

Guidance and Procedures Number: 18

Title: Approvals From Other UCLA and External Committees

Date of Last Revision: February 26, 2009

I. Overview

Certain types of research require the review and approval of additional compliance committees charged to evaluate scientific validity, subject safety, conflict of interest, etc., in addition to IRB review.

Review and approval may be required from one or more of the following committees prior to IRB approval.

II. Conflict of Interest Review Committee [CIRC]

CIRC is an independent faculty body, advisory to the Vice Chancellor for Research, that reviews investigator financial interests to determine whether real or perceived conflicts of interest may be present. (Please refer to [OPRS/IRB Policy 63: Investigator Financial Interests and Conflicts of Interest](#), [UCLA Policy 150: Conflict of Interest](#), and [UCLA Policy 925: Financial Conflicts of Interest in Research](#) for details.)

III. Institutional Biosafety Committee [IBC]

- A. In accordance with the NIH Guidelines for Research Involving Recombinant DNA Molecules, the IBC reviews and approves uses of recombinant DNA that are listed as "covered" experiments in the NIH Guidelines.
- B. The IBC also reviews and approves the use of Risk Group 2 or 3 infectious agents. Risk Group 4 agents are not allowed at UCLA. Risk group designation of specific organisms and viruses can be determined from Appendix B of the NIH Guidelines or the American Biological Safety Association's Risk Group Classifications for Infectious Agents.
- C. IBC review and approval is required at initial review for studies involving recombinant DNA, transgenic animals or infectious agents.
- D. IBC review and approval is required for human embryonic stem cell research when investigators purposefully place agents (such as vectors, recombinant DNA or pathogens) into cells or when cellular material is put into human subjects (such as clinical trials with vector agents).
- E. IRB approval of all research for which IBC review is required is contingent upon IRB's receipt and acknowledgment of a letter of approval from the IBC.

IV. Internal Scientific Peer Review Committee [ISPRC]

- A. As required by the National Cancer Institute [NCI] and agreed upon by the UCLA Executive Vice Chancellor Charles F. Kennel in a memorandum dated March 10, 1998, the ISPRC conducts a review of scientific merit of all therapeutic and diagnostic cancer trials.
 - 1. UCLA IRBs may also request ISPRC review of research involving cancer patients that does not meet the above criteria.
- B. As outlined in a memorandum dated February 13, 2001, UCLA also requires that all human gene therapy protocols receive favorable ISPRC review prior to final IRB approval.
- C. ISPRC review and approval of all studies which fall within (A) or (B) above is required at initial review, each annual IRB review and when modifications to the protocol are made.
- D. ISPRC review is not required at annual IRB reviews and when modifications are made for studies for which a letter of exemption was issued by the ISPRC at initial review.
- E. ISPRC review is not required at annual IRB review of studies for which remaining activities are limited to long-term survival follow-up only or data analysis only.
- F. IRB approval of all research for which ISPRC review is required is contingent upon the IRB's receipt and acknowledgment of ISPRC approval notice or a letter of exemption issued by the ISPRC.

V. Medical Radiation Safety Committee [MRSC]

- A. The UCLA MRSC is responsible for the evaluation of all proposals that involve the use of radioactive materials and radiation-producing machines intended for human use at UCLA. The MRSC ensures that the University is in compliance with the policies and procedures outlined in the California Code of Regulations, Title 17, and conditions of the UCLA radioactive materials license, #1335-19.
- B. MRSC review is required for research administration of radioactive material or external ionizing radiation to human subjects.
- C. MRSC review and approval of all studies which meet the description in (B) above is required at initial review and anytime the radiation dose is changed.
- D. IRB approval of all research for which MRSC review is required is contingent upon the IRB's receipt and acknowledgment of an approval notice issued by the MRSC.

VI. Embryonic Stem Cell Research Oversight Committee [ESCRO]

ESCRO is the body created pursuant to UCLA policy and California law to oversee research involving human embryonic stem cell (hESC) research. ESCRO reviews new protocols, modifications to currently approved research, and continuing research using hESCs, hESC

lines, any proposed collection and use of germ cells designed to generate hESCs, and any “covered cells” as required by State or Federal law.

VII. UCLA Clinical Engineering

- A. UCLA Clinical Engineering must approve the use of equipment in an area that operates under the hospital's license and/or equipment used on the hospital's patients and research subjects.
- B. Investigators conducting research which involves the use of equipment as described in (A) above must provide written assurance to the IRB that UCLA Clinical Engineering's approval will be obtained prior to the use of such equipment.

VIII. Radioactive Drug Research Committee [RDRC]

- A. UCLA RDRC review and approval is required for research involving the administration of radioactive drugs to human research subjects during the course of a research project intended to obtain basic information regarding the metabolism of a radioactively labeled drug or regarding human physiology, pathophysiology, or biochemistry [21 CFR 361.1].
 - 1. Research intended for immediate therapeutic, diagnostic, or similar purposes OR to determine the safety and effectiveness of the drug in humans for such purposes is NOT considered basic research and must follow the FDA regulations governing clinical investigations.
- B. RDRC review and approval of all studies which meet the description in (A) above is required at initial review and anytime the radioactive drug dose is changed.
- C. IRB approval of all research for which RDRC review is required is contingent upon the IRB's receipt and acknowledgment of a letter of approval from the RDRC.

IX. NIH Recombinant DNA Advisory Committee

- A. In accordance with National Institutes of Health [NIH] guidance, NIH Recombinant DNA Advisory Committee approval is required at initial review of all human gene transfer trials, regardless of funding.
- B. IRB approval of all research involving human gene transfer is contingent upon IRB's receipt and acknowledgment of letter of approval from the NIH Recombinant DNA Advisory Committee.

X. Research Advisory Panel – California [RAP-C]

- A. The State of California mandates the review and approval of all research involving Schedule I Controlled Substances, Schedule II Controlled Substances and all research for the treatment of drug abuse utilizing any drug, scheduled or not by The Research Advisory Panel of California in the State Attorney General's Office.

- B. IRB approval of all research for which RAP-C review is required is contingent upon the IRB's receipt and acknowledgment of a letter of approval from RAP-C at initial review.

Regulations:

45 CFR 46.111(a)
21 CFR 361.1
California Code of Regulations, Title 17
California Health & Safety Code, Section 125300

References:

NIH Guidelines for Research Involving Recombinant DNA Molecules:
<http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>

American Biological Safety Association's Risk Group Classifications for Infectious Agents:
<http://www.absa.org/resriskgroup.html>

NIH Office of Biotechnology Recombinant DNA and Gene Transfer Guidance:
<http://www4.od.nih.gov/oba/Rdna.htm>

Research Advisory Panel of California: <http://caag.state.ca.us/research/>

UCLA Policy 150: Conflict of Interest
http://www.adminvc.ucla.edu/appm/public/app_0150_0.html

UCLA Policy 925: Financial Conflicts of Interest in Research
http://www.adminvc.ucla.edu/appm/entry_900.html

Memorandum dated March 10, 1998 from Charles F. Kennel, Executive Vice Chancellor to UCLA Deans, Chair, Faculty, Research Coordinators and Students

Memorandum dated February 13, 2001, from Gerald S. Levey, M.D., Provost, Medical Sciences and Dean, UCLA School of Medicine and James S. Economou, M.D., Ph.D., Director, UCLA Human Gene Medicine Program