

## Identification and Use of *Ad hoc* Consultants

310 AOB (MC 672)  
1737 West Polk Street  
Chicago, IL 60612-7227  
Phone: 312 996-4995 Fax: 312 413-0238  
[www.research.uic.edu/protocolreview/irb](http://www.research.uic.edu/protocolreview/irb)

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### POLICY:

The UIC IRB obtains expertise from outside the IRB when the IRB lacks the experience and knowledge required to review a specific protocol.

### PROCEDURE:

#### I. Determining whether a consultant is needed:

- A. After the proposal submission deadline for each IRB meeting, the Assistant Director (AD) of the IRB prepares the *Ad Hoc Consultant Determination for Board Meetings and Agendas*. The consultant determination sheet lists initial review protocols and continuing review of protocols or amendments to protocols that might require an ad hoc consultant due to IRB member changes since initial review, use of an ad hoc reviewer at initial review or changes to the research protocol that require expertise outside of the realm of the IRB members. The consultant determination sheet also identifies when an ad hoc consultant is not necessary.
- B. The AD reviews each protocol listed on the agenda and determines whether an ad hoc consultant is required. The AD consults with the Chair, when necessary, to verify that the board has appropriate expertise to review a protocol.
- C. The need for an ad hoc consultant is documented on the Ad Hoc consultant Determination for Board Meetings and Agendas. The consultant determination sheet is attached to the agenda that is created for that deadline to demonstrate that each protocol was reviewed. The IRB Chair and the AD sign the consultant determination sheet after completing the review.
- D. If the AD determines that an Ad Hoc consultant is required for a particular submission, the AD contacts the Chair to review this decision and determine an appropriate Ad Hoc consultant.
- E. The need for an expert consultant may also be identified by the IRB member assigned as the primary reviewer for the proposal or other members before or during the IRB meeting.
- F. If the need for an *ad hoc* consultant is not identified or not brought to the AD's or Chair's attention until the IRB meeting, the protocol must be Tabled until the appropriate expertise can be obtained.

**II. Procedure for obtaining consultants:**

- A. Consultants may be IRB Members from other Boards, UIC faculty, UIC Medical Center employees, or experts outside of the UIC community.
- B. The AD and Chair evaluate the IRB rosters to identify if any members of the other boards have the needed expertise and contact them by e-mail to determine their availability for review. They also review any information OPRS has on individuals willing to serve as consultants.
- C. The AD and Chair may solicit recommendations for internal or external consultants from IRB members, UIC Department Heads or Deans associated with the area in which expertise is needed.
- D. Once an ad hoc consultant is identified, the AD or Chair contact the individual to ascertain their willingness and review their qualifications for consulting on the proposal. After the ad hoc consultant's expertise and acceptance are confirmed, arrangements are made to provide them with the materials for review and a copy of the UIC IRB member, Ad Hoc Consultant, and OPRS Staff Conflict of Interest Policy and the confidentiality and conflict of interest statements will be included for their signature.
- E. The ad hoc consultant provides their curriculum vitae for review by the IRB chairs and members. A copy of the curriculum vitae is added to the IRB file.
- F. If an ad hoc consultant with appropriate expertise is not available for the next IRB meeting, the protocol is assigned to another meeting when the expert is available or another consultant is available to conduct the review.

**III. Consultant Responsibilities:**

- A. The Chair explains to the ad hoc consultant that the same ethical, confidentiality, and COI standards apply to them as to IRB Members.
- B. Before each review, ad hoc consultants are required to complete a conflict of interest (COI) declaration; stating that they do not have any real or perceived financial and non-financial COI with the research. The AD or Chair initially asks consultants about any COIs at the time the assignment is made and again out loud at the time of the IRB meeting.
- C. The ad hoc consultant will return any materials provided by the OPRS relevant to the specific research protocol under review.
- D. Ad hoc consultants present their findings in a written report to the IRB and may also present their findings at the IRB meeting either in person or by telephone, as appropriate. A copy of the report is provided to each member.
- E. The protocol file includes both the ad hoc consultant's report and credentials regarding the area of expertise needed.
- F. The ad hoc consultant is not permitted to vote and their presence cannot count toward quorum.
- G. If an ad hoc consultant has a COI, the Director of OPRS, the HPA, and the IRB Chair will determine if the consultant can be used. If possible, another consultant should be identified.
- H. The following procedures must be taken when an ad hoc consultant with a COI is utilized:
  - 1. The Assistant Director of the IRB or the IRB Chair will announce the consultant's conflict to the appropriate IRB at the meeting;

2. The consultant may be present at the meeting to present their report and to answer any questions from the IRB members; and
3. The consultant is not permitted to be present for the discussion or IRB vote.

**REFERENCES:**

[21 CFR 56.107\(f\)](#)

[38 CFR 16.107\(f\)](#)

[45 CFR 46.107\(f\)](#)

[VHA Handbook 1200.5 par. 6\(h\)](#)