

Guidelines for protocol preparation

GENERAL

Basic formatting

- Set the word processor to 1.5 space throughout the entire manuscript
- Use one inch margins on the left, right, top, and bottom of the page for reviewer's comments
- Use normal paragraphs: the first line is indented five characters
- Use a 12 point Times New Roman font
- Single space after sentence terminators (i.e., '!', '?', '!')

Writing in General

- Use complete sentences
- Do not use slang
- Do not use contractions (like “don’t”, “can’t”, “&”)
- If you are doubtful about the spelling of a word, do not guess
- Do not use too many abbreviations
- When abbreviating any terms, spell them out the first time (in both the abstract and again in the body of the manuscript, if need be)

SPECIFIC

1- Title page:

- a. Title:
 - i. 12-15 words
 - ii. No filler words (words that can be omitted)
 - iii. Could be the aim of the study
 - iv. Font: Times New Roman, 16, Bold, Centered, Line spacing 1.5, Title (sentence case)
- b. See template of cover page for fonts and paragraphs

2- Introduction: 3-4 paragraphs

- a. Definition of the problem
- b. What the literature says about it:
 - i. International
 - ii. Local
 - iii. Rationale of the study
- c. What still needs to be known
- d. What the current study attempts to add.

3- Study aim, objectives, question(s), hypothesis(es)

- a. Aim of the study: Ultimate Goal (what the study findings are expected to improve)
- b. Specific objectives: What the study will actually achieve:
 - i. Primary: what the investigator MUST achieve
 - ii. Secondary (if ANY): what the investigator could achieve with no extra resources
- c. Research question(s): To be answered by achieving the specific objectives
- d. Research hypothesis(es)
 - i. If any (remember that descriptive studies DO NOT have hypotheses)

- ii. The hypothesis is the investigator's expected answer(s) to the research question(s) in measurable and directional forms.

4- Methodology:

- a. Research design
- b. Setting description
- c. Population and sample:
 - i. Description of the target population (upon which the results will be generalized) and study population (from which the sample will be recruited)
 - ii. Description of the study sample in terms of:
 - 1. Criteria of selection (inclusion and exclusion)
 - 2. Sample size justification (equation used and the referenced input(s) in the equation)
 - 3. Sampling technique (non-probability or probability sampling, and its type)
 - iii. Matching (if any)
 - iv. Randomization process (in randomized clinical trials)
 - v. Sampling limitations (errors/bias)
- d. Study variables:
 - i. Definition of the different variables:
 - 1. Main study variables:
 - a. Independent: exposure/risk factors
 - b. Dependent: outcomes
 - 2. Background variables (as socio-demographic data)
 - 3. Confounding variables (factors that may distort the relation between exposure and outcome variables) IF ANY
- e. Data collection tool(s):
 - i. Description of the tools in terms of:
 - 1. Source and scientific basis (references)
 - 2. Validity data (references)

3. Reliability data (references)

- ii. Potential errors (systematic/random errors) related to data collection and precautionary measures (e.g. standardization, calibration, blind assessment, etc.).

f. Data management:

- i. Computer program to be used
- ii. Significance tests related to:
 - 1. Study objectives/hypotheses
 - 2. Study variables

g. Procedures:

- i. Administrative procedures
- ii. Steps of implementation of the study
- iii. Possible feasibility problems

5- Timetable:

Use GANTT chart to define:

- i. The time of start and end of each activity
- ii. The person in charge

6- Budget:

- i. Itemized budget to include:
 - 1. All items (available and needed):
 - a. Equipment
 - b. Supplies
 - c. Manpower
 - 2. Amount of each with justification
 - 3. Price per unit
- ii. Identify the needed items and their costs separately
- iii. Include the budget even if the proposal is self-funded

7- Ethical considerations

- a. The proposal should include details of measures taken to guarantee full compliance with the principles of research ethics.
- b. Issues to be clarified:
 - i. Disclaimer and conflict of interest
 - ii. Human rights:
 1. Informed consent
 2. Confidentiality
 3. Privacy
 4. No actual or potential harm
 5. Rights to refuse participation without giving reason and with no consequences
 6. Rights to withdraw at any time without giving reason and with no consequences
 7. Professional help
 - iii. Beneficence of the study.

8- References

- a. Citations in the Text (Harvard system)
 - Forms: examples:
 - Diabetes is a chronic disease (last name, year).
 - Last name (year) mentioned that Diabetes is a chronic disease.
 - In <year>, <last name> reported that Diabetes is a chronic disease.
 - In case of 2 authors: (2 last names, year)
 - In case of >2 authors: (last name of first author et al, year)
 - Multiple citations in parentheses are placed alphabetically and are separated by a semicolon and a space.
 - Secondary references:

- Fact (John, as cited in Taylor, Year)). Note that in this example, only the Jones reference would be placed in the reference section.
 - Citing a direct quotes: Last name (year) said that "Diabetes is a chronic disease" (p. 129).
- b. List of references:
- This part helps the reader to find the references used.
 - Any citations in the protocol must be presented in this list.
 - The list should not contain references not used in the text.
 - Try to use the most up-to-date references.
 - Use the referencing system of the International committee of medical journal editors (ICMJE) uniform requirements for manuscripts submitted to biomedical journals: sample references (http://www.nlm.nih.gov/bsd/uniform_requirements.html).

9- Arabic summary

- a. Brief translation of the introduction
- b. Full translation of the aim, objectives, research question(s), and hypothesis(es)
- c. Brief but clear description of the methodology

Title in Title Capitalized Form, Times New Roman Font 15, Bold

Protocol of a Thesis submitted for partial fulfillment of the requirements of the
Master/Doctorate Degree in <Specialty>

By

Aaa Bbb Ccc

M.B.B.Ch. / M.Sc. (University, year)
Job position

Supervisors

Dr. Xxx Yyy Zzz

Professor in <specialty>
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