

WRITING A RESEARCH PROPOSAL AND A RESEARCH PROTOCOL IN CLINICAL NURSING RESEARCH

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PRESENTATION OUTLINE

- Introduction
- Explanation of concepts
- Functions/ Uses/ Purposes of Research Proposals / Protocols
- Content and Steps in writing the research proposal / protocol
- Concluding thoughts

INTRODUCTION

- A research proposal is a detailed description of a proposed study written when one wants to start a new study.
- The proposal contains brief introduction, the problem statement, aims and objectives, methodology as well as outlines the feasibility and possible output of the proposed research work.
- It may be written by a student to start a new project or by professor to obtain funding from funding agencies.

INTRODUCTION Contd

- Writing an academic project proposal requires that one demonstrates an understanding of a specific problem within ones discipline.
- A Clinical research is concerned with the study of health and illness in people. It helps us how learn how to prevent, diagnose and treat illness.
- The presentation is aimed at highlighting the components / processes involved in writing a clinical research proposal

What is a proposal

- A document that presents the case for an idea and the action that one proposes to take with respect to it and aimed at eliciting a desired action from the reader (Fatusi, 2012)
- An academic proposal is the first step in producing a thesis or major project.
- Its intent is to convince a supervisor or academic committee that your topic and approach are sound, so that you gain approval to proceed with the actual research

What is a research Protocol

- Typically a written document that describes in detail how a particular scientific study will be done. It usually describes the following:
 - Rational
 - Nature and source of material to be used
 - Procedure for collection of needed data
 - Methods for data analysis
- A research protocol clearly and plainly provides an overview of a proposed study in order to satisfy an organization's guidelines for protecting the safety of human subjects who might be impacted by the work.
- Research protocols are typically submitted to Institutional Review Boards (IRBs) within universities and research centers.

PROPOSALS AND PROTOCOLS

- Intended to convince others that you have a worthwhile research project and that you have the competence and the work-plan to complete it.
- Should generally contain all the key elements of the research process.
- Both overlap and can be used interchangeably
- Type and purpose may introduce small variability

CLINICAL RESEARCH

Simply put, clinical research involves human participants and helps translate basic research (done in labs) into new treatment and information to benefit patients.

Clinical trials
physiology
pathophysiology

Epidemiological
research

Health services
Education
Outcomes
Mental health

Purposes

The research proposal/protocol

- States the research question you aim to answer;
- Provides a structured, written working plan of the study;
- Encourages adequate consideration and planning of project detail *before* you begin;
- Provides co-investigators or peers with a living and dynamic document for contribution and early review prior to its completion;
- Allows research staff, whether at the same location or at multiple locations (in the case of a multi-centre study), to carry out the study in exactly the same way;

Purposes contd

- Acts as a record and reminder for the research team and collaborators of the initial project aims, stated procedures and researchers' duties and responsibilities;
- It enables stakeholders to monitor the progress of the project;
- It provides the basis for funding and/or human research ethics applications (including budgetary information); and
- It provides a framework for resulting publications.

Function or research proposal/protocol

- Communication tool
- Plan
- Contract
- Allows the researcher to plan and review the project's steps.
Serves as a guide throughout the research.
Forces time and budget estimates.

Stages /components / parts

- An introduction
- A statement of aims, objectives, hypotheses
- A detailed account of the methodology, which itself is divided into a number of sections including the methods used in the statistical analysis of the data
- 4 A study schedule costing
- 5 Any necessary appendices ,references
- 6 A supporting bibliography.

Getting started

- It all begins with an idea. A great idea
- 3 Cs of a great idea:
 - Curiosity** to investigate and question situation
 - Critical thinking skills** to refine your curiosity into a clearly stated idea
 - Courage** to have unusual (“crazy”) ideas

Conceptualizing the research topic

Finding your focus:

- Which aspects of your discipline interest you most
- What have you observed that you have questions about?
- What articles have you read that have raised questions in your mind?

Identify existing gaps in literature?

By topic (what is not being looked at?)

Methods (what is not being done?)

Populations (who is not being studied?)

Comparisons (who is not being done)

Getting Started

Research Topic

- Research topics broadly define the area of research, but needs narrowing to become feasible research projects

Problem Statement

- A research problem is “an enigmatic, perplexing, or troubling condition”

Purpose/ Objectives/ Research questions

- A problem statement articulates the problem to be addressed and indicates the need for a study through the development of an argument

Where to start

- Read, read, read
- Detailed literature searches
- Attend seminars, conferences and presentations
- Discuss subject area with peers & seniors
- Listen
- Ask question

IDEAS AND RESEARCH QUESTIONS: REALITY CHECKS

- Helpful questions to ask yourself:
- Has such research been done by others?
- Who cares?/ So what?
- Can it be addressed using appropriate research methods?
- Will it stimulate interest by others and the sponsor
- Is it feasible/practical/doable?
- Are the required capacities available in your team and institution or can be acquired/accessed?
- Who is likely to be interested in funding it

NOW THE PROPOSAL

Questions that a proposal answers

- WHAT you are proposing to address } Problem
WHY you are proposing it

- HOW you plan to do it } Process
WHEN you plan to do it

- HOW MUCH it is going to cost } Resource

FORMAT FOR PROPOSALS

- No universally applicable and correct format
- Certain “communication tasks” are common
- Funding agencies/ institutions may have specific formats ...
- STRICTLY follow specified format

REMEMBER...

- “innovation in ideas but NOT in presentation”

Introduction

(the Introduction and Background sections are sometimes combined into one section depending on complexity of the study)

- The introduction is a very brief overview of study (~250 words).
- Should be concise but sufficient to orientate the reader to the main purpose of the study, how it will be conducted and its expected benefits.
- It is a structured sketch of the study that will provide an overview before examining the details.
- It is placed at the head of the protocol

Background

- The most important aspect of a research proposal is the clarity of the research problem.
- An opportunity to convince the reader (or reviewer) of why the study needs to be done (and deserves funding or ethical approval).
- Should also include the rationale which specifies the reasons for conducting the research in light of current knowledge.
- Should include a well-documented statement of the need/problem that is the basis of the project, the cause of this problem and its possible solutions.
- Discussion should be clear and logical to demonstrate you are fully conversant with the ideas presented and can grasp their methodological implications.
- Brief and to the point (no longer than two A4 pages).

The following key points to guide:

- **Do a comprehensive literature search using databases if possible which:**
- **should include aspects such as the magnitude, frequency, affected geographical areas, ethnic and gender considerations of the problem and followed by a brief description of the most relevant studies published on the subject.**
- **should logically lead to the statement of the aims of the proposed project.**
- **Discuss the importance of the topic (public health and/or clinical importance and impact on individuals/community, incidence, prevalence, mortality and morbidity).**
- **Critically appraise the relevant literature and discuss the state of current knowledge on the topic (including deficiencies in knowledge or gaps that make the study worth doing).**
- **Indicate how the research question has emerged and fits logically with the above.**
- **Explain how the study will contribute to existing research and benefit other individuals or the wider community.**

Aims and Objectives

- **AIMS:** broad but concise statements of what the research study hopes to accomplish. They create a setting for the remainder of the research protocol. Your aim(s) should arise from your literature review and state what the study hopes to accomplish.
- **OBJECTIVES:** further refinement of research problem leads to one or more study objectives that relate to your aim.
- Specific objectives are statements of the research question(s).
- Objective(s) should be single, measurable/quantifiable statement(s) that will allow you to answer your research question.
- Ensure the text supports the chosen study endpoints and that it is specific (not nebulous, open-ended or otherwise not assessable) and objective.
- Avoid biased statements.

More about Objectives and Hypotheses

- Number of objectives should be kept low
(too many may make the study logistically difficult to perform.)
- Sample size calculation is based on the primary objective and it may not be possible to satisfy other objectives with this number.
- Objectives should be stated in clear, concise and specific statements.
- **HYPOTHESI(E)S** (*if needed*)
- Hypotheses are more specific than objectives
- Are amenable to statistical evaluation. Research hypotheses are the specific testable statements made about the independent and dependent variables in the study.
- Translates the research question into an evaluation of the expected outcomes.

METHODS

The heart of the proposal 'Where', 'Who', 'How'?

Elements

- Study location
 - Study design
 - Study population
 - Sampling methods
 - Data collection instruments and procedure
 - Observations & measures
 - Data analysis
 - Ethical approvals
 - Time plan (depending on use/type)
- convince
reader
that you
clearly
under-
stand
your task

**DON'T JUST DESCRIBE THESE BUT PRESENT
JUSTIFICATION**

Methods and materials

Study Design

- State the methodology and design of the research (e.g. randomised controlled study, cross-sectional survey, prospective or retrospective cohort/case-control).
- Whatever the study design, ensure that you provide the reader with a clear statement and description of the proposed design.
- Explain the justification for choice of this design in preference to other possible designs.

THE SCIENTIFIC INTEGRITY OF THE STUDY AND THE CREDIBILITY OF THE STUDY

DATA DEPEND A LOT ON THE DESIGN AND METHODOLOGY.

Study setting /locations

- The location(s) of where the study will be conducted.
- You need to mention whether the study is going to be a single-centre study or a multi-centered study (i.e. conducted in more than one location) and who is the coordinating centre.
- It is important to be mindful of other studies being conducted in the same location or among the same population as your study and to address any potential issues arising from this including limited staff resources.

Study Population

- It describes in detail about the study subjects, all aspects of the selection procedure and sample size calculation.
- Proper definition of eligibility, inclusion, exclusion and discontinuation criteria of the study subjects should be stated.
- Allocation of subjects to study arms should be explained and described in details bearing in mind the concealment and randomization process
- Potential risks

Sample and sampling

- It describes in detail about the study subjects, all aspects of the selection procedure and **sample size calculation**.
- Proper definition of eligibility, inclusion, exclusion and discontinuation criteria of the study subjects should be stated.
- Allocation of subjects to study arms should be explained and described in details bearing in mind the concealment and randomization process

Study Procedures

EXACT AND DETAILED DESCRIPTION OF WHAT IS GOING TO HAPPEN DURING CONDUCT OF THE STUDY:

- Recruitment and consent of participants
- Participants' withdrawal from study / procedures
- Randomization
- Measurement tools
- Participants' involvement (include safety issues)
- Data management and storage
- Data monitoring

Data Analysis Plan

- The statistical methods used for the study objectives/hypotheses (e.g. t-test, chi-squared, multivariate modeling) must be detailed, and related to your study aims and objectives.

Ethical consideration

- Relevant professional, ethical, legal and institutional requirements
- How the quality of the technical aspects have been assured
- Potential risks and proposed benefits of the study procedures
- Responsibility for liability of injury during the study
- Priority of the participants' interests over those of science or of society and how those interests will be safeguarded
- How they give voluntary consent to participate.

DISSEMINATION OF RESULTS AND PUBLICATIONS

- The protocol should specify not only dissemination of results in the scientific media, but also to the community and/or the participants, and consider dissemination to the policy makers where relevant.

Outcomes and significance

- Reiterate the potential benefits of answering the research question and conducting the project.
- This section restates the justification for the study in terms of the anticipated results.
- It may be important to specify the implications of the potential results and how the results of this study may inform future research or policy makers.

BUDGET

- A detailed item-wise breakdown of the funds required to successfully complete the study, including details of any funds requested, along with a justification for each item.

Note

- Make your budget realistic
- Let someone else review your budget to see how realistic you are.
- Check with the agency (in case of proposals to be submitted for funding) to see if they have suggested/required budget categories that they want you to use.
- Justify your budget

Timeline/ study duration

- The protocol should specify the time that each phase of the project is likely to take, along with a detailed month by month timeline for each activity to be undertaken. If possible a Gantt chart should be included.
- Include which member of the research team or committee responsible for what and at what time

APPENDICES /GLOSSARY OF ABBREVIATIONS/ATTACHMENTS

- All abbreviations used in the project plan, including appendices, should be listed with an explanation of each abbreviation.
- Accepted international medical abbreviations should be used.
- Project specific abbreviations should be standardised within the project plan.
- All abbreviations should be spelled out when first used in the text, followed by the abbreviation in parentheses.

References

- Include all references used throughout the write up.

Additional Components

- Your TITLE matters: make it informative but not
- snappy...save that for publications!
- your COVER LETTER matters
- Brief – usually 1 page
- Indicate appropriate approval for submission
- Contact person with telephone & e-mail
- A paragraph summarizing the project
- Total budget Should be written on official letter-head

Concluding thoughts

- The clinical research protocol is the single most important document to ensure critical elements of the research study are communicated to investigators conducting the study, the IRB, and regulatory agencies.



THANK YOU FOR
YOUR AUDIENCE