KHYBER MEDICAL UNIVERSITY
Office of Research, Innovation & Commercialization
Advanced Studies & Research Board

FORMAT OF RESEARCH PROPOSALS

Research proposal is brief outline/summary of what the postgraduate or undergraduate researcher is going to conduct. It is a brief outline (about 6 A-4 size pages or 3000 words is the maximum limit) of your future work.

The schematic format of research proposal is followed under. The proposals must be written exactly according to this format. A research proposal must be constructed on the following format:

1. **TITLE**: Should reflect the objectives of the study. It must be written or revised after the whole proposal has been written so that it is a true representative of the study plan. It must be written in capital letters and font size should be kept 14 aligned in the page center. Ideal title should not exceed 50 words.

2. **INTRODUCTION**: Has three parts as following;
   1. Identification and Statement of the problem under study (the topic chosen is presented as a problem on which research has to be conducted in order to find a solution). Also briefly describe the epidemiology, morbidity and mortality figures associated with the problem.
   2. Research Strategy undertaken by researchers so far. Obviously the problem has been perceived by other people around the world and they have also conducted research on it. Write in your own words the findings of other researchers and their successes or failures in finding solutions to the problem. This part has to be written after conducting a thorough and relevant literature search and providing appropriate references as and where needed. The literature search should be from current research, meaning that the references are one year old or at most 5 years old.
   3. Rationale of your study: State why you have decided to undertake research on this problem; what was it that posed as the motivation to conduct your study; what aspect of the problem or disease would you like to study and why? Rationale is usually in keeping with research work conducted so far, so that areas where
researchers still continue to have problems are selected and their rationale provided; areas or aspects of the problem that have been successfully resolved are not considered research topics (reinventing the wheel).

3. OBJECTIVES: Objectives are statements of mentions. They inform the reader clearly what the researcher plans to do in his/her work. The must identify the variables involved in research. Objective should be sufficiently specific, measurable, achievable, relevant and time bound (SMART). Objectives are written in ‘action verbs’ in the ‘to do…’ format, e.g.,

The objectives of this study are:

1. To determine ..... 
2. To compare.... 
3. To correlate... etc.

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. Young investigators are advised to resist the temptation to put too many objectives or over-ambitious objectives that cannot be adequately achieved by the implementation of the protocol.

4. OPERATIONAL DEFINITIONS: 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. e.g., Anemia in your patients could be defined as ‘clinically evident by inspection of fingernails, mucous membranes or inner margins of eyelids’ or as ‘hemoglobin measurement in g/dl of less than 10 g/dl’ or ‘hemoglobin measurement in g/dl of less than 12 g/dl’, etc. You are free to use standard definitions of technical terms or even make you own definitions which you will use throughout your study.
5. **HYPOTHESIS**: A hypothesis is a statement showing expected relation b/w 2 variables. 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.

   Generally there are two types of hypotheses: a) **The Null Hypothesis**, where you make a statement in support of an existing situation or make a statement of no difference from an expected outcome, e.g., ‘the audit will reveal that proper guidelines were followed’, or ‘the audit will reveal that that there were no significant differences in the policy of the hospital and internationally recommended guidelines’. b) **The Alternate Hypothesis**, where you make a statement opposing the existing state or state that a true difference does exist between expected and obtained outcomes, e.g. ‘the audit is expected to reveal that proper guidelines were not followed’ or ‘the audit will reveal significant differences in policy and practice from internationally recommended guidelines’.

   It is important to note here that descriptive studies **DO NOT** carry any hypothesis.

6. **MATERIAL AND METHODS**:

   6a. **Study Design**: Mention the name of the appropriate study design. The study design must be according to WHO classification and anything other than recommended study designs may not be acceptable. The choice of study design must relate to the objectives.

   6b. **Settings**: State the place where your research work will be undertaken. This may be a hospital and / or its department(s) or the community or both. Also mention some facilities of the setting that will help your research, e.g., number of beds (patients per month), surgical or medical facilities, researchers / supervisors, equipment, standard labs, etc. The setting usually indicates the place(s) from where you will collect your data and/or carry out your lab work; in case these are separate places, mention both, e.g., data would be collected from patients of medical/surgical wards of a hospital, while the lab work would be conducted in the clinical pathology laboratories of the hospital.

   6c. **Duration**: The expected duration of your research study and why this duration is required (number of patients, hospital tests, data collection and analysis, report writing,
etc.). You may like to prepare a detailed time table (Gantt Chart) of your activities on a weekly or monthly basis, outlining targets that you expect to achieve per week or month for the entire duration of your study. This will help to organize and allot your work to fellow researchers and give you a basis for monitoring the progress of your research per week or month, so you can make changes, if needed in the pace of work or other parameters. You may, in lieu of a detailed time table, give a brief outline, e.g., literature search – two weeks, making a Performa and pre-testing it – two weeks, getting lab supplies and setting up tests – one month, data collection – 6 months, data entry and analysis on computer – two weeks, writing a thesis – one month, thus giving as total duration of approximately ten months.

6d. **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. A larger sample size than needed to test the research hypothesis increases the cost and duration of the study and will be unethical if it exposes human subjects to any potential unnecessary risk without additional benefit. A smaller sample size than needed can also be unethical if it exposes human subjects to risk with no benefit to scientific knowledge. 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 used for sample size calculations must be clearly mentioned and must be referenced.

6e. **Sampling Technique:** Type of sampling technique employed. Whether probability or non probability and even the subtype within each category must be clearly stated.

7. **SAMPLE SELECTION:**

7a. **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.

7b. **Exclusion criteria:** On what bases will patients be excluded from the study. How the variables mentioned in exclusion criteria are detected. Exclusion must also be justified as what pushed the researcher to exclude the particular from the study.
8. 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. However, in case of animal studies an ethical approval may be exempted or in studies where human subjects are not directly involved. The candidate has to justify the non human involvement clearly.
- Clearance to be obtained from the institutional research technical board (e.g. AS&RB)
- In case of data collection from outside premises of the parent institute, it should be mentioned that the certificate for data collection may be obtained from the subject institution.
- Once the subject is evaluated for inclusion, details of informed consent to be taken must also be clearly mentioned. The process of informed consent again can be exempted for studies involving animals or not involving human subjects directly or laboratory based studies.
- 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. What type of intervention to be given in either groups.

**Interventions:** If an intervention is introduced, 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. For drugs and devices that are still in the experimental stage (or that are commercially available but are being used for a different indication or in a different mode of administration), additional information should be provided on available pre-clinical investigations in animals and/or results of studies already conducted on
humans. In such cases, the approval of the drug regulatory agency in the country is generally needed before implementing the study.

- 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 is to who will conduct interview, any training to be given to the interviewers, whether the interview will be conducted in local language, whether validity of the instrument 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.

9. DATA ANALYSIS PROCEDURE

- Software for data analysis must be mentioned
- Type of 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.
- In case of analytical studies, type of statistical test corresponding to type of comparing variables must be mentioned. The level of significance for rejecting the null hypothesis 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.
- Means of controlling confounders/effect modifiers must be mentioned e.g. stratification or regression analysis etc.
10. REFERENCES:

In Vancouver style:

**Journal Articles:**

**Standard Research Article:**

When referring to articles in standard journals, all authors should be listed, if there are six or less. When there are seven or more authors, only the first six should be listed followed by et al.

*Example:*


**Journal paginated by issue**

*Example:*


**Corporate author**


**No author given**


**Journal supplement**


**Books and other monographs**

Personal author(s).


**Chapter in a book**

**Electronic Material**

*Journal article in electronic format*


*Monograph in electronic format*


*Computer File*


For further assistance in reference writing in Vancouver style, refer to BMJ referencing guide at:


**ANNEXES:**

Annex A usually contains the Performa. Other annexes may be made to provide any detailed methods (e.g., lab procedure methodology, details of operative procedures, etc.) that cannot be included in the main text.

**DATA COLLECTION INSTRUMENT:**

The researcher must attach, as an annex, 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.

**FONTS:**

Main Headings of proposal: **bold**, CAPITAL, times new roman Font 14
General body text: 12 size in times new roman
Subheading within proposal: **bold**, CAPITAL, times new roman