

**GUIDELINES FOR USING MAGNITUDE OF HARM IN CATEGORIZING RISK LEVEL**

<b>RISK LEVEL</b>	<b>Potential Psychosocial Harm</b>	<b>Potential Privacy/Legal Harm</b>	<b>Potential Financial Harm</b>	<b>Potential Health/Physical Harm</b>
<b>No more than minimal risk</b>	<p>GENERAL DEFINITION: The probability* and magnitude of harm or discomfort anticipated in the research and 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 46.102 (i).</p> <p>For <b>children</b>, minimal risk is further defined as: the level of risk that a <b>normal, average, healthy child</b> may be exposed to in the course of that child’s everyday life, or those risks encountered by <b>normal, average, healthy children</b> living in safe environments in daily life or during the performance of routine physical or psychological examinations or tests.**</p> <p>For <b>prisoners</b>, minimal risk is further defined as: 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 46.303</p>			
<b>Minor increase over minimal risk</b>	<p>While this risk category may be used to classify research involving adult subject populations, it <u>must</u> be considered in the evaluation of risk in research involving children as defined in 45 CFR 46 sections 404-407*** Risks are more severe than those defined above (see “No more than minimal risk’) and less severe than those defined below (see “Moderate”).</p>			
<b>Moderate risk</b>	<p>Subjectively upsetting, unwanted emotional or behavioral responses that are non-impairing and transient or of short duration (days).</p> <p>Examples are feeling sad, tearful, preoccupied or nervous; mild changes in sleep, and minor alteration of relationship dynamics.</p>	<p>Temporary or moderate harm to social reputation or in any of the other three domains (health/physical, financial, psychosocial).</p> <p>Example: release of research data leads to embarrassment and discomfort.</p>	<p>Temporary or moderate financial costs or loss.</p> <p>Example: short-term absence from work causing lost wages.</p>	<p>Temporary (but reversible) or moderate discomfort (lasting greater than 24 hours), dysfunction, bodily harm, or pain.</p> <p>Example: harm to an organ or the body</p>
<b>High risk</b>	<p>Pronounced distress during the research activity, or negative outcomes that impair or persist for more than a few days.</p> <p>Examples are depressive symptoms, impulsive behavior, and major alteration of relationship dynamics or social reputation.</p>	<p>Severe or long-term harm to social reputation or any of the other three domains: (health/physical, financial, psychosocial).</p> <p>Example: release of research data leads to loss of insurance, social stigma or civil or criminal penalties.</p>	<p>Severe and/or permanent financial harm.</p> <p>Example: permanent disability resulting in job loss or loss of assets.</p>	<p>Death, severe pain and/or permanent dysfunction or harm to organ or body.</p>

\* IRBs consider both magnitude and probability of harm.

\*\*SACHRP research involving children subcommittee. Kornetsky, S.Z., Fisher, C.B. (October 4-5, 2004) Office for Human Research Protections (OHRP) Subcommittee on Research Involving Children Report/Issues 4th Report for SACHRP Consideration Clarifying 45 CFR Subpart D Definitions, Slide 14.

\*\*\* The assessment of risk to a subject is not made at the same time that benefit assessment is made except under the conditions of 45 CFR 46 sections 404-407. This guidance is not meant to replace individual judgment of risk in any particular study but rather to foster consistency to the extent possible.