GUILDELINE FOR SUBMISSION OF THESIS PROTOCOL

(MD/MS/MDS/M Sc/MPH/DM/M Ch/PhD/ FELLOWSHIP)

Submit two copies of the all documents along with Covering letter to the PG Coordinator, at Desk Number 2, Office of the Dean Academics, BPKIHS, Phone ext 2278.

The documents should also be submitted in a soft copy in two PDF files separately as an attachment to the PG Coordinator E-mail:

pgcoordinator.academics@bpkihs.edu

PDF 1(Signed Copies):

1. Covering letter (through the Head of the Department)
2. Dated undertaking that the work has not started and that the work will be done as per Good clinical practice guidelines
3. Dated undertaking that the scales/ questionnaire/scores to be used are not copyright or permission to use them has to be obtained
4. First or signed page/s of the format
5. Any other signed document/s

PDF 2:

1. Copy of Thesis Protocol except signed first page/s
2. All relevant Participant Informed Consent form (PICF) in English and Nepali
3. All relevant Participant Information Sheet (PIS) in English and Nepali
4. Questionnaire/ Participants Record Form
5. Any other relevant annexure
6. Budget (if applicable)

The PG Resident/student must submit the final research protocol to the PG Coordinator after presentation in the department with the recommendation of the Thesis guide, Co-guides and Head of the department within stipulated date and time. The department must invite all co-guides for their input. The Guide, Co-guide/s and The Head must ensure that the project has been reviewed both from the scientific and ethical point of view.

The submission should be made in the prescribed Format with signatures of all Guide, Co-guide and Head of the department. The submission must be accompanied with Participant Informed Consent form and Participant Information Sheet in a simple layman's language in a narrative form. Please ensure that all documents are enclosed and the pages are numbered.

No thesis work will be/can be started unless ethical clearance and approval from protocol committee are obtained. Please bear in mind that no retrospective/post facto approval will be provided to research projects. Research protocol not submitted through proper channel will not be considered for process and the resident/candidate is responsible for delayed process.

The PG Coordinator will hand over the research proposals to the Member Secretary, Institutional Review Committee (IRC) for the review process and Ethical clearance. IRC will send the comments/ suggestions to the resident/student for necessary corrections.

Reply resubmission: While submitting replies raised by IRC, the candidates are advised to mention the Research reference number/s and also attach a copy of the comments of IRC. The revised proposal must be submitted through the Chief guide and Head of Department. These changes should be incorporated as a soft copy to member secretary, IRC through email:irc@bpkihs.edu

Letter of approval and Ethical clearance: Start your thesis work only after getting approval and ethical clearance letters from PG Coordinator and Member secretary, IRC.

Amendment submission: While submitting amendments in protocols a covering letter must be provided clearing stating the changes and a soft copy of the same is also needed.

Project submission date: Submit the research project on time as mentioned in your prospectus.

General guidelines

1. Pages: Generally minimum 13 pages (appendices extra)
2. Font size:12 (Arial Font); A4 size paper; Line spacing: Double space
3. Margins: At least 2.5 cm on all sides& Justified

Title Page
Certificate from Institution (Guide, co- guide, HOD)
Summary of Protocol
Introduction/ background including lacunae in existing knowledge
Brief review of literature
Aims and Objectives of research project
Patients/ Subjects/ Sample size/Materials and Methods including plan of statistical evaluation
Index of references (**Vancouver** system of references) limit to 20-30 most pertinent and recent references
Appendix (Data Sheet, Case record form, Consent form, etc.)

Check list for Attached documents:

a. **Covering letter, through proper channel**
b. **Copy of the detailed protocol (two copies and soft copy)**
c. **Protocol signed by the Chief guide/co-guide and head**
d. **Participant Informed Consent form (PICF) in English and Nepali**
e. **Participant Information Sheet (PIS) in English and Nepali**
f. **Questionnaire/ Participants Record Form**
g. **Style of referencing in Vancouver style**
h. **Undertaking that the work has not started and that the work will be done as per Good clinical practice guidelines**
i. **Undertaking that the scales/ questionnaire/scores to be used are not copyright or permission to use them has to be obtained**
j. **Soft copy of all the documents in PDF in two separate files (signed and unsigned)**

Cover page

Title of thesis

PROTOCOL SUBMITTED FOR……..(Course)

DEPARTMENT OF _____
B.P.KOIRALA INSTITUTE OF HEALTH SCIENCES
DHARAN, NEPAL

Name of the student
Month, year

Title of thesis (Write in title case or capital letters)

PROTOCOL OF THESIS SUBMTTED TO B.P.KOIRALA INSTITUTE OF HEALTH SCIENCES TOWARDS PARTIAL FULFILMENT OF THE REQUIREMENT OF THE DEGREE OF _____ (SUBJECT)
(BATCH YEAR TO YEAR)

Candidate:

(Signature)
Name of candidate
Designation & Department
Email ID

Chief guide: **----------**
(Signature) Name
Designation & Department Institution, Place
Email ID

Co-guide: **----------**
(Signature)
Name
Designation & Department
Institution, Place

Co-guide: **----------**
(Signature)
Name
Designation & Department
Institution, Place

Head of Department: **----------**
Name
Designation & Department
Institution, Place
Email ID

SUMMARY OF POST GRADUATE THESIS PROTOCOL

1. **Study title:**
2. **Name of the student:**
3. **Department:**
4. **Name of Chief Guide:**
5. **Name of Co-guide/s & Department/s:**
6. **Email ID of the candidate & Chief Guide:**
7. **Rationale of the research**:
8. **Primary &Secondary (or general & specific) Objectives:**
9. **Research Hypothesis (if relevant):**
10. **Material & Methods:**
    - **(a) Whether study involves Human/animals or both :**
    - **(b) Population/ participants**:
    - **(c) Type of study design:**
    - **(d) Setting**:
    - **(e) Sample Selection criteria:**
        - **(i) Inclusion Criteria :**
        - **(ii) Exclusion Criteria :**
    - **(f) Expected sample size :**
    - **(g) Control groups :**
    - **(h) Probable duration of study:**
    - **(i) Parameter/Variables to be measured:**
    - **(j) Outcome measures**:
    - **(k) Statistical methods to be employed :**
    - **(l) Ethical clearance :**
    - **(m) Permission to use copyright questionnaire/Pro forma 11. For Intervention trial**
    - **a. Permission from Drug Controller of Nepal required/ Not required/Received/ Applied when_____**
    - **b. Safety measure**
    - **c. Plan to withdraw**
11. **Maintain the confidentiality of subject**
12. **References:**
13. **Whether available resources are adequate:**
14. **Other resources needed:**
15. **Cost involved (Approx in NRS)**
    - **a. Investigations**
    - **b. Surgery**
    - **c. Drugs**
16. **Who will bear the cost of the requirements? Patient/ Project/ Other agencies/_____**
17. **ANNEXURE:**
    - **a. Participants record form (clinical data sheet)**
    - **b. Participant Information sheet**
        - **i. Attached English**
        - **ii. Attached Nepali**
    - **c. Participant Informed consent form**
        - **i. Attached English**
        - **ii. Attached Nepali**

1. INTRODUCTION

*It should be focused on the **research question** and should be directly relevant to the **objectives** of your study. Organize the information in paragraphs, presenting the more general aspects of the topic early in the introduction (**background**), then narrowing down toward the more specific information that provides context (**statement of problem** and **rationale);** ending with the **research question/hypothesis**. It should answer the question of why and what: **why the research needs to be done** and **what will be its relevance**. Mention how you will utilize the results on future patients / subjects?*

2. REVIEW OF LITERATURE: Be brief and limit to relevant and current literature.

3. OBJECTIVES: *(It should be precise and include following information - Participant, Intervention/exposure, Comparison/control& Outcome).*

a. Primary Objectives:

b. Secondary objectives:

4. Research Hypothesis (if relevant)

5. MATERIAL AND METHODS

a. Type of study design:
b. Population/Participants:
c. Population/Participant's selection criteria
  I. Inclusion criteria:
  II. Exclusion criteria:
d. Control group(s)
e. Setting: Hospital / community
f. **Probable Study period:**
g. Ethical Clearance:
h. Conflict of Interest:
i. Sampling Technique
j. Method of Randomization (in case of RCT)and blinding

METHODS (*INTERVENTION/PROCEDURE)*:

a. **Instruments / Questionnaire**
b. **Frequency and duration of intervention/follow up of subjects(if relevant)**
c. **Procedures and schedules**
d. **Dosage, formulations, schedules, duration of drug treatments/surgical technique, suture (if relevant)**
e. **Withdrawal reason(s)**
f. **Stopping rules:**
g. **Adverse response / side effect**
h. **Procedures and conditions for breaking the codes**

OUTCOME MEASURES

a. **Primary Outcome Measures**:
b. **Secondary Outcome Measures**
c. **Flow diagram**

DATA MANAGEMENT AND STATISTICAL ANALYSIS

a. **Data handling**
b. **Coding**
c. **Monitoring**
d. **Statistical methods proposed**
e. **Calculation of the sample size**:

6. REFERENCES in Vancouver style please

7. ANNEXURES

a. **Participant record form**
b. **Participant Information sheet: English & Nepali**
c. **Participant Informed consent form: English & Nepali**

PARTICIPANT INFORMED CONSENT FORM

Protocol Number:_____
Participant Identification number for the study:_____
Title of the research:_____

Name of the candidate:_____, aged _____ years,
address_____. Telephone: (residence)
_____(mobile) _____(friend/parents)_____ Email_____,

The content of the information sheet dated_____ that was provided have been read carefully by I me/explained in detail to me, in a language that I comprehend, and have fully understood the contents. I confirm that I have had the opportunity to ask questions.

The nature and purpose of the study and its potential risks/ benefit and expected duration of the study, and other relevant details of the study have been explained to me in detail. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal right being affected.

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from BPKIHS. I give permission for these individuals to have access to my record.

I hereby give consent to take part in the above study and allow to perform the procedure and any other medical service that may become necessary during the procedure.

I also consent for medical photographs/ video and I have been informed that these photographs/ video will be used without revealing the identity. I understand that these along with the information I provide may be used in my medical record, for purpose of publication in textbook or medical journal and dissertation purpose, or for medical education.

The consent form has been signed by me when I was not under the influence of any drugs.

Patient's signature _____ Researcher/Doctor's signature _____

Date:

Witness signature _____

If illiterate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions and to understand the nature of study. I confirm that the individual has given consent freely.

Thumb print of participant

Researcher/Doctor's signature _____

Date:

Witness signature _____

Two copies of this participant Informed Consent Form should be made for Patient and researcher

PARTICIPANT INFORMATION SHEET

The research project must be accompanied by the participant information sheet addressed to the patient or participant or parent/guardian, in case of minor. While formulating the participant information sheet, investigator must provide the subjects with the following information in English and Nepali, in a simple layman's language, in a narrative form, directed to participant covering all the information, which can be understood by them:

a. **Research Title:**
b. **Introduction of the candidate and guide and co-guide:**
c. **Importance of the research:**
d. **Purpose of *this research***
e. **Participant selection**
f. **Voluntary Participation**
g. **Expected duration of the subject**
h. **Any benefits to be expected from the research to the subject or to others**
i. **Any risk to participation the subject associated with the study**
j. **Procedures and Protocol**
k. **Maintenance of Confidentiality**
l. **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**
m. **Amount of the blood sample etc in quantity, to be taken should be mentioned**
n. **Cost and source of investigations, drugs, surgery must be mentioned**
o. **Sharing the Results**
p. **Whom to Contact(address, mobile number, email, etc)**
q. **Self certification should be given that translation to vernacular is accurate**

PARTICPANT INFORMATION SHEET &PARTICIPANT INFORMED CONSENT FORM

IN NEPALI