UCLA Policy 916: Clinical Trial Protocol Review and Approval by an Independent Scientific Review Committee

Issuing Officer:	Vice Chancellor for Research and Creative Activities
Responsible Department:	Office of Clinical Research
Effective Date:	June 30, 2022
Supersedes:	New

I. PURPOSE & SCOPE

The purpose of this Policy is to establish a process for the required review and approval of Clinical Trial Protocols by an internal, independent scientific peer review committee. Scientific review and approval is required for studies that meet the National Institutes of Health (NIH) definition of a Clinical Trial and that have not already been reviewed by an external scientific review committee. This scientific review is intended to complement the Institutional Review Board (IRB) review through a detailed review of the required elements of the clinical protocol, statistical applications, adequacy of research staffing, any competing trials, well-constituted data collection forms, and utilization of institutional resources.

This Policy applies to studies proposed by:

1. A Principal Investigator(s) within one of the Schools under the UCLA Health Sciences (Medicine, Nursing, Dentistry) OR
2. Any UCLA Principal Investigator whose study requires access to UCLA Health patients, resources, or services (e.g., UCLA health data, investigational pharmacy, laboratory medicine, imaging, clinical space, etc.). Refer to FAQs for more guidance.

II. DEFINITIONS

For the purposes of this Policy:

Clinical Trial as defined by the NIH is 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. Refer to the NIH Clinical Trial Decision tool (https://grants.nih.gov/ct-decision/index.htm).

Health-Related Biomedical or Behavioral Outcome as defined by the NIH is the pre-specified goal(s) or condition(s) that reflects the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and positive or negative changes to quality of life.

Intervention as defined by the NIH is a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and diagnostic strategies.

Principal Investigator is defined in UCLA Policy 900.

Prospectively Assigned as defined by the NIH is a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters).

Protocol is a document that can serve as an effective resource for communicating the science, methods, and operations of a Clinical Trial, to guide training and accountability of study staff, to allow for efficient review by peers and oversight bodies, to ensure adherence to the International Conference on Harmonisation (ICH) E6 Good Clinical Practice guidelines (https://ichgcp.net/6-clinical-trial-protocol-and-protocol-amendments), and to guide replication studies.

Responsible Party refers to Principal Investigator(s) or their designee(s).

III. POLICY STATEMENT

A. All studies that meet the NIH definition of a Clinical Trial and have not been reviewed by an external scientific review committee and that meet one of the two requirements below must be reviewed and approved by an internal independent scientific review committee when:

   1. The Principal Investigator is affiliated with one of the schools under the UCLA Health Sciences (Medicine, Nursing, or Dentistry) OR

   2. Any UCLA Principal Investigator that proposes a study that requires access to UCLA Health patients, resources, or services (e.g., UCLA health data, investigational pharmacy, laboratory medicine, imaging, clinical space, etc.) regardless of the PI's campus affiliation. Refer to FAQs for more guidance.

B. Protocol review and approval will occur as follows (see Attachment A: Scientific Review Committee (SRC) Review Criteria and Workflow):

   1. For cancer Clinical Trials, the UCLA Jonsson Comprehensive Cancer Center's Internal Scientific Peer Review Committee (ISPRC) will conduct the review.

   2. For non-cancer Clinical Trials that have undergone documented external scientific review by a research sponsor or the FDA, no additional review is needed unless:

      i. UCLA Health requires scientific review to access limited resources, services, and patient populations that require prioritization or assessment of feasibility.

      ii. The IRB refers the study to one of the internal scientific review committees based on their review process.

   3. For non-cancer Clinical Trials that have not already been reviewed by an external scientific review committee, UCLA's internal, independent Scientific Review Committee (SRC) will conduct the review with staff support from the campus Clinical and Translational Science Institute. The SRC review will follow the NIH intramural review standards (NIH standard).

IV. PROCEDURES

1. **Protocol Creation:** A Protocol must be developed for all studies that meet the NIH definition of a Clinical Trial and have not already undergone a scientific review. Protocol templates are available for both FDA-regulated Clinical Trials as well as studies that include behavioral or social science

interventions. Information and support for Protocol development can be found online (https://www.researchgo.ucla.edu/protocol-development). Also, see UCLA Policy 917: Good Clinical Practice Training and Certification for additional requirements.

2. **Protocol and Study Submission:** Electronic applications including a Protocol are submitted through the UCLA IRB Electronic Submission System.

3. **Scientific Review Process:**

   a. Submissions that are marked as cancer-related will be reviewed and approved by the ISPRC prior to IRB approval. Please refer to the Internal Scientific Peer Review Committee (ISPRC) within the Jonsson Comprehensive Cancer Center.

   b. Non-Oncology Clinical Trials that have documented review by an external scientific review committee (e.g., NIH, FDA, etc.) will be exempted automatically from the UCLA SRC process.

   c. Non-Oncology Clinical Trials that have not undergone review by an external scientific review committee (e.g., NIH, FDA, etc.) will be reviewed and approved by the UCLA SRC prior to IRB review. The IRB Electronic Submission System will route the study to the SRC and indicate that the status of the application is "In Scientific Review."

      i. The SRC administrator will exempt and release to the IRB studies that do not require SRC review.

      ii. Studies that require review, will be scheduled for the SRC and assigned to reviewers with an initial review timeline goal of less than two (2) weeks.

      iii. SRC review outcomes include the following statuses: Approved (Exempted); Approved (No changes required); Approved (Minor changes recommended) and; Not-Approved (Major changes required).

      iv. The SRC administrator will record "Approved" statuses in the IRB Electronic Submission System, and the application will be routed immediately to the IRB for review.

      v. For studies that are "Not Approved," the SRC administrator will communicate with Responsible Party to advise that major changes are needed. The Responsible Party is expected to respond within thirty (30) days of the communication in order to initiate re-review.

      vi. If the Responsible Party does not respond to the "Not-Approved" communication requiring major changes, or does not request an extension within thirty (30) days of the date of the communication, the study will be withdrawn from scientific review.

V. REFERENCES

1. UCLA Policy 900: Principal Investigator Eligibility
2. UCLA Policy 917: Good Clinical Practice Training
3. UCLA IRB Electronic Submission System

VI. ATTACHMENTS

A. Scientific Review Committee (SRC) Review Criteria and Workflow

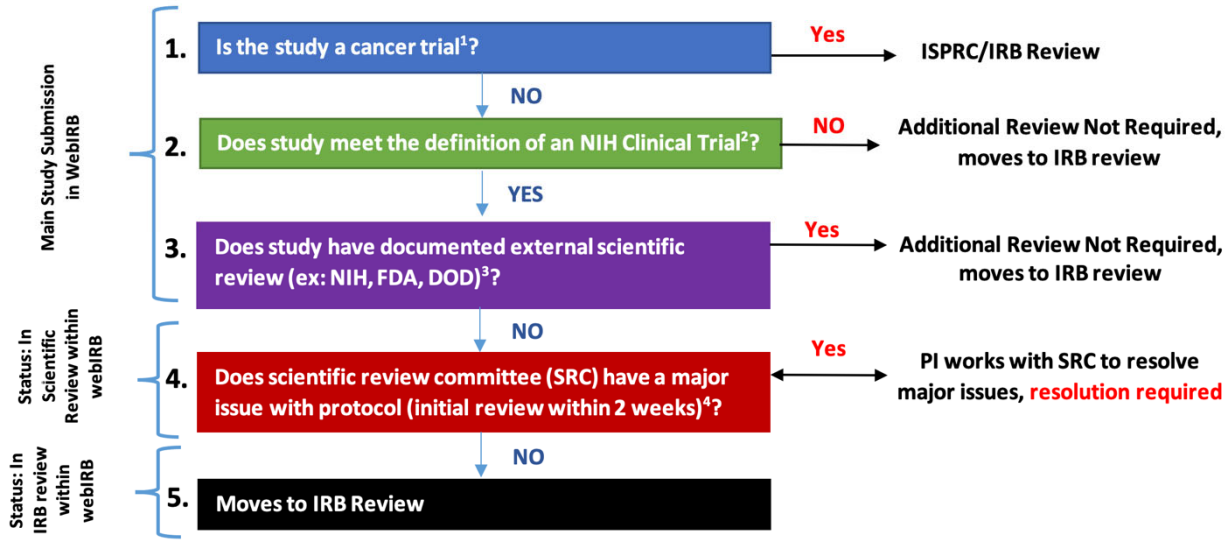
Issuing Officer

/s/ Roger Wakimoto

Vice Chancellor for Research & Creative Activities

Questions concerning this policy or procedure should be referred to the Responsible Department listed at the top of this document.

Scientific (Protocol) Review Policy Criteria and Workflow



[1] This will be determined by an answer to an existing question in the IRB Electronic Submission System that has been in use for many years.

[2]This will be determined via responses provided by the Principal Investigator to questions in the IRB Electronic Submission System modeled after the NIH Decision Tool using four (4) questions to determine if the study meets the definition of an NIH Clinical Trial. A Protocol must be uploaded for review if a study meets the NIH definition of a Clinical Trial. Incorrect responses to these questions will lead to delays in study activation that will be attributed to the PI.

[3]This will be determined automatically for sponsors that are known to require peer review. For other sponsors this will be determined based on the responses provided by the Principal Investigator to a question about documented external scientific review in the IRB Electronic Submission System. The UCLA Office of Compliance Services will conduct audits of responses to this question. UCLA Health may request to review this documentation prior to rendering services and allowing access to patient populations. Incorrect responses to this question will lead to delays in study activation that will be attributed to the PI.

[4]SRC review will be a status in the IRB Electronic Submission System. Final disposition and review time will be tracked as part of the study activation process and as a key performance indicator. Major and Minor Correspondence will be sent from the SRC committee directly to the Principal Investigator. Studies with Major Correspondence issues will require resolution prior to IRB review.