**Protocol Template for Registrar Research**

**Compiled by:**

**Dr Karis Moxley** ([karismoxley@sun.ac.za](mailto:karismoxley@sun.ac.za)), Registrar Research Support Office, Faculty of Medicine and Health Sciences, Stellenbosch University, South Africa

**Dr Tania Brodovcky** ([taniab@sun.ac.za](mailto:taniab@sun.ac.za)), Research Capacity Development and Funding, Research Development and Support, Faculty of Medicine and Health Sciences, Stellenbosch University

**Last updated:**

9 April 2020

**Disclaimer**

This document has been compiled as a generic guideline in accordance with Stellenbosch University’s Health Research Ethics Committee (HREC) requirements. This template contains all information necessary for HREC approval in most contexts. However, candidates are advised to consult with their supervisor(s) regarding the inclusion or exclusion of specific sections as well as the content therein. The examples and suggestions in this guideline always need to be qualified by the researchers’ own considerations and context.

**Title title title title title title title title title title title title title title title title title title title title title**

**Research protocol**

In partial fulfilment of the degree

Master of Medicine (MMed)

Department of xxx

Stellenbosch University

**Primary investigator**

Title and full name

Department of xxx, Stellenbosch University

**Supervisor**

Title and full name

Department of xxx, Stellenbosch University

**Co-supervisor**

Title and full name

Affiliation

**Date**

**Table of Contents**

[**1.** **Definitions** 1](#_Toc8135367)

[**2.** **Introduction** 1](#_Toc8135368)

[**3.** **Literature review** 1](#_Toc8135369)

[**3.1.** **Subheading 1** 1](#_Toc8135370)

[**3.2.** **Subheading 2** 1](#_Toc8135371)

[**4.** **Rationale** 1](#_Toc8135372)

[**5.** **Research question** 1](#_Toc8135373)

[**6.** **Hypothesis** 1](#_Toc8135374)

[**7.** **Aims and objectives** 1](#_Toc8135375)

[**8.** **Methodology** 1](#_Toc8135376)

[**8.1.** **Study design** 1](#_Toc8135377)

[**8.2.** **Study setting/site** 2](#_Toc8135378)

[**8.3.** **Study population** 2](#_Toc8135379)

[**8.4.** **Sample** 2](#_Toc8135380)

[**8.5.** **Inclusion criteria** 2](#_Toc8135381)

[**8.6.** **Exclusion criteria** 2](#_Toc8135382)

[**8.7.** **Recruitment strategy** 2](#_Toc8135383)

[**8.8.** **Data collection** 2](#_Toc8135384)

[**8.9.** **Data management plan** 2](#_Toc8135385)

[**8.10.** **Storage of biological specimens** 2](#_Toc8135386)

[**8.11.** **Data analysis plan** 2](#_Toc8135387)

[**9.** **Ethical and regulatory compliance** 3](#_Toc8135388)

[**9.1.** **Approval by regulatory authorities** 3](#_Toc8135389)

[**9.2.** **Informed consent** 3](#_Toc8135390)

[**9.3.** **Risks and benefits to participants** 3](#_Toc8135391)

[**10.** **Social value** 3](#_Toc8135392)

[**11.** **Study limitations and assumptions** 3](#_Toc8135393)

[**12.** **Conflict of interest** 3](#_Toc8135394)

[**13.** **Study timeline** 4](#_Toc8135395)

[**14.** **Study budget** 4](#_Toc8135396)

[**15.** **Dissemination of results** 4](#_Toc8135397)

[**16.** **References** 4](#_Toc8135398)

[**17.** **Appendices** 4](#_Toc8135399)

# **Definitions**

Add definitions for 3-5 key terms or concepts if necessary

# **Introduction**

Include a brief overview of your research story and purpose here. Most researchers write the introduction last i.e. once the other sections of the protocol are complete.

# **Literature review**

Provide a series of structured paragraphs that provide context for your study and develop an evidence-based story and argument for why your research is needed and important.

## **Subheading 1**

## **Subheading 2**

# **Rationale**

This can be a separate section or appear as the last paragraph of your literature review. The rationale summarises the overall story told in the literature review. It also highlights the gap that exists and motivates for why a study is needed to address this gap. Basically, this section aims to answer “so what?” and “who cares?”

# **Research question**

This is your overall aim phrased as a question so don’t forget to add a question mark!

# **Hypothesis**

Only if you are testing a hypothesis that will be answered using inferential statistical tests. If you are doing a purely descriptive study, you can state: *“No hypotheses as this is a descriptive study and no inferential statistics will be employed”.*

# **Aims and objectives**

Aim = the overall goal you want to achieve.

Objectives = a list of tasks or smaller aims that allow you to achieve your overall aim.

# **Methodology**

## **Study design**

This should provide a summary of your method i.e. this is your overall “plan of action”. State your study design, the characteristics of your sample, where the study will take place and over what time frame.

*Examples:*

*This is an observational, prospective cohort study in five European countries (Austria, Hungary, Netherlands, Poland and Scotland). Patients with type 2 diabetes mellitus will be recruited between 2020 and 2024 at the primary level of healthcare and will be followed for 5 years.*

*A retrospective cohort study will be conducted involving pregnant or postpartum women consecutively admitted to the maternity ward of the Dom Malan Hospital (São Francisco Valley, Brazil) between May and August 2011.*

## **Study setting/site**

## Where will the research take place? This section is important for readers to understand the context of your study. For example, would a study on drug abuse be the same if conducted in rural vs. urban areas.

## **Study sample**

Who will you be studying? How will you recruit and sample these people? What exclusion and inclusion criteria have you considered? What is your sample number, and have you done a power calculation?

## **Sample characteristics**

## **Inclusion criteria**

## **Exclusion criteria**

## **Recruitment strategy**

## **Data collection**

Describe your procedure for collecting data. How? By Whom? Where and under what conditions? What measures or instruments will you use to collect data? If using a survey: Is this a new survey or one that was previously used? Do you have permission to use it? Has it been validated? What questions is it made up of? How will it be scored?

## **Data management plan**

Where data will be captured and stored? Who will have access to it?

## **Storage of biological specimens**

Will any biological specimens be taken? If not, delete this section.

## **Data analysis plan**

Describe your data analysis pipeline: 1) Descriptive stats (means and frequencies), 2) Inferential statistical tests for hypothesis testing, 3) Software used, 4) Level of statistical significance.

# **Ethical and regulatory compliance**

## **Approval by regulatory authorities**

You will need to state that ethical approval will be obtained from SU HREC. Study approval will also be gained from other necessary bodies such as Institutional Research and Planning, Stellenbosch University (if staff and students or alumni are among your participants), hospital management or Department of Health (DOH) for accessing patients. Also mention that your study will be conducted in accordance with the Declaration of Helsinki and the DOH Guidelines for Good Clinical Practice.

## **Informed consent**

Describe the process you’ll follow to obtain informed consent from your participants. If minors will be recruited, please describe process of obtaining assent. If you’re doing a retrospective chart or record review, you will need to request a waiver of informed consent. You will need to write a letter to HREC requesting this (see additional resources for a template letter).

## **Risks and benefits to participants**

Describe all possible risks and benefits to participants. In a nutshell, you need to emphasise how participant data will be kept confidential (refers to access to data i.e. who will have access to the data?) and anonymous (refers to knowing to whom the data belongs i.e. you will remove all names and ID numbers from the dataset and use some other identifier such as patient folder numbers).

# **Social value**

What difference will this research make and to whom? Similar to your rationale section above – you must be able to answer “so what?” and “who cares?" about your research.

# **Study limitations and assumptions**

State any limitations, such as poor generalisability. Or any assumptions, such as “we assume all patient folders contain accurate and consistent information”.

# **Conflict of interest**

Usually none to declare. But if you’re being funded by a drug company or have any other affiliations that might be seen to bias the research, please state this.

# **Study timeline**

Example of a Gantt chart below. Update for your own purposes. Always good to factor in extra time i.e. if you think data collection will take 2 months, make it 3. Life happens!

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **List of tasks** | **Jan-Feb 2018** | **Mar-Apr 2018** | **May-Jun 2018** | **Jul-Aug 2018** | **Sep-Oct 2018** | **Nov-Dec 2018** | **Jan-Feb 2019** | **Mar-Apr 2019** | **May-Jun 2019** | **Jul-Aug 2019** | **Sep-Oct 2019** | **Nov-Dec 2019** |
| Literature review | X | X |  |  |  |  |  |  |  |  |  |  |
| Prepare protocol |  | X |  |  |  |  |  |  |  |  |  |  |
| Submit to ethics |  |  | X | X |  |  |  |  |  |  |  |  |
| Data collection |  |  |  |  | X | X | X |  |  |  |  |  |
| Data analysis |  |  |  |  |  |  |  | X | X |  |  |  |
| Drafting of dissertation |  |  |  |  |  |  |  |  | X | X | X |  |
| Submit for examination |  |  |  |  |  |  |  |  |  |  |  | X |

# **Study budget**

HREC and any other approval body will want to see that you have thought through the financial aspects of your project. If funds are required, you must state who will cover the costs.

# **Dissemination of results**

How will you share your findings and with whom? Hospital management? Departmental or conference presentations? Journal articles? The participants or community?

# **References**

Use Mendeley to assist with referencing. Manual referencing is painful – especially if you use the Vancouver (numbered) referencing style as opposed to Harvard (author-date).

# **Appendices**

Surveys, informed consent leaflet, data collection sheets, interview questions, any other permissions.