

# Anatomy and physiology of a research protocol

Morenike Oluwatoyin Folayan  
College of Health Sciences  
Obafemi Awolowo University, Ile-Ife, Nigeria



# Outline

- Why do you need a research protocol?
- Framework of a research protocol - Anatomy
- Application of ethics principles protocol development – Physiology
- Conclusion – Beyond the protocol



# Why do you need a protocol

- A protocol is a research plan
- Protocols are developed by research teams
- It enables evaluation of the scientific merits of the research plan
- It enables evaluation of the ethical merits of the research plan
- It facilitates objective monitoring of the research
- It enables reproducibility of the study



# Can protocols be amended?

- Protocols are submitted to ethics committees to facilitate unbiased evaluation of the scientific merit and ethical integrity of the proposed research
- Suggestions for protocol amendment – study design and study implementation - can come from the ethics committee. Laypersons on ethics committees understand cultural nuances and can make suggestions for study modification
- Protocol amendments may be required to improve data collection. Please request for ethics approval prior to study amendment.



# Framework of a research protocol - Anatomy

- Title of the research
- Study team members
- Protocol summary
- Introduction
- Study objective(s)



# Framework of a research protocol - Anatomy

- Methods
  - Study design
  - Study participants (inclusion and exclusion criteria)
  - Sample size
  - Study procedure (appendix informed consent document)
  - Study instrument (appendix)
  - Data analysis plan
- Dissemination plan
- Budget



# Application of ethics principles

## Team members

- Competency of the PI to undertake the magnitude of work required
- Team composition to cover range of expertise required for study
- Review of CV to ensure PI has the time for the study
- This is about reducing harm (non-maleficence) to study participant



# Application of ethics principles - 2

## Protocol summary

- Often shared with ethics committee members not reviewing protocol
- To include a brief on the need for the study and study objective(s)
- To include details on the study method
- Should a study protocol also include details on study results?





# Application of ethics principles - 3

## Introduction

- A summary of what is known in the field on the subject matter
- A summary of the gaps in the field
- Justification on why address a gap through your study is important
- Justification highlights the social value of your research
- Without a justification for the study, investment of finite resources – time, funds, equipment – is not justifiable.
- This respects the principle of maximizing benefit (beneficence)



# Application of ethics principles - 4

## Study objective(s)

- **Primary objective(s)** for which you calculate sample size. They can produce inferential results.
- **Secondary objective(s)** are analysis possible from the data collected for which the study is not powered for. They can generate hypothesis except there is evidence suggestive that the study is powered enough to produce inferential results. Adjustments during inferential analysis may be limited due to limited access to data for confounders.
- **Tertiary objective(s)** are usually exploratory and can only generate hypothesis.



# Application of ethics principles - 5

- Study objectives need to be SMART
- With specificity, there is clarity about what needs to be done
- When measurable, the right study design can be determined
- Appropriate study design enhances reliability
- When there is a time period to it, the study can be finite
- SMART objective(s) respects the principle of beneficence



# Application of ethics principles - 6

## Study design

Research is a systematic approach to the pursuit of truth using observations, comparison and experimentations. All research designs can be broadly divided into these three groups:

- **Observation:** These give descriptive information. They cannot give inferential (cause-effect relationships) outcomes.
- **Comparison:** often an analysis process that can be done using qualitative or quantitative data. They cannot give inferential outcomes.
- **Experimental:** This generates qualitative data and can give inferential outcomes.



# Study design - 1

- **Surveys:** They are cross sectional studies that gives descriptive results. Analysis limited to univariate analysis.
- **Correlational research:** they determine if there is a relationship between two quantitative variables and assess the strength of the relationship. These include analytical cross sectional studies, case control studies. Analytical tools involve the conduct of bivariate and inferential analysis. Cannot establish a cause and effect relationship. Can best help to establish an hypothesis.



# Study design - 2

- **Quasi-Experimental:** also referred to as Causal-Comparative studies. It seeks to establish a cause-effect relationship between two or more variables. The researcher does not randomise. Control groups are identified and exposed to the variable. Results are compared with results from groups not exposed to the variable.
- The dependent and independent variables need to be defined.
- Determination of the cause-effect relationship after the event has occurred either through historical data or prospective data.



# Study design - 3

- **Experimental:** Used the scientific method to establish cause-effect relationship.
- Researchers make an effort to control for all variables except the one being manipulated (the independent variable).
- The effects of the independent variable on the dependent variable are collected and analyzed for a relationship.
- This is also called clinical trials. It could be randomised or non randomised. Randomised trials could be single, double or triple blind.



# Study design - 4

## Clinical trials

- They give the highest level of scientific evidence
- Suited for biomedical research – drug testing
- They are conducted after evidence that in-vitro and animal experimentations are safe for human use
- *Phase I trials*: tries to establish the safety of drugs
- *Phase II trials*: establishes safety and efficacy
- *Phase III trials*: establishes safety and effectiveness
- *Phase IV studies*: Data collected by pharmacovigilance data





# Study design - 5

- **Implementation research:** This is the study of methods to promote the uptake of research findings into routine practice.
- The scientific study of methods to promote the systematic uptake of clinical research findings and other evidence-based practices into routine practice
- It is a mechanism for translating research into practice.
- It tests the effectiveness of a program situated within real life events.
- The challenge is controlling for multiple confounders.

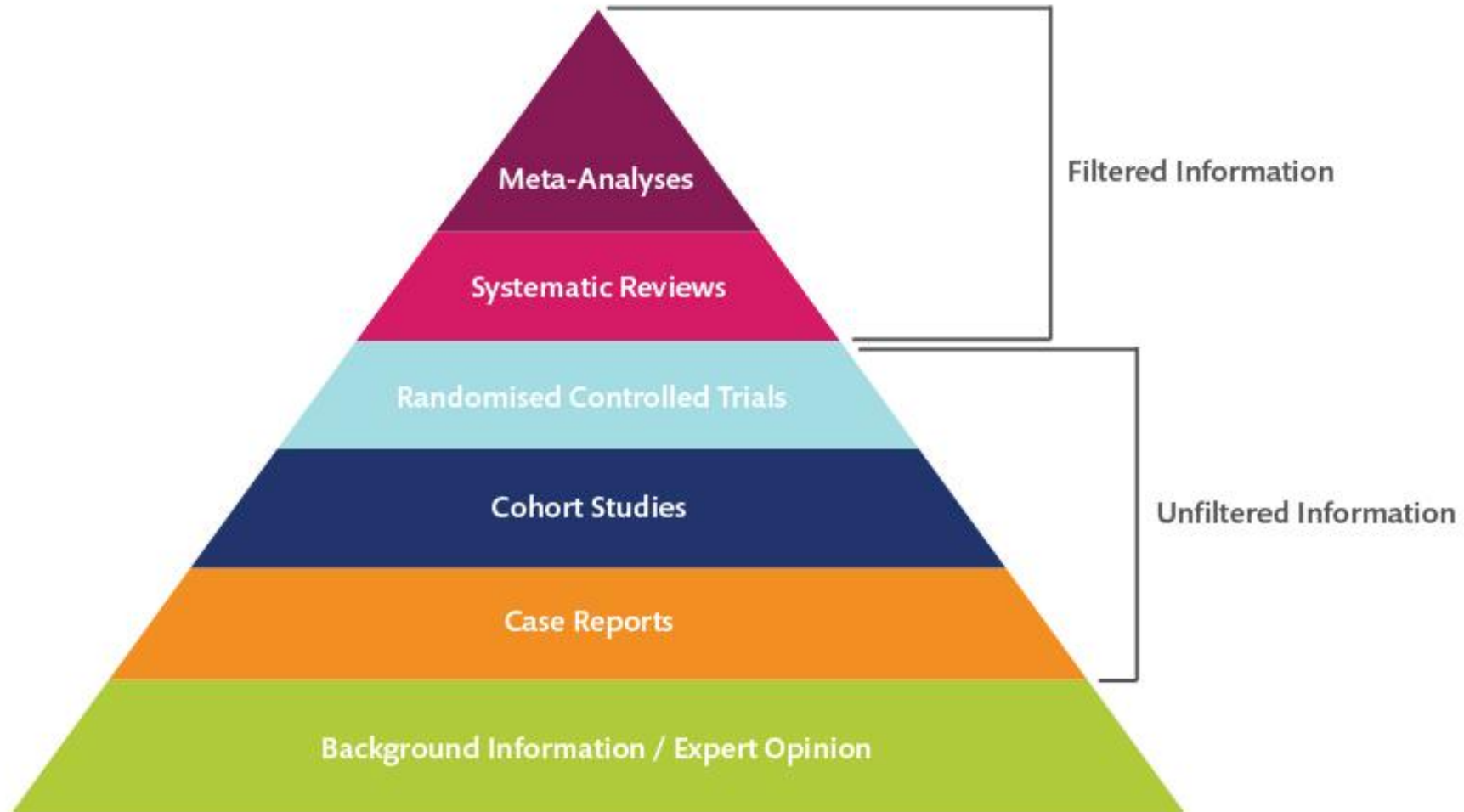


# Study design - 6

- **Systematic review:** summarises the results of available carefully designed healthcare studies and provides a high level of evidence on the effectiveness of healthcare interventions.
- **Meta-analysis:** This is a statistical analysis that combines the results of multiple scientific studies. It is an analysis of the outcome of systematic reviews
- This requires careful selection of scientific data pooled through the systematic review to produce evidence for action. A meta-analysis provide scientific evidence of higher value than clinical trials.



# Hierarchy of research evidence



# Types of qualitative research

- Qualitative research tries to understand how people make meaning of their lives and experiences in the world.
- **Basic qualitative research** is a type of qualitative research. It simply seeks to describe, interpret the meaning of people's lives and experiences.
- Data for basic qualitative research is generated through document reviews, interviews, observations.



# Types of qualitative research - 2

- **Case study** is a focused study of a specific unit – entity, person, setting or phenomenon. It seeks to understand the totality of the unit. It has depth and requires time.
- A case study may be intrinsic (study a rare unit), instrumental (study of a representative unit) or a collection of case studies to help understand a unit.
- Data can be generated through review of documents, interviews, observations among others.



# Types of qualitative research - 3

- **Ethnographic studies:** informed by anthropology with the aim being to understand cultural patterns and perspectives of a group of people in their natural setting. It tries to understand the link between culture and social behaviors.
- Tools used to generate information include document reviews, interviews, records, fieldwork diaries, artifacts, ideas, impressions.
- Hypotheses are not defined for ethnographic studies.



# Types of qualitative research - 4

- **Grounded theory studies:** It inductively builds a theory about a phenomenon or practice. It is grounded in the realities of the real world. Its aim is to develop a theory that explains a process, interaction or action.
- It is a cyclical process of building a theory and testing it against the data.
- It involves coding the data generated through interviews and observations which are the primary source of data. Other secondary data sources include documentary materials and the literature.



# Types of qualitative research - 5

- **Phenomenological studies:** it describes and interprets and lived experience by determining the meaning of the experience as perceived by people who have participated in it.
- It is based on the philosophy that there is an essence to share experiences. The defining characteristic of a phenomenological study is that there is an essence.
- Data generated through multiple interview of persons who have lived the experience. This can be complimented by other sources of data like observations, music, poetry, blogs, journals, drama, films.





# Types of qualitative research - 6

- **Narrative or historical research:** This is the use of stories as the data source especially first person account in the story.
- The story – biographies, autobiography, life history, oral history, auto-ethnography – are analyzed for meaning.
- Analysis is through the use of Hermeneutic philosophy which is the study of written text.
- Data can be generated by a personal narrative or through studies of the individuals narratives – letters, diaries, blogs, photographs



# Types of qualitative research - 8

## Other types of qualitative research

- *Critical research*: empowers change through critiquing assumptions. It questions power relations and the influence of race, gender and class.
- *Discourse analysis*: studies the relationship between words and their meanings.
- *Portriature*: seeks to merge arts and science so as to describe complex human experiences within a organizational culture.



# Application of ethics principles - 6

- Study designs need to be appropriate for study objective
- A wrongly designed study is an unethical study
- It results in waste of resources
- Results from wrong study designs can cause harm
- Appropriate study design respects the principle of non-maleficence



# Application of ethics principles - 7

## Study participants

- Criteria for study participants inclusion is needed
- Criteria for study participants exclusion is needed
- Exclusion of study participants is to eliminate study confounders
- Justifications for study participants inclusion & exclusion required
- Justification for study site is also required
- Unlawful exclusion disrespects the principle of justice



# Application of ethics principles - 8

## Sample size

- Studies are powered to be able to make appropriate deductions
- Calculated sample size is the minimum required for study
- A maximum of 20% increase in sample size is what is justifiable
- This respects the principle of non-maleficence



# Application of ethics principles - 9

## Study procedure

- Details of the study procedure required
- Review of the study procedure helps to ensure rights are not bridged
- Procedure should ensure appropriate sampling (Justice)
- Use the least invasive procedures (non-maleficence)
- Review procedures to ensure risks are mitigated (non-maleficence)
- Review procedures to ensure adherence to law – reports are planned
- Respect norms and traditions (respect for communities)
- Use appropriate consenting procedure (respect for persons)



# Application of ethics principles - 10

## Study instrument

- Usually required as an appendix
- All instruments should be tested for cultural appropriateness
- Ensure construct and content validity
- Use culturally appropriate language
- Use language that will facilitate disclosure
- Instruments should help achieve objective
- This respect the principle of non-maleficence



# Application of ethics principles - 11

## Data analysis

- Provide details on dependent (outcome) and independent variables
- Univariate analysis of which variables
- Bivariate analysis of which variables using what statistical tools?
- Inferential analysis of which variables using what statistical tools?
- How will the model for inferential analysis be developed?
- A review of the data analysis plan respects the principle of justice





# Application of ethics principles - 12

## Dissemination

- It is unethical not to disseminate the outcomes of research
- Non-dissemination results in waste of resources
- Non-dissemination results in delays in finding the ultimate truth
- What are the various ways to disseminate research results?
- What principle does this respect and why?



# Application of ethics principles - 12

## Budget

- Some ethics committee requests for this
- They want to ensure that the research is appropriately resourced
- An inappropriately resourced research leads to unethical practices
- Exploitation and infringement on rights of study participants possible
- Aim is to prevent harm – respects the principle of non-maleficence



# Conclusion – Beyond the protocol

- Ethics is about respecting the rights of individuals and collectives
- It is beyond a show and ticking of check boxes
- It is about truly giving back to the society
- Research needs to benefit the people who participate in the research
- It is beyond getting papers for prestige purposes
- Treat study participants (not subjects) with uttermost respect
- Be ethical in your practice – go beyond the ‘show’ of ethics.



Thank you and QUESTIONS??

