Human Subjects
Office of Research
UNIVERSITY OF GEORGIA
1785

IRB Member Training:
Minimal Risk vs. Greater than Minimal Risk

Minimal Risk

def. – the probability and magnitude of harm or discomfort anticipated in the research are not greater than those encountered in daily life or during the performance of routine physical or psychological examinations.

What is routine physical or psychological examinations?

- Measurements of height, weight, waist and head circumference
- Assessment of obesity with skin fold calipers
- Collection of blood or voided urine
- Measurement of heart rate and blood pressure
- Hearing and vision tests
- Modest changes in diet or schedule
- Testing of fine and gross motor development
- Non-invasive physiological monitoring
- Medical and social history
- Guidance and education interventions
- Intelligence tests
- Mental and motor scales
- Neurological or motor disorder screening
- Social development assessment
- Family and peer relationship assessments
- Emotional regulation scales
- Scales to detect feelings of sadness or hopelessness.
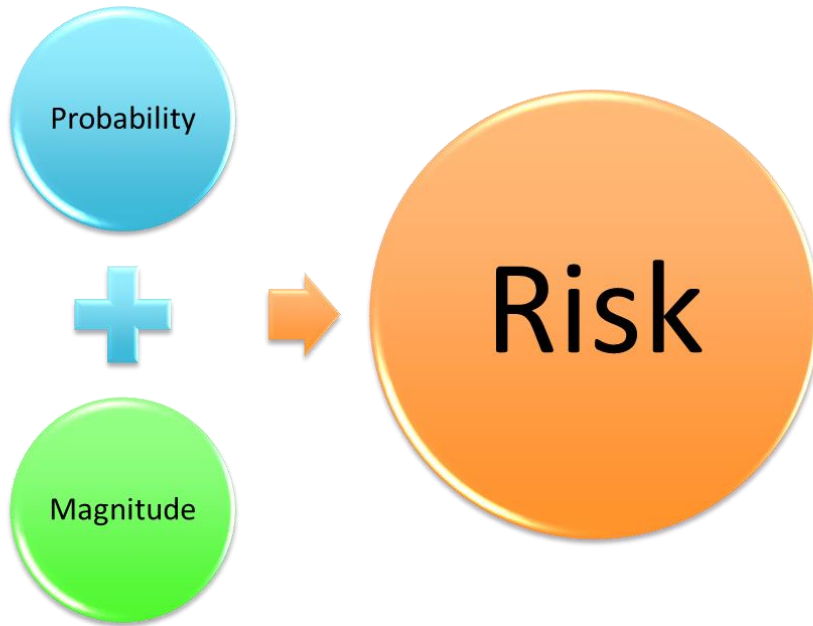
The "Fixed" or "Uniform" Minimal Risk Threshold

Estimate of probability and magnitude of…

- Daily life, **<u>OR</u>**

- For the general population, **<u>OR</u>**

- For the average person in the general population, **<u>OR</u>**

- **Daily life for the average person in the general population**

Things to Consider

- Duration of risk
- Characteristics of Risk
- Reversibility of harm

IRB Review Categories

Probability

+ → Risk

Magnitude

Risk is a function of probability and magnitude

- Expedited
  - No more than <u>minimal risk</u>

- Full Committee
  - <u>More than minimal risk</u> or does not fit within the Expedited categories

Other Things to Consider

Probability and Magnitude of harm and discomfort introduced by the research depending on…

- Subject characteristics
- Training of the researcher
- Research site (e.g., lab, office, clinic)
- Repetition and/or length of procedure

Examples of Greater than Minimal Risk Studies

- Randomized treatment studies
- Studies using investigation drugs and/or devices
- Behavioral studies involving risky interventions, observations of illegal behavior or very sensitive data/questions
- Classified research

(UCSF)

Final Thoughts

Appropriately balance the probability and magnitude of research harms

- A slight increase in probability without increase in magnitude does not elevate risk beyond the minimal risk threshold

- A slight increase in magnitude with reduction in probability does not elevate risk beyond the minimal risk threshold

LINKS:

Component Analysis: FDA Presentation to SACHRP (2012) https://wayback.archive-it.org/3919/20150824191211/http://www.hhs.gov/ohrp/sachrp/mtgings/2012%20Feb%20Mtg/componentanalysisskipnelson.pdf
Determining Minimal Risk in Social and Behavioral Research
https://www.ncbi.nlm.nih.gov/books/NBK217976/