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 UCLA Clinical Trial Feasibility Checklist tool. For industry trials, you may complete the “Sponsor Expectations” section of the checklist and include any additional information as appropriate.

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 Feasibility and Cohort Finding for more information.

Scientific Review

Scientific or scholarly review 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.

In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research.) The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall with the purview of this responsibility.”

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)

The CTSI Scientific Review Committee reviews non-oncology clinical trial protocols conducted by School of Medicine investigators. Drs. John Adams and Noah Federman serve as the Chair and Vice Chair of the SRC. Under their direction, the committee reviews the required elements of the clinical protocol, statistical design, enrollment goals, feasibility (including adequate research staffing, competing trials, funding, resources, and departmental support).

The degree of review required varies based on the type of research, funding, and institutional factors. CTSI SRC review will be conducted on those clinical trial protocols that have not already received full peer review. Please email the CTSI SRC with any questions.

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• Group 1
  ▪ Clinical Research Information Systems
  ▪ Clinical Research Business Partners
• Group 2
  ▪ Office of Research Administration
  ▪ Jonsson Comprehensive Cancer Center
• Group 3
  ▪ Office of Human Subjects Protection
  ▪ CareConnect Website

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