

WORKSHEET: IRB Composition

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This worksheet is used to evaluate whether an IRB is appropriately composed.

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1. Composition requirements (All must be met)

- 1.1 The IRB has at least five primary (non-alternate) members (see Footnote 1)
- 1.2 The IRB members have varying backgrounds to promote complete and adequate review of research activities reviewed
- 1.3 The IRB is sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and 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
- 1.4 The IRB possesses the professional competence necessary to review specific research activities
- 1.5 The IRB includes persons knowledgeable of institutional commitments, applicable law, and standards of professional conduct and practice
- 1.6 The IRB can ascertain the acceptability of research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice
- 1.7 The IRB does not consist entirely of men or entirely of women
- 1.8 The IRB does not consist entirely of members of one profession
- 1.9 The IRB includes at least one member whose primary concerns are in scientific areas
- 1.10 The IRB includes at least one member whose primary concerns are in nonscientific areas
- 1.11 The IRB includes at least one member who is not otherwise affiliated with the [Organization] and who is not part of the <Immediate Family> of a person who is affiliated with the [Organization]
- 1.12 The IRB includes at least one member who represents the perspective of research participants
- 1.13 If the IRB regularly reviews research that involves a vulnerable category of subjects, at least one or more members are knowledgeable about and experienced in working with these subjects
- 1.14 One of the following is true:
 The IRB does not review investigational drugs and devices
 The IRB includes at least one member who is a physician
- 1.15 One of the following is true:
 The IRB does not review research that involves <Prisoners> as subjects
 The IRB includes at least one member who is a prisoner or prisoner representative with a close working knowledge and understanding and appreciation of prison conditions from the prisoner's perspective
- 1.16 No IRB members are responsible for business development
- 1.17 No IRB members own equity in the [Organization]
- 1.18 An IRB member is appointed IRB chair

2. Additional composition requirements for an IRB with alternate members (see Footnote 1) (All must be met)

- 2.1 The qualification of each alternate IRB member is comparable to that of the primary IRB member whom the alternate will replace
- 2.2 Each primary and alternate member has been formally appointed and is listed on the IRB roster

3. Additional quorum requirement for an IRB that reviews protocols conducted at ANCC Nursing Magnet Institutions (All must be met) *(2014 Magnet Application Manual, Chapter 4, Organizational Overview Items, page 43)*

- 3.1 The IRB includes at least one member who is a nurse

4. Notes

5. Footnotes

- 5.1 Alternate members to the IRB substitute for primary members and otherwise serve the same function as primary members