1 PURPOSE
1.1 To provide guidance to the Institutional Review Board (IRB) on proper voting procedures and ensure compliance with federal regulations.

2 REVISIONS FROM PREVIOUS VERSION
2.1 None

3 POLICY
3.1 The quorum required to conduct business at a convened meeting is a majority of the primary members. In addition, in order for a vote to be conducted, one member whose primary concerns are in a non-scientific area must be present.

3.2 In order for an IRB member to be eligible for voting, they must be independent of the investigator and sponsor of the proposed research. An IRB member will be ineligible to vote if:
   3.2.1 The IRB member is listed as a member of the research team
   3.2.2 The investigator or sponsor is an immediate family member or relative;
   3.2.3 There is a financial conflict of interest
   3.2.4 There is a reporting relationship to the investigator or sponsor.

3.3 No member may be counted for purposes of determining quorum or participate in the IRB’s initial or continuing review of any project in which the member has a conflicting interest except to provide information requested by the IRB. In addition, the conflicted member must physically leave the room during deliberations and voting.

3.4 Meetings Convened via Conference Call
   3.4.1 Wherever possible, physical presence at the meeting is recommended. OPRR recognizes as “convened” IRB meetings conducted via telephone conference call provided that each member as long as the following two (2) conditions have been satisfied and clearly documented in the minutes:
      3.4.1.1 the members participating via conference call have received all pertinent material prior to the meeting, and
      3.4.1.2 the members actively and equally participate in the discussion of all protocols.
   3.4.2 Members participating via conference call can vote and be counted for quorum. However, opinions of absent members that are transmitted by mail, telephone, telefax or email may only be considered by the attending members and not be counted as votes or quorum.

3.5 Any meeting during which quorum should fail (e.g., those with conflicts being excused, early departures, loss of a non-scientist, etc.) will be terminated from further voting unless and until quorum can be restored.

3.6 Approval by a majority of the voting members’ present is required for a research protocol to be implemented at an AMITA Health facility.

4 RESPONSIBILITIES
4.1 IRB staff & IRB members
5 PROCESS
5.1 This section has been intentionally left blank. Please refer to related policies for applicable procedures.

6 MATERIALS
6.1 None

7 OTHER RELATED POLICY/PROCEDURES
7.1 None

8 REFERENCES
8.1 21 CFR 56.108(c)
8.2 45 CFR 46.108(b)