

Proposed FERCAP Guidelines for Ethics Review of Social Science Research

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

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Rationale for the Proposed Guidelines

There is a significant number of protocols submitted to research ethics committees in Asia about topics in social sciences or making use of social science methodologies

Researches in social sciences involve concepts and characteristics that make them distinct from biomedical research.

In health research, the Declaration of Helsinki requires the review of both biomedical and behavioral research.

The Asian region manifests common norms and values despite its socio-cultural diversities to be able to identify common threads during ethics review.

FERCAP as a regional forum is in a strategic position to incorporate common adaptation of universal guidelines to make them context specific to the Asia-Pacific region.



Basic concepts in social science research

- **Social science is the scientific study of human society and social relationships (Oxford dictionary); a branch of science that deals with the institutions and functioning of human society and with the interpersonal relationships of individuals as members of society (Merriam Webster dictionary)**
- **A social scientist is a professional who uses the scientific method to study human society and individual relationships. (Indeed.com)**
- **A social science researcher conducts a systematic investigation of social issues through observation or interaction. Social science research is usually an interdisciplinary process that draws on knowledge from various social sciences or in collaboration with other disciplines.**
- **Social scientists typically research the larger aspects of society or on individual behavior and focus on how society's bigger institutions and systems operate in different cultures and societies.**

What is Social Science Research?



A systematic investigation of social issues through observation or interaction.



An interdisciplinary and collaborative process that draws on knowledge from various social sciences, including sociology, anthropology, political science, psychology, social work, etc.

Health Social Science

- Health is the state of well being (WHO)
- It focuses on exploring, examining, and describing people and their environments, the socio-cultural, economic, and political context of complex health behaviors. (Boydell, 2007)
- It also deals with experiences of people in relation to health and illness.



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Types of Data in Social Research

Social research is a method used to learn about people and societies. It is intended for the following purposes: a. description, b. exploration, c. explanation, and d. evaluation. (<https://www.sagepub.com/>)

A social researcher may choose to use primary data or secondary data.

- **Primary data is first hand data gathered by the researchers themselves. Researchers prepare a set of questions to be answered by the target respondents and results are analyzed accordingly.**
- **Secondary data is about information that have been gathered by others (newspaper or journal articles, statistical reports etc.) that a researcher collects about a topic of interest, compares and analyzes them to be able to draw conclusions. (QuestionPro)**

Methods in Social Science Research

- **Quantitative research** – makes use of quantitative data for precise measurement of social phenomena about a target population based on a required sample size.
- It assigns objective numbers on observable, measurable, and testable phenomena that enable description of general patterns. (Kimola.com)
- Statistics are used to make statements of relationships of variables across many cases.
- Typical methods used include surveys, correlational/ causal research or experimental research.
- Surveys make use of a prepared questionnaire sent to target participants with varied demographic data that may be utilized to compare groups.
- An experimental research is conducted to establish a causal relationship between/ among variable to prove or disprove a hypothesis or theory.

Methods in Social Science Research

Qualitative methods - a broad term used to describe the body of research concerned with the study of **human experience** and the **meaning** that individuals or groups ascribe to that experience.

It is a systematic way of understanding the meaning people assign to their experiences and is a means of exploring new ideas, issues, and areas of inquiry and may be used in conjunction with other methods to gain a fuller understanding of a particular phenomenon.

It requires personal involvement of the researcher to understand and interpret the meanings that an individual or group assigns to a concept, experience, event, relationship, etc.

It is based on a small sample size but is more time consuming and labor intensive for the researcher to perform.

Common Types of Qualitative Research



The phenomenological approach explores shared experiences of different individuals or groups about a common phenomenon and makes use of in-depth interviews or focus group discussions to explore common meanings and themes respondents assign to a specific topic of interest.



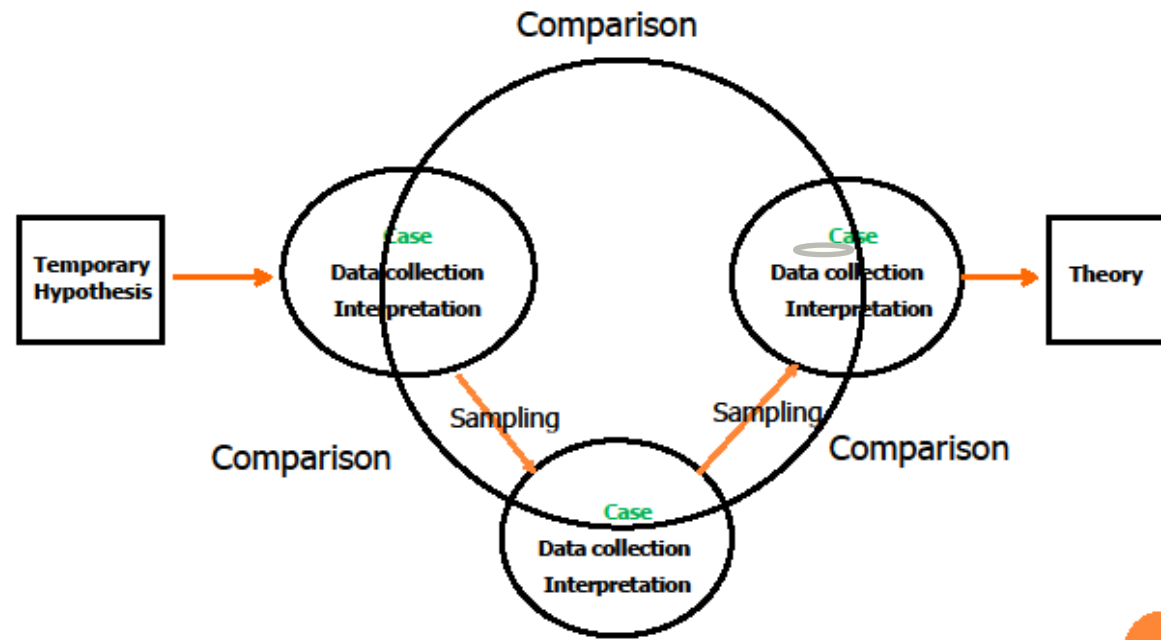
Ethnography involves researcher immersion in a specific environment to observe and understand people's/ group behavior, culture and traditions. It makes use of field notes, diaries, photographs, documents and artifacts.



Grounded theory involves systematic and simultaneous collection and analysis of data in order to arrive at patterns, concepts and theories.

Qualitative Method

CYCLICAL MODEL FOR RESEARCH PROCESS



(Uwe Flick, 1995)

Common Types of Qualitative Research

Historical method involves collection of data from past events in order to interpret the facts and explain the cause of events, and their effect in the present events. Primary source materials like direct account of events and archival materials are utilized.

Case study is used when a researcher explores in depth a program, event, activity, process, or one or more individuals.

Action research involves simultaneous investigating and solving a problem often through collaboration between the researchers and participants to bring about change.

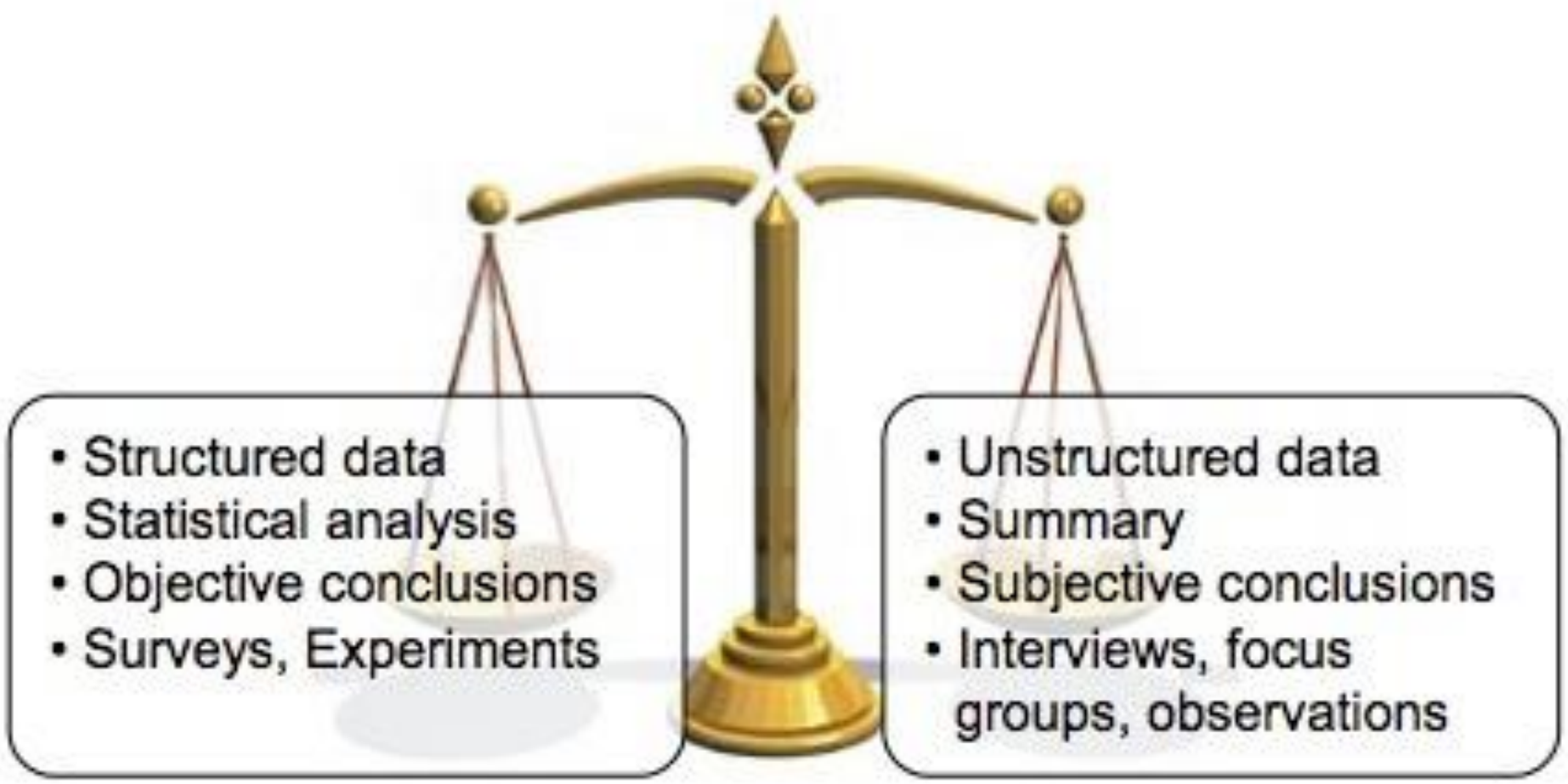
Quantitative vs. Qualitative Methods

Quantitative methods

- Makes use of deductive method
- Studies well known phenomena
- Testing of hypothesis and theories
- Large number of subjects
- Conducted in controlled settings
- Standardized numerical data collection
- Statistical analysis
- Data gathered first before analysis
- Explore outcomes due to treatments or manipulation
- Use of close ended questions in a questionnaire
- Use of statistics from aggregate accounts
- Requires systematic analytical skills

Qualitative methods

- Makes use of inductive method
- Studies little known or unknown phenomena
- Development of hypothesis and theories
- Smaller number of targeted participants
- Conducted in natural settings
- Textual, audio-visual data collection
- Content analysis
- Simultaneous data gathering and analysis
- Explore reasons for outcomes and processes
- Use of open-ended questions in a conversation
- Use of anecdotal accounts
- Requires listening and observational skills

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- Structured data
 - Statistical analysis
 - Objective conclusions
 - Surveys, Experiments

Quantitative
Research

- Unstructured data
- Summary
- Subjective conclusions
- Interviews, focus groups, observations

Qualitative
Research

Qualitative versus quantitative

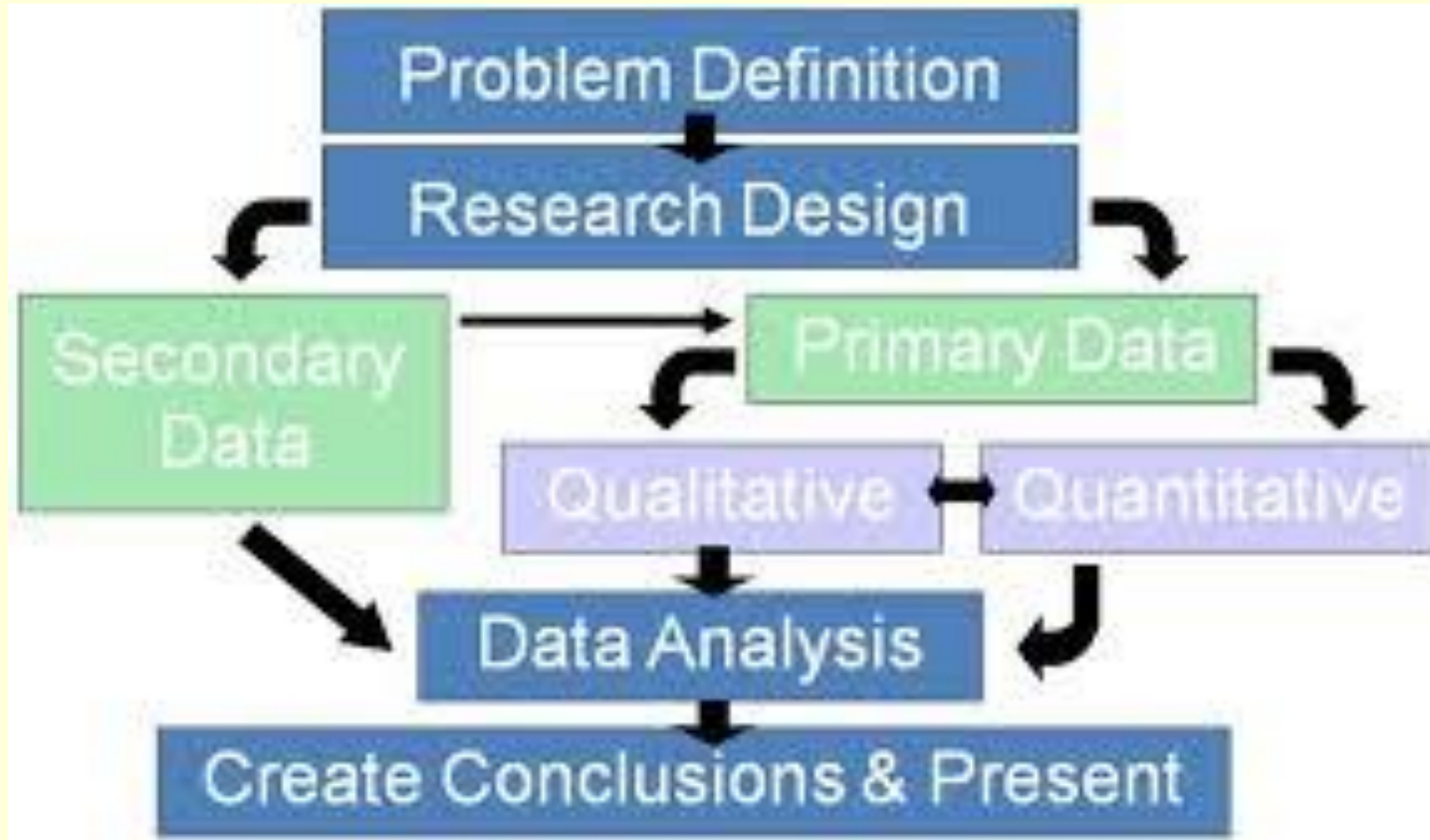
- **Qualitative (<50 samples)**

- Open ended: you are having a conversation
- Anecdotal: you derive meaning from each conversation
- Requires excellent listening and observation skills
- Best done face to face (or at least by video Skype or by voice call)
- Best used for exploratory research where you are trying to get to know a problem or a persona

- **Quantitative (>1000 samples)**

- Close ended: you are administering a questionnaire
- Statistical: you derive meaning from looking at aggregate results
- Requires systematic analysis skills
- Best done via on-line survey (or, in the olden days, via phone survey)
- Best used for confirmation research where you are trying to verify / quantify what you think is important

Social science research process



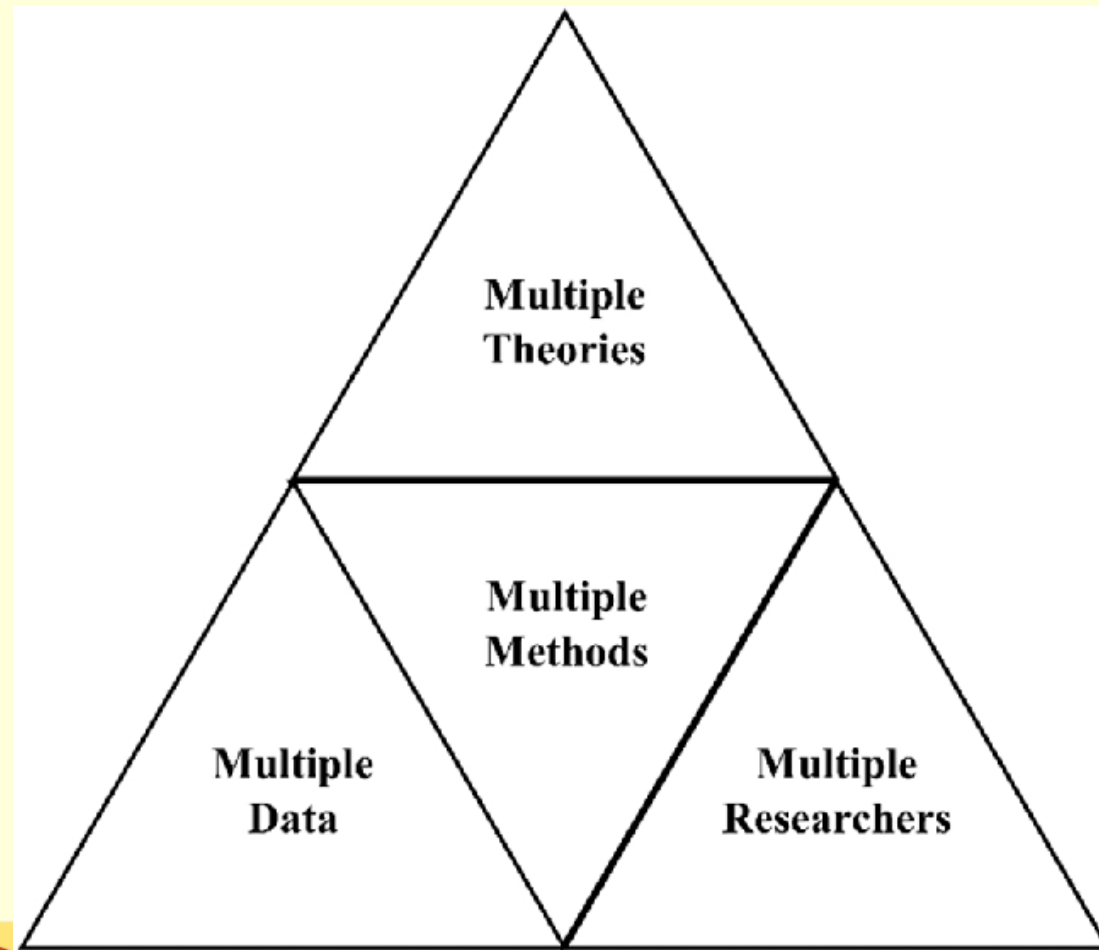
Triangulation in social research

- Triangulation refers to the use of various data/ concepts, theories, methods or observers to increase the credibility and validity of research findings.¹ Credibility refers to trustworthiness and how believable a study is; validity is concerned with the extent to which a study accurately reflects or evaluates the concept or ideas being investigated.² .
- Triangulation is capable of enriching social science research as it offers a variety of datasets to explain differing aspects of a phenomenon of interest.
- It also helps refute one dataset by generating another data set.
- It can assist the confirming of a hypothesis where one set of findings confirms another.
- Finally, triangulation can help explain the results of a study.³ Central to triangulation is the notion that methods leading to the same results give more confidence in the research findings.⁴ (<https://doi.org/10.1136/ebnurs-2019-103145>)

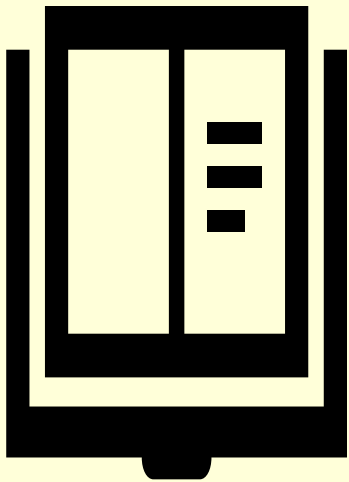
Types of Triangulation

1. **Data triangulation:** Using data from different times, spaces, and people; In data triangulation, you use multiple data sources to answer your research question. You can vary your **data collection** across time, space, or different people.
2. **Investigator triangulation:** Involving multiple researchers in collecting or analyzing data; Investigator triangulation helps you reduce the risk of **observer bias** and other experimenter biases.
3. **Theory triangulation:** Using varying theoretical perspectives in your research; Triangulating theory means applying several different theoretical frameworks in your research instead of approaching a research question from just one theoretical perspective.
4. **Methodological triangulation:** Using different methodologies to approach the same topic; use of mixed methods
(<https://www.scribbr.com/methodology/triangulation/>)

Triangulation in social research (Researchgate)



Scientific Review of Social Science Research



The social science protocol should adhere to the general characteristics of social research with the goal of better understanding of human behavior, social phenomena, problems or events through the use of rigorous social science research methods. Social research should generally contribute to good social outcomes associated with better access to social services, promoting social equity, better policy and improvement of individual and community awareness with the use of description, exploration, explanation and/or evaluation.



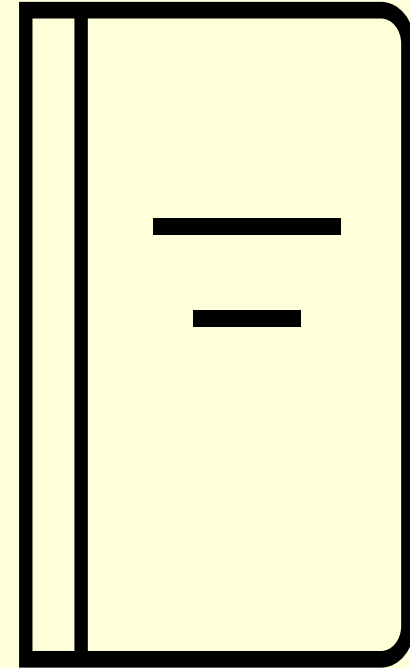
A detailed written protocol that describes planned research activities is required to be submitted to a research ethics committee (REC). It should include comprehensive information to enable an REC to determine its social value, scientific soundness and its ethical implications.

Title and Abstract

1. Title: A descriptive title is preferable that identifies the proposed relationship between the independent and dependent variable.

- Example: Gender responsiveness of the health care workers and client satisfaction of the LGBTQIA+ Patients
- The title describes the main variables that will be the focus of the study.
- The independent variable is defined as the cause and its manipulation brings about a change in the dependent variable. The dependent variable is the effect of any manipulation of the independent variable.

2. Abstract is a stand-alone summary of the study elements and includes its significance of the study, its objectives, research design, data gathering methods, data analysis and expected outcomes.



Standard Sections of Scientific Protocol

1. Rationale

2. Literature review

3. Objectives

4. Conceptual framework

5. Design/ Methodology

6. Data Analysis Plan

7. Conclusion

8. Outcomes



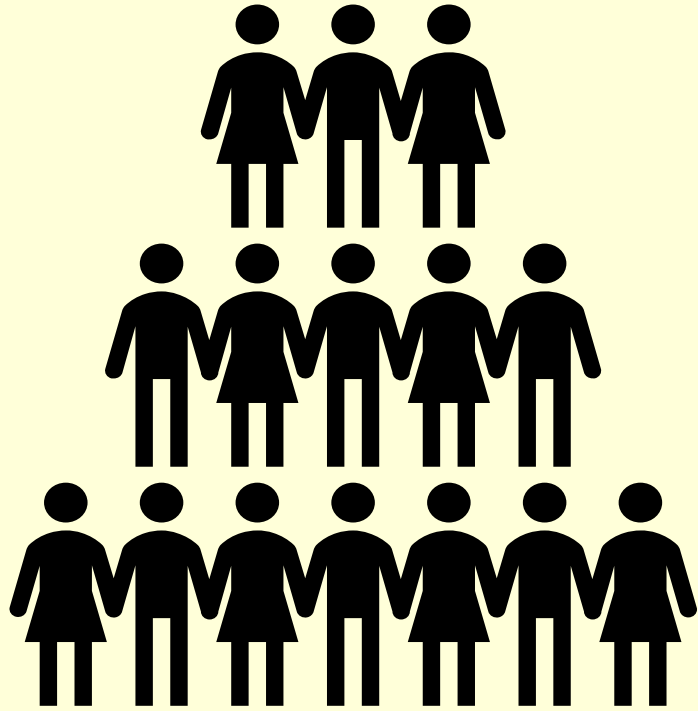
Standard Sections of a Protocol

3. Rationale - It provides an introduction to the study, why its topic is important, what the study is going to find out, how this is going to be achieved and what impact the study will have.

4. Literature Review - It describes what is already known about the topic, what are the gaps and what will be the contribution of the study to knowledge. Sources of secondary data (previous published articles, relevant documents, public statistics, etc.) should be identified.

5. Objectives - It explains the purpose of the research, including the research question. It should provide a clear and concise statement of primary and secondary objectives and a clearly defined hypothesis (where relevant). Objectives should be SMART: specific, measurable, attributable, realistic and time-bound to ensure the feasibility of the conduct of the research within the time frame indicated in the protocol.

Inclusion/ Exclusion Criteria



6. Target Population and Participating Sites

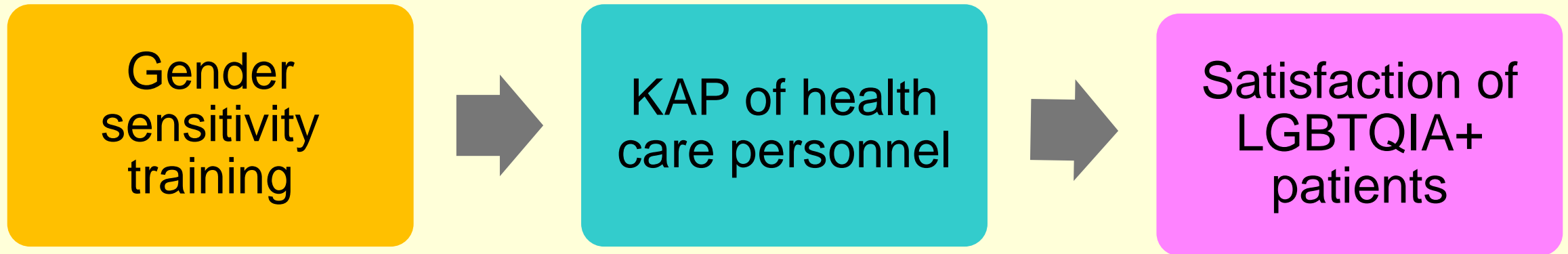
- The inclusion and exclusion criteria among the target population for the study should be appropriately described. The inclusion criteria should define eligible participants related to the topic of interest while the exclusion criteria should identify participants whose conditions may confound the cause and effect relationship between and among variables.
- The sites/ communities/ areas to be covered by the research should also be described. Community in a social science protocol should be aptly described and the area coverage
- *A community is a group of people who have common characteristics or interests. Communities can be defined by: geographical location, race, ethnicity, age, occupation, a shared interest or affinity or other common bonds..*

(<https://www.nice.org.uk/guidance/ng44>)

Conceptual Framework

- Social science research is context specific that allows specific definitions and understanding of essential concepts/ ideas used in a research protocol.
- Concepts are abstract ideas or phenomena that are being studied. The conceptual framework section may be as simple as defining basic concepts used in various sections of the protocol from the research objectives to data analysis or it may serve to explain the relationship between/ among variables used in the study.
- Variables are characteristics of the concepts. The researcher may choose the variables that will be measured in a study to be able to prove a cause and effect relationship derived from the research question.
- Two important variables should at least be identified to prove/ disprove a causal relationship: the independent variable as the cause and the dependent variable as the effect. (<https://www.scribbr.com/methodology/conceptual-framework/>)

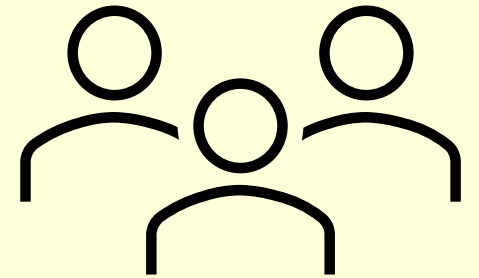
Conceptual Framework



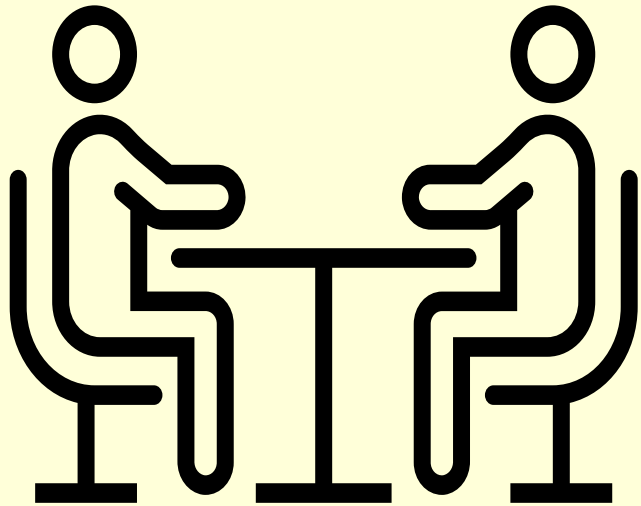
Ethical Responsibilities of Social Science Researchers

To:

- Research participants and their rights, safety, well-being and interests (or dignity, integrity, rights, and autonomy);
- Communities that are engaged and involved in the research;
- Society at large,
 - by effecting socially useful development and change,
 - avoiding potential misuse of research results.
- Charter of Fundamental Rights of the European Union (2000)



Ethical values in social science research



Ethical Issues

Scientists should not impose their own values on their research!

Research on people requires that researchers:

- Cause no harm to subjects
- Participation should be voluntary
- Subjects must give informed consent
- Researchers should fully disclose identity
- Anonymity and confidentiality must be maintained

Competent Review of Socio Behavioral Research

- Panel membership
 - Scientific/ non-scientific members (not medical/ non medical)
 - Technical primary reviewer with social science research experience to differentiate use of qualitative, quantitative or mixed method methodology
 - Non scientific member with community, NGO, social work, etc. experience



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1. Ethical analysis of protocol details



What is the topic about?

Will it cause stigma?



Are the researchers qualified to do research about a sensitive topic? Where will it be done?



Will the research intervention cause possible harm?

2. Risks and Benefits Participant Perspectives

Risks

- Physical
- Psychological
- Social
- Economic
- Political



Benefits

- Reimbursement/
remuneration
- Freebies
- Access to health care
- Access to information
- Increase in knowledge
(health literacy)
- Improvement of health
practices

More than minimal risk is reviewed at full board

Research involving justified deception without participants' valid and informed consent

Intrusive interventions or data collection methods, such as vigorous physical exercise; or techniques to reveal sensitive information

Research which might induce anxiety or humiliation, or cause distress.

Research where the safety of the researcher may be in question.

Research involving respondents recruited through the internet, where sensitive issues are discussed or where participants may be identifiable in the visual images

Social media participants recruited or identified through the internet, when privacy is involved or when quotes are identifiable.

Any research where biological samples are collected and/or medical imaging technologies are used as part of SSH research.

High Risk Matrix

1. Participants

2. Sites of research

3. Sensitive areas of research

1. Children, persons unable to consent, minorities, marginalised people, migrants, refugees, victims of abuse and violence)
2. Conflict regions, sites of historical value to indigenous people, troubled neighborhoods, or regions where the economic, political, environmental and health conditions may pose risks.
3. Risk of exposure to harm to participants, researchers; potentially sensitive topics, sexual behaviour; illegal, criminal, political activities; experience of violence, abuse; mental health; personal or family lives; or their gender or ethnic status.

High Risk Matrix

1. Deception, covert research, invasive methods as part of interdisciplinary research, profiling and web-crawling
2. Risk of traceability and re-identification through small groups of participants, linking data from different sources; sensitive data
3. Potential for misuse of findings



1. Methodology Data processing, sensitive data



2. Data collection and processing to be implemented



3. Consequences of research

3. Vulnerable research participants

School children .

Refugees, illegal migrants .

Prisoners, people deprived of liberty

Pregnant women, sex workers, drug addicts.

People with cognitive impairments

Dissidents, people in conflict areas .

Depressed, with mental health/ emotional problems

People in dependent relationships (e.g. students, employees, subordinates).

Analyzing Vulnerability

Ethics in Social Sciences and Humanities, European Commission, October 2018

Describe	the risk of exposure to harm to participants (social, psychological, physical, reputational, economic or emotional).
Be	clear about the possible or lack of benefits: avoid raising unfounded expectations.
Make	sure people can opt out of research,
Avoid involving	participants who are in any way dependent on you
Take	steps to minimize the risk If there is potential to traumatise people,
Ensure	that the research team has the appropriate expertise and skills.
Minimize	risk of stigmatization
Take	active steps to minimize physical or psychological risks to vulnerable participants



Health Data Privacy



4. Ensuring privacy and confidentiality

Anonymizing names and personal information

Use of codes in questionnaire

Keeping identifiable information under lock and key

Getting consent for sharing pictures and sensitive information

Password protection

Limiting access to database

5. Informed consent in Social Research

Clearly explain the aims, overall purpose, methods and implications of the research.

Explain that participation is voluntary.

Remind participants that they have a right to withdraw their consent at any time without any consequences.

Explain the degree of benefit, risks, burden or discomfort involved in participation. Give an estimate of the time

Explain precautions to ensure participants' safety and provide information on insurance, if there is any.

Explain who is funding the research and for what purpose.

Disclose who will benefit from the research.

Elements of informed consent: Confidentiality protection

Give	a firm commitment to protecting respondents' anonymity and privacy
Make	a clear commitment to treating personal and sensitive information confidentially.
Reassure	participants that there are secure procedures for analyzing any data gathered.
Explain	clearly who will have access to any data that participants provide.
Consider	any unintended/ unexpected/ incidental findings and explain how you intend to deal

Address conflict of interest

Types of COI

- Financial
- Professional
- Familial
- Time
- Power relationship



