Quorum

OIA IRB Committee Education February 2025

Agenda

- Regulations
- Establishment of Quorum
- Loss of Quorum
- References

FDA & OHRP regulations are the same

- 21 CFR 56.108(c)/45 CFR 46.108(b):
- In order to fulfill the requirements of these regulations, each IRB shall…Except when an expedited review procedure is used (see § 56.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.
- Except when an expedited review procedure is used (as described in § 46.110), an IRB must review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

Establishment of Quorum

- Majority of the number of “regular” members on the roster
- ***Non-scientist must be present***
- Members with a COI for the item under review may not vote and may not count towards quorum (and shall recuse themselves during the deliberation and vote)
  - Number of regular members is 5
  - Majority of 5 is 3
  - Those 3 members can be any combination of “regular” members and “alternate” members, but one of them must be a non-scientist
  - If number of regular members is an even number, use “1/2 plus 1” method of calculating quorum
- Extra-regulatory requirements at UCSD that do not affect quorum:
  - If reviewing prisoner research, prisoner “representative” must be present
  - Unaffiliated member generally present (regs require that they be on roster)
  - Nurse member generally present (magnet status requirement)

Loss of Quorum

- IRB cannot make any motions
- IRB cannot make any determinations
- IRB cannot vote

References

- 45 CFR 46.108(b)
- 21 CFR 56.108(c)
- OIA-041 SOP: Meeting Conduct
- OIA-042 SOP: IRB Meeting Attendance Monitoring
- OIA-305 Worksheet: Evaluation of Quorum and Expertise
- FDA & OHRP Joint Guidance: Minutes of IRB Meetings