

Approved by IRB Executive Committee: November 12, 2008
Supersedes Document Dated: November 15, 2005; May 1, 2004
AAHRPP Elements II.1.A., II.1.B., II.1.C. and II.1.E.

DEFINITIONS**a) Quorum**

A quorum is defined as more than half of the regular voting members. 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.

POLICY

Except when an expedited review procedure is used, the IRB will review proposed research at convened meetings at which a quorum is present. Each IRB Panel will meet monthly, or at some other frequency determined by the IRB Chair and the IRB Director. Meeting space will be made available by the IRB.

PROCEDURES**1. Procedures for Maintaining Quorum**

- 1.1. The IRB meeting may not convene until quorum is established. It is the responsibility of the IRB coordinator or the IRB administrator to inform the IRB Chair when quorum has been established.
 - 1.1.1. An alternate member may attend in the place of an absent regular member in order to meet the quorum requirements as defined in this policy.
 - 1.1.2. Ad hoc consultant reviewer(s) may not be used to establish a quorum.
 - 1.1.3. When VA research is reviewed and is FDA-regulated, one member who is a physician must be included in quorum.
 - 1.1.4. At least one of the VA members of the IRB must be present during the review of VA research.
- 1.2. The IRB coordinator and IRB administrator are responsible for monitoring the meeting for late arrivals and departures of members.
- 1.3. It is the responsibility of the IRB coordinator or the IRB administrator to inform the IRB Chair if quorum is lost during a meeting. If quorum is lost during the course of a meeting, the IRB Chair will not allow any further action or votes to be taken until quorum is restored. Quorum as defined in this policy (see "Definitions" above) must be maintained for each vote to occur.

2. Procedures for Voting

- 2.1. A majority of members present at the meeting 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.

- 2.2. The IRB coordinator and IRB administrator are responsible for counting and documenting all votes.

3. Procedures for Telephone Use During a Convened Meeting

- 3.1. **Convened Meeting Using Speaker Phone.** Should a member not be able to be physically present during a convened meeting, but is available by telephone, the meeting can be convened using a speakerphone. The member who is not physically present will be connected to the rest of the members via speakerphone. In this manner, all members will be able to discuss the protocol even though one member is not physically present. Members participating by such speakerphone call may vote, provided they have had an opportunity to review all the material the other members have reviewed.
- 3.2. **Meetings Conducted Via Telephone Conference Calls.** On occasion, meetings may be convened via a telephone conference call. A quorum (as defined above) must participate for the conference call meeting to be convened. To allow for appropriate discussion, all members must be connected simultaneously for a conference call to take place – “telephone polling” (where members are contacted individually) will not be accepted as a conference call.

Members not present at the convened meeting, nor participating in the conference call may not vote on an issue discussed during a convened meeting (voting by proxy is not permitted).

4. Procedures for Managing Conflicts of Interest

- 4.1. Each meeting agenda includes a statement reminding IRB members to declare any potential conflict(s) of interest he/she may have with research that is reviewed. Such a declaration should be made at the outset of each meeting.
- 4.2. The IRB Chair begins each meeting with a statement requesting IRB members to declare any potential conflict(s) of interest he/she may have with items on the agenda. The verbal declaration of any such conflict is recorded by the IRB coordinator and administrator in the minutes of the meeting. The IRB coordinator and administrator also document within the IRB minutes specific IRB member recusals as they occur during meetings.
 - 4.2.1. The IRB administrator or IRB coordinator is responsible to have each IRB member electronically sign the IRB Member Recusal Agreement initially and annually. The IRB Member Recusal Agreement is maintained in the ERICA system.
 - 4.2.2. 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 or coordinator provides the ad hoc consultant 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 to review the research project forming the basis for the conflict.

4.2.3. 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 absent themselves from the meeting during the IRB's deliberative discussion and vote on the affected research.

4.2.4. IRB members, ad hoc consultants, and other attendees may absent themselves from the discussion and vote for any reason, if he/she feels it is necessary to avoid any appearance of a conflicting interest.

5. Procedures for Maintaining IRB Confidentiality Agreements

5.1. All material received by the IRB will be considered confidential and will be distributed only to meeting participants (regular members, alternate members and ad hoc consultant reviewers) for the purpose of review. All application materials will be stored in ERICA, which is a secured site, with access limited to the IRB members and staff.

5.2. Ad hoc consultants and visitors will be expected to sign the IRB Confidentiality Agreement and will receive printed copies of applicable documents as necessary. The IRB administrator or IRB coordinator is responsible to have each ad hoc consultant(s) or visitor(s) sign the IRB Confidentiality Agreement prior to the start of the meeting. These agreements will be maintained and filed by the IRB Executive Secretary.

5.3. The IRB administrator or IRB coordinator is responsible to have each IRB member electronically sign the IRB Confidentiality Agreement initially and annually. These agreements are maintained in the ERICA system.