GANDHARA UNIVERSITY

ADVANCE STUDIES & RESEARCH BOARD
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RESEARCH/ SYNOPSIS PROTOCOL

GUIDELINES FOR SUPERVISOR: Respected supervisor, make sure the following requirements are met before sending the synopsis of your post graduate trainee for approval.

All the components of the synopsis have been checked thoroughly.

1. Supervisor's approval certificate has been signed.
2. You have put your signature on each page of the synopsis.
3. The post graduate residents will be required to justify/defend the synopsis IN THE PRESENCE OF HIS/HER SUPERVISOR IN THE ASRB MEETING.

GUIDELINES FOR POSTGRADUATE TRAINEE

- You must get synopsis approval certificate from your supervisor.
- Each page of your synopsis must have the signature of your supervisor.
- The following format for research proposal/synopsis must be followed and any deviation from the prescribed format will be deemed unacceptable.
- On the day of meeting at ASRB, you must have the photocopy of ALL the articles/publications mentioned as reference in the synopsis.
- Your synopsis should contain 5-6 A-4 size pages or maximum 2000 words (excluding appendices). It should be written on one side of paper (the other side of paper blank) according to the following instructions:

FORMATTING

Line Spacing 1.5

Left Margin 1.5 inch (Binding side)

Right Margin 1.0 inch

Top 1.0 inch Bottom

1.0 inch

FONTS:

General body text: 12 size, in Times New Roman

Headings: **bold**, CAPITAL, Times New Roman

Subheading: **bold**, not CAPITAL, Times New Roman

Title: 14 size, Times New Roman, CAPITAL, **bold**

STRUCTURE OF A RESEARCH/SYNOPSIS PROTOCOL

Research proposal is a brief outline/summary of research. It is a plan of research project. It must have the following structure.

1. Title
2. Introduction

- Background (general context)
- What we know about the niche (specific area) • What we don't know about the niche (specific area) • Why this study?
  - Problem analysis
  - Problem statement

- Rationale

3. Objectives
4. Operational definition/s
5. Hypotheses

- H_0 (Null hypothesis)
- H_a (Alternate hypothesis)

6. Methods

- Study design
- Study duration
- Study area/setting

- Subjects
  -sample size
  -sampling technique
  -sample selection (inclusion/exclusion criteria)
- Data collection
- Data analysis

7. Ethical considerations
8. References
9. Appendices

Separate documents must be attached to synopsis giving the details regarding the following areas, if needed.

- Implementation time plan/Gant chart,
- Budget
- Data collection instrument
- Material list with trade names
- Consent form
- Plagiarism certificate
- Ethical Certificate

TITLE: Should be brief and self explanatory. It should mention population, outcome, time and design of your study. It should reflect the objectives of the study. It should be written once you have completed designing your research protocol. It should be brief and informative and ethically acceptable so as to be a true representative of the study plan. Use key words and active verbs to formulate your title. Avoid abbreviations and passive verbs in the title. It must be written in capital letters and font size should be kept 14 aligned in the page center. Determine what factors make your study unique and stress that in the title.

INTRODUCTION: Make an introduction to your research work the final section to work on. The purpose of the introduction is to give the reader the essential information to understand why you did/want to do the study and to state the research question. It establishes the context of the work being presented by summarizing the relevant and most important literature to date (with references) and the current view on problem you want to investigate. The introduction is broadly presented as a general background, what is known, what is unknown, and why you did/ want to do this study.

The structure of an introduction is visualized as a funnel. The broadest part at the top (start) represents the general context of the topic. It then narrows down to the more specific information and problem of interest. The problem is analyzed in detail and problem statement given in precise and clear words. Problem statement condenses and combines the knowledge gap indentified in the state of the art literature and problem analysis. An introduction ends with specific rationale of the study, and vitally, the aim, purpose, or research question.

OBJECTIVES: They inform the reader clearly what the researcher plans to do in his/her work. They must identify the variables involved in research. Objective should start with an action verb and be sufficiently specific, measurable, achievable, relevant and time bound (SMART). Specific objectives are statements of the research question(s). Objectives should be simple (not complex), specific (not vague), and stated in advance (not after the research is done). After statement of the primary objective, secondary objectives may be mentioned. Objectives of descriptive studies often 'describe' ,
'determine' or 'understand' the pattern of a phenomenon, while analytical studies objectives aim to 'compare', 'evaluate' or 'analyze' the relationship between dependent and independent variables that the investigator seeks to know.

OPERATIONAL DEFINITION: Should be present in every research proposal. It guides the reader or the assessor about how the research measures individual variables, where they are measured, how they are measured. Essentially an operational definition completes once a tool of detection with possible time frame is added to conventional definition. It must be noted here that vague terminologies may be avoided in operational definitions and only confirmatory tests/tools may be sufficient in operational definitions.
Unit of measurement (i.e; millimeter, decileter, grams, seconds, millimloe,etc) and tool of measurement must be explicitly mentioned in operational definition. It should be noted that these are not descriptive definitions of different variables given in text books, rather it is a value of a variable in measurable terms e.g. Operational definition of anemia means amount of hemoglobin less than 12gm/dl as compared to low oxygen carrying capacity of hemoglobin.

HYPOTHESIS: A hypothesis is a statement showing expected relation between two variables. It is a prediction of the relationship you expect to find between variables in the data set you collect. Hypothesis may be one tail or two tails. One tail hypothesis arises from the literature or clinical experience. You need to specify the sources or reasoning behind the formulation of a hypothesis. Two tailed hypothesis may be formulated when there is no knowledge available on how an independent variable affects the dependent variable. Hypothesis must be mentioned clearly and must reflect the objectives of the study. A hypothesis is needed in the following study designs:

i. All interventional studies ii.
   Cohort iii. Case control iv.
   Comparative cross sectional.

Research hypothesis (alternate hypothesis) and statistical hypothesis (null hypothesis) must both be mentioned.

MATERIAL AND METHODS:

STUDY DESIGN: Mention the name of the appropriate study design. The choice of study design must relate to the research question, objectives of the study, and hypothesis to be tested

DURATION OF STUDY: Duration of research must match with the duration of course a trainee is pursuing, that is, a student must not choose a cohort study of ten years duration in his two years master program, otherwise, he may not be able to get his/her degree on time. A trainee should choose a study which could be completed in due course. Any expected dates from which the data collection starts and ends may be added. However, the dates may remain optional if the data collection is meant after the approval of proposals from the research board of the institution.

SETTING: Name of place (that is, laboratory, hospital, university, or a geographical study area i.e; in case of a survey/ prevalence study/cohort study) where the research work is to be conducted must be clearly mentioned.

SAMPLE SIZE: How many patients will be included. If there are groups how many per group? The protocol should provide information and justification about sample size. Calculation of sample size has been made easy by computer software programs. But the

principles underlying the estimation should be well understood. The sample size must be justified scientifically how it was calculated. The parameters of interest used for sample size calculations must be clearly mentioned and must be referenced.

SAMPLING TECHNIQUE: Type of sampling technique employed should be mentioned. It must be clearly stated whether probability or non-probability sampling technique was employed and even the subtype within that category must be mentioned. The results obtained from subjects chosen by a certain sample design have implications for the subsequent possibilities for generalization, validity, and reliability.

SAMPLE SELECTION: Sample is selected from a population on the basis of inclusion and exclusion criteria. Both (inclusion & exclusion criteria) act as filters to get a study population.

Inclusion criteria: On what bases will patients be inducted in the study? Background variables, which are considered for inclusion, must be stated. In case of special circumstances, the criteria must clearly state the inclusion strategy. First inclusion criteria are set to get included population.

Exclusion criteria: In next stage, exclusion criteria are set to transform included population into study population. After getting the study population, the investigator draws sample of appropriate size with appropriate technique. Exclusion must also be justified as what pushed the researcher to exclude the particular subjects from the study. Some researchers put confounding variables in exclusion criteria while others like to include them to study their effect by stratifying the data. As the name indicates, exclusion criteria exclude all those factors the investigator is not interested to study.

DATA COLLECTION PROCEDURE: For complete details of data collection procedure, the following information must be furnished before submission:

- Ethical clearance from the concerned ethical board to be applied and to be obtained.
- Clearance to be obtained from the institutional research board (e.g. ASRB)
- In case of data collection from outside premises of the parent institute, it should be mentioned that the certificate for data collection must be obtained from the subject institution.

- Once the subject is evaluated and found fit for inclusion, details of informed consent to be taken must also be clearly mentioned (details must be given in an appendix)
- In case of cohort studies, details of the cohort, how the subjects to be included in the exposed group and unexposed group must be clearly explained.
- In case of case control studies, details of how the subjects to be assigned to cases and controls should be explained.
- In case of clinical trials, details of how the subjects to be allocated in different groups must be clearly explained. Randomization technique and masking must also be explicitly mentioned. What type of intervention to be given in either group? A description must be given of the drugs or devices to be used, and whether they are already commercially available, or in phases of experimentation. For drugs and devices that are commercially available, the protocol must state their proprietary names, manufacturer, chemical composition, dose and frequency of administration.(details must be given in an appendix)
- The time interval of follow up etc; must be clearly mentioned (if required) for the said objective.
- In case of studies based upon questionnaires, details must be give as who will conduct the interview?, any training to be given to the interviewers, whether the interview will be conducted in local language, whether validity of the instrument was checked before or not, if yes proper reference may be quoted if the instrument is validated internationally.
- In case of diagnostic procedures, details of the equipment including the person who will conduct the procedures must also be stated to keep uniformity among procedures. In case of established procedures a reference can be sufficient however; in case of any new procedures sufficient details may be furnished.
- In case of in vitro study (laboratory based study) details of equipment and material must be provided in a separate appendix.

DATA ANALYSIS PROCEDURE

- Software for data analysis must be mentioned (generally SPSS is used and STATA may also be used)
- Type of dependent and independent variables must be mentioned.
- Data analysis plan for type of variables must be mentioned e.g. what you will do with your numerical data and what you will do with your categorical data.
- Before analytical statistics, descriptive statistics of the data set must be given such as mean and standard deviation, or mean/median, inter quartile range, and outlier etc;
- In case of analytical studies, type of statistical test corresponding to type of comparing variables must be mentioned.
- In case of correlation studies, type of test for measuring correlation must also be mentioned.
- In case of studies corresponding to validity and reliability for diagnostic procedures must be explained in detail.
- Scheme for representing results corresponding to type of variable must be mentioned.

ETHICAL CONSIDERATION:

Provide a reflection on which ethical considerations are relevant for your study, and how you will address them.

DATA COLLECTION INSTRUMENT:

The researcher must attach, as an annexure, 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. The proforma must be based upon objectives of the study and must not include unnecessary data or something, which is not utilized for analysis.

REFERENCES:

References should be written in Vancouver style. The Vancouver system has been adopted in the "Uniform Requirements for Manuscripts Submitted to Biomedical Journals" by the International Committee of Medical Journal Editors (who held their first meeting in Vancouver). Most biomedical journals follow this system. It is based largely on a standard style adapted by the US National Library of Medicine (NLM) for its databases.

Reference for an article:

Author(s) (surname followed by initials). title of article, name of journal. year; volume number, page numbers of article.

Examples

Choudary SD, Guswami A. Hyper prolactinem and reporductive disorders, a profile from North East Association Physicians India. 1996;43:617-618.

Reference for a book:

Author (surname followed by initials). title of book. Edition,

place, publisher, year; number and pages in the book.

example:

Brud and Kjaer. Measuring sound. Brud and Kjaer, 2850 Naerium, Denmark, 1984; p-p3-14

Reference for a chapter in a book:

Author of chapter (Surname followed by initials). chapter title in:Editor of book (surname followed by initials) eds; title of book. place, publisher, year: page number of chapter.

Example:

Aage R Moller. Noise as a health hazard, in Maxcy. Rossenau Public Health & preventive Medicine. 11th Edition, New York; 1980: 791.

For more details please see the BMJ referencing guide at:
https://www.imperial.ac.uk/media/imperial-college/administration-and-supportservices/library/public/vancouver.pdf
http://www.southampton.ac.uk/library/resources/documents/vancouverreferencing.pdf