

Human Participant Risk Assessment

Projects involving no more than minimal risk and those with more than minimal risk are allowed under the following guidelines.

No more than minimal risk exists when the probability and magnitude of harm or discomfort anticipated in the research are not greater (in and of themselves) than those ordinarily encountered in everyday life or during performance of routine physical or psychological examinations or tests.

More than minimal risk exists when the possibility of physical or psychological harm or harm related to breach of confidentiality or invasion of privacy is greater than what is typically encountered in everyday life. Most of these studies require documented informed consent or minor assent with the permission of parent or guardian (as applicable).

1) Examples of Greater than Minimal Physical Risk

- a. Exercise other than ordinarily encountered in everyday life
- b. Ingestion, tasting, smelling, or application of a substance. However, ingestion or tasting projects that involve commonly available food or drink will be evaluated by the IRB which determines risk level based upon the nature of the study and local norms.
- c. Exposure to any potentially hazardous material.

2) Examples of Greater than Minimal Psychological Risk

A research activity (e.g. survey, questionnaire, viewing of stimuli) or experimental condition that could potentially result in emotional stress. Some examples include: answering questions related to personal experiences such as sexual or physical abuse, divorce, depression, anxiety; answering questions that could result in feelings of depression, anxiety, or low self esteem; or viewing violent or distressing video images.

3) Privacy Concerns

The student researcher and IRB must consider whether an activity could potentially result in negative consequences for the participant due to invasion of privacy or breach of confidentiality. Protecting confidentiality requires measures to ensure that identifiable research data are not disclosed to the public or unauthorized individuals.

Risk level can be reduced by protecting confidentiality or collecting data that is strictly anonymous. This requires the collection of research in such a way that it is impossible to connect research data with the individual who provided the data.

4) Risk Groups

If the research study includes participants from any of the following groups (vulnerable populations), the IRB and student research must consider whether the

nature of the study requires special protections or accommodations:

- a. Any member of a group that is naturally at-risk (e.g. pregnant women, developmentally disabled persons, economically or educationally disadvantaged persons, individuals with diseases such as cancer, asthma, diabetes, AIDS, dyslexia, cardiac disorders, psychiatric disorders, learning disorders, etc.)
- b. Special groups that are protected by federal regulations or guidelines (e.g. children/minors, prisoners, pregnant women, students receiving services under the Individuals with Disabilities Education Act (IDEA)).