

INVITEES: Requesting Information From Consultants or Guests  
Policy Number 2876.12



**Campus Institutional Review Board**  
University of Missouri-Columbia

**INVITEES: Requesting Information from**  
**Consultants or Guests**

Policy Number 2876.12

Reviewed by: Michele Reznicek, Campus IRB Compliance Officer  
Reviewed by: Janelle Greening, Quality Assurance Associate  
Reviewed by: Campus IRB Membership

Effective Date: December 12, 2007

Board Review

A handwritten signature in black ink that reads "Cheryl B. Li".

Signed \_\_\_\_\_  
IRB Chair

Date December 12, 2007

Administrative Review

A handwritten signature in black ink, appearing to be "R. J. Hall".

Signed \_\_\_\_\_  
Associate Vice-Chancellor for Research

Date December 12, 2007

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**1.0 Policy**

The Campus IRB shall invite individuals with competence in that area to assist in the review processes of proposed research, or request supportive information from individuals with specific expertise or experience in an effort to assist in the assessment of risks to research participants.

**2.0 Scope**

This policy applies to all human subject research being conducted under the jurisdiction of the University of Missouri-Columbia Campus IRB.

**3.0 Purpose**

The Campus Institutional Review Board (Campus IRB) shall assure that it has sufficient information to consider during deliberations to facilitate the ability to make an informed decision about the issue or proposal under review.

**4.0 Standard Operating Procedure**

When the board does not have at least one person on the IRB with the appropriate scientific and scholarly expertise to conduct an in-depth review of the protocol, the Compliance Officer is charged with the responsibility to assure an evaluation of each protocol has been conducted to determine whether there was at least one person on the IRB with the necessary expertise, and if not, invite individuals with competence in that area to assist in the review process. When necessary, the Campus IRB may invite individuals (Consultants or Guests) with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the Campus IRB. The Compliance Officer will ensure that one or more individuals who are knowledgeable about or experienced in working with participants vulnerable to coercion or undue influence will be present at the meeting when the IRB reviews research that involves such participants. The Campus IRB will review the proposal in compliance with the "CIRB Review Process" Policy.

Consultants must comply with the "Conflicts of Interest" policy. Consultants who have a conflicting interest or whose spouse or immediate family members have a conflicting interest in the sponsor of the research will not be invited to provide consultation.

The Campus IRB is permitted to identify, invite and request information or presentation from the relevant visitors who may be a consultant or guests who can provide an opinion about the matter before the board. All members are expected to review all materials and investigator responses in enough depth to be prepared to discuss the proposal and make a meaningful contribution to the convened meeting.

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The individuals may fall into one of the categories below:

A. INVITEES

- a. Consultants: When a proposal is submitted requiring supportive information or the issue falls outside the expertise of the Board, an individual with the relevant expertise may be identified and invited to serve in the capacity of a non-voting consultant. Consultants are either solicited to provide an expert review of an entire protocol or a specific issue associated with a protocol. Consultants must comply with the “Conflicts of Interest” policy described herein. No consultant may participate in the review of any proposal in which there is a conflicting interest, except to provide information requested by the Campus IRB. Individuals who have a conflicting interest or whose spouse or family members have a conflicting interest in the sponsor of the research will not be invited to provide consultation.

The process is as follows:

1. The Campus IRB Compliance Officer will contact the consultant and formally request an appearance, information or opinion for consideration for either the review of the entire protocol or a specific issue associated with the proposal.
2. Upon solicitation, and prior to review of the file, the Campus IRB Compliance Officer will inform the consultant of the Conflict of Interest Policy and determine whether the consultant has a conflicting interest prior to the review of the expedited file or full board convened meeting.
  - a. If a conflict of interest is present, the consultant will be informed of the prohibition against participation in the review of protocols; the consultant **MUST** not review the file or attend the meeting. Individuals who have a conflicting interest or whose spouse or family members have a conflicting interest in the sponsor of the research will not be invited to provide consultation.
  - b. If a conflict of interest **IS NOT PRESENT**, the consultant will be reminded of the prohibition against participation in the review of protocols where there is a conflict of interest. The consultant will provide the information requested by the board. Consultants must not be present during the voting procedures.
3. The Campus IRB shall forward the consultant all of the relevant materials necessary in sufficient time to effectuate the ability to render an opinion. The board shall take the proper precautions necessary to maintain the confidentiality of the materials reviewed and inform the consultant that all materials and discussions are for internal Campus IRB use and must be kept confidential.
4. The consultant may render an opinion in person at a convened meeting or in writing.
5. The Board may take the advice of the consultant into consideration when voting on any matter before the board.
6. The Consultant does not remain in the room for voting procedures.

Example: DFS Caseworker or Director of Juvenile Justice Center

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- b. Guest Appearances: A guest is an individual(s) who is invited and “may” have a vested interest in the outcome of the IRB review. When an issue arises or a proposal is submitted requiring additional support, the board may identify and request an individual to provide information or make a guest appearance to facilitate the IRB decision-making process. The guest may be an individual who is directly or indirectly affected by the outcome of the board’s decision. The process is as follows:
1. The guest will formally contact the IRB and request an appearance or written opinion for consideration.
  2. The guest will only provide information to the Campus IRB, and has no voting authority.
  3. The Campus IRB shall forward the guest all of the relevant materials necessary to effectuate the ability to render an opinion. The board shall take the proper precautions necessary to maintain the confidentiality of the materials reviewed.
  4. The guest may render an opinion in person at a convened meeting or in writing.
  5. The Board may take the advice of the guest into consideration when voting on any matter before the board.
  6. The Guest does not remain in the room for deliberations or voting procedures.

Examples: Exports Control Compliance Officer or Department Chair.

*Revised December 2006*  
*Revised June 2007*  
*Revised December 2007*