

# Ethics Review of Academic Research

Cristina E. Torres, Ph.D.  
Social Science Professor  
FERCAP Coordinator



**Forum for Ethical Review Committees  
in the Asian & Western Pacific Region**

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# Outline

- Definitions
- Sections of a research protocol
- Research methodology in academic research
- Addressing ethical issues in academic research

# Use of humans in academic research

- Basic vs. applied research
- Social/ behavioral research
- Biomedical research
- Environmental research
- Laboratory research
- Nutrition research
- Agriculture research



# Use of humans in academic research: Common methods used

- Make use of various methods and tools:
  - Historical, philosophical methods in the humanities
  - Descriptive/ observational methods
  - Use of experimentation in the study of social behavior/ phenomena and the subjects are human beings.
- There are ethical limits (those that may inflict moral and physical harm on subjects) to the types of methods that researchers use.

# Social Research

- Study of society, social relations and human behavior
- Large, multifaceted field, encompassing a wide array of disciplines
- Cross-cutting themes
  - Emphasis on theory-driven research and general principles to explain behavioral and social functioning
  - Emphasis on individual variation, and variation across sociodemographic categories such as gender, age, and sociocultural status
  - Focus on both the social and biological contexts of behavior
  - Effect of technology on humans

# Sections of a protocol

Rationale.

Literature review.

Objectives

Methodology/ Ethical considerations

Data analysis

Outcomes

# General types of research methodologies

- Qualitative research
  - Historical studies
  - Observational, case studies
- Data gathering techniques
  - Observation
  - Interview
  - Focus group discussion
  - Purposive sampling

# Qualitative research

Qualitative - study of commonalities and key features of a group

- Structured observation
- Participatory research – process by which a people, together with a researcher, examine and analyze a problem, analyze the results and make action plans to solve such problems



# Qualitative Research

Emphasize particular context and settings

- ❑ Use methods (ethnography, KII, etc.) capable of providing sufficient detailed account or analysis
- ❑ Outcome is capable of enabling others to determine the application of the findings to other circumstances
- ❑ Provides in-depth insights about specific situations

Based on Australian National Statement on Ethical Conduct in Human Research (Sec.3.1.4 -3.1.8)

# Qualitative Research

- ❑ Capable of generating quality and credible data based on its data collection techniques and analysis plan
- ❑ No intention to generalize
- ❑ Its rigor cannot be judged based on sample size

Based on Australian National Statement on Ethical Conduct in Human Research (Sec.3.1.4 -3.1.8)

# Grounded Theory

- A systematic qualitative research methodology in the social sciences emphasizing generation of theory from data in the process of conducting research.
- This contradicts the traditional model of research, where the researcher chooses a theoretical framework, and only then applies this model to the studied phenomenon.

# Quantitative Research

- ❑ Aims to generate generalizable information/ conclusions
- ❑ Uses statistical methods
- ❑ Checks validity and reliability of data
- ❑ States the data analysis plan
- ❑ Uses simple/ stratified random sampling methods in surveys

# Quantitative Research

Quantitative – makes use of quantitative data for precise measurement of social phenomena.

- General patterns are described.
- Statistics are used to make statements of relationships of variables across many cases.
- Statistical tools include percentage, frequency distribution, measures of central tendency (arithmetic mean, median, mode and standard deviation)

# Experimental Method

- Identification, selection and definition of a problem
- Setting up the hypothesis
- Selection of subjects and measuring instruments
- Selection of design,
  - execution of procedures,
  - analysis of data
  - formulations of conclusions

# Experimental Method

- Involves at least 2 groups
  - Experimental or intervention group –receives investigational treatment
  - Control group – receives the usual treatment or another treatment
- Evaluate the difference between the 2 groups
- Ensure that both groups are equal at the start of the study
- Remove influences of other variables that may affect the performance of the dependent variable

# Ethical Considerations

University of Edinburgh School of Social and Political Studies

1. Project details

2. Type of participants

3. Risk to participants

4. Confidentiality and handling of data

5. Information and consent form

6. Conflict of interest



# 1. Project details

## a. Research topic

- Identify the ethical issues related to a research topic (partner violence, drug addiction, abortion, etc.)

## b. Investigator

- Qualification and training to address ethical issues

## c. Research objectives

- Scientific, ethical, feasible?

## 2. Type of participants

### a. Who are the participants?

- How many participants?
- How and where will they be recruited?
- What benefits (financial or material) will they derive from participation?

### b. Inclusion and exclusion criteria

### c. Does it include vulnerable participants?

## 2. Type of participants

### Types of vulnerable participants

- under 18/20 years of age? Y N
- children in the care of a Local Authority? Y N
- known to have special educational needs? Y N
- physically or mentally ill? Y N
- vulnerable in other ways ? Y N
- members of a vulnerable or stigmatized minority? Y N
- unlikely to be proficient in English? Y N

# 2. Type of participants

## Types of vulnerable participants

- in a client or professional relationship with the researchers?      Y      N
- in a student-teacher/ dependent relationship with the researchers ? Y   N
- have difficulty in reading and/or comprehending any printed material distributed as part of the study? Y   N
- If YES to any of the above, explain and describe the measures that will be used to protect and/or inform participants.

# 3. Risks to participants

a. Will the research induce any psychological stress or discomfort?

- If YES, state the nature of the risk and what measures will be taken to deal with such problems

b. Does the research involve the investigation of any illegal behaviour?

YES       NO

- If YES, give details.

### 3. Risks to participants

c. Does the research require any physically invasive or potentially physically harmful procedures? YES  NO

- If YES, give details and outline procedures to be put in place to deal with potential problems.

### 3. Risks to participants

- d. Is it possible that this research will lead to the disclosure of information about child abuse or neglect?
- e. Is there any purpose to which the research findings could be put that could adversely affect participants?
- f. Could this research adversely affect participants in any other way?

# 3. Risks to participants

g. Is this research expected to benefit the participants, directly or indirectly?

h. Will the true purpose of the research be concealed from the participants?



# 4. Confidentiality and handling of data

- a. Will the research require the collection of personal information from e.g. universities, schools, employers, or other agencies about individuals without their direct consent? Y N
- If YES, state what information will be sought and whether consent will be obtained

# 4. Confidentiality and handling of data

b. Will any part of the research involving participants be audio/film/video taped or recorded using any other electronic medium? Y N

– If YES, what medium is to be used and how will the recordings be used?

c. Who will have access to the raw data?

d. Will participants be identified? How will confidentiality be protected?

# 4. Confidentiality and handling of data

- e. How long will datafiles/audio/video tapes be kept?
- f. How will study results be used?
- g. Will feedback be given to participants?

# 5. Consent form

- a. Will written consent be obtained? Explain
- b. Will administrative consent be obtained in lieu of participants' consent?
- c. In the case of minors, will the consent or assent of parents be obtained? Explain
- d. Will the consent or assent (at least verbal) of minors be obtained? Explain

# 5. Consent form

- Administrative consent may be sufficient:
  - a) for studies where the data collection involves aggregated (not individual) statistical information and where the collection of data presents:
    - (i) no invasion of privacy;
    - (ii) no potential social or emotional risks:
  - b) for studies about development and evaluation of curriculum materials, resources, guidelines, test items, or programme evaluations.

# Conflict of interest

- Does your research involve a conflict of interest Y N Explain

A conflict of interest would arise when a researcher might be “ **compromising research objectivity or independence in return for financial or non-financial benefit for him/herself or for a relative or friend.**”

The investigator should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial and should provide evidence of such qualifications .