



WORKSHEET: Quorum and Expertise

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The purpose of this worksheet is to provide support for staff who monitor attendance at convened IRB meetings. This worksheet evaluates whether the members present at the meeting comprise a quorum. IRB staff are to consult this worksheet in preparation of meetings and when monitoring attendance at convened meetings. This worksheet is to be used. It does not need to be completed or retained.

NOTE: Ex officio status is a privilege conferred on an individual, by virtue of their position, to serve on the IRB. An ex officio member holds the right to attend and contribute comments about proposed research, however, they may not make a motion or vote. Therefore, an ex officio member in attendance must not be included when determining the number needed for quorum or counted when determining if a quorum is present.

1 Quorum Requirements (To satisfy Quorum, greater than ½ of members [on the IRB Committee Member Roster] **must** be present, and one of the members present **must** be a non-scientist.). Check if “**Yes**” or “**N/A**”. All must be checked)

- ☐ Greater than half of the IRB members (*will be/are*) present.
- ☐ At least one member whose primary concerns are in scientific areas (*will be/is*) present.
- ☐ At least one member whose primary concerns are in non-scientific areas (*will be/is*) present.¹
- ☐ At least one non-affiliated member (*will be/is*) present.^{1,3}
- ☐ At least one member who represents the general perspective of subjects (*will be/is*) present.^{1,2}
- ☐ If both an alternate IRB member and the regular IRB member for whom the alternate IRB member (*will be/is*) substituting (*will be/are*) present, only one (*will be/is*) voting and only one (*will be/is*) counting towards quorum. (“**N/A**” if both an alternate IRB member and the regular IRB member for whom the alternate IRB member (*will be/is*) substituting (*will NOT be/are NOT*) present) N/A: ☐

2 Expertise Requirements When Applicable to the Research (Check if “**Yes**” or “**N/A**”. All must be checked)

- ☐ At least one member or consultant with scientific or scholarly expertise in the area of research (*will be/is/was*) involved in the review.
- ☐ At least one member or consultant with knowledge of the local context (*will be/is*) involved in the review.
- ☐ At least one member or consultant able to ascertain the acceptability of proposed research in terms of institutional commitments to sustain the research (such as support of facilities, medical or psychological services, study personnel, etc.), applicable laws and regulations, and standards of professional conduct and practice as outlined in the protocol or confirmed by appropriate research leadership.
- ☐ When the research involves Prisoners as subjects: An IRB member who is a Prisoner or a Prisoner representative with appropriate background and experience to serve in that capacity (*will be/is*) involved in the review as a voting member. The Prisoner representative may attend the meeting by phone, video-conference, or Webinar, as long as the representative is able to participate in the meeting as if they were present in person. (“**N/A**” if no Prisoners.) N/A: ☐
- ☐ When the research involves a drug or device: An IRB member who is a licensed physician (*will be/is*) involved in the review. (“**N/A**” if no drugs or devices.) N/A: ☐
- ☐ When the research involves populations vulnerable to coercion or undue influence: An IRB member or consultant who is knowledgeable about or experienced in working with such subjects (*will be/is*) involved in the review.^{4,5} (“**N/A**” if no populations vulnerable to coercion or undue influence.) N/A: ☐
- ☐ When the research involves other specific expertise: An IRB member or consultant who has that expertise (professional competence) (*will be/is*) involved in the review. (“**N/A**” if no specific expertise needed.) N/A: ☐
- ☐ For international research the IRB has knowledge of local laws and the cultural context of the country where research is going to be conducted through one or more of the following strategies: (“**N/A**” if not international research.) N/A: ☐
 - IRB member or consultant possesses knowledge/expertise of local laws and cultural context
 - IRB members review **site/location information** submitted by Investigator with demonstrated knowledge/expertise of local laws and cultural context.
 - Application of the same processes for initial review, continuing review, and review of modifications to previously approved research; post-approval monitoring; handling of complaints, non-compliance, and unanticipated problems involving risk to subjects or others; and consent process and document and other language issues as applied to domestic research.
 - Coordination and communication with local IRBs or ECs when appropriate.
- ☐ For community-based participatory research, the IRB has done one of the following: (“**N/A**” if not community-based participatory research.) N/A: ☐
 - Educated IRB members on community-based participatory research.
 - Included IRB members with expertise in community-based participatory research
 - Obtained consultation with expertise in community-based participatory research

¹ In many cases, the same member will satisfy more than one role (e.g., a member may serve as both non-scientist and non-affiliated or as non-affiliated and represent the perspective of research subjects). However, when conducting Dept. of Energy classified research, the IRB must include both a nonscientist and non-affiliated voting member.



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- 2 A primary responsibility of a non-affiliated member is to represent the perspective of research subjects.
- 3 The IRB may, on occasion, meet without representation of the non-affiliated member and/or member who represents the perspective of subjects; however, this should be the exception. Attendance of the unaffiliated member and the member who represents the perspective of subjects at convened meetings will be monitored and assessed through Quality Assurance review of IRB minutes.
- 4 45 CFR §46.107(a): "If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects."
- 5 Research funded by the National Institute on Disability and Rehabilitation Research, when an IRB reviews research that purposefully requires inclusion of children with disabilities or individuals with mental disabilities as research subjects, the IRB will or has included at least one person primarily concerned with the welfare of these research subjects.