



## Guidance: Referral to the IRB Executive Committee

(last updated February 26, 2009)

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### Overview of Referral Process

While the UCLA Academic Policies and Procedures clearly states in *Policy 991: Protection of Human Subjects* that “The IRB has sole authority to grant IRB approval for human Research applications. If the IRB does not grant IRB approval or suspends or terminates IRB approval, these decisions may not be overturned at any higher level,” there is an avenue by which investigators or subjects may appeal an IRB decision or determination. This document describes the process of referral and review by the IRB Executive Committee. Likewise, a UCLA IRB may also refer its decision or determination to the IRB Executive Committee.

### Overview of IRB Review Process

The review of applications to involve human subjects in research consists of a process of communication and negotiation between the investigator and the IRB. The IRB communicates concerns and suggestions regarding human subject protection issues to investigators following each step of its review. In accordance with federal regulations, IRB communications regarding the approval, disapproval or modifications required to secure IRB approval of research activities are in the form of written correspondence. [[45 CFR 46.109\(d\)](#)] and [[21 CFR 56.109\(e\)](#)] Investigators are asked to provide a written response to correspondence from the IRB. As a part of the response, an investigator has the option to question and/or disagree with the IRB’s concerns and suggestions. However, in such instances, investigators must provide sufficient justification for their position.

If the IRB and investigator remain at an impasse after two written responses have been reviewed during convened meetings of the IRB, the IRB will invite the investigator to respond in person at a convened meeting of the IRB. If final resolution over pending issues is not met after meeting with the full Board, an investigator may choose to request review by the Executive Committee. Additionally, if the IRB has terminated or suspended the research, an investigator may request review by the Executive Committee.

Additionally, if after the IRB has reviewed and processed a complaint by a subject or any other complainant and the complainant is dissatisfied with the results of the review, the subject or complainant may also ask that the Vice Chancellor for Research also review the outcome. The Vice Chancellor would refer the complaint and the outcome of the IRB review to the Executive Committee.

### Executive Committee Review

- A UCLA investigator, a subject or other complainant, or a reviewing IRB may refer a case to the Executive Committee

- An investigator may submit a request for Executive Committee review to the Vice Chancellor for Research if the research activity is not approved after submitting two rounds of correspondence to the full Board and after meeting in-person at a convened meeting of the reviewing IRB, or if the research has been terminated or suspended by the IRB. All requests to the VCR must be in writing and include sufficient justification for an appeal.
- A subject or other complainant may refer the outcome of an IRB review of the complaint to the Vice Chancellor for Research.
- A reviewing IRB may choose at any time to refer any matter before it for review by the Executive Committee.
- The Vice Chancellor for Research's role in the process is to review the written request and to determine whether there are grounds for convening the Executive Committee.
- The membership of an Executive Committee will be determined by the Vice Chancellor for Research based on the nature of the appeal, the type of research involved and the ongoing scientific or ethical concerns.
  - The membership of an Executive Committee may be drawn from the three medical IRBs, the two General Campus IRBs, or all five IRBs.
  - An Executive Committee may also include one faculty member chosen on an *ad hoc* basis.
  - An Executive Committee may obtain outside expert consultation as needed.
- The charge of an Executive Committee is to review the history of a given case, examine the concerns of both the reviewing IRB and the investigator or complainant, and recommend possible methods of resolution to the reviewing IRB.
  - The Executive Committee's function is to bring broader perspectives and expertise to bear on specific protocol concerns and provide recommendations to the IRB.
  - The Executive Committee is charged with an advisory function only. Thus, an IRB is not bound to accept any recommendations offered by the Executive Committee.

As stated above and as per federal regulations, officials of the institution may not approve the research if it has not been approved by an IRB ([45 CFR 46.112](#) and [21 CFR 56.112](#)). An Executive Committee is not an IRB and does not have the authority to approve research, overturn the determinations of an IRB or require that an IRB adopt its recommendations.

- An Executive Committee may conclude that it has no recommendations to make.

## Regulations

### Department of Health and Human Services Regulations

- [45 CFR 46.109](#) – IRB Review of Research
- [45 CFR 46.112](#) – Review by Institution

### Food and Drug Regulations

- [21 CFR 56](#): Institutional Review Boards--Functions and Operations