Evaluating Risks and Benefits in Research

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Objectives

By the end of this presentation, learners should be able to :

- ✓ Define Risks/ Benefits
- ✓ Identify Types of Risks
- ✓ Identify Minimal Risk Research
- ✓ Identify Types of Benefits
- ✓ Be Familiar with the Risk Benefit Assessment

Definitions- Risks and Benefits

Benefits → Harms

Risks → Potential Benefits

Definitions- Risks and Benefits

Risks/Harms

Harms are events or experiences that set back the interests of one or more individuals

- Risk is a multidimensional concept involving both the probability and magnitude of harm

Potential Benefits/ Benefits

Benefits are events or experiences that advance the interests of one or more individuals.

Types of Risks

Levine classifies risks into four categories

(Levine, 2002)

- **Physical**
- **Psychological**
- **Social**
- **Economic**

Types of Risks

1. Physical Risks:

The type of bodily harm a research subject may suffer as a result of his or her participation in the study.

The physical harm might be minor or serious, temporary or permanent, immediate or delayed

Types of Risks

2. Psychological risks :

Risks of harm due to feeling embarrassed, uncomfortable, anxious or upset.

Psychological harms vary from study to study, from a temporary emotional reaction to a survey question to the possibility of trauma in rare cases.

Types of Risks

3. Social Risks:

Research findings, or even study participation itself, may expose subjects to the possibility of discrimination or other forms of social stigmatization.

Discrimination might be to the research subjects or the community as a whole.

Types of Risks

4. Economic:

Research subjects may directly or indirectly bear financial costs related to research participation

These include requirement to visit study site(travel expenses)/ stay in hospital

Other Types of Risks

- **Legal Risks:** illegal activities-including discovery and prosecution of criminal conduct.

- **Political Risks:** Internally displaced or refugees.

How do we minimize risk?

Examples:

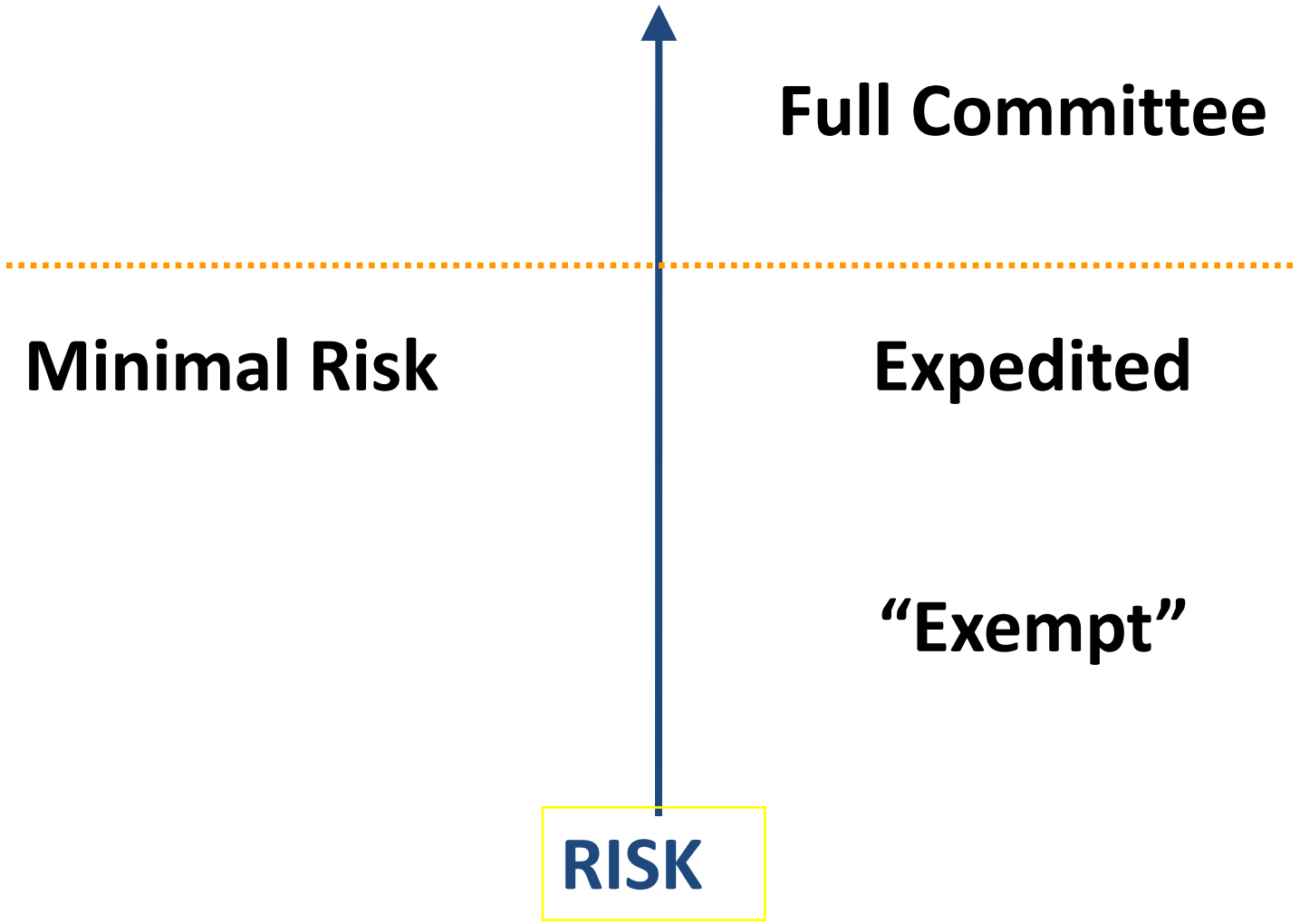
- Use of qualified personnel
- Avoiding unnecessary procedures
- Identifying less risky ways of testing a study hypothesis
- Monitoring all research participants
- Proper exclusion criteria
- Enhancing confidentiality measures

But there is no systematic account of how to minimize risks, and enhance benefits, for the individual research participant.

Minimal risk Research

A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research **are not greater, in and of themselves, than those ordinarily encountered in daily lives of the general population or during the performance of routine physical or psychological examinations or tests.**

Level of Risk Determines Level of Review



Research Benefits

Research benefits in health-related research fall into two broad categories:

- Interventions that **hold out the prospect of direct diagnostic, therapeutic or preventive benefit for the individual participants.**

- Interventions that **do not hold out the prospect of direct benefit for the research participant**, but are expected to produce scientific information that may **benefit society in the future**.

Types of Benefits

- **Potential of Direct benefits**: from intervention

Direct benefits stem from the research interventions themselves

- **Collateral benefits**: from being a subject

The US National Bioethics Advisory Commission

"direct benefits are benefits arising from receiving the intervention being studied."

- **Altruism:** The satisfaction of helping others by contributing to medical knowledge.

Nancy King

- **Benefits to the society**

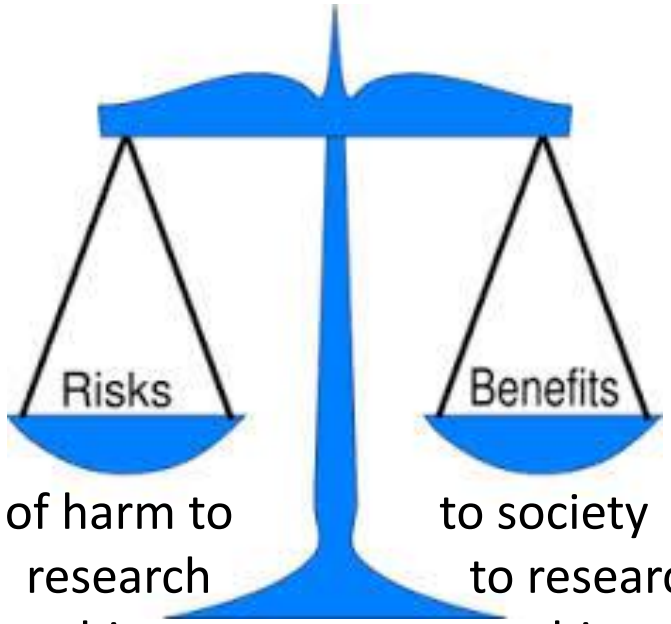
Risks Benefits Assessment

- In evaluating risks and benefits, usually the REC wil. consider only those risks and benefits that are directly related to participation in the research, as distinguished from risks and benefits of procedures/interventions individuals would receive even if not participating in the research.

- IRB reviewers identify any anticipated risks involved with the study and classify those risks as minimal or as greater than minimal risk.

Risks Benefits Assessment

- The REC then determine whether the anticipated risks to participants are reasonable in relation to the anticipated benefits to participants and society



of harm to research subjects

to society and to research subjects

Risks Benefits Assessment

Payment as a benefit

- Sometimes research subjects get paid as an inducement to participate in research

- *Should financial incentive be considered as a benefit when weighing risks and benefits?*

- While some participants may value these payments against risks, research ethics committees do not consider payments as “benefits”

Risk Benefit Assessment in Vulnerable Groups

In research involving individuals who are not capable of giving informed consent

- The risk from research interventions that **do not hold out the prospect of direct benefit** for the individual subject should limited to **minimal risk .**

- **Above minimum risk research must hold out a prospect of direct benefit to the individual subjects**

“An experiment is ethical or not at its inception. It does not become ethical post hoc”

(BEECHER,1966)

In Conclusion :

Investigators must be able to

- Identify the risks , including magnitude and probability
- Minimize the risks
- Identify the probable benefits to be derived from the research
- Maximize the benefits
- Assure that potential subjects will be provided with an accurate and fair description (during consent) of the risks or discomforts and the anticipated benefits.

Thank you !