Criteria for IRB Approval of Research

45 CFR 46.111 [OHRP]*

45 CFR 46.111 (a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:	
Risks to subjects are minimized *eProtocol Medical: 2(a)(b); 8(c)-(f); 9(c)* *eProtocol NonMedical*: 2(a)(b); 4(c)-(f); 5(a)(c)	(1) Risks to subjects are minimized: (i) By using procedures that are consistent with sound research design and that 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 *eProtocol Medical: 1; 10* *eProtocol NonMedical*: *1; 6*	(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 (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
Selection of subjects is equitable *eProtocol Medical: 2(a)(b); 8(c)-(f); 9(c)* *eProtocol NonMedical*: 2(a)(b); 4 (a)-(g)	(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. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.
Informed consent will be sought from each prospective subject *eProtocol Medical: 13* *eProtocol NonMedical*: 2(c), 9	(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.
Informed consent will be appropriately documented *eProtocol Medical: 13* *eProtocol NonMedical*: 9	(5) Informed consent will be appropriately documented or appropriately waived in accordance with §46.117.
And when appropriate:	
Data collection is monitored to ensure subject safety *eProtocol Medical: 9(e)* *eProtocol NonMedical: 5(e)*	(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
Privacy of subjects and confidentiality of data is protected *eProtocol Medical: 11* *eProtocol NonMedical: 7*	(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 *eProtocol Medical: 9 (f)* *eProtocol NonMedical: 4(c), 5 (e)*	**46.111 (b)**When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects. *[FDA-regulated research only: FDA includes "handicapped" in the list of vulnerable subjects]*

*See also 21 CFR 56.111(a), (b), (c) [FDA]