Evaluation of Research Risk

Aziz Burkhanov
Assistant Professor
NU GSPP

Why to evaluate research risks?

- To protect individuals from harm associated with participation in research
- Risks are not limited only to biomedical or clinical research
- Social and behavioral science research risks may be more ambiguous and less predictable (including individual reactions to certain events or questions)

Various kinds of risks:

- Social
- Psychological
- Economic
- Legal
- Physical harm
- Group harm (when group is the focus of study)

Risks categories:

- Invasion of privacy
- Breach of confidentiality
- Study procedures

Invasion of privacy

- personal information is accessed or collected without the subjects' knowledge or consent
- Subject's participation in a study is revealed despite assurances that this would not happen

Breach of confidentiality

- Information obtained by researchers may negatively affect subjects if disclosed outside the research setting

- Unauthorized release of data which could have a negative impact on the subjects' psychological, social, or economic status.

Breach of confidentiality

Examples:

- **accidental disclosure of a subject's health issues,**
- **sexual orientation,**
- **illegal migrant status**

Study procedures

- In some cases, simply taking part in research can put subjects at risk (subjects engaged in irregular/illegal activities)
- Focus groups: disclosure by the subjects themselves
- Trauma/abuse: asking subjects questions about trauma or abuse may pose risks of re-traumatization.

Assessing risks: Probability and Magnitude

- **Probability of harm – the likelihood that a specific harm may occur. Not all possible harms are equally probable.**
- **Magnitude (severity) of harm – in case it occurs.**

The interaction between these two elements is a crucial factor in determining the level of risk of harm in a study.

Assessing risks: Situation and time

- **Risks of harm in research participation are specific to time, situation, and culture**

- **What may be a socially sensitive issue or topic at one time or place may not be so at another time or place**

Assessing risks: Subject population

Risks of harm will differ according to the subject population.

Example:

Study of the smoking behavior will have different focus for adults (health hazard) and minors (questions of legality/morality)

Minimizing and managing risks

- Potential subjects should be given enough information to make a decision whether they are willing to accept risks and participate in the research.

- If research questions will be of a sensitive nature, subjects need to be forewarned.

Minimizing and managing risks

- Subjects need to know what steps will be taken to protect confidential information
- Any potential limits to protection of identifiable personal information should be explained (in focus groups, for example)
- When a possible disclosure of subject responses is the primary source of potential harm, collecting data anonymously may provide the best protection

Minimizing and managing risks

If collection of identifiers is necessary, there are ways to decrease risks of unauthorized access:

- Remove all direct identifiers as soon as possible.
- Substitute codes for identifiers.
- Maintain code lists and data files in separate secure locations.

Minimizing and managing risks

- Use accepted methods to protect against indirect identification, such as aggregate reporting or pseudonyms.
- Encrypt transmitted and stored data.
- Access and store data on computers without Internet connections.
- Apply for a waiver of the consent form to IREC (if consent form is the only document linking subjects to the study)