RAK MEDICAL & HEALTH SCIENCES UNIVERSITY (RAKMHSU)

A Students' Guide to Research Proposal

RAKMHSU Research Ethics Committee
Academic Year (2020-2021)

A STUDENTS' GUIDE TO RESEARCH PROPOSAL

For Developing and submitting research proposals to the Research Ethics Committee (REC)

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Preface

The research proposal is one of the most critical steps in the process of research conduction. It is a comprehensive plan for the research project and can be regarded as the backbone for the research itself. A well-written proposal that follows the universally accepted guidelines of proposal writing is a prerequisite to obtain approval from the Research Ethics Committee (REC) and to find funds. Unfortunately, many researchers lose valuable time when the REC reviewers return their submitted projects for correction because of unclear objectives, wrong formulation of a research question, poor literature review, or imprecise description of research methods. These common mistakes could be avoided if the researchers have adequate knowledge about the fundamentals of proposal writing.

The good-quality proposal would be adequate for convincing the Research Ethics Committee (REC) about the importance of the research topic and the adequacy of the research design. It starts with specifying the research question, establishing its significance, and then describing how to reach the answer. It will explain what is known about the topic under the study and propose what will be added to the general knowledge. The proposal should also include information about the time needed to conduct each stage of the research.

This handbook provides necessary information and practical steps to be followed during the preparation of either students or faculty research proposals that will be submitted for RAKMHSU-REC approval.

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Contents of the Research Proposal

The contents or formats of a research proposal vary depending on the prerequisites of the evaluation committee; however, the following requirements are standard in most proposal templates.

- **Title page containing the following:**
  - Title of the proposal
  - Name of the submitting faculty
  - Department, College & details of contact (phone number & E-mail)
  - Type of research (Undergraduate, Postgraduate, or Faculty)
  - Names, affiliations & study roles of the investigators (& their signatures)
  - Application for funding
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- Plain Language Summary
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  - Sampling method
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  - Ethical consideration
- References
- Appendices: Questionnaire, Informed consent form, etc.

Title

- The title is the expression that describes the subject of the research.
- An exciting title would capture the reader's attention to the research problem.
- The following parameters may appear in the title: the purpose of the research, type of the study & the method used.

The following title features are highly recommended:

- Brief and straightforward (generally less than 20 words & preferably 10-12 words)
- Informative and easy to understand.
- Should reflect the objective and the scope of the study.
- Usually in the form of a phrase, but can also be in the form of a question.
- All words in the title, except the prepositions, may be capitalized; however, a sentence case is also acceptable.

The title should not include:

- Roman numerals (e.g., I, III, IX, etc.).
- The semicolon (;), but you can use a colon (:).
- Certain punctuation like periods (i.e., full stops).
- Chemical formulae (e.g., SO4, CaCl2, etc.) or units (e.g., km/h).
- Unfamiliar acronyms or abbreviations (i.e., the widely known abbreviations can be used, e.g., DNA).
- Unnecessary words (e.g., "Study of," "Analysis of," "An experimental investigation."
- General words that do not provide any information on the scope of the research (e.g., "Asian Culture")

The following titles appeared in respectable scientific journals:

✓ **Novel measure of lung function for assessing disease activity in asthma**

- Smith NMJ, Couper J, Fullerton CJ, et al. Novel measure of lung function for assessing disease activity in asthma. BMJ Open Respiratory Research 2020;7:e000531. doi: 10.1136/bmjresp-2019-000531.

✓ **Patient outcomes associated with post-tuberculosis lung damage in Malawi: a prospective cohort study**

- Meghji J, Lesosky M, Joekes E, et al. Patient outcomes associated with post-tuberculosis lung damage in Malawi: a prospective cohort study. Thorax 2020;75:269-278.

- ✓ **No place like home: initiation of non-invasive ventilation for stable severe COPD**
  - Nicholas S Hill. No Place Like Home: Initiation of Non-Invasive Ventilation for Stable Severe COPD. Thorax 2020 Mar;75(3):196-197. doi: 10.1136/thoraxjnl-2019-213787.
- ✓ **Is the epidemiology of rheumatoid arthritis changing? Results from a population-based incidence study, 1985–2014**
  - Myasoedova E, Davis J, Matteson EL, Crowson CS. Is the epidemiology of rheumatoid arthritis changing? Results from a population-based incidence study, 1985-2014. Ann Rheum Dis. 2020;79(4):440-444. doi:10.1136/annrheumdis-2019-216694.
- ✓ **Hereditary spastic paraplegia SPG8 mutations impair CAV1-dependent, integrin-mediated cell adhesion**
  - Lee S, Park H, Zhu PP, et al. Hereditary spastic paraplegia SPG8 mutations impair CAV1-dependent, integrin-mediated cell adhesion. Science Signaling. 2020;13(613). DOI: 10.1126/scisignal.aau7500.
- ✓ **Testing different thresholds for patient global assessment in defining remission for rheumatoid arthritis: are the current ACR/EULAR Boolean criteria optimal?**
  - Studenic P, Felson D, de Wit M, et al. Testing different thresholds for patient global assessment in defining remission for rheumatoid arthritis: are the current ACR/EULAR Boolean criteria optimal?. Ann Rheum Dis. 2020;79(4):445-452. doi:10.1136/annrheumdis-2019-216529.

Plain Language Summary

- The plain language summary is a brief explanation of the entire project in a simple language that can be understood by non-medical persons.
- It gives the reader an overview of the research project and draws his interest in the problem being investigated.
- It should not contain jargon or medical terms, statistical test details and any technical terms should be explained.

The plain language summary must include:

- A simple description of the research subject (statement of the problem & purpose of the research)
- Why the research is being conducted (i.e., its significance)
- How it will be conducted (a brief description of the methods)
- What the investigation intends to find

Example of a well-written summary

Chronic inflammation of the nose and paranasal sinuses (rhinosinusitis) is one of the most prevalent chronic diseases worldwide. The suffering patients frequently use topical decongestants to reduce their symptoms and speed recovery. The use of some nasal decongestants should be restricted to three days to avoid complications, e.g., potential rebound swelling. The degree of knowledge and the practice of RAKMHSU students regarding nasal decongestant use is unknown. In this study, we will use a questionnaire to collect information from RAKMHSU students about their use of these drugs and assess their knowledge about complications of extended use. Such information can guide the preparation of health educational plans about the safe use of nasal decongestants in the future.

1. Introduction, Background & Literature Review (= Background)

- The introduction & background can be combined or divided into separate sections. In many research proposals, the literature review is presented in a new chapter, after the objectives. However, in this format, the introduction, background and literature review are all combined under one title "Background."
- In this section, the researcher may start with a general description of the area of study in order to create a broad foundation for the research problem (problem statement). This could be followed by a summary of relevant research studies done on similar topics as the one being investigated (i.e., literature review).
- The researcher should be able to describe the current state of knowledge, the major concepts involved, and identifies a gap in the literature that may draw readers' perception towards the research problem and promote their support for the research project.
- The researcher is advised to be as precise as possible (should not exceed 1000 words).

The background should cover the following elements:

- General statements about the topic/ field of the research
- Specific comments about the previous research (include minimum 3-5 studies done during the past five years) with a proper in-text citation.
- Statement of the problem.
- Justification of the research (rationale)
- Research questions & hypothesis (if any)
- Research objectives

Example of a paragraph in a background (*published in a scientific journal*))

"A growing body of scientific evidence indicates that childhood exposure to second-hand smoke adversely affects lung function.[1] Several studies suggested that pulmonary function decrement in school-aged children was a result of combined early life (including intrauterine life) and current exposure to parental smoking, especially maternal smoking.[2] However, the negative effect of second-hand smoke on lung function is amplified in children with residual lung insult due to asthma, cystic fibrosis or other lung diseases.[3] Intrauterine exposure to maternal smoking was associated with a significant deficit in lung function of children with asthma. This deficit was found to be independent of the effects of postnatal second-hand smoke exposure. Occasional low level of exposure to cigarette smoke seems to be associated with lung function alterations in adolescents.[4] On the other hand; some studies reported that

intrauterine exposure had no effect, suggesting that exposure to second-hand smoke after birth represents a major contributing factor to development and persistence of airflow obstruction or respiratory symptoms.[5, 6] There is a paucity of data regarding the relationship between regular second-hand smoke exposure at home and FEV1, FVC, FEF50 and PEF in healthy schoolboys in this country."*

*Merghani TH, Saeed AM. The relationship between regular second-hand smoke exposure at home and indictors of lung function in healthy schoolboys in Khartoum. Tob Control 2013; 22(5): 315-318.

2. Rationale

- Here, the researcher defines an existing problem and describes where it occurs and how it affects the area under study. He/ She identifies the gap in the current knowledge and explains how the proposed research will help to bridge that gap.
- The researcher can describe how the research differs from previous studies and may explain other points like why he/she selected the proposed study area, study population, or a particular method.
- The rationale must include precise statements that explain why the proposed study is important.

An example of a research justification (rationale)

There are various reasons for vaccine hesitancy that need to be investigated and properly addressed. Previous studies showed that certain hesitancy reasons are related to particular groups and not applicable to others.[1-5] Researchers are advised to focus on the sub-groups within populations to find the possible explanations that drive their hesitancy and the possible socio-cultural or political context that may be contributing to the problem. In this regard, the assessment of knowledge and perception of immunization among parents of school students is an important step in the evaluation of vaccine hesitancy among this population.

3. Hypothesis/ Research Question

- The decision to use hypothesis/ research question depends on many factors that include the type of research, purpose of study, methodology, audience, etc.
- The research hypothesis is the statement that describes prediction of a relation between two or more variables that will be studied.
- The research question is the inquiry that is supposed to be answered by the research. It is derived from the research hypothesis.
- In RAKMHSU-REC template, the hypothesis can be presented in the form of a research question.
- The research question could be quoted as the research title or the research aim, and it gives an idea about the suitable research design. It provides a context for reporting future results.

- The research question should be

- Original, specific, strong and focused.
- Answerable (not by "yes" or "no," but through carrying out the study).
- Informative (state the population of interest, locality, etc.).

Examples of research questions

Incorrect question/ Explanation	Correct
❖ Does Chloroquine reduce symptoms of virus infection? ○ Not focused	✓ How effective is Hydroxychloroquine in treating adults with Corona infection?
Which journal is the best? ○ Opinion-based	✓ What features do the most famous journals have in common?
❖ Does owning a car bring happiness for unemployed men? ○ Simple (can be answered with "yes" or "no")	✓ How does owning a car improve the quality of life for unemployed men?
❖ How does exercise affect people? ○ Not specific	✓ How does exercise affect glycemic control in diabetic patients?
❖ What are the advantages and disadvantages of e-learning on University students? ○ Not original	✓ How does e-learning affect the social interaction of RAKMHSU students?
❖ Why do some students do not attend their teaching activities? ○ Better to avoid "why" because it is open-ended	✓ How do the instructors of teaching activities prevent voluntary absenteeism?
❖ Is body mass index better than body surface area? ○ Vague	✓ How does body mass index compares to body surface area in the estimation of the metabolic rate?

4. Research Objectives

- The research objectives summarize what the researcher would like to achieve through the proposed research.
- The objectives should be closely related to the problem being investigated. They can be classified into general objective (or aim) & specific objectives.
- The general objective (or aim) is what is intended in broad terms. It is what the researcher wants to achieve at the end of the project (i.e., the long-term outcome).
- Specific objectives are the actions that will be taken to achieve the aim. They should specify what exactly the researcher would do to address the various parts of the problem.

The objectives should be **S.M.A.R.T.**

- **S**pecific & strong (use action verbs like to assess, to compare, to determine, to describe, to evaluate, etc.). The action verbs should be written in strong positive statements.
- **M**easurable (use assessment terms like quantity, quality, frequency, etc.). The measurement terms give an indication of accuracy.
- **A**chievable (feasible & possible to achieve).
- **R**elevant (worth doing, as should be explained in the rationale section).
- **T**ime-bound (to allow follow up, end/ check points should be built into it).

The objectives should not be

- Non-measurable (by using vague verbs like to appreciate, to understand, to believe, to study, etc.)
- Non-realistic (in terms of resources, time, money & skills)

Example of general & specific objectives

General:

- To evaluate the quality of scientific research at RAKMHSU

Specific:

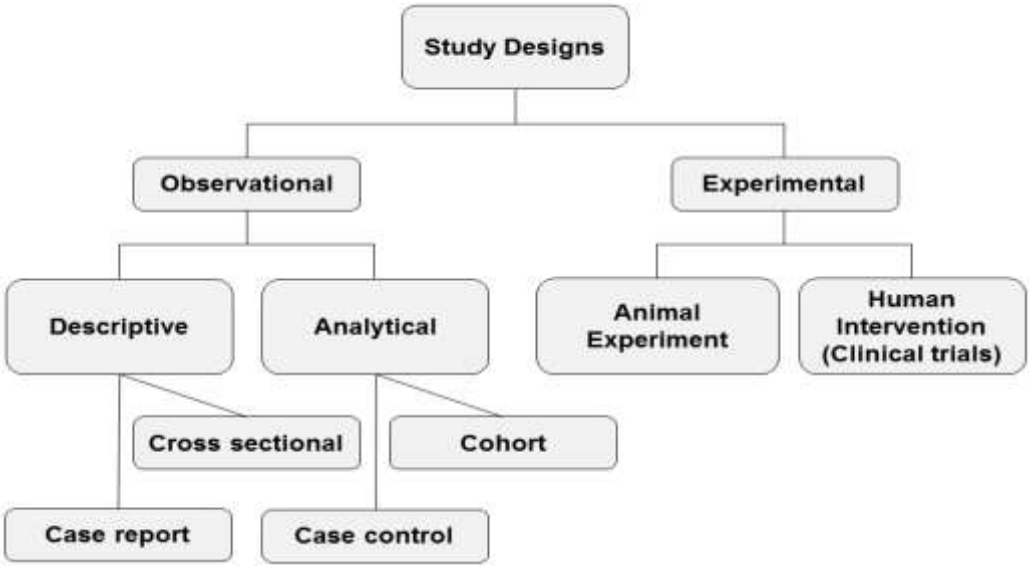
- To determine the publication rate of RAKMHSU faculty
- To appraise the quality of faculty publication in RAKMHSU
- To investigate the usage of the Central Research Lab equipment in faculty research
- To relate the provided fund to the quality of faculty publications

5. Methods

- In the research proposal, the researcher should describe each of the following in detail.
  - ❖ Research design
  - ❖ Setting
  - ❖ Study duration
  - ❖ Study population
  - ❖ Inclusion criteria & Exclusion criteria
  - ❖ Determination of sample size
  - ❖ Sampling method
  - ❖ Data collection tools
  - ❖ Data analysis plan
  - ❖ Limitations/ Challenges
  - ❖ Ethical consideration

5.1. Study design

- A detailed description of the research design (strategy) is an important step in proposal writing.
- Since there are different types of study design, the researcher should select the one that is most appropriate to answer the research question.
- Study designs can be classified into the following types:



5.1.1 The observational design

- The researcher simply observes (no intervention)
- The observational studies are of two types, descriptive & analytical.

- **The descriptive studies**

- Show associations between problems and certain variables without identifying a definitive cause. They can be cross-sectional studies, case reports, etc.
- In the cross-sectional study, the researcher collects information about a problem in a population during a specified period. The information is collected by using a questionnaire with or without laboratory investigations. E.g., a survey or a prevalence study.
- The case report describes a new or unusual presentation of a medical problem.

- **The analytical studies**

- The analytical studies search for causes. They can be a cohort or case-control.
- The cohort study involves a designation of specific subjects to be followed (traced) over some time (prospective) and periodically searched for an outcome (incidence). It is suitable when the exposure is rare. E.g., when testing the efficacy of a drug (start with diseased subjects and follow them for the outcome).
- The case-control study looks backward (retrospective) from the outcome to the cause. It is suitable when the outcome (disease) is rare. The participants will be selected based on whether they are diseased (cases) or not diseased (controls). Matching between the cases and controls is essential. E.g., when you take cases of pulmonary cancer (outcome) and try to find a cause.

5.1.2 The experimental design

- The researcher intervenes and then observes the effect of the intervention.
- The experiment should be well planned to obtain valid results.
- The researcher should describe how the participants are allocated to experimental groups (e.g., by complete randomization). This randomization decreases variability between the groups and eliminates/ reduces the possibility of bias.
- There are many types of experimental designs. The most commonly used is the between-subjects design (independent measures). Here each participant is assigned to only one

group. E.g., one group receives medication, and the other gets a placebo (can be blinded). Each participant can be a member of only one group.

Standards for reporting trials or experimental studies involving humans

Standard/checklists	Available
Consolidated Standards Of Reporting Trials CONSORT	www.consort-statement.org
Strengthening the Reporting of Observational Studies in Epidemiology STROBE	www.strobe-statement.org
Standards for Reporting Studies of Diagnostic Accuracy STARD	www.stard-statement.org
Quality assessment of diagnostic accuracy studies QUADAS	www.bris.ac.uk/quadas
Preferred Reporting Items for Systematic Reviews and Meta-Analyses PRISMA	www.prisma-statement.org
Consolidated criteria for reporting qualitative research COREQ	www.equator-network.org/reporting-guidelines/
Statistical Analyses and Methods in the Published Literature SAMPL	www.equator-network.org/reporting-guidelines/
Consensus-based Clinical Case Reporting Guideline Development CARE	www.care-statement.org/
Standards for Quality Improvement Reporting Excellence SQUIRE	www.squire-statement.org
Consolidated Health Economic Evaluation Reporting Standards CHEERS	www.ispor.org/taskforces/ EconomicPubGuidelines.asp
Enhancing transparency in reporting the synthesis of qualitative research ENTREQ	www.equator-network.org/reporting-guidelines/

- **Study designs in animal experimentation**
  - Typically, studies involving animals are experimental in nature.
  - The study design in animals also should follow statistical methods such as drawing controlled animals, randomization and blinding. A sample size calculation is also required. The ARRIVE (Animal Research: Reporting of *In Vivo* Experiments) guidelines/checklist are formulated to improve the reporting of research using animals, which could help in designing the animal experiment as well.

- **Requirements for reporting Molecular Biology/ Microbiology/ Genetics Methods.**
  - Reports that describe molecular biology & genetics methods may not follow the same steps stated in this standard template. Many items could be not applicable (NA). However, researchers should describe all the following points (if applicable) in full details:

- ❖ Sources of specimens used in the study. The researcher should describe the patient (even if a single patient), hospital & how the sample was transferred.
- ❖ Bacterial strains, viruses, plasmids, cell lines, & their growth conditions.
- ❖ Chemical & biochemical reagents (sources, manufacturers, transfer …etc.).
- ❖ Techniques used in full details, these may include:
  - Biofilm formation assay
  - RNA isolation, cDNA synthesis, and real-time-PCR analysis.
  - Protein localization experiments
  - Western blotting
  - Other methods (e.g., Enzyme activity assay)

5.1.3 Other study designs

- Longitudinal Design
- Pretest-Posttest Design
- Quasi-Experimental Design

5.2. Setting

- The area where the study will be conducted.
- For example, the central research lab of the RAK Medical and Health Sciences University.

5.3. Study duration

- The expected duration of the study.
- For example, the study will take about ten months.

5.4. Study population

- The study population refers to the individuals who will be invited to participate in the study. The study population should be the most relevant population for the research problem.
- For example, if the research is evaluating patients' use of bronchodilators, then the study population will be the adult asthmatic patients (in the above setting).

5.5. Inclusion and exclusion criteria

- The study population should be clearly defined according to specific inclusion and exclusion criteria.
- The inclusion criteria are the characteristics that the subjects must have to be included in the study, while the exclusion criteria are the characteristics that disqualify subjects from inclusion.

- The inclusion & exclusion criteria should be:

- Written in a positive way
- Based on certain variables like age, sex, residence, location, specific disease, unique exposure, ethnicity, social history, etc.

- The inclusion & exclusion criteria should not use:

- The same variable twice (e.g., the gender should not be used in both inclusion & exclusion criteria. Like using males as inclusion and females as exclusion).

- Examples of inclusion criteria for a chronic obstructive pulmonary disease (COPD) study

- Adults ≥40 years of age
- Diagnosis of COPD at least for one year
- Current or former smokers (of more than 10 pack-years)
- Stable disease (no recent exacerbation)

- Examples of exclusion criteria

- Diagnosis of sleep apnea
- Inability to perform spirometry
- Refusal to give informed consent

5.6. Determination of sample size

- The sample size is the recommended number of individuals who will represent the population under study. Without scientific calculation of the sample size, the findings may not be reflecting the whole community.

- Many factors influence the sample size, and accordingly, different formulae are used for its calculation. In the research project, the researcher should mention the size of the proposed sample and explain how it was calculated.

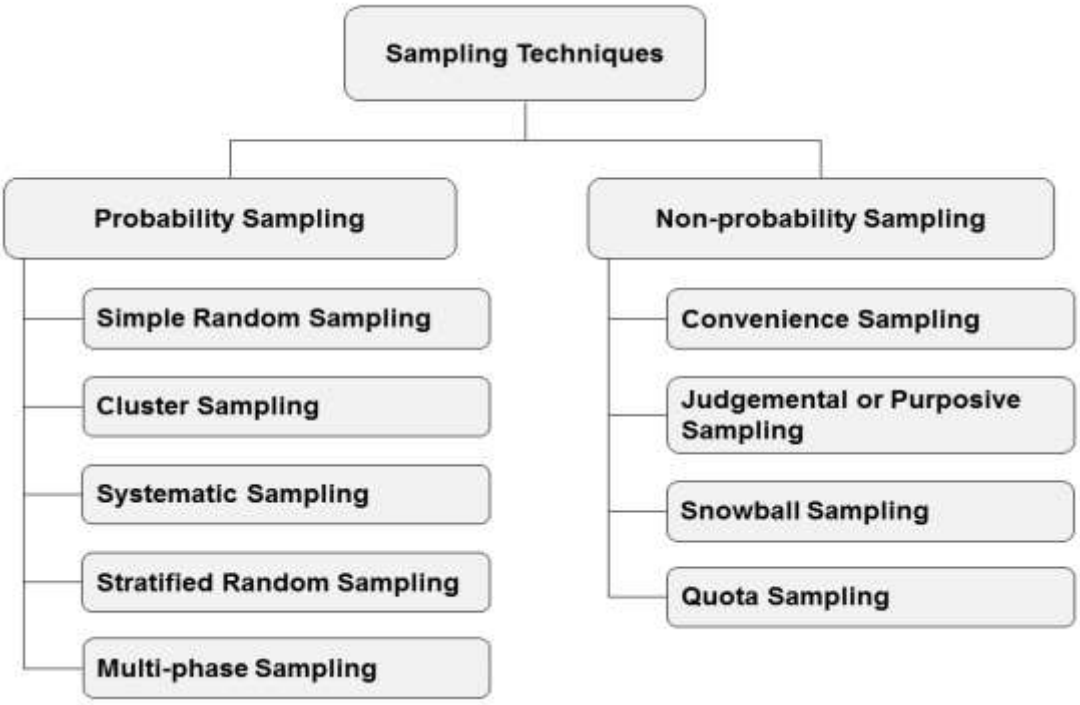
Example of what should be written in this section

- The calculated sample size is 138. The following equation was used for calculation of the sample size for infinite (unknown) population: $n= Z\ (1-\alpha)^2\ P(1-P)/d^2$; where: n= sample size, Z= standard normal variate = 1.96 (at 5% type I error, p= 0.05), P= expected proportion = 10%, and d= precision error (or confidence interval) = 5%.

**(When the population is known (N), the above result can be divided by: 1 + (n-1/N))*

5.7. Sampling method

- It is impractical to include all members of a population in a study or experimental design; therefore, a sample can be selected to represent the whole population. The inferences drawn can be generalized to that population. Therefore, sampling helps in saving time and resources.
- The sample should be selected using an appropriate sampling technique so that all subjects of the population will have equal opportunities of being selected.
- Sampling techniques include the following:



5.7.1 Probability Sampling:

- It depends on predefined selection criteria to choose random members of a population.
- Every member of the population has an equal opportunity as other members to be selected in the sample.
- Probability sampling can be simple random, cluster, systematic, stratified, or multi-phase sampling.

- **Simple random sampling (SRS)**
  - Suitable for small & homogenous population.
  - Randomization can be done by lottery method or with the table of random numbers.
  - Example of the lottery method, when a researcher writes the names (or serial numbers) of each member of a population on cards, puts the cards in a bowl, shuffle them well, and then asks someone to pick the required sample from the bowl.
  - The tables of random numbers can be found in specialized statistical books or from the web (random number generator). They ensure the randomness of the selection of sampling units.

- **Cluster sampling**
  - Suitable for the population that can be divided into similar sections or groups (clusters). A typical example is the geographical areas.
  - The researcher will give numbers to the clusters and select one or more clusters from them by simple random sampling (SRS). Then he/ she may choose all individuals in the selected groups (= one-stage cluster sampling) or may do SRS again to select individuals from the selected groups (= two-stage cluster sampling).
  - For example, the WHO evaluates vaccination coverage in a population by examining a sample taken from different clusters rather than examining the whole population. This sampling reduces time & cost.

- **Systematic sampling**
  - Suitable when a complete list of a population is available.
  - Example, a sample of 100 individuals can be selected from a population of 1000 as follows:
    - First step: select any number from1000 by SRS; e.g., take it as 835.
    - Second step: calculate the sampling interval by dividing the population size/ sample size, i.e., 1000/100 = 10 (or 10th).

- Third step: select every 10th element, starting from 835 until you complete the 100 elements (i.e., 835, 845, 855, etc.). When you reach the end of the list, you should restart from the top of the list to complete the sample of 100.

- **Stratified random sampling**
  - Suitable for the non-homogenous population.
  - The researcher will classify the population into homogenous groups or strata. Each stratum is considered as a separate population. Then he will sample every stratum, using simple random sampling or systematic sampling, to collect the desired sample size.
  - Suppose a population is divided into three socioeconomic strata, poor (2000), middle class (4000) and high class (1000). If the desired sample size is 390, then there are two methods to take the desired sample size from the three strata:
    - Method of equal allocation: Equal number of subjects will be selected from each stratum.
    - Method of proportional allocation: The number of individuals to be selected from each stratum will be proportional to the original size of the stratum.
  - Note that, in stratified random sampling, each stratum is sampled, whereas, in cluster sampling, the clusters themselves are sampled (at least in the first stage).

- **Multi-phase sampling**
  - Suitable for large populations for economic reasons. Basic information can be collected initially from the whole sample and then more detailed information can be selected from the subsample (i.e., double-phase sampling). Further phases may be added if required.
  - For example, in a tuberculosis survey, the phases will be as follows:
    - Phase I → Mantoux test is done in all cases.
    - Phase II → Chest x-ray is done only for Mantoux positive cases.
    - Phase III → Sputum examination is done only for positive x-ray cases.

    Then, the tuberculous cases can be selected (note that the sub-samples of the second and the 3rd phases became successively smaller and smaller).

5.7.2 Non-probability sampling

- It does not depend on predefined selection criteria but on the researcher's ability and the feasibility of sampling.
- The population members have unequal opportunities to be included in the sample.
- Probability sampling can be convenience, purposive, snowball and quota sampling.

- **Convenience (haphazard or accidental sampling)**
  - Members of the population are chosen based on their relative ease of access or proximity to the researcher. For example, co-workers or customers at a single mall.
  - Such samples may or may not be representative of the population.

- **Judgmental or Purposive sampling**
  - The researcher chooses the sample based on whom they think would be appropriate for the study.
  - It is best used when there is a limited number of people who know the area of study. For example, the selection criteria will be, "do you want to apply for postgraduate studies?" Those who respond with a "No" will be excluded from the sample.

- **Snowball sampling**
  - It is suitable for subjects that are difficult to find. For example, drug addicts or HIV patients.
  - The researcher may ask the first selected patients who meet the criteria to recommend others who also meet the requirements.

- **Quota Sampling**
  - This is a non-random sampling. It gives the same proportions of individuals as the entire population with respect to certain pre-set standards (gender, age, education, etc.).
  - For example, if the population has 45% women and 55% men, then the researcher will divide the population into two groups (strata). Then he will sample each group to get the same percentage in his sample.

Examples of what should be written in this section

- The participants will be selected by random sampling, with stratification for gender, age and residence.
- Participants will be recruited from the outpatient clinic at Saqr Hospital, Ras Al-Khaimah, over six-months. All participants fulfilling the above inclusion & exclusion criteria will be invited to participate in the study.

5.8. Data Collection Tools

- The researcher should describe in detail the instruments (materials) used in data collection and the protocol (or procedure) of data collection.
- The instruments of data collection vary according to the type of data being collected (e.g., quantitative or qualitative, and primary or secondary).
- Examples of quantitative data collection strategies:
    - Questionnaires (closed-ended questions)
    - Interviews (closed-ended questions during face to face or telephone interviews)
    - Observation of well-defined events
    - Bio-physiologic measures
- Examples of qualitative data collection strategies:
    - Interviews (open-ended questions)
    - Focus group discussion
    - Observations
    - Document review

Important points to be considered

- If a researcher is using a validated questionnaire or interview schedules from a published article, reference to this work should be given, and the tool must be appended to the research proposal.
- If a researcher is designing a new questionnaire for a study, the details of its preparation and review should be provided. Then after approval, the researchers may need to conduct a pilot study to test the questionnaire reliability and validity.
- If Arabic speaking individuals are participating, an Arabic version of the questionnaire should be provided. The RAKMHSU-REC recommends that the questionnaire translation to be checked and approved by an Arabic speaking faculty/ staff.
- The equipment and steps of bio-physiologic measures should be provided in detail. For example, in a study on oral temperature measurement, the measurement steps should be described. These may include precautions to be taken by the investigator while using the thermometer, instructions to be given to the patient/ subject, type of thermometer used and manufacturer, appropriate use of the thermometer, who will take the measurement, etc.

5.9. Data Analysis Plan

- In this section, the researcher should describe how the data would be processed and summarized. The researcher should indicate the statistical tests that will be used to analyse different types of data and how the results will be reported.

Examples of what should be written in this section

- Data will be analysed using the Statistical Package for the Social Sciences (SPSS) version 22 (IBM Corp., Armonk, NY, USA). The chi-square test will be used to analyse categorical variables and student's t-test for continuous variables. The data will be presented as frequency and percentage or mean ± standard deviation. Statistical significance will be accepted for $p < 0.05$.

5.10. Limitations/ Challenges

- The limitations and challenges are the flaws and difficulties in many aspects that may affect the results. These may include taking consents of subjects, availability of animals, methodology, and standardization of procedures. In addition, they include the availability of chemicals, resources, instruments, research staff and authority approvals. Pointing them out shows that the researcher is aware of them and can explain how they may influence the findings.

Examples of limitations/ Challenges

- Selection bias
- Small sample size
- Recall bias
- Limited access to data
- Time constraints
- Cultural bias
- Attrition bias
- Reporting bias

5.11. Ethical Consideration

- This is one of the most critical parts of the research proposal.
- All aspects related to the research should be communicated with honesty and transparency.
- The researcher should declare that the participants will be respected, their privacy will be protected, and they will not be subjected to harm.
- The researcher should inform the participants about the research and should provide sufficient information about the implications of their participation.
- The participants should know that their participation is voluntary (without pressure or coercion), and they have the right to withdraw from the study at any stage.
- Informed consent should be obtained from the participants before the survey (a template for creating an informed consent letter is attached).

Important note

6 GCP (Good Clinical Practice) Certification is mandatory before participation in every research activity concerned with human subjects.

7 GCP Certification can be obtained from the NIDA GCP website:

8 https://gcp.nidatraining.org/

6. Work-plan

- In a simple timetable, the researcher should provide the chronology of the project activities, the expected start date and the duration of each activity.

Example of a research work plan

Expected start date: 22/12/2021		
No.	**Activity**	**Period**
1.	Literature review	1 month
2.	Preparation and official letters	2 month
3.	Data collection	3 month
4.	Analysis of collected data	1 month
5.	Discussion of results	1 month
6.	Presentation of the results	1 month

7. Budget

- A detailed budget is usually requested by the funding agencies.

- For RAKMHSU-REC applications, it is optional unless requested by the reviewers.

8. References

- The researcher should provide references for all statements that are not of common knowledge to avoid plagiarism.
- He should use the most recent publications, avoiding unpublished works, internet sources and textbooks (whenever possible).
- There are many types of referencing styles, but the researcher is advised to follow the citation guidelines of one of the following formats:
    - Vancouver style
    - APA style

Vancouver style

- Vancouver is a numbered referencing style commonly used in medicine and science.
- In Vancouver style, the references are given numbers as they are cited in the text in sequence.
- Either square [ ] or curved brackets ( ) can be used as long as it is consistent; however, superscripts[1,3] can also be used rather than brackets.
- If the same reference is cited more than once, the same number is cited again, as in this sample,

> This bacterium is a food-borne pathogen that causes many human disease and as many as 500 deaths per year worldwide (1-3). It is responsible for about 0.1% of all fatal food-borne illnesses (4). Previous researches have shown that serious illness may occur in both pregnant and non-pregnant women (2,5). It is also reported in neonates (6,7).

- Then the references should be listed in numeric order in the "References List" at the end of the document.
- All references cited in the text document must be listed in the "References List", & all references listed in the "References List" must be cited in the text.

- The following steps should be followed when citing a journal article:

- List the author's last name and initials. Mention up to six authors, each one is separated by a comma from the next. When you reach the sixth author, mention "et al" and put a full stop.
- Mention the title of the article followed by a full stop.

- Mention the abbreviated journal name (*in italics*) and after a space mention the year of publication followed by a semicolon (;)
- Mention the journal's volume followed by the issue number in brackets followed by a colon (:)
- Mention the page numbers followed by a full stop.

Summary

Author AA, Author BB, Author CC, Author DD. Title of article. *Abbreviated name of journal* Year of publication YYYY;volume number(issue number):page numbers.

Examples:

1- McLauchlin J. Listeriosis during pregnancy and in the newborn. *Epidemiol Infect* 1990;104(2):181–189.

2- Notermans S, Dufrenne J, Teunis P, Chackraborty T. Studies on the risk assessment of Listeria monocytogenes. *J Food Protect* 1998;61(2):244–248.

- For citations from books, websites, or other sources, the researcher is advised to check author's guidelines of any relevant journal, he will find detailed description in the reference section. In addition, the following table may help.

Source	Referencing in order	Example
Book	Author/ editor (if an editor put, ed.). Title: subtitle (if available). Edition (other than 1st). Place of publication: Publisher; Year	Name XX. The brain: mental illness. 3rd ed. Ras Al-Khaimah: RAK University Press; 2012
Chapter within a book	Chapter author. Title of chapter. In: Book author/editor (if an editor put, ed.). Title of book. Place of publication: Publisher; Year. Page numbers.	Name XX. Research Methodology. In: Name XX, Name YX, editors. A students' guide. 3rd ed. London: Blackwell; 2020. p. 21-26.
E-book	Author/Editor (if an editor put (ed.) Title [Internet]. Place of publication: Publisher; Year [Date of access]. Available from: URL	Name XX, Name XX. *A Students' guide*. Ras Al-Khaimah: RAK Publishing; 2020 [Accessed 18th June 2020]. Available from: https://www.rakmhsu.ac.ae/

Web page/Web site	Author(s)/Editor(s) or you can use the corporate author. Title of article [Internet]. Date of publication [date of access]. Available from: Article URL	Name X. COVID 19 may cause mental illness [Internet]. 2009 Mar 31 [cited 2009 Apr 2]. Available from: http://www.abc.net.au/ science/articles/

(Note: In some journals, the date of access may come after the URL)

APA Style

- This is the American Psychological Association style of citation. It is commonly used for citing scientific sources.
- APA in-text citation style uses the author's last name and the year of publication, for example: (Hossain, 2017).
- For two Authors, cite both last names in the text, for example (Fleming and Cochi, 1985).
- For more than two authors, mention the last name of the 1st author followed by et al, then the year of publication
- Multiple authors of different publications are separated by semicolon (;) as in the following sample,

This bacterium is a food-borne pathogen that causes many human disease and as many as 500 deaths per year worldwide (Ragavendra, 2019; Nagaraj et al., 2018; Hakim et al., 2015). It is responsible for about 0.1% of all fatal food-borne illnesses (Ragavendra, 2018). Previous researches have shown that serious illness may occur in both pregnant and non-pregnant women (Nagaraj et al., 2018; Siegman et al., 2017). It is also reported in neonates (Godftred and Cichi, 2015; Ahmed, 2014).

- Then the references should be listed in alphabetical order (by the name of the first author) in the references section at the end of the document.
- All references cited in the text document must be listed in the “References List”, & all references listed in the “References List” must be cited in the text.
- The following format should be followed when citing a journal article,

Author surname, initial (s). (Year). Article title. *Journal title, volume number*(issue number optional), page numbers.

Examples

Fleming, D. W., and Cochi, S. L. (1985). Pasteurized milk as a vehicle of infection in an outbreak of listeriosis. *New England Journal of Medicine, 312*(7): 404–407.

McLauchlin, J. (1990). Listeriosis during pregnancy and in the newborn. *Epidemiology and Infection*, *104*: 181–189.

Mead, P. S., Slutsker, L., Dietz, V. et al. (1999). Food-related illness and death in the United States. *Emerging Infectious Diseases, 5:* 607–625.

- For citations from books, websites, or other sources, the researcher is advised to check author's guidelines of any relevant journal, or he can access this site:

https://www.mendeley.com/guides/apa-citation-guide

- The following software packages are available commercially to be used for references management:

- EndNote
- Mendeley
- RefWorks
- Zotero
- CiteULike

9. APPENDICES

9.1 Title page

RAKMHSU- Research & Ethics Committee

Ras Al Khaimah, UAE

Date: DD/MMM/YYYY

Research Application/ Title Page

Title of the project

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……
……

Name of the submitting faculty ……

Department		College	
Phone No.		E-mail	
Signature			

Type of Research (tick the appropriate box)

☐ Undergraduate Research

☐ Postgraduate Research/ Which Degree program? ……

☐ Faculty research

Investigators

Name	Institution	Study Role	Signature

Are you applying (or applied) for funding of this project? Yes No

If "Yes", indicate source(s) of funding:

Forwarded by Chairperson & Dean (Signatures)

Chairperson	**Dean**

9.2. Template of the research proposal

RAKMHSU Research & Ethics Committee

Ras Al Khaimah, UAE

Date: DD/MMM/YYYY

Research Proposal

Title:

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Plain Language Summary of project

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1. Background (*includes problem statement & literature review in less than 1000 words)*

2. Rationale

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3. Research question

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4. Aim & objectives

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5. Methodology

5.1. Study design

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5.2. Study area/ Setting

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5.3. Study Duration

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5.4. Study population

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5.5. Inclusion & Exclusion criteria

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5.6. Determination of Sample Size

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5.7. Sampling method

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5.8. Data Collection Tools (materials & procedure)

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5.9. Data Analysis Plan

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5.10. Limitations/ expected challenges

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5.11. Ethical Considerations

1. How will participants be recruited or cases be identified?

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2. How will informed consent be obtained from participants?

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3. What procedures will be followed to maintain confidentiality and privacy of participant's data?

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4. Provide details of who will have access to the data.

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5. Risks to participants or researchers. Indicate "Yes" or "No" for each question and give explanation for your answer.

Question	Yes	No	Explanation
I. Does this study involve physical risk to participants?			
II. Does this study involve psychological risk to participants?			
III. Does this study involve release of a sensitive or personal information?			
IV. Are there medical conditions, which increase the participants risk while in the study?			
V. Does this study require participants to release information, which may reveal illegal activity?			
VI. Are there any risks to the researchers?			
VII. Are there any other risks to participants, researchers or any other individuals?			

6. In undertaking this research, do any "conflict of interest" issues arise?
   Yes/No

7. Are the participants in a dependent relationship with the investigators?
   Yes/ No

8. Are the participants working as staff at the institution where the study is taking place?
   Yes/ No

6. Work-plan

Proposed start date: …/ …/ …

Activity	**Period**

7. Budget (OPTIONAL)

8. References List (Use Vancouver or APA reference style)

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9. Appendices

- Questionnaire
- Consent form

9.3. Informed Consent Form

Template for Creating an Informed Consent Form

General comments

- This is an ethical requirement for every research involving human subjects. It includes description of all research aspects that are essential for the participant to take a voluntary decision whether to participate or to decline participation in the study.
- While preparing the form, it is always better to keep the language and vocabulary simple and straightforward.
- While submitting research proposals to RAKMHSU-REC, the researchers should adhere to this template. The wordings mentioned under each section are optional and can be altered. The highlighted statements are explanatory. You can delete and replace them with appropriate ones that suits your project.
- Except for the "Consent" section, all other sections of the form should be stated in second person (e.g., you will receive…").
- The researcher should make sure that the form includes all components relevant to the study.

Informed Consent Form

Informed Consent Form for [Name the target group of participants]

Title of the Research [**Insert the title here**]

Principal Investigator Details

[Full Name]
[Official Address]
[Phone Number-Official/Personal]

General Information to the Participants

- You are kindly requested to participate in this research study.
- Before giving consent for this study, you should understand what it is about and what it will involve and you should know its relevance. Therefore, please go through the information below and sign only if you wish to participate.
- You have absolute freedom to ask the researcher for more explanation if any of the sections is not clear or need additional information.
- You have absolute freedom not to answer any/all questions or withdraw from the study at any time if you feel that your participation may cause harm or pose a risk to you.

Purpose

[Briefly describe the purpose of the study here.]

Participant selection

[Explain why this participant has been chosen for this study. For example, you can mention that you are inviting all adults with diabetes mellitus who attend X Hospital to participate in this study.]

Procedures

[Briefly describe the procedures that will be used in this study. If audiotaping or videotaping is involved, clearly state that and then describe the nature of use and the confidential storage of these files.]

Duration

[Mention the time commitments for the participant. Mention the need for follow-up if relevant.]

RISKS

[List any/all expected risks to participants while taking part in this study. Highlight any/all procedures which will be considered to reduce the expected risks.]

Benefits

[List all benefits which will be achieved by conducting this study. These includes; benefits to participants, others, or advancement of scientific knowledge.]
[Mention the following statement if the study offers no benefits to the participants, "You will receive no direct benefit for taking part in this research."]

Confidentiality

Your personal information/ responses will remain confidential. All efforts will be made to retain the anonymity of data. The records will be used only for research purposes.

Compensation

[Indicate what each participant will receive while taking part in the study. If the participant will not receive any compensation, this section may be deleted from the template.]

Contact information

You are free to contact the principal investigator or any of the people involved in the research. You can also contact the RAKMHSU-REC (+971 72269000, Ext No. 249) for more discussion related to your participation.

Voluntary participation

Your participation in this study is voluntary. Your signature is required only if you wish to participate in this study. However, you can withdraw from the study at any time without giving any reason.

Consent

I hereby confirm that I have read and completely understood all the above information and have had adequate opportunity to ask questions to the researcher. I understand that my

participation is voluntary and I can withdraw from the study at any time without giving any reason and without cost. I understand that I can receive a copy of this form. I hereby voluntarily agree to participate in this study.

Participant's Signature: ……. Date……..

Investigator's Signature: ……. Date…….

9.3. نموذج الموافقة المستنيرة

استمارة الموافقة المسبقة

هذا نموذج الموافقة المستنيرة ل[اسم المجموعة المستهدفة من المشاركين]

عنوان البحث [أدخل العنوان هنا]

تفاصيل الباحث الرئيسي

[الاسم الكامل]
[العنوان الرسمي]
[رقم الهاتف - رسمي / شخصي]

معلومات عامة للمشاركين

•يرجى التكرم بالمشاركة في هذه الدراسة البحثية.
•قبل منح الموافقة على هذه الدراسة ، يجب أن تفهم ما هو موضوعها ، وما ستشمله ، وما هي أهميتها. لذلك يرجى الاطلاع على المعلومات أدناه والتوقيع فقط إذا كنت ترغب في المشاركة.
•لديك الحرية المطلقة في أن تطلب من الباحث المزيد من التوضيح إذا كان أي من الأقسام غير واضح أو بحاجة إلى معلومات إضافية.
•لديك الحرية المطلقة في عدم الرد على أي / جميع الأسئلة أو الانسحاب من الدراسة في أي وقت إذا شعرت أن مشاركتك قد تسبب ضررًا أو تشكل خطرًا عليك.

الغرض

[صف بإيجاز الغرض من الدراسة هنا].

اختيار المشاركين

[وضح سبب اختيار هذا المشارك لهذه الدراسة. على سبيل المثال ، يمكنك الإشارة إلى أنك تدعو جميع البالغين المصابين بداء السكري الذين يحضرون إلى مستشفى X للمشاركة].

الإجراءات

[صف بإيجاز الإجراءات التي ستستخدم في هذه الدراسة. في حالة وجود تسجيل صوتي أو تصوير بالفيديو ، اذكر ذلك بوضوح ثم قم بوصف طبيعة الاستخدام والتخزين السري لهذه الملفات].

المدة الزمنية

[اذكر الالتزامات الزمنية للمشارك. اذكر الحاجة للمتابعة إذا لزم الأمر].

المخاطر

[اذكر أي / جميع المخاطر المتوقعة للمشاركين أثناء المشاركة في هذه الدراسة. تسليط الضوء على أي / جميع الإجراءات التي سيتم النظر فيها للحد من المخاطر المتوقعة].

الفوائد

[اذكر جميع الفوائد التي ستتحقق بإجراء هذه الدراسة. وتشمل هذه ؛ الفوائد للمشاركين ، أو الآخرين ، أو تقدم المعرفة العلمية].

[اذكر العبارة التالية إذا لم تقدم الدراسة أي فوائد للمشاركين ، "لن تحصل على أي فائدة مباشرة للمشاركة في هذا البحث]".

السرية

ستبقى معلوماتك الشخصية / ردودك سرية. ستبذل كل الجهود للحفاظ على سرية البيانات. سيتم استخدام السجلات فقط لأغراض البحث.

التعويضات

[وضح ما سيحصل عليه كل مشارك أثناء المشاركة في الدراسة. إذا لم يتلق المشارك أي تعويض ، فقد يتم حذف هذا القسم من القالب].

معلومات للتواصل

لك الحرية في الاتصال بالباحث الرئيسي أو أي من الأشخاص المشاركين في البحث. يمكنك أيضًا الاتصال بـ RAKMHSU-REC (+971 72269000 Ext No. 249) ، لمزيد من المناقشة المتعلقة بمشاركتك.

المشاركة الطوعية

مشاركتك في هذه الدراسة طوعية تمامًا. توقيعك مطلوب فقط إذا كنت ترغب في المشاركة في هذه الدراسة. ومع ذلك ، يمكنك الانسحاب من الدراسة في أي وقت ، ودون إبداء أي سبب.

الموافقة

أؤكد بموجب هذا أنني قرأت وفهمت تمامًا جميع المعلومات المذكورة أعلاه وأتيحت لي الفرصة الكافية لطرح الأسئلة على الباحث. أفهم أن مشاركتي طوعية ويمكنني الانسحاب من الدراسة في أي وقت دون إبداء أي سبب وبدون تكلفة. أفهم أنه يمكنني تلقي نسخة من هذا النموذج. أوافق بموجب هذا طواعية على المشاركة في هذه الدراسة.

توقيع المشارك: ..... تاريخ.....

توقيع الباحث الرئيسي: ..... تاريخ.....

Further reading

- Elaine M. Boyle. Writing a good research grant proposal. Paediatrics and Child Health 2020;30(2):52-56.
- Cuschieri S, Schembri-Wismayer P, Grech V. WASP (Write a Scientific Paper): Writing a Research Grant – 2, Drafting the Proposal. Early Human Development 2018;127:109-111.
- Lathlean J, Gerrish K. The Research Process in Nursing [Internet]. Vol. Seventh edition edited by Kate Gerrish, Judith Lathlean. Chichester, West Sussex, UK: Wiley-Blackwell; 2015 [cited 2020 Jun 12].
  Available from: http://search.ebscohost.com/login.aspx?direct=true&db=nlebk&AN=946114&site=ehost-live
- Steven R. Terrell. 2016. Writing a Proposal for Your Dissertation. THE GUILFORD PRESS New York. 296 pp
- Baguma SD, Anandajayasekeram P and Puskur R. 2010. Writing convincing research proposals and effective scientific reports: A learning module. Part A: Writing a convincing proposal. ILRI (International Livestock Research Institute), Nairobi, Kenya. 174 pp.