



SOP 304: CONVENED IRB MEETING ADMINISTRATION

PURPOSE

This SOP outlines the procedures used by University of Utah Institutional Review Board (IRB) staff to facilitate convened board meetings.

SCOPE

This SOP applies to the University of Utah IRB.

DEFINITIONS

- A.** A **majority** is defined as more than half of the total number of voting members attending the meeting at which the vote takes place.
- B.** A **quorum** is defined as more than half of the regular voting members present at a board meeting. A quorum consists of regular members or their alternate and includes at least one member whose primary concerns are in scientific areas, and one member whose primary concerns are in nonscientific areas. Ad hoc consultant reviewer(s) may not be used to establish a quorum.

POLICY

Except when an expedited review procedure is used, the University of Utah IRB will review proposed research at convened meetings at which a quorum is present. The University of Utah IRB members are organized into panels. Each IRB panel meets monthly, or at some other frequency determined by the IRB Chair and the IRB Director. Meeting space will be made available for the IRB.

University of Utah IRB meetings may not convene until a quorum is established. Quorum must be maintained for each vote to occur.

A majority of members must vote in favor of an action for that category of action to be accepted by the IRB. Only regular and alternate members acting in place of absent regular members may vote. The IRB administrator is responsible for counting and documenting all votes in the meeting minutes.

IRB members, alternates, or others with a conflicting interest may not participate in any portion of the review of research activities except to provide information requested by the IRB and must excuse themselves from the meeting during the IRB's deliberative discussion and vote on the affected research. IRB members, ad hoc consultant reviewers, and other attendees may excuse themselves from the discussion and vote for any reason, if they feel it is necessary to avoid any appearance of a conflicting interest.

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.

All material received by the IRB is considered confidential and is distributed only to meeting participants (regular members, alternate members, and ad hoc consultant reviewers) for the purpose of review. All application materials are stored in the University of Utah Electronic Research Integrity and Compliance Administration system (ERICA), which is a secured site, with access limited to the IRB members and staff. IRB members are required to electronically sign the IRB Confidentiality Agreement initially and at the beginning of each three-year term. Agreements are maintained in ERICA.

Convened Meeting with a Member Joining Remotely

Should a member not be able to be physically present during a convened meeting, but is available remotely, the meeting can be convened using video or audio conferencing. The member who is not physically present will be connected to the rest of the members via conferencing technology. The member must be able to hear the discussion and be heard by the convened members. In this manner, all members will be able to discuss the protocol even though one or more members are not physically present. Members participating by audio or video conferencing may vote, provided they have had an opportunity to review all the material the other members have reviewed.

Meetings Conducted Via Conferencing Technology (Virtual Meetings)

Meetings may be convened via audio or video conferencing. To allow for appropriate discussion, all members must be connected simultaneously for an audio conference call or video meeting. All members must be able to hear one another to allow for discussion. A quorum (as defined above) must participate in the audio conference call or video meeting to be convened.

To allow for the IRB administrator to take minutes during the virtual meeting, an additional IRB staff member may be assigned as the virtual meeting facilitator. The virtual meeting facilitator will not count toward quorum for the meeting. Members who are not present at the convened virtual meeting via audio or video technology may not vote on an issue discussed during that meeting. Voting by proxy is not permitted. Contacting members individually via telephone is not acceptable as a method to conduct a virtual meeting. However, using conferencing technology tools to poll members present in a virtual meeting is acceptable.

PROCEDURES

1. Maintaining Quorum

- 1.1. It is the responsibility of the IRB administrator to inform the IRB Chair when quorum has been established. Once quorum is established, the IRB Chair calls the meeting to order.
- 1.2. The IRB administrator is responsible for monitoring the meeting for late arrivals and departures of members. If quorum is lost during a meeting, the IRB administrator informs the IRB Chair if the IRB Chair has not already noted the loss of quorum. The IRB Chair must not allow any further action or votes to be taken until quorum is restored.

2. Conflicts of Interest

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.



- 2.1. Each meeting agenda includes a statement reminding IRB members that any potential conflict(s) of interest with research that is reviewed must be declared. Members are asked to be excused during the discussion and vote of the affected research.
- 2.2. The IRB Chair begins each meeting requesting that any potential conflict(s) of interest with items on the agenda to be declared by IRB members in attendance. A verbal declaration of any such conflict is recorded by the IRB administrator in the minutes of the meeting. The IRB Chair will be informed if the IRB administrator is aware of conflicts. The IRB administrator will document specific IRB member recusals as they occur throughout a meeting in the meeting minutes.
 - 2.2.1. IRB members are required to electronically sign the IRB Member Recusal Agreement initially and at the beginning of each three-year term. The IRB Member Recusal Agreement is maintained in ERICA.
 - 2.2.2. Ad hoc consultant reviewers are required to disclose to the IRB any real or potential conflicts of interests involving the review of any specific research protocol. The IRB administrator provides the ad hoc consultant reviewer with the IRB Conflict of Interest Disclosure prior to the review of a research protocol. If a conflict of interest is disclosed, the IRB will not permit the requested ad hoc consultant reviewer to review the research project forming the basis for the conflict.

3. IRB Confidentiality Agreements

- 3.1. Prior to disseminating application materials to ad hoc consultant reviewers in preparation for a protocol review at an IRB meeting, IRB administrators ensure that ad hoc consultant reviewers sign the IRB Confidentiality Agreement. Once confirmation is made that the agreement has been signed, the IRB administrator may provide printed copies of applicable application materials from ERICA. Agreements are maintained by the IRB executive secretary.
- 3.2. Prior to a convened meeting, the IRB administrator identifies any individuals that may require a signed IRB Confidentiality Agreement (e.g., visitors) and ensures that visitor(s) sign the IRB Confidentiality Agreement prior to the start of the meeting. Agreements are maintained by the IRB executive secretary.

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