



DUHS IRB USE OF CONSULTANTS

4/4/2021

As set forth in 45 CFR 46.107(e) 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 a protocol which requires expertise in addition to that available on the IRB roster.

When the IRB 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 determines that additional expertise is needed to review the protocol, that Chair, in consultation with others as necessary, identifies potential consultants to assist the IRB.

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

Consultants are subject to the policy titled "Conflict of Interest Pertaining to DUHS IRB Members and Consultants".

If the consultant agrees to review the protocol and has no conflict of interest, s/he is provided with all relevant information available to the IRB to perform an in-depth review of the research. Consultants may be asked to attend the IRB meeting to discuss the protocol and to answer questions or, if the consultant is unavailable to attend the meeting, s/he may provide written comments for distribution to the IRB members in attendance. Meeting minutes will include a summary of the Consultant's remarks. Consultants attending an IRB meeting are not voting members and do not vote with the IRB.

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

Previous Version Dates: 6/25/2008, 3/1/2016