

OIA-305 WORKSHEET: Evaluation of Quorum and Expertise

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

1 Quorum Requirements (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.
- At least one unaffiliated member is generally present. A meeting may be held without an unaffiliated member.
- 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*) counted 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)
- IRB members or alternates who have a conflicting interest relating to a specific item under review cannot be counted towards the quorum for the review of that item.

2 Expertise Requirements (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/was*) involved in the review.
- 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 of such research as a voting member. The prisoner representative may attend the meeting by phone, video-conference, webinar, or similar as long as the representative is able to participate in the meeting as if they were present in person. The prisoner representative need only be present for the deliberation and vote on research involving prisoners and need not attend the entire meeting. (“N/A” if no research involving prisoners.)
- When the research involves a drug or device: An IRB member who is a licensed physician (*will be/is*) present and in voting status (“N/A” if no drugs or devices.)
- 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/was*) involved in the review. (“N/A” if no populations vulnerable to coercion or undue influence.)
- When the research involves other specific expertise: An IRB member or consultant who has that expertise (*will be/is/was*) involved in the review. (“N/A” if no specific expertise needed.)
- If the research is conducted or funded by the National Institute on Disability and Rehabilitation Research (NIDRR) and the research includes children with disabilities or individuals with mental disabilities as research subjects, a person who is primarily concerned with the welfare of these research subjects (*will be/is*) present. (“N/A” if not conducted or funded by the NIDRR or the research does not include children with disabilities or individuals with mental disabilities as research subjects.)
- For international research, the IRB has knowledge of local laws and the cultural context of the country where research is going to be conducted, including: (Can be through consultation with a local IRB, government agency, or other qualified consultant.) (“N/A” if not international research.)
 - Appropriate expertise and knowledge of the country(ies) either through IRB members or consultants.
 - Knowledge of cultural context (e.g. using Office of Human Research Protection’s International Compilation of Human Research Standards¹)
 - 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 risks to subjects or others/unanticipated problem report; and consent process and document and other language issues as applied to domestic research.
 - Coordination and communication with local IRBs or ethics committees when appropriate.
- For community-based participatory research, the IRB has done one of the following: (“N/A” if not community-based participatory research.)
 - 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 [International Compilation of Human Research Standards | HHS.gov](https://www.hhs.gov/ohrt/standards/)