FSU RESEARCH
Advancing Creativity and Innovation

GUIDANCE: RISK LEVELS, RISK TYPES, EXAMPLES & FSU IRB REVIEW PATHWAY MATRIX

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RISK TYPE / RISK LEVEL	Psychological or Social	Privacy or Legal	Financial	Physical or Health	IRB REVIEW PATHWAY[i]
Minimal Risk					
LEGAL DEFINITION: *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 (45 CFR 46, section 46.102(j)). The objective standard for assessing an individual's risk is based upon the **average, healthy person in the general population, living in a safe environment, and aged-indexed**, and NOT based upon proposed subjects or any specific population (DHHS, 2005, 2008; National Academies, 2014). For children, *minimal risk* is interpreted as those risks encountered during daily life by normal, average, healthy children living in safe environments or during the performance of routine physical or psychological examinations or tests; risks should be age-indexed (DHHS, 2005).[ii] For prisoners, *minimal risk* means 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 (45 CFR 46, section 46.303(d)).					**EXPEDITED REVIEW** Studies involving minimal risk may be reviewed via expedited review IAW 45 CFR 46, section 46.110 and 63 Federal Register 60353 (1998).
Greater than Minimal Risk[iii]					
Minor increase over minimal risk	*Minor increase over minimal risk* is interpreted as (1) an increase in the probability and magnitude of harm or discomfort that is *only slightly* more than minimal risk, (2) there is no or an extremely small probability that participants will experience as severe any potential pain, discomfort, stress, or harm associated with the research and (3) any potential harm or discomfort associated with the research will be transient and reversible in consideration of the nature of the harm (restricted to time of procedure or short post-experimental period). This *minor increase over minimal risk* level is specified in regulations pertaining to permissible research involving children as human subjects when there is no prospect of direct benefit to the individual subject (45 CFR 46, section 46.406); any study involving children for which there is no prospect of direct benefit but which poses more than a minor increase over minimal risk will require federal DHHS Secretarial approval. As needed in order to characterize a study's risk and required commensurate safeguards, this risk level may also be applied to research involving adults. For ANY risk to be considered to present only a minor increase over minimal risk, the risk must be less severe than those depicted below as Moderate or High risks.				**CONVENED MEETING REVIEW** (FULL BOARD)

RISK TYPE / RISK LEVEL	Psychological or Social	Privacy or Legal	Financial	Physical or Health	IRB REVIEW PATHWAY[i]
Moderate risk	Subjectively upsetting, unwanted emotional or behavioral responses that are non-impairing and transient or of short duration. Examples: feeling sad, tearful, distressed, preoccupied or nervous; mild changes in sleep; minor alteration of relationship dynamics.	Temporary or moderate harm to social reputation or in any of the other three domains (psychological or social, financial, physical or health). Example: release of research information or biospecimens leads to embarrassment and discomfort.	Temporary or moderate financial costs or loss. Example: short-term absence from work causing lost wages.	Temporary (but reversible) or moderate physical discomfort (lasting greater than 24 hours), dysfunction, bodily harm, or pain. Example: harm to an organ, body or function	**CONVENED MEETING REVIEW** (FULL BOARD)
High risk	Pronounced distress during the research activity, or negative outcomes that impair or persist for more than a few days. Examples: depressive symptoms, impulsive behavior; major alteration of relationship dynamics or social reputation.	Severe or long-term harm to social reputation or any of the other three domains (psychological/social, financial, physical/health). Examples: release of research information or biospecimens leads to loss of insurance; stigma; damage to educational opportunity; civil penalties; or criminal prosecution.	Severe and/or permanent financial harm. Example: long-term or permanent disability resulting in job loss, or loss of income or assets.	Severe or chronic pain, disfigurement, injury, disability, permanent harm to an organ, body or function, or death.	**CONVENED MEETING REVIEW** (FULL BOARD)

[i] The IRB has in accordance with federal law the final authority to determine the risk level and review pathway for any study involving human subjects; institutional officials may not approve of human research that has not, including with regard to risk determination, been approved by the IRB (45 CFR 46, sections 46.109, 46.112).
[ii] A study involving children who are objectively not normal, average, healthy, or a study involving normal, average or healthy children who will undergo any interaction or intervention that is not a routine physical or psychological examination or test, is presumptively a greater than minimal risk study. Risks should be age-indexed (DHHS, 2005).
[iii] The IRB's evaluation of the harms and discomforts of the research should consider the nature of the study procedures, other study characteristics, subject characteristics, and steps taken to minimize risk (U.S. Department of Health and Human Services (DHHS), 2008). In order for the IRB to determine that a study presents only a minor increase over minimal risk, researchers must provide sufficient evidence about the procedures, activities, sample population, and the qualifications of research personnel. Note that a study that is presumptively greater than minimal risk may, after the convened IRB's consideration of sufficient evidence provided in the reviewed protocol about steps that the study team will take to minimize risks and maximize benefits, determine at the time of convened review that on balance the study is no greater than minimal risk (DHHS, 2017).

Gratitude is extended to the University of Michigan Office of Research, upon whose risk-related guidelines this matrix was developed.