**Scientific Review Frequently Asked Questions**

1. **What is the NIH definition of a clinical trial?**

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

1. **How does the PI determine if their study meets the definition of an NIH clinical trial?**

**The study meets the NIH definition of a clinical trial if the answers to ALL of the following questions are YES:**

* Does the study involve human participants?
* Are the participants prospectively assigned to an intervention?
* Is the study designed to evaluate the effect of the intervention on the participants?
* Is the effect being evaluated a health-related biomedical or behavioral outcome?

**The study is considered to meet the NIH definition of a clinical trial even if:**

* The study uses healthy participants, or does not include a comparison group (e.g., placebo or control)
* The study is only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug
* The study utilizes a behavioral intervention
* The study uses an intervention for the purposes of understanding fundamental aspects of a phenomenon (See [more information about Basic Experimental Studies with Humans](https://grants.nih.gov/policy/clinical-trials/besh.htm)).

**The study is NOT considered to meet the NIH definition of a clinical trial if:**

* The study is intended solely to refine measures.
* The study involves secondary research with biological specimens or health information.
	+ Please see the [NIH Clinical Trial Decision Tool](https://grants.nih.gov/ct-decision/index.htm) for more information.
1. **What are examples of studies that are considered to be NIH clinical trials?**

The NIH has many examples of studies that do and do not meet the NIH definition of a clinical trial: <https://grants.nih.gov/policy/clinical-trials/case-studies.htm>.

1. **What if the PI still can’t tell if their study meets the definition of an NIH clinical trial?**

 Please contact the SRC administrator at uclasrc@mednet.ucla.edu.

1. **Do all studies need a UCLA internal scientific review?**

No.

* All cancer studies are reviewed by the JCCC Internal Scientific Peer Review Committee, a longstanding campus policy that is unchanged by UCLA Policy 916.
* For non-cancer studies, a UCLA internal scientific review must be conducted **ONLY** for studies that meet the NIH definition of a Clinical Trial AND have not already received external scientific review. This is a small minority of studies.
1. **How does the PI submit to the SRC?**

IRB applications are automatically forwarded to the SRC for review. No additional applications or submissions are needed. If your study does not meet the requirements for SRC review, but you still wish to have the study reviewed, please email the SRC at uclasrc@mednet.ucla.edu.

1. **When does the SRC meet and what are the SRC submission deadlines?**

Please see the SRC website for current meeting dates and deadlines at: https://www.researchgo.ucla.edu/office-regulatory-affairs

1. **The PI’s study underwent external scientific review, but the PI does not have written documentation.**

If your study has been reviewed and approved for funding by any of the following agencies, written documentation is NOT needed and your study will be automatically excluded from SRC review:

1. U.S. Department of Health & Human Services (HHS) Agencies, including:
* National Institutes of Health (NIH)
* Administration For Children and Families (ACF)
* Food and Drug Administration (FDA)
* Centers for Disease Control (CDC)
* Centers for Medicare & Medicaid Services (CMS)
* Agency for Healthcare Research and Quality (AHRQ)
* Substance Abuse and Mental Health Services Administration (SAMHSA)

### Agency for Toxic Substances and Disease Registry (ATSDR)

### Health Resources and Services Administration (HRSA)

* + Indian Health Service (IHS)

### National Science Foundation (NSF)

1. U.S. Department of Defense (DOD)
2. U.S. Department of Energy (DOE)
3. U.S. Department of Justice (DOJ)
4. U.S. Environmental Protection Agency (EPA)
5. Veterans Administration (VA)
6. California Institute for Regenerative Medicine (CIRM)
7. American Heart Association
8. American Kidney Foundation

Please note that this list will be updated on a regular basis. If you have recommendations for additional agencies that should be added to this list, please contact the SRC administrator at uclasrc@mednet.ucla.edu.

**9. What if the PI’s clinical trial was reviewed or approved by the IRB prior to UCLA Policy 916?**

Clinical trials reviewed or approved by the IRB prior to UCLA Policy 916 will be exempt from the new scientific review process.

1. **How does the new process for Scientific Review Committee differ from those under the pilot review that has been ongoing for the last 4 years?**

 The scope of studies that require scientific review has been significantly narrowed. As a result, the number of studies that require scientific review has been reduced. For example, studies that do not meet the definition of an NIH clinical trial and non-interventional trials will no longer be reviewed by the scientific review committee.

1. **What is the oversight for the Scientific Review Committee?**

The metrics associated with the Scientific Review Committee (# of studies reviewed, turn-around time for review, impact on study activation, % of studies with major comments) will be provided to the UCLA Health Sciences Executive Compliance Oversight Committee.

1. **What are the outcome options for SRC review?**
2. Exempt from SRC review
3. Approved (No changes required)
4. Approved (Minor changes recommended). This approval is given when the science is sound; but, the Committee has recommendations about ways the study could be improved. The PI may choose to modify their IRB application and their protocol to include these recommendations, but modification is not required.
5. Not-Approved (Major changes required). There are significant scientific concerns that the PI must address before the study may proceed. The PI will be asked to update their protocol and their IRB application. All revisions will be reviewed by the SRC before approval is issued.
6. **How will the SRC communicate with Principal Investigators?**

The SRC will send approvals only through the IRB Electronic Submission System.

Correspondence will be sent via email and through the IRB Electronic Submission System.

1. **How quickly will a response be reviewed?**

The SRC typically reviews responses within 2 business days. The review may take longer if the response requires full Committee review. If it requires full Committee review, the response will be scheduled for review at the next SRC meeting.

1. **What should be done if the PI strongly disagrees with the Scientific Review Committee feedback?**
2. Reach out to the SRC administrator at ucalsrc@mednet.ucla.edu to request a meeting. The SRC Administrator will work with you to see if a meeting with the SRC Chair may be helpful.
3. In the DGSOM, escalate your concern to your Division Chief and Chair, who can then escalate to the Vice Dean for Research.
4. PIs who do not report through the DGSOM, should escalate to the Department Chair, Vice Dean for Research, or Dean.
5. **What other approvals may the studies need?**

**Institutional Review Board (IRB)**

Approval must be obtained before the study may be conducted: <https://ohrpp.research.ucla.edu>

**UCLA Clinical Research Finance (Coverage Analysis)**

Clinical trials and clinical research studies must obtain coverage analysis review at initial and continuing review.

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.

circadmin@research.ucla.edu

**Human Pluripotent Stem Cell Research Oversight Committee (hPSCRO)**

hPSCRO review and approval must take place before IRB review.

<https://stemcell.ucla.edu/oversight-review>

**Institutional Biosafety Committee (IBC)**

oibc@research.ucla.edu

<https://rsawa.research.ucla.edu/ibc/>

IBC review should be conducted in parallel with IRB review.

IBC approval is required prior to IRB approval.

**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.

<https://rsawa.research.ucla.edu/rsc/>

**Research Advisory Panel (RAP-C), State of California**

RAP-C review should be conducted in parallel with IRB review.

RAP-C approval is required prior to IRB approval.

https://oag.ca.gov/research

1. **I have more questions, whom can I contact?**

Please contact the SRC Administrator at uclasrc@mednet.ucla.edu.