

Guidance and Procedures Number: 16
Title: IRB Process – Consultant Review
Date of Last Revision: July 5, 2007

I. Regulatory Basis

Federal regulations require that IRBs be adequately constituted to represent “the anticipated scope of the institution's research activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.”¹

In accordance with federal regulations, “An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.”² Needed expertise may be in terms of scientific knowledge, scholarly knowledge, knowledge or experience working with vulnerable populations or knowledge of the local context.

II. Internal Consultant Review

- A. Internal consultant review refers to the identification and recruitment of an individual who serves as an IRB member on one of the other UCLA IRBs (i.e., one of the Boards not reviewing the given study) with expertise beyond or in addition to that available on the reviewing IRB.
- B. IRB staff and/or the IRB Chair/designee may request internal consultant review for studies which qualify for expedited review.
- C. IRB staff, the IRB Chair and/or a convened IRB may request internal consultant review for studies requiring full Committee review.
 - 1. For studies which require full Committee review, the IRB staff and/or IRB Chair may request internal consultant review prior to the convened IRB's review of a given study, or the Committee may determine, upon review of a study, that internal consultant review is required.
- D. IRB staff, the IRB Chair and/or a convened IRB may identify an appropriate internal consultant.
- E. Once the internal consultant is identified, IRB staff will provide the consultant with appropriate and relevant study materials as well as an outline of the Board's request(s).
- F. Conflicts of interest of internal consultants are identified, evaluated and managed according to [HRPP Policy # 67: IRB Member Conflict of Interest](#).

¹ 45 CFR 46.103(d)

² 45CFR 46.107(f) & 21CFR 56.107(f)

- G. Consultants may be asked to provide their expertise regarding a specific issue, or to provide an overall review and assessment of a research project.

III. **External Consultant Review**

- A. External consultant review refers to the identification and recruitment of individuals with expertise beyond or in addition to that available on the Board, who are not IRB members on any of the five UCLA IRBs, and who may or may not be affiliated with UCLA.
- B. The IRB Chair/designee may request external consultant review for studies which qualify for expedited review.
- C. The IRB Chair and/or a convened IRB may request external consultant review for studies requiring full Committee review.
 - 1. For studies which require full Committee review, the IRB Chair may request external consultant review prior to the IRB's review of a given study, or the Committee may determine, upon review of a study, that external consultant review is required.
- D. Consultants may be asked to provide their expertise regarding a specific issue, or to provide an overall review and assessment of a research project.
- E. The following procedures are followed when obtaining external consultant review:
 - 1. Out of respect for the investigator's intellectual property and to avoid professional conflicts, the PI will be informed, via email, of the request for consultant review, and provided an opportunity to identify individuals, if any, s/he does not wish to review the protocol.
 - 2. The IRB Chair and IRB staff, in consultation with other IRB members and/or the appropriate department Chair, will identify an external consultant with the required expertise, giving consideration to the investigator's response to (1) above.
 - 3. Once a potential consultant has been identified, IRB staff will contact this individual to request his/her consultation, and follow up as necessary.
 - 4. Upon agreement from the identified individual to serve as a consultant, IRB staff will provide the consultant with a formal written request to serve as a consultant, appropriate and relevant study materials as well as an outline of specific issues regarding which the Board requests consultation.
 - a. As a part of the formal request, the consultant is asked to disclose any conflicts of interest.³ The determination of a consultant's conflict of interest is based on the consultant's self-assessment. Please see attached template for consultant review request.

³ An interest in the outcome of the research that might compromise the integrity of the research, or a financial interest in the sponsor of the research study.

- b. If the consultant discloses a financial or other interest in the research, the IRB Chair and IRB staff will identify an alternate consultant as described above.

IV. Conveyance of Consultant Review to the Board

- A. A consultant is requested to provide his/her comments to the Board in writing. Comments may be delivered to the IRB staff by a given deadline, and/or the consultant may be asked to present his/her comments to the Board in person.
 - 1. For research requiring full Committee review, consultant comments are distributed to the Board members along with related study materials approximately one week prior to the scheduled meeting. Please refer to [HRPP Guidance & Procedure # 9: IRB Review Process—Full Committee Review](#) for details.
 - 2. If a consultant is asked to attend a convened IRB meeting, the consultant will be excused prior to the vote. The consultant may not vote or count towards quorum.
- B. The consultant's written comments are retained by OPRS as part of the protocol file.

Regulations:

45 CFR 46.103(d)
45 CFR 46.107(f)
21 CFR 56.107(f)

References:

U.S. Office for Human Research Protections' (OHRP, formerly OPRR) *Guidance on IRB Knowledge of Local Research Context*, August 27, 1998 [updated July 21, 2000].
<http://www.hhs.gov/ohrp/humansubjects/guidance/local.htm>