

Issuing Department: Human Subjects Protection Program (HSPP)
Policy Number: 2011-009.6
Policy Title: Institutional Review Board (IRB) - Consultants

Purpose

The purpose of this policy is to describe when and how the IRB may implement the use of a consultant to aid in the review of a research protocol.

Definitions

See policy 2011-007.0 for definition of the following term:

Conflict of Interest Financial Interest Related to the Research Immediate Family Member

Policy

As related to vulnerable populations, the IRB will follow policy 2011-006.0 regarding use of consultants. The IRB may also enlist the help of a consultant who is not a member of the IRB as it deems necessary. Such consultants will be called upon when, in the opinion of the IRB, someone with a specific expertise is needed to conduct a thorough review of a study or to address specific questions related to a study.

In all cases, consultants may not have a conflict with the research being reviewed (regardless of the type of review (initial, continuation, modification, non-compliance, unanticipated problem, etc.) or level of review (full board, expedited, exempt)). Conflict of interest for a consultant is defined in the same manner as a conflict of interest for an IRB member and investigator.

No UConn Health employee will be paid for conducting a review. Consultants will have full access to the IRB file for the specific study being reviewed, including access to previous minutes.

Procedure

Need for Consultant:

For vulnerable populations policy 2011-009.6 is followed. Otherwise, the Chair may determine that a consultant is required at the time of initially assigning reviewers, an assigned reviewer may make a request to the Chair that a consultant be called upon, or the IRB may come to this conclusion at a meeting. An assigned reviewer may also elect to contact a consultant during the course of conducting a review, e.g. by calling a colleague with known expertise.

Identifying Consultant:

If the Director of the HSPP has not appointed a standing consultant (e.g. to review studies involving particular vulnerable groups such as children or of a particular design such as Community Based Participatory Research) and the IRB membership does not have the required expertise, the IRB Chair will seek a consultant from within the institution or neighboring facilities and ask the individual to perform the review as a courtesy to the IRB.

If an individual cannot be identified from within the institution or neighboring facility an external consultant will be sought. The operating budget of the IRB or HSPP will pay for such consultation if payment is required.

Conflicts of Interest:

Standing consultants are informed at the time of appointment that they cannot have a conflict with any study for which their services are sought. They are reminded of this when being assigned to a review through the reviewer form which states that no conflict may exist. When using an ad-hoc consultant the Chair or reviewer will determine that no conflict exists in the course of communication with the consultant and confirm orally that such determination was made at the convened meeting.

Participation of Consultant:

The IRB Regulatory Specialist will provide the consultant with the same material that a primary reviewer receives. The consultant will be invited to attend the convened meeting at which the review will occur to participate in the discussion and make recommendations. The Chair will excuse the consultant prior to deliberations and voting. As noted in policy 2011-006.0, when expertise of a consultant is required for vulnerable populations; the consultant must be present for the initial review of the research. When consultation is called upon for issues related to research design, if the consultant cannot attend the meeting, but can provide a written summary of recommendations; the Chair may determine on a case-by-case basis whether to proceed with the review at the meeting based on the written recommendation.

The IRB RS will note participation of a consultant in the minutes of the IRB meeting.

Related Policies

- 2011-006.0 – Vulnerable Populations – General Policy
- 2011-007.0 – Definitions Applied to Policies
- 2011-012.0 – Conflict of Interest – Research Personnel
- 2011-012.1 - Conflict of Interest – IRB members

Basis

- 45 CFR 46
- 21 CFR 56

Document Attributes

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Reviewed and Approved By:

Signed Richard H. Simon

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Date:

