John Carroll University | Institutional Review Board

Criteria for IRB Approval of Research 45CFR46.111

In order to approve research, the IRB shall determine that all of the following requirements are satisfied:

(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.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any.

(3) Selection of subjects is equitable.

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 aware of the special problems of research that involves 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.

(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.

(5) Informed consent will be appropriately documented or waived per §46.117.

(6) The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. (Requirement of *Limited IRB Review* found in Exempt categories (d)(2) and (d)(3))

(8) Determination of Broad Consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (see regulations for details)

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.