Criteria for IRB Approval of Research

Common Rule 45 CFR 46.111 [HHS] 21 CFR 56.111 [FDA]	**In order to approve research covered by this policy the IRB shall determine that all the following requirements are satisfied:**
Risks to subjects are minimized	(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes
Risks to subjects are reasonable in relation to anticipated benefits	(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among these research risks that fall within the purview of its responsibility.
Selection of subjects is equitable	(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
Informed consent will be sought from each prospective subject	(4) Informed consent will be sought from each prospective subject of the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116 [or by 21 CFR 50 for FDA regulated research].
Informed consent will be appropriately documented	(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117 [or by 21 CFR 50 for FDA regulated research].
And when appropriate:	
Data collection is monitored to ensure subject safety	(6) When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects.
Privacy of subjects and confidentiality of data is protected	(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
Additional safeguards are included for vulnerable populations	46.111 (b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.