



Office of the  
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# Determining Minimal Risk

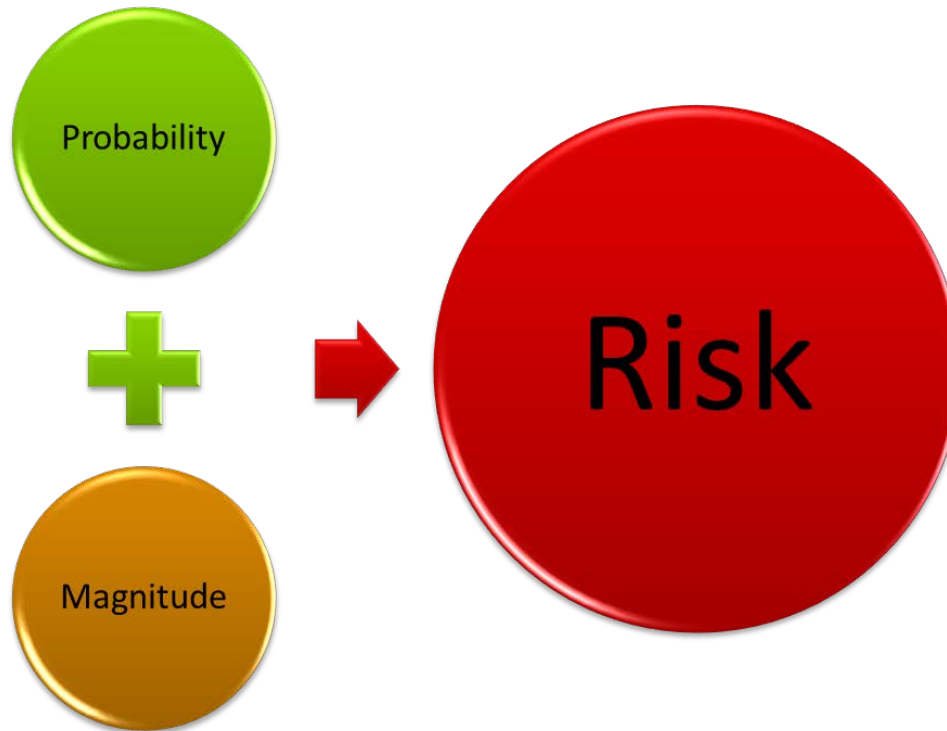
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# Risk Assessment



# What is Minimal Risk?

The federal regulations define minimal risk as 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”

45CFR 46.102(i)

# Expedited vs. Committee Review

- Under the proposed revised regulations, the “default” assumption will be that a study otherwise eligible for expedited review will be considered minimal risk unless a reviewer documents the rationale for classifying the study as involving more than minimal risk.
- Higher-risk studies should be subject to the highest level of scrutiny. Research involving more-than-minimal risk requires review by a convened IRB

# Unjustified Variability

The variability in IRB assessment of the risks of procedures may result in inappropriate review:

- Approving some risky studies, or
- Disapproving some safe studies

# Data Based Determinations

- Recommendations in the NPRM specifically state “Determinations about the risks imposed by various research activities should be based upon appropriate data.”

# Judgement in the Absence of Data

- IRB members may assume they are familiar with the risks of daily life or rely on intuition.
- Psychological studies show that individuals' risk perception is severely and systematically flawed.
  - People focus on how *familiar* an activity is or how much *control* they have when participating.
- To ensure accurate application of the minimal risk standard, we must quantify the risks of daily life.

# How should we interpret the minimal risk standard?

- The Procedure Based Standard
- The Relative Standard
- The Objective Standard



# Procedure-based Standard

- Categorizes as minimal risk only those procedures that people regularly encounter during ordinary life.
- Blood draws and eye exams are minimal risk, but MRIs and glucose tolerance tests are not.

# Problems

- Federal regulations do not limit minimal risk procedures to procedures people actually encounter in daily life.
- Rather, the risk level of research procedures must be no greater than the risk level of every day activities, including medical procedures.

# The Relative Risk Standard

Which people's daily lives should serve as the baseline for determining when research risks are minimal?

- The relative risk standard categorizes as minimal risk those risks that the people enrolled regularly experience in daily life.
- Minimal risk is “relativized” to the population under study.

# Problems

- This relative standard has the potential to result in an unjust distribution of risks.
- A population-specific definition unjustly permits individuals to be exposed to higher levels of risk under the minimal risk category, simply because their daily lives are filled with greater risk than healthy individuals or those living in safe conditions.

# The Objective Risk Standard

- The objective risk standard categorizes as minimal risk those risks that average, healthy, normal people experience during the course of daily life.
- The IRB must ensure that the application of the general population standard does not result in the inadvertent application of an adult minimal risk standard to child participants.

# The Risk Threshold

- Activities of daily life pose different levels of risk to people
- Bike riding is more dangerous than napping or reading a book.
- Data on Risks of daily life:
  - Cars: .02 deaths per 1 million car rides
  - Sports: 2,400 injuries per 1 million events
- People with diabetes, regardless of age, spend more time sticking their fingers than people who do not have diabetes.

# The Risk Threshold

- The minimal risk standard insists that research risks 'cannot be greater than' the risks that average, healthy, normal people face in daily life.
- Research risks cannot exceed *the range* of risks presented by daily life activities.
- Research risks must lie below the top of the range of daily life risks.
- Therefore, the risks of research procedures must not be riskier than the *riskier* activities of daily life.

# Summary

A given research procedure is minimal risk if the

- *risks* posed by the research procedure *do not exceed* the risks of the riskier activities
- in the daily life of *average, healthy, normal people*.



# Overestimation and Underestimation of Risk

The vagueness of the definition of minimal risk leads to both overestimation and underestimation of risk, due in large part to:

- The lack of specificity in examples provided for minimal risk under the expedited risk category
- Difficulty distinguishing research risk from participant vulnerabilities
- The tendency to apply subjective estimations of the level of harms

# What did we learn?

- We must be wary of considering intuitions about risks and should instead define what we do consider
- Minimal Risk must be defined by data: is this only the list of expedited categories or can our new guidances help (e.g., exercise, radiographic procedures)?
- People first: population-specific harms are important