



## What are the Criteria for Approval of a Research Study?

Federal regulations allow IRBs to approve research studies that satisfy all the criteria described below. For additional information refer to the UB Human Research Protection Program Policies and Procedures Manual, Section 9. Criteria for IRB Approval of Research Projects. ([www.research.buffalo.edu/forms/hs/ubsop.pdf](http://www.research.buffalo.edu/forms/hs/ubsop.pdf))

**Risks to Subjects are Minimized.** "Risk" refers to the possibility that harm may occur to the subject. The IRB considers the probability and the severity of any risks associated with the study. While the most likely harms to research subjects are those of psychological or physical injury, other possible risks (e.g., social, legal and financial) are considered if applicable.

**Risks to Subjects are Reasonable in Relation to Anticipated Benefits.** "Benefit" is used in the research context to refer to something of positive value related to the health or welfare of the research subject. Often benefits of research accrue to the society as a whole and not the individual research subject. The IRB must determine that the risk/benefit ratio is reasonable.

**Selection of Research Subjects is Equitable.** There should be a just distribution of both risk and benefit across the proposed study population. The use of vulnerable populations including children, prisoners, the mentally disabled or the disadvantaged must be justified and the IRB gives special attention to their protection.

**Research Subjects Can Provide Informed Consent.** The IRB reviews the proposed informed consent process that begins with the first contact between the research team and prospective subject and continues throughout the course of the study. The consent process must fully inform research subjects in language that they can understand about the study's risks and benefits and the subject's participation must be voluntary and not susceptible to any form of coercion.

**The Research Study Makes Provision for Monitoring the Data Collected to Ensure Subject Safety.**

A data monitoring plan commensurate with the risk is proposed so that unexpected risks or harms to subjects can be promptly identified and corrective action initiated.

**The Privacy of Research Subjects is Protected.** "Privacy" is the research subject's right to control the extent, timing and circumstances under which they share any aspect of themselves with others. Consenting a subject in an ER waiting room would be a violation of the subject's right to privacy.

**The Confidentiality of Research Data is Protected.** "Confidentiality of Research Data" refers to the investigator's responsibility to intentionally limit disclosure of a subject's research data to those parties identified in the consent form and to prevent unauthorized access to the data through effective data security measures.

