

Approved by IRB Executive Committee: November 12, 2008
Supersedes Document Dated: N/A (previously approved in SOP 201)
AAHRPP Element II.1.B.

POLICY

The IRB will, at 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 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 SOP 304). Ad hoc consultants may be requested regardless of the field of research being conducted.

PROCEDURES FOR OBTAINING AD HOC CONSULTANT REVIEWERS

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 coordinator or IRB Chair in a timely manner (i.e. before the convened meeting, if possible).
2. The board member may consult with a known expert in the field or contact the IRB office for assistance in obtaining an ad hoc consultant reviewer. The IRB office 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.
3. Ad hoc consultants are provided with all printed materials from the ERICA online system submitted by the Investigator and any other materials requested by the IRB. (Please see SOP 301 for 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 the ERICA online system and becomes part of the permanent electronic record. IRB coordinator or administrator attaches the written assessment to the appropriate study for accessibility and documents the consultant's review within the minutes at a convened board meeting.
4. In the event that 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.
5. In the event that 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 IRB requires a protocol be deferred to another IRB meeting where the appropriate consultation or expertise is available for in-depth review of a protocol.