
- (f) Provisions are made to ensure the existence of a non-coercive environment for all students, including those who choose not to participate.
- (g) The school or other institution grants written approval for the research to be conducted.

**45 CFR 46.101(b)(2):** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

- (1) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; *and*
- (2) 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.

**Based on 45 CFR 46.401(b), the above exemption category applies to research with children <sup>2</sup> 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

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)(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 category 45 CFR 46.101(b)(2), if:

- (1) the human subjects are elected or appointed public officials or candidates for public office; or

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<sup>2</sup> In California, a child gains majority at age 18 or upon marriage. Pregnancy does not confer majority status. See [HRPP Guidance and Procedure #21: Special Populations: Children](#) for additional information.

- (2) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

**45 CFR 46.101(b)(4):** Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available<sup>3</sup> 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.

**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 of the principal investigator's signature on the HS-7 Form.**

Research involving access to UCLA medical records does not qualify for exemption from IRB review.

**45 CFR 46.101(b)(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:

- (1) public benefit or service programs;
- (2) procedures for obtaining benefits or services under those programs;
- (3) possible changes in or alternative to those programs or procedures; or
- (4) possible changes in methods or levels of payment for benefits or services under those programs.

Based on OHRP (previously OPRR) guidance, the following criteria must be satisfied to invoke the exemption for research and demonstration projects examining "public benefit or service programs." OPRS will consult with the Federal funding agency regarding these conditions before invoking this exemption.

- (a) The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act);
- (b) The research or demonstration project must be conducted pursuant to specific federal statutory authority;
- (c) There must be no statutory requirement that the project be reviewed by an Institutional Review Board (IRB); and
- (d) The project must not involve significant physical invasions or intrusions upon the privacy of participants.

**45 CFR 46.101(b)(6) and 21 CFR 56.104(d):** Taste and food quality evaluation and consumer acceptance studies:

- (1) If wholesome foods without additives are consumed, or
- (2) 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 containment at or below the level found to be safe, by the FDA or approved by the EPA or the Food Safety and Inspection Service of the USDA.

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<sup>3</sup> The term "publicly available" means that the general public can obtain the data/biological specimens. Sources are not considered "publicly available" if access to the data/specimen source is limited to researchers.

## **II. OPRS Assessment of the Research**

In reviewing the research, the OPRS 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.

Additionally, all human subjects research will be assessed to ensure that it is conducted in accordance with [The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research](#) (April 1979).

## **III. Responsibility for Review and Determination**

The OPRS is responsible for reviewing the preliminary determinations of exemption by investigators and for making the final determination. 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 OPRS. Evaluation and certification of exempt status is performed by the OPRS in consultation with the IRB. In general, the IRB Administrator performs exempt review. However, the IRB Chairs, designated IRB members, Director, Assistant Directors, and Administrators may review and approve claims of exemption submitted by investigators. The IRB Chair, a designated IRB member, Director or Assistant Director will provide guidance to the IRB Administrator as needed.

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

When a study has been certified exempt from IRB review, continuing annual review is not required. Certification of Exemption is effective for the life of the project. (See also Section V below, *Modifications to an Exempt Protocol*.)

## **IV. Exemption Review Process**

The IRB Administrator (or other designated reviewer) will enter the protocol into the OPRS exemption database and assign the application a number for tracking purposes. The application will be reviewed within approximately 5 to 7 working days and the investigator is promptly notified via email regarding the determination.

The IRB Administrator (or other designated reviewer) may make one of the following determinations:

- A. **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. The exemption category(ies) is documented in writing on the HS-7 Form and exemption is confirmed by signature and date of the reviewer. The investigator is notified in writing (generally via email) that their project has been certified exempt from IRB review. The investigator is provided with a certified copy of their application which includes the official OPRS "Certified Exempt" stamp on the cover page, and the OPRS authorized signature and date on the last page.
- B. **Additional information needed to determine exempt status:** The reviewer will communicate requests for additional information to the investigator via 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.
- C. **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 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.
- D. **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 email) that the request for exemption from IRB review has been denied. The reviewer will either forward the HS-7 application to the IRB for expedited or full review or ask the investigator to resubmit the research project using the Application to Involve Human Subjects in Research. The decision regarding whether the Application to Involve Human Subjects in Research is required is made in consultation with the appropriate Administrator and/or Chair for the IRB that will be responsible for the review of the protocol.
- E. **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 notify the investigator in writing (generally via email) that the project does not require UCLA IRB review and approval or Certification of Exemption from IRB review.
- F. **Not Engaged in Human Subjects Research:** If a reviewer determines that UCLA is not "engaged" in a human subjects research protocol, the reviewer will notify the investigator in writing (generally via email) that the project does not require UCLA IRB review and approval or Certification of Exemption from IRB review.

## V. Modifications to an Exempt Protocol

All modifications to a project that has been certified exempt from IRB review must be submitted to the OPRS for prospective review and certification of exemption prior to implementation. In some circumstances, changes to the protocol may disqualify the project from exempt status.

## **VI. Materials for Review**

The following materials are provided to the reviewer for claim of exemption applications:

### **A. Initial Review**

1. List of Exemption Categories
2. Completed Claim of Exemption from IRB Review Application
3. Recruitment materials, if applicable
4. Informed consent documents, if applicable
5. Data collection instruments, if applicable
6. Any additional documents provided by the investigator

### **B. Modifications to an Exempt Protocol**

1. Application cover page signed by the investigator
2. Letter from investigator explaining the proposed modifications
3. Relevant modified study documents
4. Any additional documents provided by the investigator
5. Current study file

### **Regulations:**

45 CFR 46.101(b)  
45 CFR 46.101(i)(footnote 1)  
45 CFR 46.201(b)

45 CFR 46.401(b)  
21 CFR 56.104(c) and (d)

### **References:**

- OHRP, *Compliance Oversight Activities: Significant Findings and Concerns of Noncompliance*, October 12, 2005. <http://hhs.gov/ohrp/compliance/findings.pdf>
- OHRP (formerly OPRR), *Exemption for Research and Demonstration Projects on Public Benefit and Service Programs*. <http://www.hhs.gov/ohrp/humansubjects/guidance/exmpt-pb.htm>
- OHRP (formerly OPRR), *Exempt Research and Research That May Undergo Expedited Review*, May 5, 1995. <http://www.hhs.gov/ohrp/humansubjects/guidance/hcdc95-02.htm>