



Office of the  
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# Determining Minimal Risk

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# 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)

# Whose “Daily Life”?

Is it the daily life of an average person in the general population or the specific population to be enrolled in the study?

# General Population

Is it the daily life of an average person in the general population or the specific population to be enrolled in the study?

# 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.

# 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.
- Institute of Medicine:  
*IRBs “should interpret minimal risk in relation to the normal experiences of average, healthy, normal people.”*

# 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.
- The minimal risk standard insists that research risks 'cannot be greater than' the risks that average, healthy, normal people face in daily life.



# The Risk Threshold

- 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.

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# Summary

- A given research procedure is minimal risk if the
  - (i) *risks* posed by the research procedure
  - (ii) *do not exceed* the risks of the riskier activities
  - (iii) in the daily life of *average, healthy, normal children.*

# Conclusions

- Minimal Risk must be defined by data.
- We must be wary of considering intuitions about risks.
- Data on Risks of daily life:
  - Cars: .02 deaths per million car rides
  - Sports: 2,400 injuries per 1 million events
- Many procedures ruled unacceptable actually meet the minimal risk criteria.