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 meeting agenda and Ad Hoc Consultant Determination for Board Agendas form.
   B. The AD completes the form by listing 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.
   C. The AD then reviews each protocol listed on the form and determines whether an ad hoc consultant is required. The need for an ad hoc consultant is documented on the Ad Hoc Consultant Determination for Board Agendas form.
   D. The Ad Hoc Consultant Determination for Board Agendas form is attached to the agenda that is created for the meeting deadline to demonstrate that each protocol was assessed. The AD signs the form after completing the review.
   E. The AD contacts the Chair to review the proposed agenda and Ad Hoc Consultant Determination for Board Agendas form. If the AD and/or Chair determine that an ad hoc consultant is required for a particular submission, the AD and Chair review this decision and determine an appropriate ad hoc consultant.
   F. Once the Chair agrees with the determinations as to whether or not an ad hoc consultant is required, the Chair signs the Ad Hoc Consultant Determination for Board Agendas form and the agenda is considered to be approved.
      1. The review and approval of the agenda and ad hoc determinations may also occur via email as long as written documentation can be provided.
G. 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.

H. 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 individual is identified, the AD or Chair contacts the individual to ascertain their willingness and review their qualifications for consulting on the proposal. After the individual’s expertise and acceptance are confirmed, arrangements are made to provide them with the materials for review, 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 for signature.
   E. The individual 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 individual 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 consultant that the same ethical, confidentiality, and COI standards apply to them as to IRB Members.
   B. Before each review, 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 consultant will return any materials provided by the OPRS relevant to the specific research protocol under review.
   D. 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 consultant’s report and credentials regarding the area of expertise needed.
   F. The consultant is not permitted to vote and their presence cannot count toward quorum.
G. If a 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 a 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.

IV. Research Review by CHAIRb:
   A. The policy and procedures described above will be followed by CHAIRb; however, the CHAIRb Portal will be utilized.
   B. CHAIRb members may be asked to provide assistance in identifying an *ad hoc* consultant.

REFERENCES:
21 CFR 56.107(f)
38 CFR 16.107(f)
45 CFR 46.107(f)

ENCLOSURE:

REVISION LOG:

<table>
<thead>
<tr>
<th>Version (#, date)</th>
<th>Replaces (#, date)</th>
<th>Summary of changes</th>
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<tbody>
<tr>
<td>1.0, 10/15/08</td>
<td>NA</td>
<td>Creation of policy.</td>
</tr>
<tr>
<td>1.1, 7/24/15</td>
<td>1.0, 10/15/08</td>
<td>Clarification of procedures related to the <em>Ad Hoc Consultant Determination for Board Agendas</em> form. Inclusion of the <em>Ad Hoc Consultant Determination for Board Agendas</em> form as an enclosure to the policy.</td>
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<tr>
<td>1.2, 02/10/16</td>
<td>1.1, 7/24/15</td>
<td>Addition of CHAIRb.</td>
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Ad Hoc Consultant Determination for Board Agendas

The __________________ agenda for IRB# ___ has been reviewed and the following determination made:

☐ Based on the review of the agenda no outside consultant is required. It was determined that there is sufficient expertise on the Board to provide a thorough review of each of the research protocols.

☐ The agenda includes research that was found to be outside the expertise of the Board. An outside consultant is required. The research protocols requiring an ad hoc consultant and the expertise needed are listed below:

<table>
<thead>
<tr>
<th>Protocol Number</th>
<th>Submission Type (IR, CR, AM)</th>
<th>Ad Hoc Consultant Expertise</th>
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Comments:

___________________________________________________________________________

IRB Chair / Vice Chair                                           Date

___________________________________________________________________________

Assistant Director/Coordinator                                    Date