

BASIC IRB REVIEW (Taken from OHRP's *Institutional Review Board Guidebook*, CHAPTER III)

A. Review Requirements

The IRB must:

1. identify the risks associated with the research, as distinguished from the risks of therapies the subjects would receive even if not participating in research
2. determine that the risks will be minimized to the extent possible
3. identify the probable benefits to be derived from the research
4. determine that the risks are reasonable in relation to the benefits to subjects, if any, and the importance of the knowledge to be gained
5. assure that potential subjects will be provided with an accurate and fair description of the risks or discomforts and the anticipated benefits
6. determine intervals of periodic review, and, where appropriate, determine that adequate provisions are in place for monitoring the data collected
7. determine the adequacy of the provisions to protect the **privacy** of subjects and to maintain the **confidentiality** of the data
8. where the subjects are likely to be members of a vulnerable population (*e.g.*, mentally disabled), determine that appropriate additional safeguards are in place to protect the rights and welfare of these subjects

B. Definitions

Benefit: A valued or desired outcome; an advantage.

Minimal Risk: A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [45 CFR 46.102(i)]. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.

Risk: The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk."

C. Required Elements for an Informed Consent

1. a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental
2. a description of any reasonably foreseeable risks or discomforts to the subject
3. a description of any benefits to the subject or to others which may reasonably be expected from the research
4. a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
5. a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
6. for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained
7. an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
8. a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled

NOTE: Language in the consent/assent forms must be consistent with the Privacy Rule, Institutional Policy and all other applicable laws and regulations as well.

THIS REVIEW CHECK SHEET SHOULD BE USED BY IRB MEMBERS AS A GUIDE FOR CONVENED REVIEW OF NEW REVIEW PROPOSALS, AMENDMENTS CONDUCTED AT THE TIME OF CONTINUING REVIEW

I. ASSESSMENT OF PROTOCOL	YES	NO	N/A	Needs Discussion
A. Is the proposed research scientifically sound?				
B. Will the research design yield useful data?				
II. ASSESSMENT OF SUBJECT POPULATION/RECRUITMENT				
A. Is enrollment of subjects equitable?				
B. Is the subject population appropriate for the research?				
C. Are there any vulnerable populations?				
D. If applicable, are appropriate safeguards in place for vulnerable populations?				
E. Is recruitment non-coercive and consistent with all regulations, laws and institutional policy?				
III. ASSESSMENT OF RISK				
A. Is this research more than minimal risk? (See definition on reverse side.)				
B. Are subjects being subjected to unnecessary risks?				
IV. MINIMALIZATION OF RISK				
A. Are adequate provisions in place to minimize research risks? (Examples include frequent monitoring, qualified personnel, response to emergency situations)				
B. Does monitoring include a data safety monitoring board?				
C. Should this research be periodically reviewed more frequently than once per year?				
V. ASSESSMENT OF ANTICIPATED BENEFITS				
A. Is there direct benefit to the subject?				
B. Does research provide therapeutic benefit?				
C. Does research primarily benefit society (involves procedures performed for research purposes only without direct benefit to subject)?				
D. Is compensation offered to subject?				
E. Do the benefits of this research outweigh the risks?				
VI. INFORMED CONSENT				
A. Does the informed consent include the eight required elements? (See list on reverse side.)				
B. Is the consent form in lay language?				
C. Will the potential subject be approached for informed consent in an appropriate manner?				
D. Will qualified study personnel be consenting the subject?				
VII. PRIVACY/CONFIDENTIALITY				
A. Will the P.I. collect sensitive information about the subject?				
B. Are adequate provisions in place to protect privacy/confidentiality?				
C. Will participation be documented in subject's institutional medical record (including a copy of the consent/assent form(s))?				
D. Are issues related to the Privacy Rule adequately addressed in the protocol, consent/assent form(s) and the IRB application?				
VIII. OTHER CONSIDERATIONS				
A. Does research involve genetic testing?				
B. Will samples be kept for future, unspecified use?				
C. Is security related to electronic data adequately addressed?				
D. Is there any conflict of interest for the PI or other study personnel?				
E. If this research is related to a grant or contract, is the information in the grant or contract appropriate and consistent with the research documents submitted to the IRB?				

Reviewer Signature: _____ **Date:** _____ Please remember to complete the Primary Reviewer **Comment Sheet** (on the M-Drive) as well and e-mail it to the IRB office at least 24 hours prior to the meeting as well. Thank you!