

UNIVERSITY OF CALIFORNIA, LOS ANGELES

**APPLICATION TO INVOLVE
HUMAN SUBJECTS IN RESEARCH**

(Form HS-1)

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CODES FOR PROTECTION OF THE RIGHTS AND WELFARE OF HUMAN SUBJECTS IN RESEARCH AT UCLA

The UCLA Human Subject Protection Committee (HSPC) holds the primary responsibility for the oversight of the protection of human subjects recruited to participate or actively participating in research projects conducted by or under the auspices of UCLA.

University policy requires that researchers respect and protect the rights and welfare of individuals recruited for or participating in research conducted by or under the auspices of UCLA. In the conduct of research, actions of UCLA will be guided by the principles as set forth in the Belmont Report (specifically respect for persons, beneficence, and justice).

In accordance with the HSPC Multiple Project Assurance maintained with the Department of Health and Human Services (DHHS), National Institutes of Health (NIH), Office for Protection from Research Risks (OPRR), all human subjects research conducted by or under the auspices of the UCLA will be performed in accordance with Title 45 Code of Federal Regulations, Part 46 (45 CFR 46).

The actions of UCLA will also conform to all applicable federal, State and local laws and regulations.

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SUMMARY GUIDELINES

1. **HSPC Approval:** University policy requires that research^{1[1]} involving human subjects^{2[2]} conducted by or under the direction of UCLA personnel (faculty, students, or staff), using any property or facility of the University, extramurally funded or not, regardless of location, must be submitted to the HSPC for review and approval.

Investigators may not begin recruitment of subjects or initiate research prior to receipt of a written approval notice from the HSPC. All recruiting and consent documents must be approved by the HSPC. **Only documents (i.e., consent form, posters, etc.) bearing the HSPC approval stamp may be used in the conduct of research.**

Investigators may not implement any changes in the approved protocol or consent form without prior HSPC approval obtained by submitting an addendum application to the HSPC.

The HSPC **cannot** approve a protocol for a period longer than one year. In addition, the Committees **cannot** under any circumstances grant retroactive approval. Two months before the expiration date, the HSPC office will send a Continuation form to the investigator of record. Three successive continuations may be requested. After four years (initial year plus three continuation years), a renewal submission is required.

You may not conduct research activities involving human subjects following the expiration of your HSPC approval. The investigator of record holds the primary responsibility for continuation or renewal, without lapse of approval, of his/her research protocol.

2. **Investigational Drugs:** FDA regulations mandate that investigators wishing to study an investigational drug or a biological agent (either an experimental drug, or the use of certain approved drugs for non-FDA-approved use) must submit a Notice of Claimed Exemption for a New Drug (IND) to the FDA and provide the HSPC with the IND number. *Please be advised that the HSPC will not issue approval for recruitment of human subjects until a copy of the IND is provided by the investigator.*

^{1[1]} **Research** is defined by the regulations as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”

^{2[2]} **Human subjects** are defined by the regulations as “living individual(s) about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.”

Summary Guidelines (continued)

UCLA Hospital and Clinics policy requires that the storing and distribution of investigational drugs be routed through the Department of Pharmaceutical Services. Also, if the research is blinded, a copy of the code must be made available to the Pharmaceutical Services. To comply with this policy, please complete Section IV (Investigational Drug Information Record) of this form. A pregnancy test prior to subject enrollment should be considered if the subject population includes women of child bearing potential.

For reasons of clinical care, all HSPC approved protocols involving the administration of drugs will be shared by OPRS with the Department of Pharmacy.

3. **Investigational Medical Devices:** FDA regulations mandate that investigators wishing to study a significant risk investigational medical device must obtain an Investigational Device Exemption (IDE) from the FDA. The HSPC application should include an initial risk assessment (non-significant/significant risk) of the device, made by the investigator or the sponsor, based upon the proposed use indicated in the research protocol. The HSPC will review the research application and make its own risk assessment for the device. If the HSPC concurs with an investigator that a device poses non-significant risk to subjects the project does not require an IDE. If the HSPC states that a device poses significant risk, the investigator (or the sponsor) must obtain an IDE. *Please be advised that the HSPC will not issue approval for recruitment of human subjects until a copy of the IDE is provided by the investigator.*
4. **Cancer-Related Research:** If you propose to conduct cancer related research, your project may be subject to review by the Jonsson Comprehensive Cancer Center-Internal Scientific Peer Review Committee (JCCC-ISPRC). If you need additional information regarding this requirement, please contact the JCCC-ISPRC at x41274.
5. **Research Involving Radiation:** Since the participation of humans in research involving radiation requires special considerations, the HSPC may require the investigator to obtain an approval notice of the Medical Radiation Safety Committee (MRSC) prior to issuing HSPC approval for recruitment of human subjects. If you need additional information regarding this requirement, please contact the Chair of MRSC at x41007.
6. **Controlled Substances:** If the proposed research involves the investigation of either Schedule I or Schedule II controlled substances (narcotics, stimulants, or depressants), the investigator must solicit approval of the Research Advisory Panel of the State of California, 6000 State Building, San Francisco, CA 94102; (415) 356-6212 or 356-6213.

Summary Guidelines (continued)

7. **Research Involving Microorganisms or Recombinant DNA:** If the research involves the use of microorganisms or recombinant DNA procedures, it may require review by the Institutional Biosafety Committee (IBC). The issuance of HSPC approval, however, is not contingent on the IBC approval. Please contact the Biosafety Officer at x63929 for additional information.
8. **Potential Development of Commercial Products from Human Biological Materials:** If any human materials (tumor tissue, bone marrow, blood, etc.) are used for establishing a cell line which may be shared with other researchers and which may in the future be of commercial value, the subject must be informed of the fact in the consent form. See *Sample Consent Form for Medical Research* (Form HS-2) regarding the required disclosure statement to be used in the consent form.
9. **Conflict of Interest Disclosure:** According to UC Policy, informed consent now requires that (a) *“a physician must disclose personal interest unrelated to the patient's health, whether research or economic, that may affect the physician's professional judgment; and (b) a physician's failure to disclose such interests may give rise to a cause of action for performing medical [research] procedures without informed consent or breach of confidentiality.”*

If you have submitted either a Form 730-U, "Principal Investigator's Statement of Economic Interests" for non-governmental funded projects or a Form 740-U, "Investigator's Statement of Financial Interests" for NSF or PHS funded projects to the Office of Sponsored Research, please provide a copy of the form(s) to the HSPC for evaluation. The forms are available through the Office of Sponsored Research. If you need additional information regarding this requirement, please contact the OPRS staff (x55344 or x57122).

10. **Student Health Services:** If the subject population includes the recruitment of students from the Student Health Services (SHS), approval must be obtained from the projects Review Committee of the SHS (x58547). *Please be advised that the HSPC will not issue an approval for recruitment of human subjects until a copy of the SHS Review Committee approval is provided by the investigator.*
11. **Translation of the Consent Form:** An appropriate translation of the HSPC APPROVED consent form must be provided to subjects whose native language is not English and who are poorly versed in the English language. The accurate translation of the HSPC approved consent form is the responsibility of the investigator. In addition, the HSPC will request that you forward a translated consent form to the OPRS.

Summary Guidelines (continued)

- 12. Study of Existing Data, Documents, Records, Pathological Specimens, or Diagnostic Specimens:** Federal regulations stipulate that “*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*” may qualify as exempt from HSPC review. In accordance with the federal guidelines, if the data/biological specimen are collected after the submission of the application, or the information is recorded with direct or indirect identifying links to subjects, the protocol requires HSPC review. For information regarding under what circumstances the study of biological specimens gathered from diagnostic or clinical procedures may be exempt from HSPC review, please see *Investigator’s Manual on Research with Human Subjects*.

If the proposed research involves only this type of activities and requires HSPC review, complete Sections I, II, III, and VII of this form.

- 13. Exemptions:** There are certain categories of research specified in 45 CFR 46.101 (b)1-6 that are exempt from the review of HSPC. To request a claim of exemption, please submit a Claim of Exemption (HS form 7) to the OPRS. Exemption categories are listed in the exemption packet. If you have any questions, please call the General Campus Human Subject Protection Committee at x57122.
- 14. Training Grants:** For a Training Grant, submit a copy of the grant application and an assurance in a letter of transmittal that no funds will be disbursed to individuals proposing to do research involving human subjects until the proposed project has been reviewed and approved by the HSPC.

Program Project/Multiple Project Grants: For a Program Project Grant or Multiple Project Grant, submit a copy of the grant application and a list of those projects proposed/developed under the grant. In addition, principal investigators applying for HSPC approval for Program Project/Multiple Project Grants will need to submit, at the same time, all individual components of the grant which propose to involve human subjects.

Center Grants: For a Center Grant that includes sub-projects, submit a copy of the grant application and an assurance in a letter of transmittal that no funds will be made available to individuals proposing to do research involving human subjects until individual projects have been reviewed and approved by the HSPC.

NOTE: Center Grants, much like Program Projects, may support individual protocols (sub-projects) in addition to the "core" (shared resources). In some instances, only core support is provided in a Center Grant. If sub-projects are to be

Summary Guidelines (continued)

supported by the Center Grant, the HSPC will review the protocols on an individual basis as they are developed. If only core support is provided under the grant, the HSPC will perform an administrative review.