UCLA OHRPP
Office of the Human Research Protection Program

Guidance and Procedure: Approvals from Other UCLA and External Committees (last updated August 10, 2011)

Overview

In addition to IRB review and approval, additional committees charged with evaluating scientific validity, radiation safety, management of financial conflicts of interest and other important aspects of human subject research may be required.

This document describes some of those committees and provides information about the timing of those other committee reviews. When the UCLA IRB relies upon another committee to review scientific validity, that committee review should occur prior to IRB submission.

A Tip Sheet is available for quick reference and for website links and contact information.

UCLA Clinical Engineering

- UCLA Clinical Engineering must approve the use of equipment in an area that operates under the hospital's license and/or equipment used with clinical patients and research subjects.
- UCLA Clinical Engineering is responsible for completing incoming inspections of investigational devices that are used to diagnose, treat or monitor patients at UCLA, but *not* at other hospitals such as Cedars Sinai, Charles Drew, or LA BioMED.
- ***Timing*:** Investigators conducting research with this type of equipment must provide written assurance to the IRB that UCLA Clinical Engineering approval will be obtained prior to use. In some situations, the IRB may request Clinical Engineering review and approval prior to granting IRB approval.

UCLA Conflict of Interest Review Committee (CIRC)

- The CIRC is an independent faculty body, advisory to the Vice Chancellor for Research, which reviews investigator financial interests to determine whether real or perceived conflicts of interest may be present and to recommend ways to manage such conflicts. For more information about UCLA policies related to conflict of interest refer to the UCLA Research Policy and Compliance website.

- The CIRC and IRBs coordinate reviews to ensure that potential conflicts of interest are managed appropriately. Please refer to *OHRPP Guidance and Procedures: Investigator Financial Interests and Conflicts of Interest* for more details about IRB requirements.
- The PI must submit the results of the CIRC review via webIRB as the results may require changes to the IRB application or consent form.
- **Timing:** CIRC review should be conducted ***prior to or in parallel*** with IRB review.

UCLA Embryonic Stem Cell Research Oversight Committee (ESCRO)

- ESCRO is the body created pursuant to UCLA policy and California law to oversee research involving human pluripotent stem cells (hPSCs) including human embryonic stem cells (hESCs) and induced pluripotent stem cells (iPSCs). ESCRO reviews new protocols, modifications to currently approved research, and continuing research using hPSCs, and any "covered cells" as required by State or Federal law.
- ***Timing:*** ESCRO approval should be included with webIRB initial submission as ***IRB review will not occur without such an approval in place***.

UCLA Institutional Biosafety Committee (IBC)

- 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.
- 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.*
- IBC review and approval is required ***at initial review*** for studies involving recombinant DNA, transgenic animals or infectious agents.
- IBC review and approval is required for ***human 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).
- ***Timing:*** IBC approval of covered experiments, as described above, must be submitted via WebIRB ***prior to IRB approval*****.**

UCLA Internal Scientific Peer Review Committee (ISPRC)

The Jonsson Comprehensive Cancer Center ISPRC conducts a review of the scientific merit of a study.

- **I**SPRC review and approval is required ***at initial review, at annual review, and when major modifications*** to the protocol are made for:
    - ***All therapeutic and diagnostic cancer trials***, as required by the National Cancer Institute (NCI).
    - ***Any other cancer-related research*** including the recruitment of individuals with cancer or the collection of specimens from such individuals, or research involving cancer survivors or those at risk of developing cancer.
    - ***All human gene therapy protocols***.

- For study for which the ISPRC issued a letter of exemption at initial review, ISPRC review is ***not*** required at annual IRB review or for modifications made to these studies .

- ***Timing:*** ISRPC approval or ISPRC letter of exemption should be submitted via webIRB ***prior to IRB review***, as any scientific design changes required by the ISPRC must be finalized prior to IRB submission. However, reviews may occur in parallel though ISPRC review is required ***prior to IRB approval***.

UCLA Medical Radiation Safety Committee (MRSC)

- The UCLA MRSC is responsible for the evaluation of all research 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.

- MRSC review is required at the time of initial review and when the radiation dose is changed for research administration of radioactive material or external ionizing radiation to human subjects.

- ***Timing:*** Reviews may occur in parallel but MRSC approval must be submitted via WebIRB ***prior to IRB approval***.

UCLA Radioactive Drug Research Committee (RDRC)

- 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 research information*** regarding the metabolism of a radioactively labeled drug or regarding human physiology, pathophysiology, or biochemistry (21 CFR 361.1).

- RDRC review and approval of such studies is required at ***initial review and when the radioactive drug dose is changed***.

- 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***.*** Such ***uses of unapproved radioactive drugs require an IND application to be approved by the FDA***.

- ***Timing:*** Reviews may occur in parallel but RDRC approval must be submitted via WebIRB ***prior to IRB approval***.

NIH Recombinant DNA Advisory Committee (RAC)

- In accordance with National Institutes of Health (NIH) guidance, NIH Recombinant DNA Advisory Committee (RAC) review is required at initial review of all human gene transfer trials, regardless of funding.

- Because RAC conducts scientific review of the study, investigators should not submit an IRB application until the RAC review has occurred. As UCLA IBC approval is also required for human gene transfer trials, the timing of these three reviews requires careful planning on the part of the investigator.

- ***Timing:*** The recommendations from RAC must be submitted via WebIRB prior to IRB review and approval.

State of California Research Advisory Panel (RAP-C)

- 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.

- ***Timing:*** Although reviews may be conducted in parallel, the RAP-C letter of approval must be submitted via WebIRB prior to IRB approval.

Regulations and References

UCLA

- Tip Sheet: Determining When Approvals Are Needed from Other UCLA and External Committees

- American Biological Safety Association's Risk Group Classifications for Infectious Agents

California Regulations

- California Code of Regulations, Title 17, Subchapter 4: Rules for Conducting [Human] Research
- California Health & Safety Code, Section 125300: Derivation and use of human embryonic stem cells, human embryonic germ cells and human adult stem cells, including somatic cell nuclear transplantation
- State of California, Department of Justice: Research Advisory Panel of California

DHHS Regulations

- 45 CFR 46.111(a): Criteria for IRB approval of research

Food and Drug Regulations

- 21 CFR 361.1: Radioactive drugs for certain research uses

National Institutes of Health Guidance

- NIH Guidelines for Research Involving Recombinant DNA Molecules
- NIH Office of Biotechnology Recombinant DNA and Gene Transfer Guidance