A. Minimal Risk: Definitions, Criteria, and Examples

Minimal Risk means that the probability and magnitude of physical, psychological, or informational harm or discomfort does not exceed that which is ordinarily encountered in daily life or in the routine physical and psychological examinations or tests, and that confidentiality is adequately protected (HHS, 2018).

Definitions:

- "Probability and magnitude": The researcher must assess both the likelihood that harm will occur and the severity or seriousness of such harm.
- "Physical harm": The researcher must consider the likelihood that physical harm could occur, such as an adverse reaction to a blood draw.
- "Psychological harm": The researcher must also consider the likelihood of psychological harm occurring, and analyze whether such effects would be short-term immediate reactions (e.g., momentary distress) or longer-term more pervasive reactions (e.g., exacerbation of symptoms of anxiety or depression).
- "Informational harm": The researcher must consider the likelihood that information collected during the study or recruitment process would create risk to the privacy of the individual, put them at greater-than-otherwise risk of being identified or arrested, or create employment or interpersonal risks through revelation of otherwise private opinions or information.
- "Daily life": When considering the standard of risks that would be encountered in daily life, one must compare the risks to those that would be experienced by a an average, healthy person living in a safe environment.

Examples: Not Greater than Minimal Risk:

The following examples could be deemed to have no greater than minimal risk, according to the National Institute on Mental Health:

- Research involving routine blood draws, physical exams, educational tests (e.g., aptitude tests or academic achievement tests) or psychological tests (e.g., measures of motivation or personality traits).
- Non-interventional studies, such as observational studies of public behavior or research on individual or group behavior, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate participants.
- Surveys, questionnaires, or interviews of a non-sensitive nature which are unlikely to produce discomfort in respondents.
- Electrophysiological studies in healthy participants or clinical populations (e.g., surface recordings such as EEG or skin conductance).
- Research involving the analysis or meta-analysis of existing data, documents, records, pathological specimens, or diagnostic specimens.
- Research involving benign behavioral interventions (e.g., Interventions that are not likely to be perceived as offensive or embarrassing) in adult participants for whom identification would not put participants at risk of criminal, work, financial, or other harm.

Examples: Greater than Minimal Risk:
The following examples from the University of Connecticut would likely be deemed greater than minimal risk:

- The participant population is known to have decisional vulnerabilities and require enhanced informed consent protections for the type of study to be conducted.
  Example: A survey study asking adults with intellectual disabilities about their adaptation to independent living housing.
- The study is designed to (a) produce clinical changes in health, health-related behaviors or symptomology, and (b) includes identifiable information.
  Example: Research exploring the effectiveness of college program to encourage condom use for safe sex in which people's safe or unsafe sex practices are recorded along with identifying information.
- Public awareness of recruitment procedures can jeopardize participant physical safety or reveal criminal behavior.
  Example: A study of sex workers that recruits prostitutes in a public space known as a "red light district" that has the potential to alert local police to prospective participants' illegal behaviors.
- The nature of the research data collected requires specific plans for reporting illegal behaviors, providing emergency treatment, or protecting a participant or third party from physical harm.
  Example: A focus group study on parenting that may reveal isolated incidents of child abuse that an investigator is required by law to report.
- Use of deceptive techniques includes procedures that are specifically designed to induce psychological, social, or physical discomfort.
  Example: A deception study using a confederate to assess participants' emotional reactions to peer rejection.
- Additional protections are necessary to avoid harms produced by an existing professional or service relationship with research staff that would compromise voluntary participation.
  Example: A study on nursing aides' attitudes toward patients hospitalized for complications of Type II Diabetes
- Research which previous experience (by the particular investigator or other investigators) has shown to create a potential of risk to participants
- Research which potentially could put the participant at risk for legal or civil liability or invade a participant's privacy in regard to sensitive aspects of his/her behavior (e.g., illegal conduct, drug use, sexual behavior, alcohol use).