

## **Human Subjects Protection Guidelines for Social Science Research**

(Note: Detailed guidelines on IRB procedures are available at [www.oprs.ucla.edu](http://www.oprs.ucla.edu))

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### **UCLA Policy on the Protection of Human Subjects**

University policy requires that research involving human subjects conducted by or under the direction of UCLA personnel (faculty, staff or students), using any property or facility of the university, extramurally funded or not, regardless of location or research site, must be submitted to the Human Subjects Protection Committee (HSPC) for review and approval. The HSPC is operated by the Office for the Protection of Research Subjects (OPRS), and via three institutional review boards (IRBs) which meet frequently.

This requirement is in compliance with Federal policy governing the protection of research subjects (56FR28003), as stipulated in the Department of Health and Human Services (DHHS) regulations for the protection of human research subjects, 45 CFR Part 46. This policy specifies that the involvement of human subjects in your research will not be permitted until the UCLA IRB has reviewed and approved the research protocol and informed consent has been obtained from the subject(s) or the subject's legal representative. PLEASE NOTE: no UCLA faculty, staff, or students may conduct human subject research without obtaining prospective IRB approval or a certified Claim of Exemption from IRB review PRIOR to commencing their research.

### **Exemption from the Review Process**

Some categories of research are exempt from the HSPC review. However, all researchers need to submit a claim of exemption, form HS 7, to the OPRS. This form is available at: <http://www.oprs.ucla.edu/human/FORMS.htm> A claim of exemption means that a research activity does not require HSPC review and approval. The university, however (OPRS), is still obligated to review all such activities, whether funded or not, and certify that the research meets the federal requirements for a "Claim of Exemption". In order to fulfill federal requirements for the proper review of research, investigators cannot "self-exempt" from this process. The university has determined that evaluation and certification of exempt status is performed by the OPRS in consultation with the HSPC. The Claim of Exemption does not necessarily mean that the investigator is exempted from the informed consent requirements. (Please see Chapter 3, "The HSPC Review Process" and Chapter 4, "Informed Consent Requirements" for more details on the OPRS website: <http://www.oprs.ucla.edu/human/hspcmanual/2Ac.htm#Ch2Ah>) If the activity does not qualify for a Claim of Exemption, the investigator is notified by the OPRS within three working days of submitting the application (please confirm with OPRS as to the exact turn-around time since it may vary depending on the volume of exemption applications they are processing at a given time.)

The following materials are required when submitting a Claim of Exemption:

- Claim of Exemption From HSPC Review - Form HS-7
- An abstract of the research, purpose and objectives of the study, and if the applicant is a student, a signature from a faculty advisor who agrees to sponsor the project;
- Consent forms or a statement indicating that the activity qualifies for a waiver of informed consent under the guidelines outlined in Chapter 4, "Informed Consent Requirements"
- Recruitment materials for the human subjects, i.e., advertisements, flyers, phone scripts, etc. as relevant;
- Approval from participating institutions, i.e., schools or agencies, if applicable.

### **Institutional Review Boards (IRBs) at UCLA**

UCLA has three IRBs charged with the protection of the rights and welfare of human subjects participating in research. Currently, one IRB is primarily responsible for reviewing socio-behavioral research applications, called the General Campus Institutional Review Board (GC-IRB). Two other IRBs, called the Medical Institutional Review Boards 1 and 2 (M-IRB1 and M-IRB2) are primarily responsible for reviewing applications involving medically invasive procedures.

### **Applying for IRB clearance**

The Office for the Protection of Research Subjects (OPRS) has a website which provides the application for IRB clearance. The site includes other material such as a template for informed consent forms (<http://www.oprs.ucla.edu/human/FORMS.htm>), and educational material such as the Investigator's Manual for the Protection of Human Subjects are available from the OPRS and the website: [www.oprs.ucla.edu](http://www.oprs.ucla.edu)

Note: IRB requires TWO complete sets (original and one copy) of the application materials.

## Human Subjects Protection (continued)

### **Required Items in the IRB Application**

IRB clearance requires three core documents:

- 1) The Form HS-1 which is the Application to Involve Human Subjects in Research;
- 2) The informed consent form; and
- 3) Grant proposal.

The Grant proposal should specify the following Research Protocol required by HSPC for their review of your application. Section IV of the HS-Form 1, is acceptable in lieu of a detailed scientific protocol for non-medical research. All applications should include a research protocol that includes a complete explanation of the following information:

- Background of the research
- Objectives
- Significance
- Detailed description of how human subjects will participate in the research
- Eligibility requirements for subjects
- Research Design/methodology
- Analysis of the collected data
- References

### **Period of Applicability and turn-around time for Approval**

The HSPC approves research protocol for a period of one year. If your project will stretch beyond one year, you need to obtain IRB approval at the end of the first year for the subsequent year of research. Two months prior to the expiration of the approval, the HSPC office will send a Continuation form to the primary investigator which will allow your review to proceed for the second year. IRB clearance will not be granted retroactively.

### **Contact Information**

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