

University of California, Los Angeles  
OFFICE FOR PROTECTION OF RESEARCH SUBJECTS

**Guidelines for Submitting a Claim of Exemption from  
Institutional Review Board (IRB) Review**

University policy requires that approval to involve human subjects in research be obtained **prior** to initiation of a research activity involving UCLA personnel, time, facilities, resources, and/or students, by submitting an Application to Involve Human Subjects in Research or a Claim of Exemption from IRB Review Form to the Office for Protection of Research Subjects for review.

Exemption categories are specific, follow federal guidelines (Title 45 CFR Part 46), and are listed on the attached page. Your research must fit into one or more of the listed categories in order to file the Claim of Exemption from IRB Review Form (HS-7 Form).

**Checklist for Exemption Submission**

Please submit **two complete sets** (original and one copy) of the following materials to the OPRS office (please note that an incomplete submission may delay the processing of your application):

1. Claim of Exemption from IRB Review Form (HS-7 Form)  
*The application must include the principal investigator's signed assurance, along with the signature of a Faculty Sponsor who agrees to sponsor the PI (if the PI is a student or a fellow). **The form must be typed.** The application should be written in clear, jargon-free language, understandable to people outside of the researcher's field.*
2. Recruitment materials (*e.g., advertisements, recruitment flyers, recruitment scripts, etc.*)
3. Informed consent document(s)<sup>1</sup> (*e.g., information sheet, informed consent script, survey cover letter, etc.*)
4. Research instruments (*surveys, questionnaires, interview and focus group protocols, etc.*)

**Please submit two copies of your application to:**

*On campus:*  
Office for Protection of Research Subjects  
11000 Kinross Avenue, Suite 102  
Campus Mail Code 169407

*Off campus:*  
Office for Protection of Research Subjects  
11000 Kinross Avenue, Suite 102  
Box 951694  
Los Angeles, California, 90095-1694

**If you have any questions, please contact:**

Wendy Brunt, Administrator  
Tel: (310) 825-7122  
Fax: (310) 794-9565  
Email: [wbrunt@oprs.ucla.edu](mailto:wbrunt@oprs.ucla.edu)

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The requirement to obtain subjects' **signed** informed consent may be waived, provided that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

### **Checklist for Submitting Amendments to Certified Exemptions**

Please submit **two complete sets** (original and one copy) of the following materials to the OPRS office (please note that an incomplete submission may delay the processing of your application):

#### **Required:**

1. Page 1 of the HS-7 Form – signed by the principal investigator (and faculty sponsor, if applicable)
2. Explanatory cover letter – signed by the principal investigator  
*The cover letter should: (a) provide a summary of the modifications made to the protocol, contact documents and/or instruments, and (b) describe the reason(s) for the modifications.*

#### **As Applicable:**

1. Modified HS-7 Form  
***When to submit a revised HS-7 Form:*** *For proposed amendments which result in new recruitment or study procedures, such as a change in the inclusion/exclusion criteria, please submit a REVISED copy of the HS-7 Form which reflects the proposed modifications in all applicable sections. Please submit two copies of the modified HS-7 Form: (a) please bold/underline added text or proposed changes AND please show all deleted text using strikethrough markings (e.g., ~~strikethrough~~) on one copy, and (b) please provide a "clean" (unmarked) copy.*
2. New/modified recruitment materials
3. New/modified informed consent documents
4. New/modified instruments

## EXEMPTION CATEGORIES

None of these exemptions apply to research involving prisoners. Categories 1-5 do not apply to FDA-regulated research. **It is the prerogative of the Office for Protection of Research Subjects to prohibit exemptions that are allowable under federal policy** (45 CFR §46.101(b)).

Exempt status applies to research activities in which the only involvement of human subjects will be in one or more of the following 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:
  - (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
  - (ii) 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.

*The above exemption category applies to research with children 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.*

- (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 (2), if:
  - (i) the human subjects are elected or appointed public officials or candidates for public office; or
  - (ii) 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 that are conducted by or subject to the approval of [federal] department or agency heads, and that are designed to study, evaluate, or otherwise examine:
  - (i) public benefit or service programs;
  - (ii) procedures for obtaining benefits or services under those programs;
  - (iii) possible changes in or alternatives to those programs or procedures; or
  - (iv) possible changes in methods or levels of payment for benefits or services under those programs.

**Please note:** *Federal guidance includes several criteria which must be satisfied to qualify under this category. Please see [OPRS/IRB Policy 5: Certification of Exemption from IRB Review](#) for additional details.*

- (6) Taste and food quality evaluation and consumer acceptance studies,
  - (i) if wholesome foods without additives are consumed, or
  - (ii) 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.