Research Protocol

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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.

  A research protocol is the road map you will follow in writing a grant proposal and carrying out your research.

  A well-written research protocol is particularly important for obtaining institutional review board clearance for the research, as well as for seeking funding opportunities.

Essential components of a research protocol

- Abstract (not included in the word limit)
- Introduction
- Literature Review
- Research Question
- Methodology
- Data Analysis Plan (if any)
- Practicalities and Contingency Plan.
- Resources Required.
- Timeline.

Abstract

- The Abstract should not exceed 350 words. Please minimize the use of abbreviations and do not cite references in the abstract. The abstract must include the following separate sections:
- **Background:** the context and purpose of the study
- **Methods:** how the study will be performed
- **Discussion:** a brief summary and potential implications

Keywords

- Three to ten keywords representing the main content of the article.

Research Design

- Identify the type of study you will be doing.
- Usually called the “Research Design”.
  - Qualitative or Quantitative
  - Observational or interventional
  - Descriptive or analytic
  - Cross-sectional or longitudinal
- Usually identified in the methods section of the research protocol.
- In computer science, generally it could be an experimental study (hardware related or software simulation based) or observational study (data analytic study).

Research Question

- 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

Research Question Example

We investigate the association between **type-2 diabetes (primary outcome)** and two types of exercises: **cardio (CR) and weight lifting (WL)**. Specifically, the **relationship between duration of time spent in the two exercises** and the **odds of type-2 diabetes** is explored.

Reference: Y. Bhargava, A. Bopardikar and M. Bland, "Diabetes and Composition of Weight Lifting and Cardio in Exercise," *2020 42nd Annual International Conference of the IEEE Engineering in Medicine & Biology Society (EMBC)*, Montreal, QC, Canada, 2020, pp. 5353-5356, doi: 10.1109/EMBC44109.2020.9175262.

Methodology

- Most important aspect of a protocol, and should be written in detail.
- Provides **details** (WHAT) and **justification** (WHY) of the techniques and procedures that will be employed to achieve the proposed objectives.
- A step by step description of what will be done and why.
- In brief:
  - the aim, design and setting of the study
  - the characteristics of participants or description of materials
  - a clear description of all processes, interventions and comparisons. Generic drug names should generally be used. When proprietary brands are used in research, include the brand names in parentheses
  - the type of statistical analysis used, including a power calculation if appropriate.

Example

- Collection of data (How, From where, source justification). If you are collecting it - how?
- Or if it is hardware based, justify why?
- What you plan to do with data?
- Imagine a flow-chart for your entire research describe step wise.
- Methods is a strategy on how to plan to move from your research question to actually solving it.

Data Analysis Plan

- Justify the analysis plan you have decided for your research.
- For eg: If it is a binary classification problem then state you are using Logistic Regression or any of its variant (state why).
- Mention the statistical tests, if any, you shall be doing.
- Mention the modelling technique you'll use and the software (why).

Practicalities and Contingency Plan

- Think about how anything unexpected may happen and how you resort to address it.
- A discussion of any practical or operational issues involved in performing the study and any issues not covered in other sections
- Example: Not getting the required sample required for the study. Then what will you do?
- Or abrupt breakdown of hardware.
- If your study involves human subjects and you lose your subjects how will it impact your study and what do you plan to do about it?

Additional details

- Resources Required.
- Timeline. (Can use Gantt Chart)

Sample Research Protocol

- Refer to the Research Protocol Sample (by no means perfect). Just a guideline.