

	ASSESSMENT OF RISKS TO SUBJECTS			
	P & P	VERSION DATE	REPLACES P & P	PREVIOUS VERSION DATE
	4.01	02.08.2020	5.2	03.25.2019

No subject in a scientific investigation may be exposed to unreasonable risks to health or well-being. An individual is at risk if exposed to the possibility of any harm (e.g. physical, psychological, sociological, or legal). Determination of risk is a matter of the application of common sense and sound professional judgment. The LSUHSC-NO IRB is the final authority regarding the determination of risk to subjects participating in research at this institution.

- A. "No risk" refers to investigations in which the subject is not placed in jeopardy of any kind. Examples are use of educational tests, observation of public behavior or interview procedures, each under certain conditions. This type of investigation may qualify for exempt status verification by the IRB.
- B. "Minimal risk" means that the risks of harm anticipated in the proposed research are no greater, considering the probability of and magnitude of harm, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Examples are voice recordings made for research purposes, moderate exercise by healthy volunteers, veni-puncture under certain conditions, or collection of urine specimens. Some "minimal risk" protocols may qualify as involving "vulnerable populations." Definitions of minimal risk are as follows:

Definition of Minimal Risk:

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the 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 (45CFR46.102.(i))

Definition of Minimal Risk for Prisoners:

Minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons (45CFR46.303(d))

- C. Psychological injury might involve subjection of subjects to deceit or withholding of information, public exposure, humiliation, invasion of privacy, or coercion. Social injury can occur if there is risk of loss of personal reputation or professional status, defamation of character, personal degradation in the eyes of others, or revelation of information related to sensitive social issues.

Examples of projects which may involve "greater than minimal risk" are surgical procedures, including removal of organs or tissues for biopsy, transplantation, or banking; administration of drugs, chemicals, biological agents, or radiation; use of indwelling catheters or electrodes; or the requirement of strenuous physical exertion. Greater than minimal risk may also include studies in which extremely sensitive information is collected through surveys, for example, studies asking about the use of illegal drugs or unusual sex-practices, or other questions that might place the subject's reputation at risk or that may reveal illegal activities. All projects involving greater than minimal risk and/or vulnerable populations must be reviewed at a regularly-scheduled meeting of the IRB.