

RESEARCH PROTOCOL TEMPLATE

A synopsis must have the following headings:

TITLE: Should reflect the objectives of the study. It must be written after the whole synopsis has been written so that it is a true representative of the plan (i.e. the synopsis).

INTRODUCTION: Should contain brief background of the selected topic. It must identify the importance of study, its relevance and applicability of results. It must clearly state the purpose of the study.

OBJECTIVES: An objective is an intent of what the researcher wants to do stated in clear measurable terms.”

OPERATIONAL DEFINITION: Is the definition of the exposure and outcome variables of interest in context to objective in a particular study and their means of measurement/determination.

Examples:

- Anemia
- Effectiveness
- PPH
- Wound healing

HYPOTHESIS: A hypothesis is a statement showing expected relation b/w 2 variables. A hypothesis is needed in the following study designs:

- i. All interventional studies
- ii. Cohort
- iii. Case control

MATERIAL AND METHODS:

STUDY DESIGN: Mention the name of the appropriate study design.

SETTING: Name and place where the research work is to be conducted.

DURATION OF STUDY: How long will the study take with dates.

SAMPLE SIZE: How many patients will be included. If there are groups how many per group?

SAMPLING TECHNIQUE: Type of sampling technique employed.

SAMPLE SELECTION:

Inclusion criteria: on what bases will patients be inducted in the study.

Exclusion criteria: On what bases will patients be excluded from the study.

DATA COLLECTION PROCEDURE: A detailed account of how the researcher will perform research; how she/he will measure the variable.

It includes: Identification of the study variables
Methods for collection of data
Data collection tools (proforma/questionnaire)

DATA ANALYSIS PROCEDURE: Relevant details naming software to be used, which descriptive statistics and which test of significance if and when required, specifying variables where it will be applied.

REFERENCE:

In Vancouver style.

DATA COLLECTION INSTRUMENT:

The researcher must attach, as an annex, the proforma or questionnaire with the help of which he/she intends to collect data. The proforma/questionnaire must match the objectives and must not contain irrelevant sections like inclusion and exclusion criteria etc.