

GUIDELINES FOR PROTOCOL WRITING

1. Format
 - a. Font type – Times New Roman
 - b. Size – 12 for text, 14 for first page
 - c. Line spacing 1.5
 - d. Justify
 - e. Same throughout protocol document
 - f. Avoid unnecessary use of capital letters
2. Total number of pages
 - a. 1 Title page
 - b. 1 page with signature and stamp
 - c. 1 page IEC certificate
 - d. 1 page introduction & lacunae
 - e. 3 pages ROL
 - f. 1 page aims & objectives
 - g. 3-4 pages materials & methods
 - h. 2 pages references
 - i. Annexures – PIS, CF, Proforma
3. Title page
 - a. Title must be on Page 1 – Ensure that title is same everywhere
 - b. Title should not start with ‘To determine---’, should not include measures like prevalence etc.
 - c. Avoid abbreviations in title
 - d. With signature (including student’s sign)
 - i. At least one co-supervisor from same department
 - ii. Maximum 3 co-supervisors, including from same department
 - iii. Co-supervisor from same department should be placed first, followed by other departments
 - iv. Signature of Student, Supervisor, and all Co-Supervisors (no stamp)
4. Certificate page
 - a. With signature and stamp
 - b. Ensure that title is same as that of title page
5. IEC certificate
 - a. On letterhead of institution with logo
 - b. Ensure that title is same as that of title page
 - c. Name of student, supervisor, Member Secretary IEC
6. Introduction & Lacunae
 - a. To be on the same page
 - b. 1 page only
 - c. References to be given in introduction sequentially numbered

7. Review of literature

- a. Maximum 3 pages
- b. All references need to be arranged sequentially, in continuation with references in introduction, written in chronological order

8. Aims & objectives

- a. 1 page
- b. Research question if given
- c. Write full form of abbreviations here also
- d. Should not include measures like prevalence etc.

9. Materials & Methods

- a. Maximum 4 pages unless essential for the topic
- b. Study design
- c. Place of study
- d. Study period – write One Year
- e. Study population
- f. Inclusion & exclusion criteria
- g. Operational definitions, if any
- h. Study outcome – in measurable terms like incidence, prevalence, proportion, mean, correlation, sensitivity etc.
- i. Sample size – reference number of article used for calculation, give formula, explain and give value of each component, show calculation, write calculated sample size and sample size to be taken
- j. Sampling technique – how the subjects will be selected
- k. Study tools
- l. Methodology
- m. Statistical analysis – SPSS 25 as this is licensed version available with college
- n. Ethical considerations
- o. In case of RCT – CONSORT diagram to be included

10. References

- a. Citation in text should be as superscript without brackets, placed after punctuation mark
- b. All Reference pages must be checked and signed by the Supervisor, with date and stamp
- c. Maximum number 20-25, in 2-3 pages
- d. Vancouver style
- e. For journals –
 - i. Author surname followed by name initials; all authors separated by comma
 - ii. No dot or comma between surname & initials
 - iii. Names of first 6 authors to be written – after that write et al
 - iv. Journal name should be abbreviated
 - v. Article title, journal name year (semicolon); volume issue in bracket (colon);pages.

- vi. Month not required
- vii. Page numbers not to be repeated. For pages 100-105 write 100-5
- f. For e-journals give doi
- g. For online material write [Internet] and [cited year month date] available from – give website
- h. Ref for books and online material to be correctly written etc.

11. PIS

- a. In MAMC format
- b. Study procedures need to be explained in detail in both Hindi & English
- c. Use simple language that subjects understand
- d. Number of contacts and duration of each contact to be mentioned
- e. In case the study involves biological tissue – details of collection (frequency of collection, amount etc.) needs to be mentioned.
- f. Details of PG Student, Supervisor and IEC Member Secretary need to be correct, with phone numbers
- g. IEC Member Secretary – Room No. 306A, Landline number of IEC Cell 011 – 23239271

12. Consent

- a. In MAMC format
- b. For adult subjects – Consent form
- c. For 7-12 years – Parental consent form, Assent form
- d. For 13-17 years – Assent form
- e. Consent for biological tissue must be taken properly
- f. Consent for genetic study must be taken properly
- g. Animal Studies require clearance from Animal ethics committee.

13. Annexures

- a. Data collection form
- b. Any other

14. Submission

- a. 6 copies of corrected protocols signed by all supervisors, co-supervisors
- b. 1 copy of fully filled reply template, signed by Supervisor with date and stamp
- c. All 6 protocols and 1 copy of reply template must be kept in one plastic folder, with name of the PG in front – else it won't be accepted. Same will be returned to the PG once signed, within 2 days of submission.
- d. Submit the folder with above contents, in Department of Community Medicine, MAMC (**Room number – 347**)
- e. During submission the student, or any other person submitting on student's behalf, should write name, phone number, sign and give date in the form provided at office

GUIDELIENS FOR POWERPOINT PRESENTATION OF PROTOCOLS

- Dark font in white background – no design
- Font size – minimum 32
- Maximum 10-15 slides
- First slide – title, name of student, supervisor & co-supervisors
- Introduction & lacunae – not more than 1 slide
- Aims & objectives – 1 slide
- Materials & methods should be explained in detail
 - Study design, place, period
 - Study population, inclusion & exclusion criteria
 - Outcomes, sample size estimation and sampling technique
 - Method of data collection
 - Method of statistical analysis
 - Ethical considerations

Protocol Committee