How to develop a competitive research protocol

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Overview of presentation

This presentation will:

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

Introduction

A research is:

- A **planned** investigation that **uses scientific methodology** to solve an **important problem** and **generates a new knowledge**.

- It tests hypothesis, answers existing questions, produces new queries, finds solutions.

- To be termed a research, an investigation must be valid (logical procedure), reliable (quality measurements) with unbiased conclusion.

What is a research protocol?

A research protocol or proposal is a written detailed plan of a study.

- It informs on **what** will be done? **why**? and **how**?
- It clarifies ideas and directs focus to all aspects of the investigation.
- It guides research, especially if there are multiple investigators.
- It is necessary for institutional ethical approvals.
- It is necessary for fund application.

Al-Riyami, 2008; 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, 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

Project title

- A preview of the project
- Concise but detailed
- Accurately expressed to reflect the study
- Describes 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."

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

- Explains 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 to address the problem- any knowledge gap?

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
- Should include literatures that supports or disproves researcher's point of view

Hilsden and Verhoef, 2004

4. Study goals and objectives

Study goal

- Aim/ General objective
- Informs 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

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 estimate the prevalence of breast-feeding in low-risk primiparous women covered by the program for rooming-in at home and the prevalence of breast-feeding in primiparous women that receive standard health care."

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."

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

Aveyard, 2014

5. Research question / hypothesis cont'd.

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 cont'd.

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, 2019; 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

Hilsden and Verhoef, 2004; WHO, 2016

6. Study design cont'd.

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.
- Provides details and justification of the techniques and procedures that will be employed to achieve the proposed objectives.

7. Research Methodology cont'd.

The following information should be provided:

1) Variables
2) Study population/ research setting, sampling, sample size, selection of samples- cases, controls, inclusion and exclusion criteria, criteria for discontinuation
3) 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.

4) All procedure for data collection: data collection instruments, pilot testing, recruitment of study participants, data quality control
5) 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 evidence will be obtained from the study?
- How will the evidence contribute to improvement in knowledge?
- Who will benefit or use the findings?
- Any effect on health care, health systems or policies?

Dissemination and publication of study findings

- How will research findings be communicated and to who?
- Should 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

Ethical Considerations

Based on the principles of autonomy, beneficence (doing good), non-maleficence (avoiding harm) 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 detailed 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 little 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

Referencing

- Cite relevant and current literatures
- All sources of information must be cited - avoid plagiarism
- 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
- Reference style should be uniform
- Formatting should be consistent

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.

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 cont'd.

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

Thank you and good luck with your research!

References

Al-Riyami A. How to prepare a Research Proposal. Oman Med J. 2008 Apr;23(2):66-9. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3282423/

Aveyard H. Doing a Literature Review in Health and Social Care: A Practical Guide. 3rd ed. Maidenhead: Open University Press. Oxford: Routledge; 2014.

Bates College. Tips for preparing a strong grant proposal. Bates College; no date. Available from: http://www.bates.edu/academics/files/2014/11/Tips-for-Preparing-a-Strong-Grant-Proposal.pdf

Bruce N, Stanistreet D, Pope D. Quantitative methods for health research: a practical interactive guide to epidemiology and statistics. 2nd ed. Chichester: Wiley; 2008.

Cherry K. Forming a Good Hypothesis for Scientific Research. Verywellmind [Internet] https://www.verywellmind.com/what-is-a-hypothesis-2795239 (Accessed: 26 December 2019).

Faryadi Q. How to write your PhD proposal: A step-by-step guide. American International Journal of Contemporary Research. 2012;2(4):111–115.

Fathalla MF, Fathalla MM. A practical guide for health researchers (WHO Regional Publications, Eastern Mediterranean. Series 30). WHO; 2004. Available from: https://apps.who.int/iris/rest/bitstreams/527138/retrieve

References

Hilsden RJ, Verhoef MJ. Writing an effective research proposal. University of Calgary; 2004. Available from: https://www.up.ac.za/media/shared/Legacy/HS%20Res%20Office/SHSPH/protocolwriting.zp38083.pdf

Research Grants Program. Guide for writing a research protocol. Washington: Pan American Health Organization; 2011.

The University of Edinburgh. How to write a good postgraduate research proposal. The University of Edinburgh; 2015. Available from: https://www.ed.ac.uk/files/imports/fileManager/HowToWriteProposal090415.pdf

UNDP, UNFPA, WHO and World Bank Special Programme of Research, Development and Research Training in Human Reproduction. Preparing a research project proposal: Guideline and forms. 4th ed. WHO; 2003. Available from: http://www.gfmer.ch/SRH-Course-2011/research-methodology/pdf/WHO-proposal-guidelines-forms-2003.pdf

World Health Organization. Recommended format for a Research Protocol. World Health Organization; c2023. Available from: https://www.who.int/groups/research-ethics-review-committee/recommended-format-for-a-research-protocol