Global PaedSurg Research Training Fellowship



**Session 4: 22 February 2019**

**How to write a study protocol.**

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# Aim of the session

 To summarise the most important steps and guidelines for a standard research protocol

# Objectives of the session

* Provide a **structure** for a standard protocol
* Discuss important **content**
* Identify **guidelines** that should be followed for different study types.
* **Registering** your protocol
* **Publishing** your protocol

# Aims of the protocol

* Summarise existing knowledge of subject (literature review)
* Defining the research question and clarify its importance
* Formulation of aims and objectives (with or without hypothesis)
* Methodology required for solving the question and achieving the objectives
* Ethical considerations
* Discussion of strengths and limitations of the study and potential outcome

# **Writing a Protocol - Components**

## Title of the study

* The title of the study should be accurate; short and concise; details study type, population, outcome measure(s); aim for 12-15 words long.

## Administrative details

* Title page should contain the following details:
	+ Title and authorship
	+ Affiliations
	+ Corresponding author/ principal investigator contact details (postal address, email address, telephone number)
	+ Version of protocol with a date
	+ Study registration number
	+ Funding
* Contents page: important especially if the protocol is lengthy
* List of abbreviations

## Abstract

* Concise, summing up all the essentials of the protocol
* 300 words at most
* Typically consists of:
* **Background**: 1-2 sentences
* **Aim:** 1 short sentence
* **Methodology** (bulk of the abstract - made up of study design, population, data collection, analysis, ethics)
* **Dissemination** (international presentation, peer-reviewed publication)
* **Outcome** (1-2 sentences regarding what you hope the study will achieve)

(executive summary – alternative – slightly longer around 500 words)

## Introduction

* Outline the problem broadly - could be global and then more focused locally
* Summarise what is already known about the problem/subject from previous studies
* Describe local context and population
* Finish with a few sentences regarding the aims that the study seeks to achieve so as to fill the current knowledge gap/ address the problem

## Study aims

* 1 sentence summary of the primary objective of the study
* Can be included instead of a research question in a protocol, but a research question can be included too

*Should be logical, coherent, feasible, concise, realistic, considering local condition, phrased to clearly meet the purpose of the study and related to what the specific research is intended to accomplish*

## Study objectives

* Typically, 3-4 objectives providing further detail regarding primary and secondary objectives

SMART:

*Specific
Measurable
Achievable
Relevant
Time based*

Aims and Objectives - Can also be put as primary and secondary aims.

Hypothesis – transforms research question into a format amenable to testing or into a statement that predicts an expected outcome (null vs alternative). Null hypothesis assumes there will be no difference between two groups. Alternative hypothesis assumes there will – is in line with what researchers predict.

## Materials and Methods (Methodology)

* Describes where, who, how and when the research will be conducted
* Explains study design
* Population, inclusion/exclusion criteria, sample size calculation
* Details intervention (+/- implementation strategy) if included
* Defines primary and secondary outcomes
* Defines the variables and details of how they will be measured and collected (key demographics, possible confounding factors, effect modifiers)

**Data collection methods and instruments**

* Retrospective, prospective data collection
* Questionnaires, interviews and data collection form
* Laboratory tests, clinical examinations, others

A description of the instruments/tools to be used for data collection and the methods used to test the validity and reliability of the instrument should be provided

* Use pre-validated data collection tools or surveys
* Use of pilot study
* Include copies of the data collection tools to be used in the appendix
* Consider data validation

**Data analysis plan**

* Advice/input from statistician (have them mentioned or acknowledged in the protocol)
* Statistical tests will be used to check significance to research question/ hypothesis.
* Appropriate statistical tests should be described, mention significance level.
* Important to mention software used and its version.

## Data management and sharing

**Management and storage of data should consider the following:**

* Level of confidentiality, anonymity, who has access to it, where is it going to be stored, level of protection, how long will it be stored for
* How will data be managed

**Sharing of data**

* Which platforms will the data be shared on?
* It should be shared in an appropriate manner
* Open access sharing of the full de-identified, anonymous dataset following publication of the study is becoming increasingly common. It allows transparency of the study results and it allows others to put the data to further use.

## Project Management

* Work plan – this is an outline of activities of all the phases of the research to be carried out according to an anticipated time schedule.
* Time table for each major step of the study should be defined and the personnel involved in the study or data should be properly trained.

## Strengths and limitations

* Clearly outline what the study can achieve and cannot achieve.

## Ethical considerations

* In accordance with the Declaration of Helsinki. The study should not start unless approval from the ethics committee is received.
* Explaining: the benefits and risks for the subjects involved. The physical, social and psychological implications of the research.
* Details of the information to be given to the study patients with alternative treatments/ approaches.
* Informed consent of the participants (justification for research, outline of study, risks, confidentiality, voluntary participation)

## Dissemination

* A dissemination plan is necessary

## Budget summary of funding

* Each item should be justified.
* All costs including personnel, consumables, equipment, supplies, communication and funds for patients and data.

## Outcome

* One paragraph summary of what you hope your study should achieve.

## References

* Vancouver and Harvard citation systems are commonly used
* Use of software such as Endnote can help with efficiency and accuracy

## Appendix

Supplementary files attached at the end of the protocol such as:

* Consent form
* Letters from ethics committees
* Study questionnaire
* Case record forms
* Budget details
* Other information relevant and important for conduction of the study

*NB: A researcher should be able to read you protocol like a recipe and if followed should be able to conduct the same study and achieve the same results*

# Protocol Reporting Guidelines

Specific reporting guidelines for different study designs

* CONSORT guidelines – RCTs (<http://www.consort-statement.org>)
* SPIRIT guidelines – interventional studies (<http://www.spirit-statement.org>)
* STROBE guidelines – observational studies (<https://www.strobe-statement.org/index.php?id=strobe-home>)
* PRISMA-P guidelines – systematic reviews & meta-analyses (<http://www.prisma-statement.org/Extensions/Protocols.aspx>)
* STARD guidelines – studies of diagnostic accuracy (<http://www.equator-network.org/reporting-guidelines/stard>)
* STREGA guidelines – genetic studies (<http://www.equator-network.org/reporting-guidelines/strobe-strega/>)
* GATHER statement – studies of global health estimates (<http://gather-statement.org/>)

# Protocol registration

It is important to register the study before recruitment of the first patient in the study. Protocol can be registered on the following platforms:

* **ClinicalTrials.gov**: <https://clinicaltrials.gov>
* **WHO’s International Clinical Trial Registry Platform**: <https://www.who.int/ictrp/search/en/>
* **PROPSPERO** (for systematic reviews) <https://www.crd.york.ac.uk/prospero/>

# Publishing

## Why?

* Adds scientific rigor - presented results / analysis will be compared to what was originally intended
* Results paper can reference the protocol (in the methodology section) leaving more words for results/ discussion
* Additional publication
* Avoid duplicate work, especially systematic review

Where?

* Many journals - check the website prior to preparation /submission