



# How to develop a competitive research protocol

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**Geneva Foundation for Medical Education and Research**

**From Research to Practice:  
Training Course in Sexual and Reproductive Health Research  
Geneva Workshop 2016**



# Overview of presentation

- Explain what research is
- Define research proposal is and explain its purpose
- Describe the main elements of a research proposal
- List the criteria for proposal review



# Introduction

- A research is a planned investigation that uses scientific methodology to solve an important problem, to create a new knowledge.
- Research tests hypothesis, answers existing questions, produces new queries, finds solutions and creates new knowledge.
- To be termed a research, an investigation must be valid (logical procedure), reliable (quality measurements) with unbiased conclusion (Faryadi, 2012).



# What is a research protocol?

- A written detailed plan of a study
- It informs on **what** will be done? **why?** and **how?**
- Clarifies ideas and directs focus to all aspects of the investigation
- Guides research, especially if there are multiple investigators
- Necessary for institutional ethical approvals
- Necessary for fund application (Al-Riyami, 2008; Fathalla and Fathalla, 2004)



# Criteria for a good research protocol

## **A good research protocol should:**

- Answer the study question(s)
- Achieve the study objectives
- Be doable/feasible
- Be replicable, that is, the information provided should be sufficient enough to permit study replicability.
- Convincingly show the importance of the research, the research process and the competence of the investigators.  
(Al-Riyami, 2008; Fathalla and Fathalla, 2004)



# Elements of a research protocol

- Project title
- Project Summary / Abstract
- Project description
- Dissemination of results and publication
- Ethical considerations
- Timetable
- Problems anticipated
- Budget
- References
- Research team
- Annexes

(Hilsden and Verhoef, 2004; Research Grants Program, 2011; WHO, 2016)



## Project title

- A preview of the project
- Concise but detailed
- Accurately expressed to reflect the study
- Describe what is to be done, the study population and the variables of interest

### **Example:**

***“Effects of the program for rooming-in at home on breast-feeding indicators: Experimental test with low-risk primiparous women attended at La Esperanza Maternal Hospital in Guatemala City.”*** (Research Grants Program, 2011).



# Project summary / abstract

- A brief outline of the entire project of about 300 words
- Should stand alone (WHO, 2016)
- Should briefly and clearly state:
  - The research problem
  - The main research questions and or hypotheses
  - The justification for the research- how will it differ from existing studies
  - The research objectives
  - The study design- what will be done? by whom? to who? when? how? and for how long?
  - The expected outcomes
  - Anticipated problems- scientific, ethical, managerial (UNDP, UNFPA, WHO and World Bank, 2003)





# Project description

1. Research problem identification
2. Research problem justification/rationale
3. Literature review
4. Study goals and objectives
5. Research question / Hypothesis,
6. Study design
7. Research methodology
8. Expected outcomes of the study



# 1. Research problem identification

- States the research problem.

## **Should answer the following questions in a logical flow:**

- What is the problem?
- Magnitude/ significance of the problem- who is affected?  
Frequency of occurrence? Of public health interest?
- Are the causes of the problem known? Consensus?  
Controversies?
- Solvability of the problem- can the problem be solved? what  
has been done? what are the effects?
- Need for research at addressing- any knowledge gap?  
(Research Grants Program, 2011).



## 2. Research problem justification / rationale

- Argues why the research should be done.

### **Should answer the following questions:**

- Country needs- does it fit into current local or national priorities?
- What knowledge/ information will it provide? New knowledge?
- Contribution of research results – what is the relevance of the knowledge? Population benefits? Improved understanding of the problem- gaps, controversies? Influence policy?
- What are the plans to disseminate result?
- How will the results be applied? Who will benefit? (Hilsden and Verhoef, 2004; Research Grants Program, 2011)



## 3. Literature review

- A summary of the critical review of literatures on the research problem.
- Puts the research problem into perspective.
- Justifies the new research by identifying gaps and weaknesses in existing literature.
- Should be thorough, logical and well organized.
- Should include current and relevant literature.
- Should focus on original research and systematic reviews.
- Include literatures that supports or disproves researcher's point of view (Hilsden and Verhoef, 2004).



## 4. Study goals and objectives

### **Study goal**

- Aims/ General objectives
- Inform broadly on what the research proposal will do (WHO, 2016)

### **An ideal study goal:**

- Should be clear
- Should state the purpose of the study, that is, what it aims to achieve and why
- Should define what will be described, determined, identified, compared, and, where there are hypotheses, it should indicate what will be confirmed (Research Grants Program, 2011).



## 4. Study goals and objectives cont'd.

### **Specific study objectives:**

- Statements of the research questions
- Should be formulated before starting the research
- Indicate how the study will accomplish its goals
- Introduce the study design
- Should be simple, concise and specific (Research Grants Program, 2011; WHO, 2016)



## Example of study goal and objectives

### General objective (study goal)

*“To verify the differences in the length of time low-risk primiparous women breast-feed when they participate in the program for rooming-in at home as compared to those who do not participate.”*

### Specific objectives

- 1. “To verify the differences in the length of time low-risk primiparous women breast-feed when they participate in the program for rooming-in at home as compared to those who do not participate.”*
- 2. “To determine the existence of statistically significant differences in the prevalence of breast-feeding in the group of women who receive standard health care and the group treated at home.”*
- 3. “To identify the protective factors that from the women's perspective help to explain the differences in the prevalence of breast-feeding according to the type of attention received.” (Research Grants Program, 2011).*



## 5. Research question / hypothesis

### A good research question should be:

- Simple
- Clear and unambiguous
- Focused
- Realistic
- Answerable- clearly indicate what data will be needed to answer the question and how it will be collected
- Logical if there are more than one questions
- Expressed as a question

### Use acronyms to refine and focus questions:

- **PICO**: Population, Intervention or Issue, Comparison or Context and Outcome
- **SPIDER**: Sample, Phenomena of Interest, Design, Evaluation and Research (specific to qualitative research) (Aveyard, 2014).





## 5. Research question / hypothesis

### **Research hypothesis**

- Used in analytical studies
- A declaration of the relationship between two or more variables, one being dependent
- Tentatively predicts the research outcome
- Should clearly state the variables that may be likely associated and the population of interest

### **How is it expressed?**

Null hypothesis- there is no association between the variables of interest.

Alternative hypothesis- there is an association between the variables. (Cherry, 2013; Bruce et al., 2008)



# Examples

## **Study purpose:**

*“The purpose of this study is to determine if there are differences in pain control with nurse versus patient administered analgesia following surgery.”*

## **Research question:**

*“Does the administration of analgesic by nurses vs. by patients themselves affect pain intensity during postoperative recovery in older adults?”*

## **Hypothesis:**

*“Patients who self-administered narcotics will be more satisfied than patients who receive narcotics administered by nurses.” (Hilsden and Verhoef, 2004).*



## 6. Study design

- Determines the credibility of the study
- State and justify the study design

### **Choice depends on:**

- The research question / hypothesis
- Comparison with alternative study designs
- Feasibility, resource availability, timeline, ethical consideration

### **Types of design:**

- Qualitative or quantitative
- Observational or interventional
- Descriptive or analytic
- Cross-sectional or longitudinal

(Hilsden and Verhoef, 2004; WHO, 2016)



## 7. Research Methodology

- Most important aspect of a protocol, and should be written in detail.
- Provide details and justification of the techniques and procedures that will be employed to achieve the proposed objectives (WHO, 2016).



## 7. Research Methodology

### **The following information should be provided:**

- Variables
- Study population/ research setting, sampling, sample size, selection of samples- cases, controls, inclusion and exclusion criteria, criteria for discontinuation
- Proposed intervention, if any: What is it? Who will administer it? Where? What is the extent? How often? How will subjects be allocated? Safety considerations? Follow-ups?

(Fathalla and Fathalla, 2004; Hilsden and Verhoef, 2004; WHO, 2016)



## 7. Research Methodology cont'd.

### **The following information should be provided:**

- All procedure for data collection: data collection instruments, pilot testing, recruitment of study participants, data quality control
- Data management and analysis: data coding, monitoring and verification, computer software, statistical methods, sample size justification, study power, significance level

(Fathalla and Fathalla, 2004; Hilsden and Verhoef, 2004; WHO, 2016)



## 8. Expected Outcomes of the Study

### **Should answer the following questions:**

- What new knowledge will be obtained from the study?
- How will the knowledge will contribute to improvement in knowledge?
- Who will benefit or use the findings?
- Any effect on health care, health systems or policies? (WHO, 2016).



## Dissemination and publication of study findings

- How will research findings be communicated and to who?
- Include dissemination to participants or communities and policy makers as applicable (WHO, 2016).

### **Findings can be disseminated through:**

- Internal seminars
- Regular reporting to stakeholders
- Publications, for example journal articles, reviews or book chapters
- Conference presentations
- Exhibitions
- Outreaches and public engagement events

(The University of Edinburgh, 2015)





# Ethical Considerations

Based on the principles of autonomy, beneficence, non-maleficence and justice.

## **Should consider:**

- Study validity
- Recruitment
- Ethical approval for the study- local, institutional, national ethic committee
- Informed consent process
- Other issues that may be of ethical concern especially when the study involves human subjects

(Fathalla and Fathalla, 2004; Hilsden and Verhoef, 2004).



## Ethical Considerations cont'd.

### **The following should be clearly stated:**

- Known benefits, risks and disadvantages
- Information to be provided to subjects and how
- Extent and alternative to participation
- Incentives to be provided to subjects if any
- Treatment to be provided to subjects if any
- Information confidentiality

(Fathalla and Fathalla, 2004; Hilsden and Verhoef, 2004)



# Timeline

- Specifies the duration for each project
- Provides the detail monthly timeline for each activity

## Consider:

- Preparatory stage- training of research workers, equipment procurement,
- Pilot studies
- Data collection
- Data analysis
- Report writing
- Milestones- for long-term projects (Fathalla and Fathalla, 2004; Hilsden and Verhoef, 2004)



## Problems anticipated

- State all the obstacles or difficulties that can prevent the realization of project within stipulated timeline and budget.
- Explain how the obstacles would be overcome (Fathalla and Fathalla, 2004).



# Budget

- Itemize and justify the budget.
- For long-term projects, provide detail budget for at least the first year and outline budget for subsequent years.
- Realistic budget- too much or too may lead to unsuccessful funding application.
- Types of expenses include: Personnel (include names and contributions to project), equipment, supplies, patient care and costs, travel, data processing, communications, secretarial expenses, publication/dissemination of research findings. (Fathalla and Fathalla, 2004).



# References

- All sources of information must be cited- avoid plagiarism
  - Reference style should be uniform
  - Formatting should be consistent
  - Cite relevant and current literatures
  - All cited authors in the text should be in the reference list
  - All listed references must have been cited in the text
  - References should be cited and listed sequentially
- (The University of Edinburgh, 2015)



## Research team

- Describe the role and responsibility of each member of the team.
- Include information on previous studies or preliminary work done on the research problem by the investigators.
- Attached Curriculum vitae (CV) of investigators of investigators: this shows the competence of the investigator to conduct the research (UNDP, UNFPA, WHO and World Bank, 2003)



# Annexes

Include the following as appropriate:

- Interview protocols
- Sample of informed consent forms
- Cover letters sent to appropriate stakeholders
- Official letters for permission to conduct research
- Original study instrument, written permission to re-reproduce instrument or proof of purchase of instrument
- Other support for the project
- Collaboration with other scientists or research institutions
- Link to other projects
- Financing and insurance

(Al-Riyami, 2008; WHO, 2016)





# General considerations

- Include table of contents
- Include list of acronyms/ abbreviations in alphabetical order
- Explain technical terms if used
- Be logical in flow of thoughts and use section headings
- Keep tense and voice consistent- present versus past tense and active versus passive voice
- Keep sentences short and use paragraphs appropriately
- Avoid repetitions
- Be consistent in formatting- font size, font style
- Make effective use of tables, figures and charts
- Make sure your proposal stand out

(Bates College, n.d.; The University of Edinburgh, 2015)



## Points to note when applying for funding

- Apply to funders whose program goals are related to your project.
- Understand and follow the guidelines/instructions of funders.
- Know the method of application, submission, timeline and budget limits.
- Provide sufficient description of project.
- Follow guidelines and instructions for the style and organization of your proposal- formatting, spacing, paging, word limits etc.
- Show enthusiasm and commitment (Bates College, n.d.)



# Sources of research funding

- Public
  - Governmental organizations- health ministries, health institutes, universities, national research councils
  - Intergovernmental organizations- World Health Organization
- Private
  - Not-for-profit organizations- non-governmental organizations and philanthropists, e.g. Rockefeller Foundation, Bill and Melinda Gates Foundation
  - Profit making industries- pharmaceutical companies
- Intermediary organizations, e.g. PATH (Program for Appropriate Technology in Health), Population Council  
(UNDP, UNFPA, WHO and World Bank, 2003)



# Proposal review criteria

Funding for research is competitive and is determined by researcher's qualification, experience and research goals (The University of Edinburgh, 2015).

## **The following questions are usually considered:**

- Is the research question important?
- Is the study relevant to the funders' interest?
- What is the quality of the research design ?
- Are the investigators competent enough to conduct the research?
- Is the research facility capable of conducting the research?  
(Fathalla and Fathalla, 2004)



# Proposal review criteria

## **The following questions are usually considered cont'd.:**

- Can the institution manage the research administratively and financially?
- Have all ethical issues been considered?
- Is the budget realistic and justifiable?
- Is the budget within the budgetary limit of funders?
- Is the time-line reasonable?
- Anticipation and good plan to manage potential problems?
- Is the proposal clearly and well written? (Fathalla and Fathalla, 2004)



# Submitting a research proposal

## **Funding agencies may accept proposals by:**

- Soliciting proposals from research institutions
- Advertising invitations for proposal submission for research in specific areas of interest
- Open-door policy for submission of any good proposal (Fathalla and Fathalla, 2004)



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