1.1 NHREC PROTOCOL APPLICATION FORM

THE FEDRAL MINISTRY OF HEALTH
DIRECTORATE FOR HEALTH RESEARCH
THE NATIONAL HEALTH RESEARCH ETHICAL REVIEW COMMITTEE
RESEARCH PROPOSAL FORM

For office use only

Proposal No: _____

Date of submission: _____

Type of Review: Exempt ☐ Expedited ☐ Full board ☐

Part A

1. Study Title

_____
_____
_____
_____
_____

2. Short Description of the Study 100 words

_____
_____
_____
_____
_____
_____
_____

PART B

Principal Investigator/ Applicant

Name:
Affiliation:
Current position:

Address:	Email Address
Office Phone :	Mobile Phone:
Signature	

1. Co- Investigator 1

Name:	
Affiliation:	
Current position:	
Address:	Email Address
Office Phone :	Mobile Phone:
Signature	

2. Co- Investigator 2

Name:	
Affiliation:	
Current position:	
Address:	Email Address
Office Phone :	Mobile Phone:
Signature	

For more co- investigators copy and attach in a separate page

Part C

1. **Type of Study**

Undergraduate ☐

Postgraduate ☐ MSC☐ PhD☐

Other ☐ Specify _____

2. **Aims /Objectives**

1. General Objectives

2. Specific Objectives

3. **Background and Rationale (less than 500 words)**

4. **Methodology**

1. Study Design

2. Study Area: (provide justification for selecting the study area)

3. Study Population:(Demographic profile, sampling frame, inclusion and exclusion criteria)

4. TheSample (sampling technique,sample size calculation , inclusion and exclusion criteria)

5. Participants /Study Subjects

1. Vulnerability:

   Does your study involve any of the following?

Children	☐
Elderly individuals	☐
Mentally disabled	☐
Prisoners	☐
Pregnant ladies	☐
Refugees	☐
Underprivileged population	☐

2. Recruitment Plan – Describe how will you identify, approach, and inform, the potential participants about the study recruit

3. Privacy and Confidentiality Protection Plan

6. The Consent Process

Please describe the following details about consenting the subjects

1. Who will obtain informed consent and their qualifications?

2. How, where and when will the consenting take place?

3. How will you determine if the potential research subject meets the eligibility criteria?

4. Does your inclusion include illiterate subjects? If yes, please explain how will you obtain their signature?

5. Will a surrogate or legal authorized representative be needed to sign the consent?

6. Do require a waiver of informed consent? If yes then explain the justification for waiving the informed consent?

7. Implementation

1. Describe the study procedure?

2. Describe the number and duration of study visits?

3. Describe the duration of the study?

4. Describe briefly data analysis plans?

5. Describe whether you are collecting or storing personal identifiers and if yes please justify the need for personal identifiers. Also provide your plan to dispose such identifiers.

8. Risks

1. Identify the risks of the study to the research participants (Risks include physical, social, psychological, financial, legal and political risks)

2. How will risks be minimized

9. Direct and Social Benefits

1. Describe the potential direct benefits to the research subjects(payment is not a benefit)

2. Describe the social value of your research.

10. Payment

If you are considering giving patients incentives or compensations please specify

1. Amount :

2. Payment Schedule :

11. Study Management

1. Study oversight plan

2. Safety Management

3. Reporting unanticipated problems

4. Collaborators:

12. Budget (Personal/ consumables/ transportation/ field expenses……etc.)

13. Time plan

14. References

15. Appendices

1. Sample Consent Form

2.Data collection tools (questionnaire, survey etc…..) including questioners