



WORKSHEET: IRB Composition

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The purpose of this worksheet is to provide support for IRB staff reviewing whether the IRB is appropriately composed. This worksheet is to be used. It does not need to be completed or retained. Note: All IRB members are voting members. There are no “non-voting IRB members.”

1 Objective Composition (Check if “Yes”. All must be checked)

- The IRB has at least five members, not counting alternate IRB members.
- The IRB does not consist entirely of men or entirely of women *[FDA and DOJ only]*.
- The IRB does not consist entirely of members of one profession *[FDA and DOJ only]*.
- The IRB has at least one member whose primary concerns are in scientific areas.
- The IRB has at least one member whose primary concerns are in non-scientific areas.
- The IRB has at least one member who is unaffiliated with the institution and whose Immediate Family is unaffiliated with the institution.

2 Subjective Composition (Check if “Yes”. All must be checked)

- The qualifications of alternate members are comparable to the primary member to be replaced.
- The members have varying backgrounds to promote complete and adequate review of research activities commonly reviewed.
- The IRB is sufficiently qualified through its experience, expertise, diversity in terms of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes to promote respect for its advice and counsel in safeguarding the rights and welfare of Human Subjects.
- The IRB includes persons knowledgeable of institutional commitments and regulations, applicable law, and standards of professional conduct and practice and has the ability to ascertain the acceptability of proposed research in terms of these areas.
- The IRB has the ability to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice.
- The IRB possesses the professional competence necessary to review research activities.
- If the 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, the IRB includes one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.
- The IRB has at least one member who represents the perspective of research subjects.
- The IRB has no members responsible for business development.
- The IRB has no members that own equity in the organization.

3 Additional Requirements (Check if “Yes”. All must be checked)

- The IRB has an IRB chair.
- There are sufficient alternate IRB members.

4 Composition of an IRB that Reviews Research Involving Prisoners (Check if “Yes”. If the IRB reviews research involving Prisoners, all must be checked)

- A majority of the Board (exclusive of Prisoner members) has no association with the prison(s) involved, apart from their membership on the Board.
- At least one voting member of the Board is a Prisoner, or a Prisoner representative with appropriate background and experience to serve in that capacity, including a working knowledge of the population to be recruited, a reasonable familiarity with the operations of the prison or confinement facility, and any other legally imposed restrictive conditions involved in the research. (The prisoner representative may be an alternate member who becomes a voting member when needed.)

5 Scope and Composition (Check if “Yes”. All must be checked)

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|---|--|---------------------------------------|
| <input type="checkbox"/> | This IRB conducts: (Select one) | List limitations on types of reviews: |
| | <input type="checkbox"/> All reviews without limitation. | |
| <input type="checkbox"/> Limited to the following types of reviews: | | |
| <input type="checkbox"/> The type of research reviewed matches the description in the roster. | | |
| <input type="checkbox"/> | The composition of the IRB is appropriate to the types of research reviewed. | |