1 PURPOSE
   1.1 This procedure establishes the process to monitor quorum at convened IRB meetings.
   1.2 The process begins when the HSRO staff member responsible for monitoring quorum notifies the IRB chair that quorum has been attained.
   1.3 The process ends when the meeting is adjourned.

2 REVISIONS FROM PREVIOUS VERSION
   2.1 None.
   2.2 11/23/2020 – added information about alternates substituting for core members who are present at the meeting.

3 GUIDING PRINCIPLES
   3.1 None.

4 RESPONSIBILITIES
   4.1 HSRO staff members carry out these procedures.

5 PROCEDURE
   5.1 At meetings consult the “WORKSHEET: Quorum and Expertise (HRP-305)” to determine that the meeting is appropriately convened by meeting the “QUORUM REQUIREMENTS” and notify the IRB chair when the meeting is appropriately convened.
   5.2 Before each protocol consult the “WORKSHEET: Quorum and Expertise (HRP-305)” to determine that the meeting is appropriately convened by meeting the “EXPERTISE REQUIREMENTS” and notify the IRB chair when the meeting is not appropriately constituted for the review of that protocol.
   5.3 When a member leaves the meeting room for any reason (including a Conflicting Interest) consult the “WORKSHEET: Quorum and Expertise (HRP-305)” to determine that the meeting continues to be appropriately convened by meeting the “QUORUM REQUIREMENTS” and notify the IRB chair when the meeting is not appropriately convened.
   5.4 If a core member and an alternate who is substituting for a core member on an agenda item are both present at a meeting:
      5.4.1 Before the IRB begins the presentation of the agenda item, the core member will automatically go out of voting status and the alternate member will automatically move into voting status for that agenda item.
      5.4.2 Following the vote, the alternate member will automatically move out of voting status and the core member for whom the alternate member substituted will move back into voting status.

6 MATERIALS
   6.1 WORKSHEET: Quorum and Expertise (HRP-305).

7 REFERENCES
   7.1 45 CFR §46.108(b)
   7.2 21 CFR §56.108(c)