INVITING CONSULTANTS TO REVIEW INSTITUTIONAL REVIEW BOARD PROTOCOL DOCUMENTS

DESCRIPTION

The Institutional Review Board (IRB) Chair, an IRB member or the full 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 by the IRB membership.

RESPONSIBILITY

The IRB Chair, IRB member or the full IRB, as appropriate to the documents being reviewed, are responsible for selecting a consultant to be included in the review process. When there is not at least one IRB member with appropriate expertise in a scientific or research area to provide an in-depth review of a research protocol, the IRB chair must require the participation of a consultant for the purposes of review of the research protocol.

PROCESS

As part of initial review, the IRB Chair shall review each protocol to ensure that appropriate expertise is represented on the Board to adequately review the protocol. A similar determination will be made by the primary and secondary reviewers.

The IRB Chair or reviewer who seeks consultation shall review Human Research Protection Program (HRPP) Procedure 102, Managing Conflicts of Interest of IRB Members and Consultants, with the consultant to ensure that the consultant does not have a conflicting interest. If such a conflicting interest is identified, then the IRB Chair or primary reviewer seeking consultation will identify an alternate consultant.

The responsible person(s) will determine an appropriate candidate to provide the consultation on a protocol. The consultant may, or may not, be affiliated with the University of Cincinnati or an affiliated institution. The consultant will be contacted by telephone, email, or letter, and if agreeable, will be provided with all appropriate protocol materials for review. The consultant will respond to the IRB’s request by telephone, written documentation or in person at a convened meeting. The IRB Chair or full IRB, as appropriate, will evaluate and take into consideration the consultant’s review when evaluating the protocol for approval.
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Human Research Protection Program Procedure

If the consultant chooses to present his/her comments at a convened meeting, he/she will not be present for the discussion and will not vote on that protocol.

If the consultant provides written information, HRPP staff will keep the consultant’s review in the IRB electronic record for the study. If the consultant provides information by telephone or in person, outside the IRB meeting, the responsible person will report this information at the meeting and the HRPP staff will record the key information in the minutes. If the consultant provides information by telephone or in person at an IRB meeting, HRPP staff will record key information in the minutes and identify the name of the consultant providing the review.

Applicable Regulations, Document(s):
21 CFR 56.107
21 CFR 56.115(a)(5)
45 CFR 46.107
HRPP Policy III.01 Review of Human Subjects Research by the IRB
HRPP Procedure 102 Managing Conflicts of Interest in IRB Members and Consultants

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Date Adopted __March 2015__ Signature __signed copy on file__