

IRB Review of Social and Behavioral Research: How Might Psychologists View It?

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A Research Question:

What Should Psychologists
Think About Institutional
Review Board (IRB)
Decision-Making?

Why do IRBs make strange decisions about research projects?

1. The local circumstances are peculiar.
2. The IRB members don't know the facts.
3. The IRB members don't understand the rules.
4. IRB members exhibit psychological behavior.

Do IRB members exhibit rational choice?

Do IRB members make value decisions based on the expected utilities of the alternative courses of action?

Jeremy Bentham

- Founder of *Utilitarianism*, the *Principle of Utility of the Greatest Happiness of the Greatest Number*, and the *Felicific Calculus*

The Factors of the Felicific Calculus of Pleasures and Pains

- Intensity
- Duration
- Certainty or Uncertainty
- Propinquity or Remoteness
- Fecundity
- Purity
- Extent, the number of persons to whom it extends

(Bentham)

The Regulatory Factors of Risk Assessment

- Probability
- Magnitude
- Harm
- Discomfort

The Kinds of Pain in the Felicific Calculus

- Privation
- The Senses
- Awkwardness
- Enmity
- An Ill name
- Piety
- Benevolence
- Malevolence
- Memory
- Imagination
- Expectation
- Association

(Bentham)

The Conventional Regulatory Conception of Harm or Discomfort

- Physical
- Psychological
- Legal
- Economic
- Social
- Dignitary
- [Moral]

The Kinds of Pleasures in the Felicific Calculus

- Sense
- Wealth
- Skill
- Amity
- Good name
- Power
- Piety
- Benevolence
- Malevolence
- Memory
- Imagination
- Expectation
- Association
- Relief

(Bentham)

The Conventional Regulatory Conception of Benefit

- Benefits to subjects
- Benefits to others
- Importance of Knowledge
- Compensation
- Treatment if injury occurs

The Fallacy of Predicting Risk/Benefit Decisions based on Rational Choice or Expected Utility Theory:

People do not make risk/benefit decisions based entirely on calculations of the objective risks and benefits involved in activities.

What are People's Preferences Regarding Risks?

Risk Preference Cases #1 & #2

Risk Preference Case #1: Which Approach is More Acceptable?

- 600 people are exposed to a trauma.
- With treatment A, 200 people will be fine.
- With treatment B, there is a $1/3$ chance of 600 being fine, and a $2/3$ chance of no one being fine.
- Do you prefer Treatment A or Treatment B?
- [Treatment A is generally preferred]

Risk Preference Case #2: Which Approach is More Acceptable?

- 600 people are exposed to a trauma.
- With treatment A, 400 people will be ill.
- With treatment B, there is a $1/3$ chance of no one being ill, and a $2/3$ chance of 600 being ill.
- Do you prefer Treatment A or Treatment B?
- [Treatment B is generally preferred.]

What factors influence variation in assessments of acceptable levels of risk?

- Loss Aversion
- Familiarity
- Stigma
- Cultural Worldview
- Trust
- Status
- Affect
- Probability Neglect
- Status Quo
- Gender
- Race
- Group Interactions

(Kahneman et al., Slovic et al., others)

How will familiarity with the kind of risk influence risk assessment in IRB members' judgments?

- IRB members unfamiliar with the risks of proposed social and behavioral research will judge the same risks to be greater than investigators and IRB members familiar with those risks.
- Members of IRBs that regularly review social and behavioral research of any particular kind will judge the same risks to be lower than members of IRBs that do not regularly review research involving similar kinds of risk.
- Members of IRBs reviewing social and behavioral research involving a wide variety of risks will judge the same risks to be greater than members of IRBs reviewing social and behavioral research involving little variety in the risks.

What is “minimal risk”?

“*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 tests.” (.102(i))

Three alternative standards of the risks of harm or discomfort

- Routine Physical Examinations or Tests
- Routine Psychological Examinations or Tests
- Daily Life

What are the risks of harm or discomfort “...ordinarily encountered in daily life...”?

What Kind of Decision-Makers
are IRB Members?

What Kind of Decision-Maker are
You?

Decision-making: 3 Survey Questions

On a scale of 1 to 7, with 1= 'Completely Disagree' and 7= 'Completely Agree', rate yourself for the following 3 statements:

1. “Whenever I’m faced with a choice, I try to imagine what all the other possibilities are, even ones that aren’t present at the moment.”
2. “Renting videos is really difficult. I’m always struggling to pick the best one.”
3. “No matter what I do, I have the highest standards for myself”.

(Schwartz/APA)

Maximizers differ from Satisficers with respect to:

- The amount of time they take to decide
- The number of alternatives they consider
- Their assessment of the decision
- Their response to the decision

(Schwartz, 2004)

A Maximizer's Regulatory Standard: Approval Criterion .111(a)(1)

“Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.”

The Satisficer's rewrite:

“Reasonable precautions have been taken to reduce the risks to subjects: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.”

A Satisficer's Regulatory Standard: Approval Criterion .111(a)(2)

“Risks to subjects are *reasonable in relation* to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result....”

The Maximizer's rewrite:

“Risks to subjects are *outweighed to the greatest extent possible by* the potential benefits, if any, to the subjects, and the importance of the knowledge that may reasonably be expected to result...”

Hypothetical Conclusions

- IRB members make decisions about proposed research influenced by factors other than the objective nature of the proposed research itself or the risks involved.
- IRB member biases in decisions are potentially predictable and manageable.
- Similar considerations apply to the decisions of investigators and subjects.