Feasibility Guidance and Scientific Review

Feasibility Analysis

The purpose of Feasibility Analysis is to evaluate studies involving human subjects for feasibility. If required by your Division, Department, or Organization, PIs, Sub-Investigators, or Study Coordinators may conduct a Feasibility Analysis using the Clinical Trial Feasibility Checklist tool. For industry sponsored clinical trials, you may complete the "Sponsor Expectations" section of the checklist and include any additional information as appropriate.

For sponsor-investigator clinical trials (investigator-initiated), you may conduct a Feasibility Analysis using the Sponsor-Investigator Initiated Clinical Trial Feasibility Checklist.

Feasibility analysis is not required at UCLA but is included as part of the Clinical and Translational Science Institute (CTSI) Scientific Review Committee (SRC) review process. Please visit Cohort Finding for more information.

Scientific Review

Scientific or scholarly review of human subjects research protocols is required before an Institutional Review Board (IRB) can approve a human research study, to ensure that the following regulatory criteria for approval of research are met. Regulations 45 CFR 46.111(a) and 21 CFR 56.111(a) are quoted below:

1. "Risks to participants are minimized (i) By using procedures consistent with sound research design and which do not unnecessarily expose participants to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.

Currently there are two groups that provide formal scientific review at UCLA:

Jonsson Comprehensive Cancer Center (JCCC) Internal Scientific Peer Review Committee (ISPRC)

The Internal Scientific Peer Review Committee reviews clinical oncology protocols conducted by JCCC investigators. Drs. John Glaspy and Albert Lai serve as Co-Chairmen of the ISPRC. Under their direction, the committee reviews the required elements of the clinical protocol, statistical applications and other factors such as adequate research staffing, any competing trials, well-constituted data collection forms and utilization of other JCCC resources.

Clinical and Translational Science Institute (CTSI) Scientific Review Committee (SRC)

Established in September 2016 and formally mandated in July 2022, the UCLA Scientific Review Committee (SRC) provides a scientific and feasibility review for non-oncology 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.

Last updated: 29 Jul 2025

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