***Tuguegarao, Cagayan, 27-28 February2012***

# D. Assessment of Risks and Benefits

Marita V. T. Reyes
Philippine Health Research Ethics Board

*adapted from lecture of Prof. Tina Torres*

# *Topics*

Risks: Types of Risks
- Components of Risk Assessments
- Assessment in a Scientific Review
- Assessment in an Ethical Review

Benefits: Types,
- Who benefits

Categories of Research based on Risk/Benefit

Decisions

# *Elements of an Ethical Review*

1. Need for human research participants
2. Relevance of research topic
3. Scientific soundness
4. Assessment of Risks and Benefits
5. Selection of Participants
6. Informed consent process
7. Protection of Privacy
8. Standard of Care
9. Compensation
10. After Study procedures

# *Definition of Risk*

"Risk" refers both to the probability and magnitude of a harm resulting from an activity.

"Risk" often stands for the combined probabilities and magnitude of several potential harms.

# *Types of Risks*

- Physical
  - bodily harm
- Psychological
  - emotional suffering
  - breach of confidentiality
- Social
  - discrimination
  - stigmatization
- Economic
  - loss of potential and real income,

# *Components of Assessments*

- Magnitude and duration of harm
  - Death, Slight discomfort
  - long-term, single event

- Probability of harm

- Additional risks
  - long term risks of research project
  - risks to communities

*Consider uncertainties in the evaluation.*

# ***Minimal Risk***

The probability and magnitude of harm and discomfort anticipated in the research are not greater, in and of themselves, than those ordinarily encountered in daily life or during routine performance of physical or psychological examination or tests.

# *Risks to consider in a Scientific Review*

"risks that result from the research itself"

e.g.,

- In "non-therapeutic research"
  - risks of all procedures that are done.
- In "therapeutic research"
  - risks from additional procedures that are not necessary for treatment purposes
  - risks of the study medication or experimental intervention

# *Guideline in Risk assessment in Scientific Review*

Identify the risks and minimize risks
(re: methodology and interventions)

e.g., use of qualified personnel,
substitution of procedure
close monitoring,
exclusion of susceptible subjects
“rescue” medication.

# *Risks to consider in Ethical Review*

- Direct/indirect/no benefit: individual/society
- In the initial review: examination of all relevant parts of the protocol.
  - objectives
  - research design
  - number of subjects
  - method of randomization
  - inclusion/exclusion criteria
  - SAE management and reporting
  - consent form and questionnaires
  - source of funding

Ethical Risk  Assessment...

- Privacy and  confidentiality
- Protection of  vulnerable individuals/groups
- Equitable selection
- Investigator qualification and facility adequacy
- Management of Conflict of Interest
- Recruitment materials. e.g., advertisement

- Continuing Review and monitoring

# *Definition of Benefits*

- Refers to any favourable outcome of the activity to the individual or society.

- “Benefit” stands for the combined probabilities and magnitudes of several possible favorable outcomes.

# *Benefits*

To Whom?

- Benefits to research participants
- Benefits to society, community

How?

- Directly: effective intervention
- Indirectly: knowledge which may lead to effective interventions for other groups or in the future.

# *Benefit to participants*

- Benefit of being in the research project itself
  - actual diagnosis of illness
  - obtaining a new promising treatment
  - increased monitoring and follow-up

- There are cases of research where there is no benefit to research participants
  - Phase I trials
  - Non-therapeutic research

  (Benefit to society!)

# *Types of Benefits*

- Physical Benefits
  - cure of disease
  - return of body function
- Psychological benefits
  - alleviation of pain and suffering
  - positive contribution to society
- Economic Benefits
  - financial incentives?
- Benefit to science/ society/ institution
  - new knowledge
  - future effective intervention

# *Risk/Benefit Assessment: Magnitude and Duration*

- Magnitude of potential harm and potential benefits
  - Organ dysfunction vs. slight discomfort
  - Cancer cure vs. tumor shrinkage
- Duration of potential harm and potential benefits
  - Short-term vs. long term

# *Risk-Benefit Assessment: Levels*

Individual
Society

- Benefits: Knowledge gained + benefit to participants
- Risks : Misuse of societal resources + risks to participants

# *Categories of Research based on Risk-Benefit Assessment*

*Category 1* – not greater than minimal risk
*Category 2* – greater than minimal risk with prospect of direct benefit.
*Category 3* – minor increase over minimal risk but no prospect of direct benefit to individual but likely to yield generalizable knowledge about subjects.
*Category 4* – research not fitting any category but presents an opportunity to understand, prevent, alleviate a serious problem affecting health or welfare.

# *Decisions*

Approval-

Benefits outweigh risks (consider magnitude and probability) at the participant level.

(Society's benefit should not override high risk/harm to participant.)

Disapproval-

Risk or harm cannot be managed.

Risks overwhelm benefits for participants.

Risks to society are high.

# *Conclusion*

- There is inherent uncertainty in the degree of risks and benefits.

- Balancing risks and benefits requires collective competence of the ERC. The variety of experiences of the members helps inform the ERB decision.

- Benefits to society/institution should not be a primary consideration at the expense of the participant.

- Risks to society, on the other hand, should be considered over and above benefit to the individual.