



DUHS IRB USE OF CONSULTANTS

06/25/2008

As set forth in 45 CFR 46.107(f) and 21 CFR 56.107(f), the IRB may, 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 available on the IRB.

When the IRB Chair/Vice-Chair reviews the draft agenda to make primary reviewer assignments, s/he determines if the IRB membership includes the necessary expertise to review the protocol in terms of scientific expertise, knowledge of local context, and representation of any subjects likely to be vulnerable to coercion or undue influence. When the IRB Chair/Vice-Chair determines that the available IRB members lack the expertise needed to review the protocol, that person, perhaps in consultation with experts in the scientific area of concern, identifies potential consultants and asks one or more to assist the IRB.

In addition, the IRB may vote to defer action on a protocol and may require an expert in the scientific area of concern to review the research and provide consultation to the IRB. Potential consultants will either be identified and agreed upon by the convened IRB, or identified as indicated above.

Consultants are subject to the Policy Statement Regarding Conflict of Interest Pertaining To DUHS IRB Members and Consultants. IRB staff review this policy with consultants and have them declare in writing that they have no conflicting interest regarding their review of the protocol. If the consultant agrees to review the protocol and the consultant has no conflicting interest, s/he is provided with all relevant information available to the IRB in order to perform an in-depth review of the research. The consultant will understand the background, aims and methods of the research.

Consultants are asked to attend the IRB meeting to present their findings relative to the scientific merits of the study and risks and benefits to subjects, and to answer questions; however, if the consultant is unavailable to attend the meeting, s/he may provide written comments for distribution to the IRB members in attendance.

Consultants are not voting members, and the IRB Writer records their attendance in the minutes as a Guest (Consultant).

The minutes will document key information provided by consultants at a meeting. Any written comments provided by consultants are maintained in the paper or electronic e-IRB records, as applicable depending on how the comments are provided.

The IRB does not delegate its responsibility to judge whether the regulatory criteria for approval are met.