

Ethical Issues in Behavioral and Epidemiological Research

Cristina E. Torres, Ph.D.
Social Science Professor
University of the Philippines/
National Institutes of Health
FERCAP Coordinator





Useful Definitions

- ❑ “Research means a systematic investigation to include research development, testing and evaluation, designed to develop or contribute some information or generalizable knowledge.”
- ❑ “Human subject is a living individual about whom an investigator (professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.”



Useful Definitions

- Minimal risk – 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 or tests



Useful Definitions

- ❑ Private Information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation is taking place.
- ❑ Information provided for specific purposes by which the individual can reasonably expect that it will not be made public (like a medical record).



Common Research Methodologies

□ Types

- Quantitative – generalizable information
- Qualitative – in depth case studies

□ Methods

- Interviews
- Focus group discussion
- Survey



Research Exempt from IRB Review

- ❑ Anonymous databases
- ❑ Opinion surveys
- ❑ Interview and questionnaire research about general (not private) behavior
- ❑ Observation of public behavior (no identifiers)
- ❑ Data collected from elected officials

Unethical research?

- ❑ Tea room trade study – study of homosexual sex in public toilets - 1960
- ❑ Arrests for homosexual conduct resulted from sex in public toilets
- ❑ Behavior stigmatized and illegal
- ❑ Sociologist Laud Humphrey decided to observe men who engaged in this type of sex by pretending to be the watcher for the police for these men.
- ❑ He made detailed description of 50 sex encounters.



Unethical research?

- ❑ He copied the car plate numbers of the men and traced where they lived and got more information about them.
- ❑ He interviewed them pretending to be a market research interviewer and found out that some of them were straight men with wives and families.
- ❑ He used the results to advocate for decriminalizing homosexual sex.

Determination of significant risk

- Sensitive nature of the topic
 - May cause stigmatization – loss of reputation
- Type of social interaction
 - Intervention may cause psychological stress or harm – Milgram study
- Financial implications
 - Loss of job or profession
- Legal implications
 - Drug addiction, prostitution, abortion as criminal activities



Minimizing risk

- Avoid disclosing identifiable data
 - Use of surrogate subjects
 - Adequate physical structures

- Protecting confidentiality of data – key element in minimizing risk



Epidemiological Research

Epidemiology is the basic scientific tool which public health professionals use to study disease. It is a perspective in which systematic observation is the basis on which grounded inferences can be made about observed phenomena.

Epidemiological research is essential to identify the causes of disease, to examine the efficacy of treatments and preventive measures, and to elucidate their relationships.



Epidemiological research

- Research data bases
 - Who owns them?
 - Who has access to them?
 - Who may use them?
- Need to protect privacy and confidentiality of data to prevent stigmatization and other types of harm
- Need to anonymize data



Recruitment Issues

- How does a researcher gain access to a database of probable research participants?
- What recruitment methods are used?
 - Personal contact
 - Recruiters
 - Power relationships between researcher and participants
- Inducement to participate

Case Study of Epidemiological Research among Tsunami Victims in Thailand

Methodology

- ❑ **Study design:** Cross sectional study
- ❑ **Subject selection:** Study populations in tsunami area
- ❑ **Study area:** Ranong province
- ❑ **Community approach:** asking permission from the community leader
- ❑ **Sampling method:** Simple random sampling
shelter, random household
- ❑ **Subjects:** Knowledgeable person in the house or household head, housewife

Orapin C. Laosee, 2005 FERCAP Conference

Sampling methods

Define area

6 provinces in Thailand

Province

Sample random sampling

Shelters

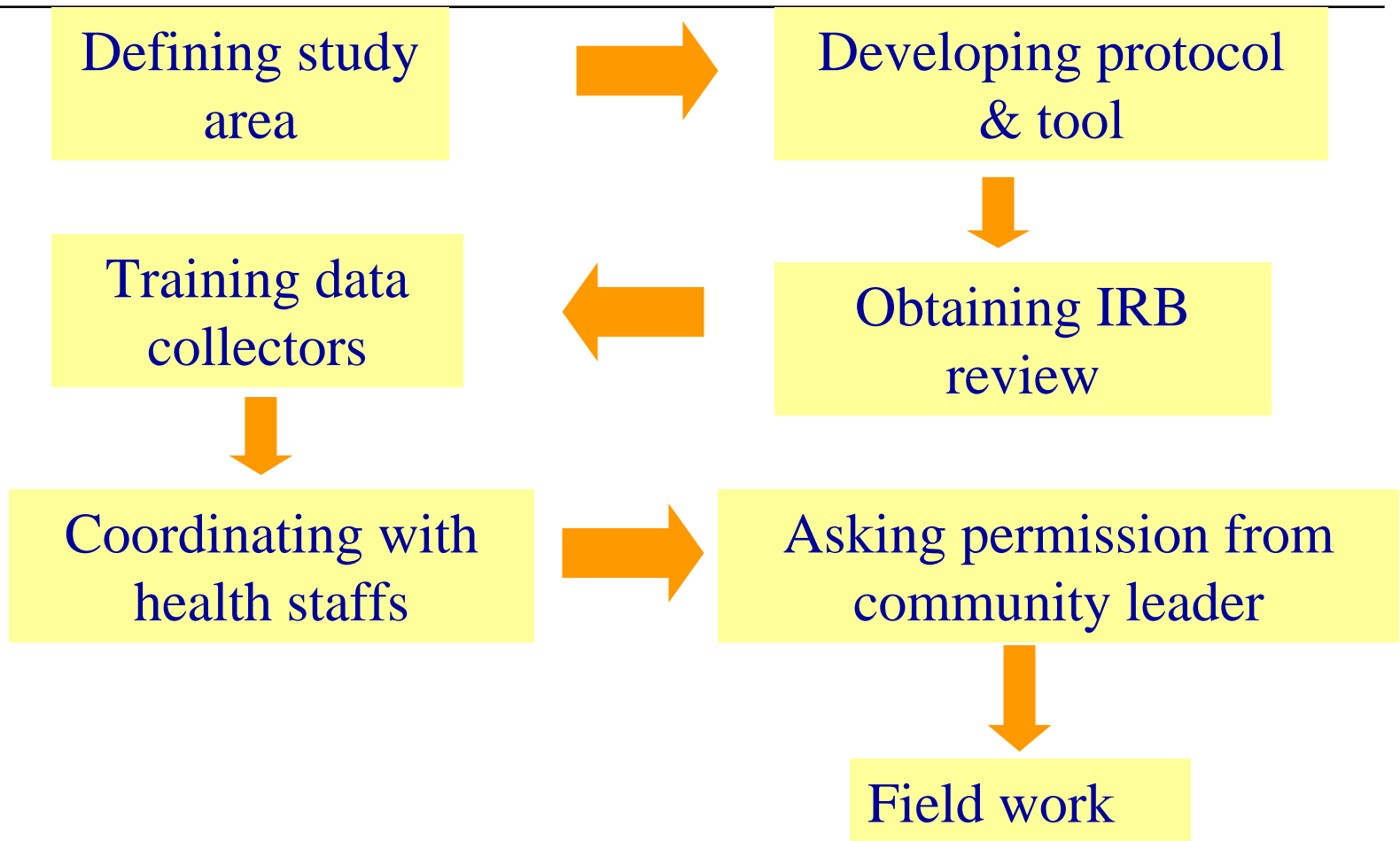
Sample random sampling

Households

Knowledgeable household member

Respondents

Summary of study procedure



Field Work



Had Sai Kao Beach # 2



Key strategies

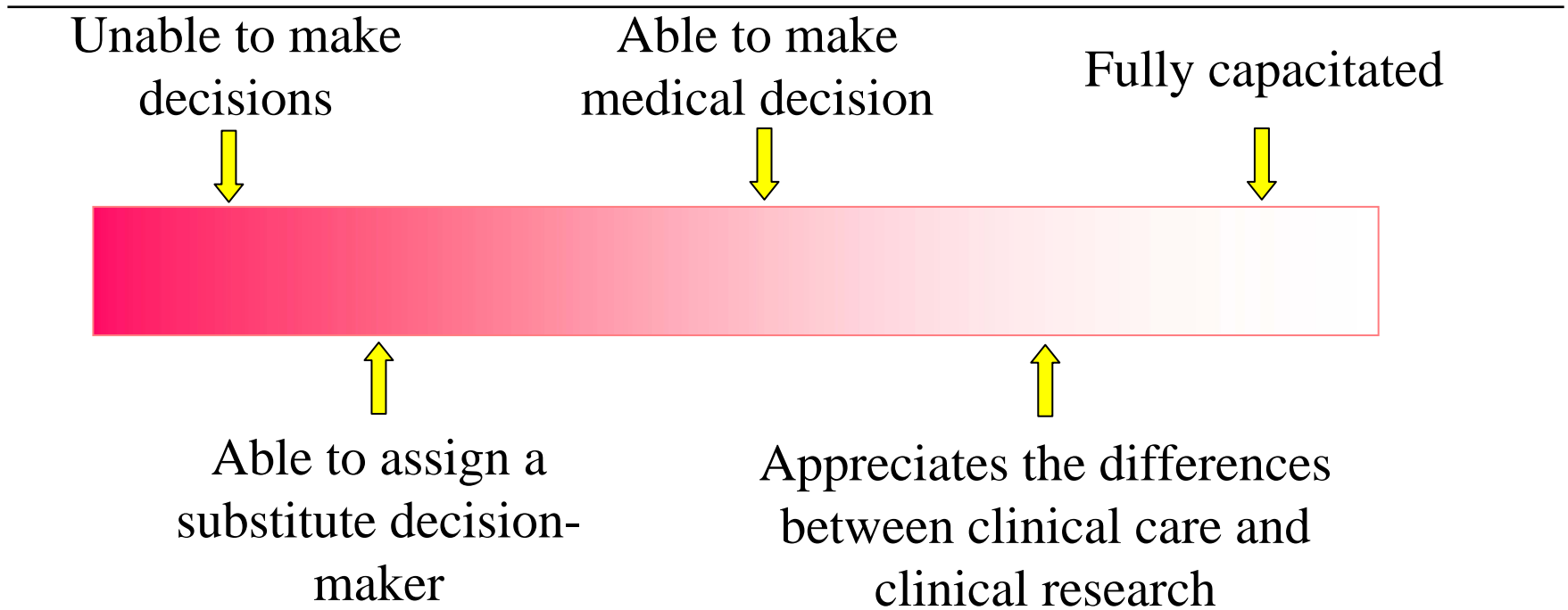
- ❑ Coordinating with the health staff
- ❑ Community permission
- ❑ Training data collectors



Ethical Issues in Disaster Research

- ❑ Decisional capacity
- ❑ Vulnerability
- ❑ Risks and benefits
- ❑ Informed consent & community permission

Continuum of decision-making capacity





Vulnerability

Characteristics of the research subjects

- ❑ Loss of family, their love's one, neighborhood, or community
- ❑ Loss of home, job
- ❑ Life-threatening danger or physical harm
- ❑ Exposure to horrible death, and injury
- ❑ Loss of communication or support from important people in one's life

Vulnerability



Stress reactions after the disaster

- **Feeling reaction:** shock, fear, hopelessness, depression
- **Thinking reaction:** confusion, worry, difficulty concentrating, unwanted memories
- **Bodily reaction:** tension, fatigue, difficulty sleeping, worsening health condition, change in appetite
- **Interpersonal reactions:** dependency, conflict, judgmental, isolation
- **Spiritual reactions:** wondering why, why me, feeling as if life is not worth living, loss of hope

Risks and Benefits

Potential risks should be considered

- ☐ Physical harm
- ☐ Inconvenience
- ☐ Legal action
- ☐ Economic hardship
- ☐ Psychological discomfort
- ☐ Loss of dignity
- ☐ Breach of confidentiality

Risks and Benefits

Benefits to participation in disaster research

- ❑ Enhanced awareness of material resources
- ❑ Medical and mental health services
- ❑ Empowerment
- ❑ Learning and insight
- ❑ Altruism
- ❑ Kinship with other
- ❑ Feeling of satisfaction or value after participating
- ❑ Favorable attention from investigator



Informed consent & community permission

- Information
- Understanding
- Voluntary

“Individuals in this group have suffered injury and loss, therefore extra protection must be considered.”

Consent process in social science research

- ❑ Full disclosure of confidentiality risks
 - Identifying who has access to database
- ❑ Disclosure of psycho-social and economic risks
 - Identification of potential psychological stress
- ❑ Disclosure of use of data and reporting methods
(anonymize names of persons, places, organizations in the final report)
- ❑ Withholding information
- ❑ Debriefing

Data protection plan in the protocol

- Minimize need to collect identifiable data
- IRB review
- Describe appropriate level of confidentiality based on potential magnitude of risk from disclosure.
 - Physical security of data – lock and key, data disposal
 - Social measures – people in the know
 - Confidentiality training for research team



Confidentiality Protection

- Recognize confidentiality issues in
 - Initial study design
 - Identification, recruitment and consent processes for the study population
 - Security, analysis and final disposition of data
 - Publication or dissemination of data and results