

UC San Diego INSTITUTIONAL REVIEW BOARD ADMINISTRATION	OIA-051 SOP: Consultation to the IRB				
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1 PURPOSE

- 1.1 This procedure establishes the process for the IRB to obtain consultants.
- 1.2 The process begins when the Office of IRB Administration (OIA) staff, an IRB chair, an IRB member, or the institutional official has identified the need for consultation.
- 1.3 The process ends when the consultant has provided requested expertise to the IRB.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 GUIDANCE

- 3.1 The IRB invites consultants with competence in specific areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB.
- 3.2 Consultants with a conflicting interest may not provide information to the IRB.

4 RESPONSIBILITIES

- 4.1 OIA staff members carry out these procedures.

5 PROCEDURE

- 5.1 Identify a consultant with the required expertise who can provide a review. Identify individuals as follows:
 - 5.1.1 IRB members from other IRB committees at the institution
 - 5.1.2 Other employees of the institution
 - 5.1.3 External consultants
- 5.2 Contact the consultant and determine availability for review.
- 5.3 Determine whether the consultant has a conflicting interest. If so, obtain another consultant.
- 5.4 Use *OIA-301 WORKSHEET: Review Materials*, or equivalent, to determine which documents to make available to the consultant so the IRB can obtain the additional expertise needed, and make these documents available to the consultant. If the additional expertise needed does not require review of any materials, no materials need be provided.
- 5.5 For review by the convened IRB:
 - 5.5.1 Make the consultant's written comments, if any, or documentation of comments delivered orally to OIA staff, available to the IRB members attending the meeting.
 - 5.5.2 If requested by the IRB chair, invite the consultant to the IRB meeting.
- 5.6 For non-committee review:
 - 5.6.1 Directly obtain the information (oral or written) from the consultant.
 - 5.6.2 Document information received with the name of the consultant.

6 MATERIALS

- 6.1 *OIA-001 SOP: Definitions*
- 6.2 *OIA-301 WORKSHEET: Review Materials*

7 REFERENCES

- 7.1 [21 CFR 56.107\(f\)](#)
- 7.2 [45 CFR 46.107\(e\)](#)