

RESEARCH PROJECT
Institution

PROTOCOL

Title of the project

Investigator(s):

SUPERVISOR (PI):
Institution:

Month - Year

Protocol Declaration

We hereby declare that this protocol is entirely the product of our own independent investigation. The various sources to which we are indebted are clearly indicated in the paper and our references.

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Principle Investigator (PI)

.....

List of Researcher (s)

.....

.....

.....

Date:

INTRODUCTION

500 words introducing the background of the topic with salient literature in the subject matter (*20 references maximum*).

RESEARCH OBJECTIVES

Clearly state the direct the aims and objectives of the study

Primary Objective *(The fundamental question that will be addressed by the study. How that question will be answered.):*

Secondary Objective *(Explore issues that arise from the primary objective. Can be used to explain reasons behind the primary outcome. Usually more than one.):*

DESIGN AND METHODS

Methods should be precise and describing the exact methodology that will be adopted in the following sub-heading:

1. DESCRIPTION OF THE STUDY (Prospective/retrospective/ cohort/ etc.)

2. SAMPLE SPECIFICATION

- **Target Population** (*This is the total group of individuals from which the sample might be drawn.*) **State:**
- **Sample Selection** (*In research terms a sample is a group of people, objects, or items that are taken from a larger population for measurement.*) / **Recruitment methodology** (*This is the process by which individuals are recruited as potential subjects in a research study.*) **State:**
- **Inclusion Criteria** (*These are the characteristics that the prospective subjects must have if they are to be included in the study*) **State:**
- **Exclusion Criteria** (*These are those characteristics that disqualify prospective subjects from inclusion in the study.*) **State:**

3. DATA COLLECTION (List all of the items below)

- *Demographic Data (where applicable)*
- *Clinical Data (where applicable)*
- *Outcome data (where applicable)*

4. STATISTICAL ISSUES

- *Justification of Sample Size*
- *Plan for Analysis*
- *Presentation of Data*

5. ETHICAL CONSIDERATIONS

- *Risks and benefits*

DATA SHEET / INSTRUMENT (*where applicable e.g. Survey's, Questionnaire's, etc.*)