

II. What is “Minimal Risk”?

In order to be eligible for expedited review, a research activity must be determined to be no more than “minimal risk,” a regulatory concept defined in the Common Rule as follows:

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 tests⁸.

Social and behavioral research studies may involve the possibility of various kinds of harm or discomfort. Harm or discomfort may be physical, psychological, or social; other harms may be economic, legal, or moral. Some social and behavioral research studies are designed to obtain sensitive personal information about people, the disclosure of which may be a major source of risk in social science research. Strengthening procedures to protect the confidentiality of acquired sensitive information decreases the risks of research studies involving sensitive information by decreasing the probability that subjects will experience harm or discomfort resulting from the disclosure of such information. Any effective strategy used to avoid, prevent, ameliorate or protect against the occurrence of harm or discomfort in a research study lowers the total value of the probability and magnitude of harm or discomfort – that is, the *potential for negative effects* - of the proposed research study. The reviewer should take into account any protective measures included in the research design as part of the process of determining if the proposed research involves no more than minimal risk. However, some social and behavioral studies involve more than minimal risk, even though they include such protective measures.

The judgment that a research activity involves “minimal risk” depends on a comparative assessment that the potential for negative effects to the human subjects of the research must be judged to be no more than the potential for negative effects ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Assessing the potential for negative effects of research involves considering the *probability* of harm or discomfort – the chances that the subjects will experience harm or discomfort, and the *magnitude* of the harm or discomfort - that is, how great or small the harm or discomfort would be, in terms of such factors as the kind of harm, duration, intensity, reversibility, etc. The potential for negative effects is the product of how likely it is that the subjects will experience harm or discomfort and the degree of harm or discomfort subjects would suffer if the harms or discomforts were to occur.

The definition of minimal risk provides three alternative standards against which the potential for negative effects of the research may be compared to determine whether the research involves minimal risk:

1. the probability and magnitude of harm or discomfort ordinarily encountered *in daily life*; or,

⁸ 45 CFR 46.102(i).

2. the probability and magnitude of harm or discomfort ordinarily encountered *during the performance of routine physical examinations or tests*; or,
3. the probability and magnitude of harm or discomfort ordinarily encountered *during the performance of routine psychological examinations or tests*.

Depending on the nature of the specific research activity, one or another of these three alternative standards may be most suitable. The particular risks of the research activity may not be identical to those of any of these three standards; however, these standards serve as guides for the types of possible harm or discomfort that are determined to be of minimal risk to subjects. The routine-physical-examinations-or-tests standard may be most appropriate for evaluating the potential for negative effects of medical research activities. The routine-psychological-examinations-or-tests standard may be more suitable for evaluating the potential for negative effects of behavioral research projects carried out in psychological laboratories. One of these two standards may also be suitable for evaluating the potential negative effects of survey or interview research in which sensitive personal information is obtained, since routine physical or psychological examinations and tests frequently involve such information.

The daily-life standard may be most appropriate for evaluating the potential for negative effects of social and behavioral research studies that take place in natural settings, where individuals' participation in research as human subjects is intertwined with everyday life. The physical-examinations-or-tests standard and the psychological-examinations-or-tests standard both offer the advantage of establishing a relatively precise measure of the potential for negative effects involved. This is not so simple for the daily-life standard, which requires taking into account a larger array of human activities, including activity in the home, transportation to school or work, the experiences of school or workplace activity, ordinary social or recreational activity, or routine exercise, etc. But while the variations among and between these activities make it more difficult to precisely assess the potential for negative effects ordinarily encountered in daily life, the resemblance between these activities and the activities of human subjects in many social or behavioral research studies may make the daily-life standard more directly suitable for determining whether the potential for negative effects involved in those social or behavioral studies meets the standard of minimal risk.

Determining whether a study involves minimal risk or not involves comparing the potential for negative effects of the research for the subjects of the particular research study with the potential for negative effects of individuals engaged in everyday life or undergoing routine physical or psychological examinations or tests. The potential for negative effects of a particular study may vary depending on whether the subjects are children, adults, members of a vulnerable population, or people chosen for a specific condition, background, or social status. Similarly, the potential for negative effects for the population of individuals whose ordinary daily lives or routine physical or psychological examinations or tests serve as the basis for comparison also varies depending on those individuals' age, vulnerability, health, culture, and social environment.

The minimal-risk standard is sometimes interpreted to require comparing the potential for negative effects for the subjects of the research activity to the potential for negative effects of everyday life or routine physical or psychological examinations or tests for the same specific population of individuals outside of the research, which is sometimes called the 'relative standard'. Alternatively, the minimal-risk standard has also been interpreted to require comparing the potential for negative effects for the subjects of the research activity to the potential for negative effects of everyday life or routine physical or psychological examinations or tests for a population of normal healthy individuals, sometimes called the 'uniform standard'. Whatever standard or population is chosen as the appropriate basis for comparison with the potential for negative effects of the research for the subjects in the research study, it is important to avoid an interpretation that leads to taking unfair advantage of a population of individuals who are already vulnerable in some way. The assessment of minimal risk should be sensitive to the concern that the impact of the assessment of minimal risk should not serve to exploit the research subjects in violation of the principle of justice.