IADVL ACADEMY

PG THESIS

PROTOCOL

SIG CLINICAL DERMATOLOGY RESEARCH

IADVL ACADEMY

Name _____

Year of Admission _____

Reg. No. (Univ) _____

Suggested Template for Postgraduate Thesis Protocol

[SIG Clinical Dermatology Research (IADVL Academy)]

2020-2021

Cover page

PG Thesis Protocol

[Follow the format as suggested by the University or Institution. It may include the following information]

APPLICATION FOR THE APPROVAL OF THE SUBJECT OF THESIS FOR M.D. (Dermatology, Venereology, Leprology) EXAMINATION

1. Name of the student
2. Registration Number
3. Name of the Department
4. Name of the Institution
5. The proposed topic of thesis
6. Date from which registered
7. Degree for which plan of: M.D (Subject Name) thesis is submitted
8. Year and month of passing: MBBS examination
9. Name of the university from: which passed

PART 1: TEMPLATE OF PLAN OF THESIS

Table of contents

ABBREVIATIONS

INTRODUCTION (2-3 pages max)

- Give general introduction into the subject
- Describe the background of the study
  (Maximum 2 paragraphs)
- Include lacunae in the existing knowledge
- Briefly mention what do you plan to do to address the lacunae

REVIEW OF LITERATURE

- Give a focused topic-specific review of the existing literature (1-5 pages)
- Avoid a detailed literature review at this stage
- Summarize the current knowledge, using existing literature
- This should help to contextualize the proposed research question and explain and highlight the gaps in the existing knowledge
- Justification for the study (how your study expects to contribute in addressing the existing gaps) and selection of control/ comparator

AIMS AND OBJECTIVES

Research question

Preferably in PICO (T) – [Population, Intervention, Comparator, Outcome, (Time)] format – if applicable to the study design.

AIM

The intention or aspiration of the research study: It summarises in a single sentence what you hope to achieve at the end of a research project.

OBJECTIVES

Primary objective: It is the main question to be answered in research and the statistical planning (E.g., sample size) is based on this.

Secondary objectives: It addresses the potential additional effects of the research. Statistical planning is ideally not based on these.

STUDY DESIGN, MATERIALS AND METHODS

Study period: Expected duration of the entire study process from conceptualizing the project to completion (Use Gantt chart)

Study design

Sample size

Inclusion criteria

Exclusion criteria

Control's inclusion criteria

Control's exclusion criteria

Intervention if any

Data collection (including methods, tools etc. to be used to facilitate data collection)

Clinical data collection

Laboratory data collection

Study Flowchart: This can show how the study subjects will be recruited, allocated (for intervention), analyzed etc.

How blinding would be done if required?

Under what conditions unblinding shall be done?

Rescue medications if required in cases of intervention?

PLAN FOR STATISTICAL ANALYSIS:

- Procedure for data entry, statistical methods/software for statistical analysis, methods for handling missing data
- Mention the plan for analysis and statistical tools proposed
- If appropriate, dummy tables can be included

ETHICAL JUSTIFICATION (sample)

[Please read through the following paragraph and include the parts relevant to your study]

1. Please include the specific ethical challenges expected during your study and measures to address those issues here

2. According to the guidelines set up by ICMR (2017) and Helsinki declaration (modified 2000), the following will be adhered in all subjects enrolled in the study:

- The individuals involved in the research project will be informed participants
- Each participant will be adequately informed of the aims, methods, the anticipated benefits and potential risks of the study and the discomfort it may entail to him/her and the remedies thereof
- Every precaution will be taken to respect the privacy of the participant the confidentiality of the participant's information and to minimize the impact of the study on his/her physical and mental integrity and his/her personality
- The participant will be given the right to abstain from taking part in the study or to withdraw consent to participate at any time of the study without reprisal
- Due care and caution will be taken at all stages of the research to ensure that the patient is put to the minimum risk, suffer from no irreversible adverse effects and, generally, benefit from and by the research or experiment
- The research will be conducted in a fair, honest, impartial and transparent manner after full disclosure is made by those associated with the research of each aspect of their interest in the research, and any conflict of interest that may exist; and whereby, subject to the principles of privacy and confidentiality and the rights of the researcher. Full and complete records of the research inclusive of data and notes are retained for such reasonable period as may be prescribed or considered necessary for the purposes of post-research monitoring, evaluation of the research, conducting further

research (whether by the initial researcher or otherwise) and in order to make such records available for scrutiny by the appropriate legal and administrative authority, if necessary

- The research will be always conducted by competent and qualified persons who act with total integrity and impartiality and who have been made aware of, and are mindful of the ethical considerations to be borne in mind in respect of such research
- All the procedures required to be complied with and all institutional arrangements required to be made in respect of the research and its subsequent use or application are duly made in a bonafide and transparent manner; and all appropriate steps will be taken to ensure that research reports, materials and data connected with the research are duly preserved and archived
- Iinformed consent will be obtained from all the patients included in the study as accepted by the Institutional ethics committee

REFERENCES

- In standard Vancouver format (or other standard formats as per the university/institute guidelines)
- Include references to substantiate the background, relevance research question and methodology
- Avoid too exhaustive and superfluous references
- References published during last 5 years are preferred
- Make sure the references are cited appropriately
- Make sure the original references are used and that you have access to the full text for the same

ANNEXURE I

UNDERTAKING BY THEGUIDE/CO-GUIDE INVESTIGATORS

[Adapt this as per the guidelines from University/ Institute]

01. Title of the protocol:

02. We the undersigned Guide/ Co Guide/ co-investigators of the research proposal hereby state that

we are competent to be guide/ co-guide as per the existing regulations

we are ready to Guide the proposed study by Dr…….. as part of his thesis titled ……..

Guide/ Co Guides/Investigators name Signature with the date(Include the name of the department of Co Guide)

1.
2.

ANNEXURE II

PATIENT INFORMATION SHEET (PIS)

The protocol must be accompanied by the patient information sheet addressed to the patient in vernacular.

The PIS should include the following information in **simple language (no scientific terms), which the study subject can understand**.

It should include

i. Aims and methods of the research
ii. Expected duration of the subject participation
iii. The benefits to be expected from the research to the subject or to others
iv. Any possible risk to the subject associated with study
v. Maintenance of confidentiality
vi. Provision of free treatment for research-related injury (if applicable)
vii. Provision for compensation of subjects for disability or death resulting from such injury (If applicable)
viii. Freedom of individual to participate and to withdraw from research at any time without penalty or loss of benefits to which the subject would otherwise be entitled
ix. Amount of blood sample to be taken should be mentioned in PIS in ml if relevant for the study
x. Address and phone number of the student

ANNEXURE III

INFORMED CONSENT FORM

[Modify this format as required by the specific research question and methodology, Clinical Trials may need more detailed consent procedures. Follow Guidelines by New clinical trial rules 2019 and ICMR Guidelines]

Subject's name…… Age…… Sex……

I confirm that I have read and understood/have been explained information given by the researcher/moderator of the study…… conducted by Dr……..and I had an opportunity to clarify my doubts. I understand this study will not incur any expenditure for me. I understand that participation in the study is voluntary and I am free to withdraw at any time without giving any reason and without my medical care and legal rights being affected. I understand that my identity will not be revealed to any third party or in publication. I understand that the researchers/ regulatory authorities/ ethics committee will not need my permission to access my health records if necessary for the current study. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for the scientific purpose(s).

I agree to take part in the above study.

Signature of the subject……. Date……..

Name of the Investigator (printed)……. Date……

Signature of the investigator…….. Date……

Signature of the witness……. Date……

ANNEXURE IV

ASSENT FORM

I_____, my consent for participation in the study titled: "……". I have been informed, to my satisfaction, by the attending doctor , that this study is done to……. The nature of the procedure to be done (Give details of the procedure in simple language). I am aware that my parents/guardians do not have to bear the expenses of the treatment if I suffer from any injury caused as part of the study. I am also aware of the right to opt-out of the study, at any time during the course of the trial, without having to give reasons for doing so.

Name and Signature of the study participant ……Date:.....

Name and Signature of the parent/guardian …….Date:…….

Name and Signature of the Investogator ……Date…….

Note: Please use patient Information form, consent form and assent form in vernacular / in a language the study participant understands

ANNEXURE V

Tools (Including the Disease Severity Scores)

ANNEXURE VI

CASE RECORD FORM/PROFORMA

Thesis Protocol Checklist

	ITEM	COMMENTS	Check (✓) if the protocol is as per checklist	Notes
1	Title	Descriptive, consisting of study design, population, intervention, comparator and study setting etc. (PICOT)		
2	Trial registration (in case of trials)	Trial identifier and name of the registry to be mentioned (after ethics committee approval)		
	Introduction			
3	Background and rationale/ introduction	1-2 paragraphs on background One para introducing the research topic		
4	Literature review	1-5 pages Include relevant literature of recent years Identify the knowledge gap		
	Aims and Objectives			
5	Objectives	Primary objective Secondary objectives, if any		

6	Study design	Type of the study/trial and full description of it to be given – Descriptive (observational/analytical) or intervention (clinical trial – randomized/non-randomized) etc.		
7	Study setting	Site where the study will be conducted		
8	Eligibility criteria	Inclusion and exclusion criteria for the participants Make sure inclusion criteria is not repeated in exclusion criteria		
9	Interventions	Detail description of the kind of intervention planned, how to monitor the intervention, etc. (Someone who read it should be able to repeat the procedure using this) Can give citation for methodology used by previous investigators		
10	Outcomes	Primary and secondary outcomes mentioned		
11	Participant timeline	Time schedule for participants like enrollment, visits, follow up etc.		

12	Sample size	Give sample size calculation with explanation Number of participants needed to satisfy primary objective of the study to be justified		
13	Recruitment	The process to enroll adequate number of participants explained		
14	Allocation: Sequence generation, allocation concealment mechanism, implementation	Mentions details how sequence will be generated etc.		
15	Blinding	Type of blinding being done in the trial		
16	Data collection methods	Elaborates the ways in which data will be collected whilst maintaining the data quality Include tools used, scales used etc.		
17	Proposed statistical methods	Methods to analyze primary and secondary outcomes explained		
18	Consent	Describes how and who will obtain the consent/assent and who will give the same		

19	Confidentiality	Procedures to be adopted to maintain confidentiality of participants' data before, during and after the study/ trial to be elaborated		
20	Ethics	IRB Clearance obtained		
21	Biological specimens	Mentions the type of specimen and ways to collect, store, transport process and analyze it		
22	Periodic thesis reviews (This is not part of protocol but better to have a plan for this)	Procedure and frequency of audits (6-monthly departmental reviews)		
23	Bibliography	As per guidelines of the Institute/University e.g., Vancouver style etc.		
Appendices				
24	Patient Information sheet	Explains the details of study, his/ her right and obligations in a language study subject can understand		
24	Informed consent materials	Consent forms along with the participant information sheets and other documents provided to the participants in English/vernacular language		

25	Permission letters	Attached the various permission letters needed - Permission to use tools such as disease severity scales, quality of life scales, etc.		
26	IRB	Institutional Ethics committee approval letter appended		
27	Proforma and tools	Appended		
28	Roles and responsibilities of team members defined?	Make sure the roles and responsibilities of guides/ co-guides/ co investigators involved in the study are defined		
27	Plagiarism check and percentage similarity	It is a good practice to make sure there is no plagiarism crept especially in literature review and methodology		

Resources

1. Chan AW, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med*. 2013;158(3):200-207. doi:10.7326/0003-4819-158-3-201302050-00583
2. Schulz, K.F., Altman, D.G., Moher, D. *et al.* CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. *BMC Med* **8,** 18 (2010).
3. Cuschieri S. The STROBE guidelines. Saudi J Anaesth. 2019 Apr;13(Suppl 1):S31-S34. doi: 10.4103/sja.SJA_543_18.
4. Format for pg thesis protocol; Government Medical College & Hospital, Sector 32, Chandigarh, India [Internet]. [cited 2021 Aug 23]. Available from: http://gmch.gov.in/format-for-pg-thesis-protocol
5. For submission of protocol involving research format in human subjects for clearance by ethics sub-committee and committee of AIIMS for DM. https://www.aiims.edu/aiims/academic/Format-Thesis-Dissertation.pdf Accessed: 2021-08-23
6. Thesis protocol formats of Kerala University of health sciences (http://14.139.185.154/kuhs_new/images/uploads/pdf/research/PG-Thesis/synopsis-guidelines-1.pdf)

Disclaimer: This is a proposed template and checklist to help postgraduates in preparing their thesis proposal. The format required may vary between Institutes/ Universities. This proposed template only will help the student/ researcher to prepare the proposal. They are advised to follow the format prescribed by their Institute/ University.