

1.31 Observers at IRB Meetings

1.0 Purpose

The purpose of this policy and procedure is to describe the Organization's requirements for allowing observers at convened IRB meetings.

2.0 Policy

- **2.1.** It is the policy of the Organization that non-members who have a legitimate reason, may be allowed to observe convened IRB meetings.
 - **2.2.** It is the policy of the Organization that an investigator whose protocol is being reviewed by the IRB at that convened meeting may attend that portion of the meeting for the purpose of providing information to, and answering questions of, the convened board.
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3.0 Justification for Attendance

- **3.1.** With appropriate justification, the full IRB, the IRB Executive Committee, or the IRB Executive Chair has authority to permit an observer at a convened meeting of any of the IRBs
 - **3.1.1.** In general, adequate justification would include a legitimate job related interest in the process of IRB review, or an academic interest in research ethics and the functioning of IRBs in general.
 - **3.1.2.** Persons who are being considered as potential IRB members may observe one or more convened IRB meetings.
 - **3.2.** In deciding whether to allow a particular observer, the full IRB, the IRB Executive Committee, or the IRB Executive Chair will consider whether the same or similar benefit could be obtained from alternate experience (for example, an IRB orientation or didactic presentation).
 - **3.3.** The full IRB may invite an investigator whose protocol is being reviewed by the IRB at that convened meeting to attend that portion of the meeting, for the purpose of providing information to, and answering questions of, the convened board.
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4.0 Procedure

- **4.1.** The IRB Administrator responsible for coordinating the meetings will arrange for the appropriate meeting for the observer to attend.

- **4.2.** The observer will be required to sign a confidentiality agreement prior to the scheduled meeting.
 - **4.3.** The presence of an observer will be recorded in the IRB minutes, as per HRPP policy 2.2 (Full IRB Review).
 - **4.4.** For observers:
 - **4.4.1.** In general, observers will not participate in the discussion of agenda items.
 - **4.4.2.** The observer may be required to leave the room during any discussion or vote as determined by the Chair or Executive Chair, or at the request of any board member.
 - **4.4.3.** No observer will be permitted to attend a portion of the meeting where he/she has a COI, as per HRPP policy 1.7 (IRB Member, Consultant, Staff COI Identification and Management).
 - **4.5.** For invited investigators:
 - **4.5.1.** An invited investigator may only attend during the review of his/her protocol.
 - **4.5.2.** An invited investigators may provide information to, and answer questions of, the convened board. He/she may, at the request of the board, participate in the discussion regarding his/her protocol.
 - **4.5.3.** The invited investigator will leave the room after he/she has provided the requested information, before final discussion or vote.
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