



SOP 306: AD HOC CONSULTANT REVIEWERS

PURPOSE

The University of Utah Institutional Review Board (IRB) is composed of members in accordance with federal regulations. If the University of Utah IRB lacks specific expertise among panel members, ad hoc consultant reviewers may be utilized.

SCOPE

This SOP applies to the University of Utah IRB.

POLICY

The University of Utah IRB, at its discretion, may invite individuals with competence in special areas to assist in the review of issues which require expertise beyond, or in addition to, that of available IRB panel members. Ad hoc consultants are not voting members of the IRB. Ad hoc consultants are subject to the IRB's policy regarding conflicts of interest and confidentiality (see IRB SOP 304: Convened IRB Meeting Administration). Ad hoc consultants may be requested regardless of the field of research being conducted.

PROCEDURES

1. Obtaining Additional Expertise

- 1.1. It is the responsibility of the primary reviewer to make the determination that a consultation for additional expertise is needed beyond the expertise available to the board. The primary reviewer contacts the secondary reviewer (if applicable) to notify him/her of the needed expertise and notifies the IRB staff or IRB Chair in a timely manner (i.e., before the convened meeting, if possible).
- 1.2. The primary reviewer may consult with a known expert in the field or contact IRB staff for assistance in obtaining an ad hoc consultant reviewer. The IRB staff may contact department chairs of the appropriate discipline for references of qualified individuals. This will preferably be handled before the study is reviewed at a convened board meeting to allow for dissemination of any applicable information and/or comments from the ad hoc consultant reviewer.
- 1.3. If additional expertise is requested during the convened board review of a study, discussion will be deferred until an ad hoc consultant with additional expertise can provide more information. The study will be reviewed at the next available board meeting.
- 1.4. If there is no member with appropriate scientific and scholarly expertise to provide an in-depth review of a protocol and ad hoc consultation is not available, the protocol must be deferred to another IRB meeting where the appropriate consultation or expertise is available for in-depth review of a protocol.

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.



2. Provision of Materials

- 2.1.** Ad hoc consultants are provided with relevant printed materials (either hard copy or electronic format) from the University of Utah Electronic Research Integrity and Compliance Administration system (ERICA) submitted by the Investigator and any other materials requested by the IRB (see IRB SOP 301: Research Submission Requirements). Ad hoc consultants must review the materials and provide the IRB with a written assessment and evaluation of a risk-benefit ratio, any ethical concerns, identify any additional safety concerns or procedures which may pose serious harm to subjects, and respond to other specific requests made by the IRB. This written assessment is made available to IRB members via ERICA and becomes part of the permanent electronic record. The IRB coordinator or administrator attaches the written assessment to the appropriate study for accessibility and may summarize the consultant's review in the minutes at a convened board meeting.

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