Protocol writing and Presentation

Prof Sabina Khan

MEU Co-coordinator

Secretary, Thesis protocol approval committee

HIMSR

Protocol writing

What is Research/thesis protocol?

- It is the 'operating manual' to refer to while conducting a particular study.

- It is a study plan, designed to describe the background, research question, aim and objectives, and detailed methodology of the study.

Relevance of protocol

- Considered as a **first step** towards writing Thesis
- To be considered valid official document ,needs to be presented in thesis committee for a critical appraisal
- The protocol needs to be corrected according to the suggestions given by the committee .
- Finally, it needs to be approved by the IEC.
- The thesis protocol is then considered an official document and the **thesis work needs to conform to the same.**

Thesis protocol format

- Title Page page1
- Certificate from lnstitution page 2
- lntroduction/ background page3
- Brief review of literature page 4-6
- Objectives of research project page 7
- Patients/ Subjects/Material and Methods page 8-10
- lndex of references (Vancouver system) page 11-12
- Appendix, if any (consent form, data sheet etc)

- Pg 22 Revised PG byelaws HIMSR website

Components of Thesis protocol

- Title
- Introduction
- Brief Review of literature
- Aims and Objectives
- Material and Methods (plan of statistical analysis)
- References
- Appendix (Consent form, Pt information sheet, proforma)

Title

- Should be brief and concise
- Yet informative, succinct, relevant.
- Should summarize/convey proposed study holistically
- Abbreviations(acronyms) should be avoided
- It should be preferably one sentence/phrase
- PICO elements should be there

Introduction/background

- Describe the problem statement (disease or condition) briefly.
- Discuss what is known & what are the gaps in knowledge
- Summarise briefly the review of literature
- Focus on research question and its importance
- Write how would answering the research question amend the current knowledge
- Should also justify need for the study (no studies to date have reported outcomes, we examined or evaluation of the results of program was necessary to develop future programs).

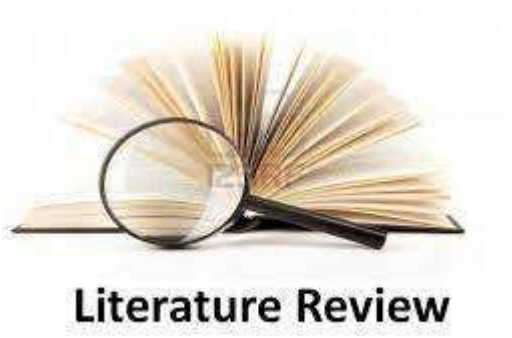
- *Logical flow of statements:*

- Magnitude, frequency, and distribution
- Probable causes of the problem
- Possible solutions
- Unanswered questions

Introduction- important questions

- What am I studying?
- Why is it an important question?
- What do I already know about it before undertaking this study?
- How will this study help us advance the knowledge?

Review of Literature



- Critical analysis of previous knowledge about the present study to be carried out (disease or condition)- What is already known
- Should include a description of the most relevant and recent research/studies published on the topic
- Information to be written in form of summary
- Discuss the related relevant pathology or pathophysiology
- Identify relevant gaps in knowledge
- Lastly write “basis/rationale for the study” in the concluding section of review of literature.

Why literature review

- To improve our understanding about the topic
- Update about current status of research
- Identify gaps in knowledge

Literature review must cover

- Author name
- Year of publication
- Objective of study (time period, region)
- Methodology
- Statistical tools
- Result

Aims and objectives

- Aim- refer to what is to be achieved by present study or how the present study would address bigger question or issue.
- Objectives- refer to what would you actually do in the present study.
- Primary objective refers to the main research question (the primary outcome) and is the basis for sample size.
- Secondary objective refers to the additional questions that are typically for ‘generation of the hypotheses’.

Objectives

- Not too many ; 2-4 best
- Feasible
- Be *specific*, no general and ambiguous statements
- Be *realistic*, no unachievable objectives

Material and Methods

- Study setting
- Study duration
- Study design
- Study population
- Inclusion/exclusion criteria
- Sample size
- Sample selection (Randomization if applicable)
- Intervention if any
- Data collection
- Outcome measures
- Statistical methods (name of statistical program)

Material and Methods

- Study setting- Place from where the subjects would be recruited
- Study design (Type of study) - Prospective/Retrospective

  Descriptive / analytical;

  if analytical,- (cohort, case- control or cross-sectional)

interventional (RCT, cross-over)

- Study population- define the target population
- Sample size: basis of the number of cases
- Sampling technique
- The inclusion criteria-Define age groups, the criteria for defining the disease condition or normalcy
- The exclusion criteria-Subjects who other-wise were eligible for inclusion but are excluded
- If RCT then method of Randomization- How the Randomization is done? How the blinding is performed?

Study design

Interventional study

Clinical trial

Observational study

Cohort study

Cross-sectional study

Case – control study

Ecological study

Subjects/ participants

Depending on the type of study, answer the following questions:

- What are the criteria for inclusion or selection?
- What are the criteria for exclusion?
- In intervention studies, how will subjects be allocated to index and comparison groups (Randomization procedure)?
- What are the criteria for discontinuation?

Sample size

- Sample size calculation is recommeded for economical and ethical reasons
- Level of error, power and expected impact of exposure on outcome have to be set

Data collection tools

- Questionnaire (attach to the protocol)
- Type of interview (describe structure of the interview)
- Laboratory test (refer to literature or personal knowledge, if established test, or describe in detail, if not established)
- Clinical examinations (describe gadget/procedure)

- Details if using the new method or quote the standard reference if anyone else has described the method already that you are going to use in your study.
- Be certain to describe any alterations made of the standard or the published method.
- Quantitative aspects: masses, incubation times, volumes, concentrations, the machine specifications (include the manufacturer's name & address)
- Duration and frequency of intervention

- Procedures and the schedules of examination or investigations or treatment, and the observation of the outcome measures
- Dosage, schedules, formulations, duration of the drug treatments, if any
- Outcome measures (like the union of fracture, birth weight, hemoglobin, etc.)
- Follow up of the study participant, if applicable.

Statistical analysis

- One should mention the procedure for data entry, statistical methods or software for the statistical analysis,version, methods for handing the missing data etc.

- Level of significance or the level of confidence should also be defined

Ethical considerations

One of the most important aspects of biomedical research!

Important aspects to consider:

- Data safety / confidentiality
- Any possibly harm/ side effects/ consequences
- Right of discontinuation at any time
- Role of data safety and monitoring board (in trials)
- Financial buden to patients

References

- End part but most critical
- Vancouver style of referencing (ICMJE style)
- Include the reference that the candidate has accessed and read.
- Number of references should be limited to 15-20 preferably.
- Relevant References should be cited in the text of the protocol (in superscripts)

- **Citation:** acknowledging within the text the documents from which one has obtained information
- **Reference:** detailed description of the document from which one has obtained information
- **Bibliography:** list of publications one has consulted

Why cite reference

What to reference

How to reference

WHY CITE REFERENCE

- Due credit should be given to original researcher
- Helps in identifying the source
- Also helps in avoiding plagiarism

WHAT TO REFERENCE

- Facts taken from the other studies should be referenced
- If direct quotation is used, than it should be put in quotation marks and referenced
- Authentic articles: Standard text book articles/journal articles
- Newspaper articles, nonpeer reviewed articles should not be used

Journal Reference

- Two main Components of a Journal Reference
- **Bibliographic Elements and Punctuations Marks**

Bibliographic Elements

- Authors (use et al. after 3/6 authors, if there are more than six authors, complete names should not be written. “et al” must be in italics)
- Article title (should be exact as existing)
- Journal name (should be in standard PubMed abbreviations, full journal name should not be written)
- Year
- Volume
- Page numbers (165-169 to be written as 165-69)
- Panhotra S,**Khan S**,Jetley S . Importance of Eosinophilic structures and its correlation with acid fast bacilli in fine needle aspiration smears of tubercular lymphadenitis. **Indian J Tubercul** 2021;68:445-49.

Bibliographic Elements

Authors in correct sequence, and names checked from PubMed

Correct title of the article to come after the authors name.

•**Sabina Khan**, Inara Abeer, Musharraf Husain, Mohd Jaseem Hassan, Sujata Jetley. Xanthogranulomatous Cholecystitis mimicking advanced gallbladder carcinoma- Analysis of 8 cases. **J Cancer Res Ther** 2021;17:969-74.

Correct journal abbreviation as given in Pubmed

Year of the article given after the journal abbreviation

Year of publication is followed by the volume no.

Page no comes last this **should not** be written as 969-974

SOFTWARES FOR REFERENCING

- Endnote reference manager
- Bibbase
- Bibdesk
- CiteUlike
- Docear
- Refme
- Zotero

Annexures

- Case Record Forms (CRFs)
- Questionnaires
- Patient information form (in required languages)
- Consent form (in required languages)
- CV of investigators

Annexures

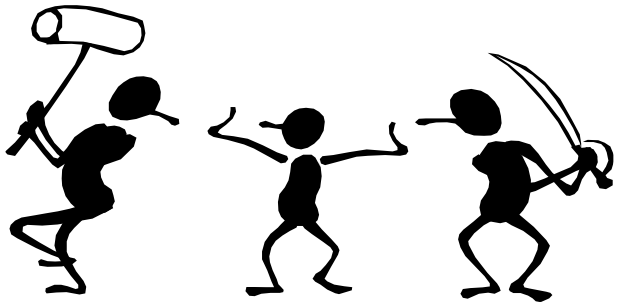
- Study proforma/Questionnaires/measurement tools etc.
- Patient information sheet & consent form: Both in local and English languages

Common mistakes

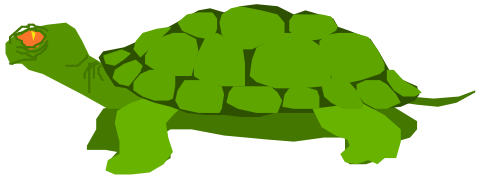
- including too little detail about proposed studies
- insufficient justification for the significance of the problem
- proposing far more work than can be reasonably done during the period
- Using abbreviations in title
- Too many objectives
- Sample size too less or too many
- Using very few references

Protocol Writing Stages

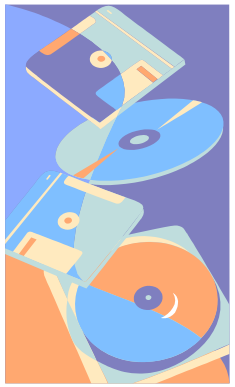
1. Getting in the Mood



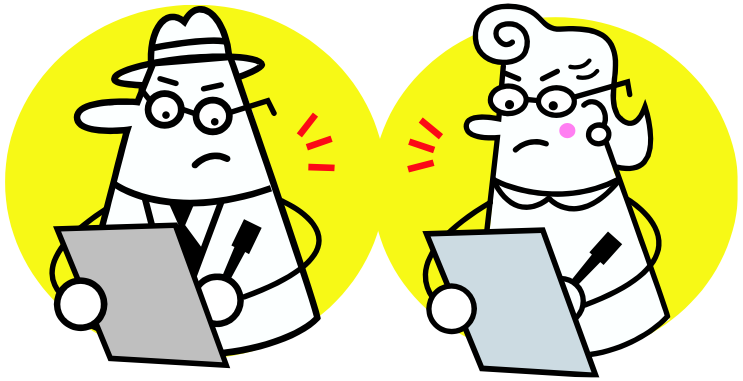
2. Writing the First Draft



Save **multiple** copies of your draft



3. Revising, Revising, Revising



4. Finishing

Thesis protocol presentation

- The thesis protocol should be restricted to about 12-15 pages .
- The suggested format should include:
- (a) Title and details 1 page
- (b) Introduction and Background 1-2 pages
- (c) Review of literature and lacunae 2-3 pages
- (d) Aims and Objectives 1 page
  (e) Material and Methods 2-3 pages
- (f) References 2-3 pages
- (g) Data Collection Forms, PIS, ICF 4-6 pages

Tips

- The Protocol should be typed in 1.5 space
- Use Times New Roman size 12 font
- 1” margins should be left on all four sides.
- Major sections viz., Introduction, Review of Literature, Aim & Objectives, Material and Methods and References should start from a new page.
- Study proforma (Case record form), informed consent form, and patient information sheet may be printed in single space.

Title page

- Name of the institute/University
- Degree (with discipline) for which thesis is being submitted
- Year of batch
- Title
- Name and Signature of Candidate
- Name and Signature(s) of Supervisor and Co-supervisor(s)

CERTIFICATE

I certify that facilities for working on the thesis entitled “xxxxxx” do exist in the department/ hospital/ laboratory and these shall be provided to candidate for his/her research work in pursuance of his/her plan of thesis. I/We shall guide the candidate in his/her work and shall ensure that the data being included in the thesis are genuine and that the work is being done by the candidate himself/ herself.

(Signature of Supervisor)

Name and Designation

(Signature of Co-supervisor)

Name and Designation

PROTOCOL PRESENTATION

- Max 5 mts duration
- Follow power point presentation rules (6X6)
- First slide – Title should be legible

  Names of student

  Names of supervisors/co supervisors
- Next slide- Introduction
- Next slide- Brief ROL
- Next slide – Aims and objectives
- Next slide- Methodology (maybe 2-3 slides)
- References
- Annexures- proforma, consent form,PIS (bilingual)

- Once thesis protocol is ready , 3 hard copies of protocol to be submitted in PG Academics section (spiral bound)

- Protocol ppt to be mailed at pgacademics@himsr.co.in


Thank You!