

IRB Reviewer Worksheet

ATTENTION PIs: To evaluate your Human Subjects protocol fully in accordance with federally mandated criteria, the IRB must receive well-organized information about your study. The following are questions that must be adequately addressed to facilitate the IRB's review of your protocol. If you follow this checklist of questions, then the turn-around time for review and approval will be greatly reduced.

1. **Introduction, Specific Aims, Background, and Significance** [as specified in 45 CFR 46.111]
 - a. Are the study aim/objectives clearly expressed?
 - b. Are there adequate preliminary data to justify the research?
 - c. Are adequate references provided?
 - d. Is there appropriate justification for this research protocol?
2. **Scientific Design** [as specified in 45 CFR 46.111]
 - a. Is the scientific design adequate to answer the [research] question(s)?
 - b. Are the aims/objectives likely to be achievable within a given time period?
 - c. Is the scientific design (i.e., randomization; placebo controls; Phase I, II, or III) described and adequately justified?
3. **Research Procedures** [as specified in 45 CFR 46.111]
 - a. Are the rationale and details of the research procedures accurately described and acceptable?
 - b. Is there a clear differentiation between research procedures and standard care and evaluation?
 - c. Are there adequate plans to inform subjects about specific research results that might affect the subject's health and/or decision to continue participation?
4. **Inclusion/Exclusion Criteria for Subjects** [as specified in 45 CFR 46.111; Belmont Report—principle of Justice]
 - a. Are the inclusion and exclusion criteria clearly stated and reasonable?
 - b. Is the principle of distributive justice adequately incorporated into the inclusion and exclusion criteria for the research protocol? Is subject selection equitable?
 - c. Are minorities, women, children, or other vulnerable populations included in the study design? Is the inclusion or the exclusion of special populations justified?
 - d. For subjects vulnerable to coercion or undue influence, are additional safeguards included to protect the rights and welfare of these subjects (e.g., prisoners, mentally ill, economically/educationally disadvantaged, employees)?
5. **Statistical Analysis and Data Monitoring** [as specified in 45 CFR 46.111]
 - a. Is the rationale for the proposed number of subjects reasonable? Were formal sample size calculations performed and are they available for review?
 - b. Are the plans for data and statistical analysis defined and justified, including the use of stopping rules and endpoints?
 - c. Are there adequate provisions for monitoring data (Data and Safety Monitoring Board/Plan)?
6. **Subject Privacy and Confidentiality** [as specified in 45 CFR 46.111; Belmont Report—principle of Respect for Persons]
 - a. Are there adequate provisions to protect the privacy and assure the confidentiality of the research subject?
 - b. Are there adequate plans and provisions to protect the confidentiality of data during and after research?
 - c. Is the use of identifiers or links to identifiers necessary, and how is this information protected? Are these measures adequate?
 - d. Does the PI specify in the protocol and consent form whether research data and information (including informed consent) will be placed in the medical records? **NOTE:**

this question most likely will apply to studies coming out of the Nursing program or from the Psychology Department.

7. **Recruitment of Subjects** [as specified in 45 CFR 46.111]
 - a. Are the methods for recruiting potential subjects well defined?
 - b. Are the location and timing of the recruitment process acceptable?
 - c. Is the individual performing the recruitment appropriate for the process?
 - d. Are all recruitment materials submitted and appropriate?
 - e. Are there acceptable methods for screening subjects before recruitment (e.g., mailings, record reviews)?
8. **Subject Compensation and Costs** [as specified in 45 CFR 46.111]
 - a. Is the amount or type of compensation or reimbursement reasonable and noncoercive?
 - b. Are there adequate provisions to avoid out-of-pocket expenses and costs by the research subject if insurance denies payment? If not, is there sufficient justification to allow subjects to pay for these expenses? **NOTE:** this question most likely will apply to studies coming out of the Nursing program or from the Psychology Department.
9. **Potential Risks/Discomforts and Benefits for Subjects** [as specified in 45 CFR 46.111; Belmont Report—principle of Beneficence]
 - a. Are the risks and benefits adequately identified, evaluated, and described?
 - b. Are the risks reasonable in relation to the benefits to be gained? Are the risks reasonable in relation to importance of knowledge to be gained?
 - c. Are the risks minimized to the greatest extent possible?
 - i. This study uses procedures that are consistent with sound research design.
 - ii. This study uses procedures that do not unnecessarily expose subjects to risk.
 - iii. When possible, study uses procedures already being performed on subjects for diagnostic/treatment purposes.
 - d. Example of more specific questions for a vulnerable population: If children are involved, within which category of risk/benefit does the protocol fall? Are all criteria within the category adequately addressed? [Section 9-7, page 367]
10. **Informed Consent/Assent** [as specified in 45 CFR 46.111, 45 CFR 46.116 & 45 CFR 46.117; Belmont Report—principle of Respect for Persons]

11a. The Consent/Assent Document

- a. Is Assent required?
- b. If yes, is a separate Assent form required? Is a witness signature or an attestation to the Assent required?
- c. For parental consent, if the subject is unable to consent, is the signature of one or both parents/guardians required?

Checklist of Informed Consent Required Elements

1. Consent/Assent form checklist
2. Statement that the study involves research
3. Purpose of research stated in lay language
4. Reason subject is asked to participate
5. Expected duration of the study
6. Study design described in lay language (number of groups, randomization, use of placebo)
7. Study procedures or treatments
8. Compensation or reimbursement
9. Number of subjects in the trial
10. Potential risks or discomforts to the subject

11. Potential direct benefits or benefits to society
12. Alternatives available (indicate if none)
13. Statement that participation is voluntary and subject may withdraw
14. Additional costs associated with participating—who will pay for what
15. How confidentiality will be protected; who has access to the data

Elements required only if applicable to the study:

16. Anticipated circumstances under which a subject's participation may be terminated
17. Statement that significant new findings will be disclosed
18. Consequences of withdrawal
19. If greater than minimal risk, statement included regarding compensation in event of injury

11b. Process of Obtaining Informed Consent/Assent

1. Is the process well defined?
2. Does the process provide sufficient time, privacy, and an adequate setting for the subject to consider participation?
3. Does this process minimize the possibility of coercion or undue influence?
4. Is the individual obtaining consent/assent appropriate to do so?
5. Are the issues of subject's comprehension and autonomy considered?

11c. Waiver or Modification of Informed Consent

Consider when appropriate:

1. Have the criteria for waiver/modification of informed consent documentation been met?
 - a. The consent form would be the only record linking the subject with the research, *and* a potential risk would be a breach of confidentiality. In such case, it is up to the subject when asked if they want documentation.
 - b. Study is no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.
2. If informed consent documentation is waived, should the investigator be required to provide subjects with a written statement regarding the research?
3. If children are included, have the criteria for waiver of parental/guardian consent been met?
 - a. IRB must determine parental/guardian permission is not a reasonable requirement to protect subjects.
 - b. Appropriate mechanisms must be implemented to protect children as subjects.
4. *If waiver or modification* to required consent elements was proposed, have all the criteria been met?
 - a. The research involves no more than minimal risk to the subjects.
 - b. The waiver/alteration will not adversely affect the rights and welfare of the subjects.
 - c. The research could not practicably be conducted without the waiver or alteration, and when appropriate, the subject will be provided with pertinent information after participation.

11. Other Issues and Considerations

- a. When should the next review occur? Should it occur before the required annual review of the study? If frequent reviews are necessary, how should the interval be determined?

- b. Are there any notable conflicts of interest?
- c. Institution-specific questions should also be listed here.
- d. Are there appropriate resources (such as equipment, space, funding, staff) to conduct this research safely?
- e. Has the investigator assured appropriate monitoring of subjects during and after the research? If applicable, will counseling, referrals, or other support services be provided?
- f. If applicable, are there provisions included for research-related injuries?