UCLA Research Administration
Human Research Protection Program

Guidance and Procedure: Approvals from Other UCLA and External Committees (updated January 21, 2022)

Overview
UCLA Clinical Research Finance – Coverage Analysis
UCLA Clinical Engineering
UCLA Conflict of Interest Review Committee (CIRC)
UCLA Human Pluripotent Stem Cell Research Oversight Committee (hPSCRO)
UCLA Institutional Biosafety Committee (IBC)
UCLA Internal Scientific Peer Review Committee (ISPRC)
UCLA Medical Radiation Safety Committee (MRSC)
UCLA Radioactive Drug Research Committee (RDRC)
State of California Research Advisory Panel (RAP-C)

Contact Information and Timing of Review

Regulations and References

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.

A table below is available for quick reference and for website links and contact information.

UCLA Clinical Research Finance (Coverage Analysis)

- Coverage Analysis is a financial review that is required for any clinical research study requiring UCLA Health System resources, including but not limited to any patient care costs.

- ***Timing***: Coverage Analysis may occur in parallel to the IRB review and documentation of the coverage analysis is not required prior to IRB approval but must be completed prior to study activation.

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 Procedure: Investigator Financial Conflict of Interest for more details about IRB requirements.

- The PI must submit the results of the CIRC review via online IRB submission 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.

Human Pluripotent Stem Cell Research Oversight (hPSCRO) Committee

- hPSCRO 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). hPSCRO 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:*** hPSCRO approval may be obtained prior to submission to IRB review or in parallel with the IRB review.

UCLA Institutional Biosafety Committee (IBC)

- In accordance with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid 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 for the American Biological Safety Association's Risk Group Classifications for Infectious Agents.*

- IBC 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 the online system ***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.

- ISPRC 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.
- 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 may occur in parallel with IRB review, however, documentation of ISPRC approval in the IRB online submission system is only required for UCLA Investigator Initiated projects for which the JCCC DSMB has oversite. This requirement is limited to the initial ISPRC approval and for amendments requiring changes to the protocol. Aside from this small subset of studies, documentation of ISPRC approval is not required for 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 obtained ***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 obtained ***prior to IRB 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:*** IRB approval should be obtained prior to submitting to the RAP-C.

Contact Information and timing of review

Committee	Timing of review	Who can I contact If I have questions?
UCLA Clinical Research Finance (Coverage Analysis)	Clinical trials and clinical research studies must obtain coverage analysis review at initial and continuing review. See: UCLA Policy 915	CoverageAnalysis@mednet.ucla.edu https://www.researchgo.ucla.edu/coverage-analysis-and-budget
Clinical Engineering	PI must provide assurance that Clinical Engineering approval will be obtained prior to use of equipment.	Barbrow David, Director, Clinical Engineering (310) 26**7-9000** dbarbrow@mednet.ucla.edu
Conflict of Interest Review Committee (CIRC)	CIRC review may be conducted in parallel or prior to IRB review. PI must submit CIRC review results via IRB's online submission.	circadmin@research.ucla.edu UCLA Research Policy & Compliance website
CTSI Scientific Review Committee (SRC)	CTSI SRC review must be conducted prior to IRB review. PI must submit application via the IRB's online submission.	https://www.researchgo.ucla.edu/feasibility-guidance-and-scientific-review
Human Pluripotent Stem Cell Research Oversight Committee (hPSCRO)	hPCRO review and approval must take place before IRB review. hPSCRO approval should be obtained prior to IRB approval.	hPSCRO website
Institutional Biosafety Committee (IBC)	IBC review should be conducted in parallel with IRB review. PI must submit IBC approval via IRB online submission prior to IRB approval.	Phone: (310) 794-0262 Email: oibc@research.ucla.edu UCLA IBC website
Internal Scientific Peer Review Committee (ISPRC)	ISPRC may be conducted prior to or in parallel with IRB review. PI must submit ISPRC letter of approval for UCLA Investigator Initiated studies subject to JCCC DSMB at initial review and protocol amendments prior to IRB approval.	JCCC ISPRC website
Medical Radiation Safety Committee (MRSC) **Radioactive Drug Research Committee (RDRC)**	MRSC and/or RDRC review should be conducted in parallel with IRB review. MRSC or RDRC approval is required prior to IRB approval.	UCLA Radiation Safety Committees website Application for MRSC or RDRC review are now submitted in the IRB's online system. Details here.

Research Advisory Panel (RAP-C), State of California	PI must submit to RAP-C after obtaining IRB approval.	RAP-C website

Regulations and References

UCLA

- UCLA Policy 915: Clinical Studies Coverage Analysis
- American Biological Safety Association's Risk Group Classifications for Infectious Agents
- CTSI Scientific Review Committee
- OHRPP Guidance and Procedure: Gene Transfer Therapy/Recombinant DNA

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 or Synthetic Nucleic Acid Molecules

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Change Log:
09/23/2021: Added table of timing of ancillary review and contact information and removed the tip sheet; Added coverage analysis information; Renamed ESCRO to hPSCRP; Removed information on gene therapy protocols require review from ISPRC; Timing of ISPRC has changed to happen in parallel to IRB review; Timing of RAP-C has changed to happen after IRB approval has been obtained; Removed information on NIH RAC; removed references to webIRB; updated links.
01/21/2022: Clarified that RAP-C approval must be obtained after IRB approval.