UCLA Research Administration
Human Research Protection Program

Guidance: Scientific or Scholarly Review of Human Subjects Research Protocols (August 12, 2011)

Introduction and Background

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."

For the majority of studies being reviewed and approved by the UCLA IRB, the IRB itself has traditionally performed this review, with a few exceptions.

Criteria for Scientific or Scholarly Review

The regulations quoted above provide the regulatory requirements for scientific or scholarly review. The following guidelines provide examples of questions to consider when reviewing for scientific or scholarly merit. Please note that not all questions are relevant for every study and there may be additional questions to ask for any given study. The following are *suggestions* but not requirements of what to consider.

Sound Scientific Basis and Rationale: Is the protocol scientifically sound and based on well-established scientific principles? Is there convincing clinical and/or preclinical evidence that the trial will have valuable results? Do preclinical studies demonstrate promising results regarding safety and potential efficacy? Is the technology/ understanding sufficiently advanced to warrant detailed clinical investigation?

Appropriateness of the Proposed Study Design: Are the primary and secondary objectives scientifically sound? Is the study designed to meet the objectives? Has an appropriate study configuration been chosen? Are patient populations and associated criteria for inclusion/exclusion well defined? Are the sample sizes appropriate? Is the statistical design appropriate? Are the endpoints clearly defined? Does the protocol distinguish between standard and/or routine care and research?

Competency of Personnel and Adequacy of Proposed Resources: Does the principal investigator have the appropriate expertise and experience to conduct this study? Does the investigative team bring sufficient expertise to the project? Is there sufficient access to resources (e.g., appropriate personnel, equipment, facilities) for the successful and safe conduct of this study?

Options for Reviews

UCLA IRB

- Scientific or scholarly review performed by the IRB is not designed to serve as a peer review intended to maximize scientific quality, but is designed to meet the regulatory criteria outlined above. Scientific/scholarly review is performed by the members of the IRB reviewing the study, and is based on the Criteria Required by Federal Regulations for IRB Approval of a Human Research Study.
- If the IRB does not believe it has the appropriate expertise to review a particular study, then it will call upon the help of an outside consultant who does have the appropriate expertise.
- The UCLA IRBs will continue as they have in the past to provide scientific or scholarly review of expedited studies. With rare exceptions, the IRB may request an outside review of an expedited study.

An External Funding Agency

There are various external funding agencies that conduct scientific or scholarly review according to commonly accepted standards. A few examples include but are not limited to the Alzheimer's Disease Research, American Cancer Society, Cystic Fibrosis Foundation, Deafness Research Foundation, The Education Research Trust Award, Muscular Dystrophy Association, National Heart Foundation, National Glaucoma Research, Pew Scholars Program in Biomedical Sciences, Searle Scholars, and several UC funding programs.

An Internal Scientific Review Committee

The Jonsson Comprehensive Cancer Center Internal Scientific Peer Review Committee (ISPRC) is an example of an internal scientific review committee. Other internal review committees may be added to this list. Please call the UCLA OHRPP Director at 310-825-5855 to discuss this matter.

Faculty Sponsors for Student Research

Faculty sponsors may provide scientific or scholarly review of expedited and exempt student-initiated studies.

UCLA Clinical and Translational Science Institute

The Office of Investigator Services (OIS) of the UCLA CTSI provides assistance and guidance in research project development. The mission of this office is to provide expert consultation to investigators on all aspects of their project in areas such as study methodology and design, translational technologies and IRB submissions.

Department of Defense Supported Research

Department of Defense supported research must meet additional requirements for scientific review. Click here for additional information.

Coordinating with IRB Review

If the investigator wants the IRB to consider external scientific or scholarly review, evidence of scientific review must be included with the webIRB application. Otherwise, the IRB will conduct the scientific or scholarly review.