Application for Approval of Research Proposal

Research Title:

Research Unit

Shahid Gangalal National Heart Centre (SGNHC)

Bansbari, Kathmandu, Nepal

Telephone no: 977-01-4370622/4371322/4371374 Ext :620

Email : ircsgnhc@gmail.com, irb@sgnhc.org.np

Section A

(To be retained in Research unit office)

Data Sheet

1. Name and Title of Principal Investigator responsible for the proposed research:

   Title: …….

   Full Name: …….

   Designation: …….

   Department: ……..

   Telephone No.: …… Email: ……...……

   Passport size photograph (Compulsory)

   Please attach a copy of your curriculum vitae and list of publications relevant to the proposed research)

2. Name and Title of Co-Investigator (if any) for the proposed research:

   Title: …….

   Full Name: …….

   Designation: …….

   Department: …….

   Telephone No.: …… Email: ……...……

   (Please attach a copy of your curriculum vitae and list of publications relevant to the proposed research)

3. Name and Title of Co-Investigator (if any) for the proposed research:

   Title: …….

   Full Name: …….

   Designation: …….

   Department: …….

   Telephone No.: …… Email: ……...……

   Please attach a copy of your curriculum vitae and list of publications relevant to the proposed research)

4. Expected duration of the research project:
5. Tentative date of initiating the project:
6. Funded by SGNHC: (if yes then section E is must, if no then section E is not needed)

For Official Use Only

(Please see the checklist before registration of the application form)

Research Unit	**Institutional Review Board**
Registration No.& Date:	Registration No.& Date:
Date and number of time modified:	Approval status: Approved/ Approved with minor modification/ Not approved
Approval date:	Ethical Clearance Date:
Name of Reviewer:	Name of Reviewer:
Tentative date of starting the research :	
Amount of budget approved:	
Signature of Member Secretary:	Signature of Member Secretary:

ACCEPTANCE OF GENERAL CONDITIONS AND DECLARATION

1. I/we hereby certify that the above-mentioned statements are true.
2. I/we have read and understood the guidelines for submission of research proposal.
3. I/we agree to accept responsibility for the scientific conduct of the research project.
4. I/we shall provide progress reports **6 monthly** and agree to submit final report to Research Unit, SGNHC within three months from the date of completion of the project.
5. If a grant is awarded as a result of this application, I/we agree to maintain a stock book for purchases made for the project and I/we shall submit the complete statement of account within three months of the termination of the project, and at any other time as required by the accounts section. I/we also agree to acknowledge the grant in any publication resulting from the project if it is approved for financial assistance.
6. I/we declare that the project will be conducted as per the highest ethical standards applicable to animal/human experiments.
7. If the research is terminated, for any reason, I/we will notify Research Unit, SGNHC of this decision and provide the reasons for such actions.

Signatures (with date):

a) Principal Investigator:

Full Name_____Signature _____ Date: _____

b) Co-investigator (s):

Full Name_____Signature _____ Date: _____

Remarks from the HOD of the Principal Investigator:

Full Name_____

_____

Date: Signature of the HOD

Remarks from the HOD of the Co-Investigator:

Full Name_____

_____

Date: Signature of the HOD

(All signatures should be on the same sheet)

Recently updated Curriculum Vitae of Principal Investigator & Co-investigators

Format for
CURRICULUM VITAE OF THE INVESTIGATOR(S)

1. Name :
2. Designation :
3. Address for correspondence :
4. Date of birth :
5. Educational qualifications :
6. Research experience in the related field (if any)

Section B

Reg no.:

Research Proposal Description

(To be sent for review)

1. Research Title: (maximum 20 words)

2. Summary of the Research Proposal (maximum 500 words, one sentence each for each point):

Rationale: **Aim:** **General Objectives:** **Specific Objectives:** **Research Hypothesis (if relevant):** **Materials & Methods:** **(a) Whether study involves humans/animals or both:** **(b) Population/ participants**: **(c) Type of study design:** **(d) Human study:** **(i) Inclusion Criteria:** **(ii) Exclusion Criteria:** **(e) Expected sample size:** **(i) Sample size calculation** **(f) Control groups:** **(g) Probable duration of study:** **(h) Setting**: **(i) Parameter/Variables to be applied/measured**

(j) Outcome measures:

(k) Rationale for statistical methods to be employed:

3. Details of Research Proposal

3.1 Background of Study (maximum 1000 words) including review of recent studies relevant to your current proposal:

3.2 Statement of the Problem and Rationale / Justification for the current study. (maximum 500 words)

3.3 Research Aims & Objectives: *It should be precise and should include following information - Participant, Intervention/exposure, Comparison /control & Outcome).*

3.3.1 General

3.3.2 Specific

3.4 Research Hypothesis (if relevant)

4. Research Design and Methodology

4.1 Research Method

Qualitative ☐ Quantitative ☐ Combined ☐

4.2 Study Variables:

4.2.1 Predictor / baseline variables

4.2.2 Outcome variables

4.3 Research Design (Specify):

4.3.1 Type of study

4.3.2 Conceptual Frame work

4.4 Study Site and Its Justification:

4.5 Study Population (Specify):

4.6 Sampling Methods/Techniques (Specify):

4.7 Sample size (with justification):

4.8 Criteria for Sample Selection:

4.9 Data Collection Technique / Methods (Specify):

4.10 Data Collection Tools/ Dummy Tables: (please attach in annexes along with participant/case record form):

4.11 Pre-testing the Data Collection Tools (if relevant):

4.12 Validity and Reliability of the Research (if relevant): Mention, how will you assess validity and reliability?

4.13 Potential Biases (if relevant):

4.14 Limitation of the Study (if relevant):

4.15 Possible Challenges of the Study:

5. Plan for Supervision and Monitoring:

6. Plan for Data Management and Statistical Analysis:

7. Expected Outcome of the Research:

8. Plan for Dissemination of Research Results:

9. Plan for Utilization of the Research Findings (optional):

10. Work Plan *(should include duration of study, tentative date of starting the project and work schedule / Gantt chart):*

Section C

Ethical Consideration

11. Regarding the human participants:

11.1 Are human participants required in this research? If yes, provide justification.

Yes ☐ No ☐

Justification

11.2 How many participants are required for the research? Explain.

11.3 What is the frequency of the participants' involvement in the research? Explain.

What is the follow up schedule?

11.4 Clearly indicate the participant's responsibilities in the research. What is expected of the research participants during the research?

11.5 Does your study involve vulnerable members like – pregnant women / newborn / children below 12 years / physically or mentally challenged / persons with HIV / AIDS / IV drug users? If yes, provide justification.

11.6 Are there any risks involved to the participants? If yes, identify clearly what are the expected risks for the human participants in the research and provide a justification for these risks.

11.7 Are there any benefits involved to the participants? If yes, identify clearly what are the expected benefits for the participants.

12. Informed Written Consent Form / Ethical Issues (please attach in annex):

It has two parts: a. Information sheet (to be explained and given to participants) and b. Consent form (consent by participant and retained by PI).

(Both a and b will be linked to the guidelines mentioned in the page 15 and 16)

(Informed Consent form should be submitted in Nepali & English and in the language appropriate to the research participants)

Section D

Annexure

Annexes should include

a. CV of PI
b. CV of CO-I(if any)
c. Conceptual Framework
d. Work Schedule/ Gantt Chart
e. Information Sheet
f. Budget Form
g. References
h. Participant/Case record form
i. Data Collection Instruments including questionnaires
j. Data Collection tools/Dummy Tables
k. Participant Information Sheet and Participant Informed consent Form
l. List of abbreviations,

Section E

(BUDGET)*

<u>* Required for application of SGNHC Research Grant</u>

Source: Self ( ), SGNHC ( ), Other ( )

13. If SGNHC, mention the total amount of funds (in Nepalese currency) requested for proposed research project:
14. If, Other, please clarify the source:

Budget Items

- Personnel Person(s) x Rate x Duration Total (NRs.)
- Non consumable supplies (if relevant)
  (Include major and minor equipment etc.)
- Consumable and expendable supplies
  (Include stationery, photocopying, etc.)
- Clinical expenses (if relevant)
  (Include Drugs, Special Clinical Investigations like Clinical Tests, Patients Cost i.e. Transportation/Reimbursement of Travel Expenses etc.)
- Field / Community related costs (if relevant)
  (Include refreshment cost for focus group discussion and other related costs etc.)
- Travel cost within the country (if relevant) for investigator.
  (Include airfare, Bus fare, Vehicle hiring, Fuel etc.)
- Report Writing (Include Printing and Binding)
- Contingency (5 %)

GRAND TOTAL:

- Other sources of supplementary funds (if any)
  If yes, indicate the amount in Nepalese currency:
  Name of funding organization / agency:
  Address of funding organization / agency:
  Telephone No.: Fax No.: Email:

Explanation and Justification of Budget Items

Principal Investigator: .....……

Certified by Account Officer: .....

Guidelines to develop Information sheet and Consent form

Statements required in the Participant Information Sheet include:

Logo of the institute

The research project must be accompanied by the Participant Information Sheet addressed to the patient or participant or parent (in case of minor). This sheet should be provided to the participants. While formulating the Participant Information Sheet, investigator must include the following information in a simple layman's language and in a narrative form, directed to the participant.

- Research Title:
- Introduction of the candidate and guide and co-guide:
- Importance of the research:
- Purpose of this research:
- Participant selection
- Voluntary participation
- Expected duration of the subject
- Any benefits to be expected from the research to the subject or to others
- Any risk to participation the subject associated with the study
- Procedures and proposal
- State, how you will guarantee confidentiality of the research participants. storage and disposal of information.
- Mention a statement that the human participants can withdraw from the study at any time without giving reason and without fear. State clearly how the participants can opt out of the study.
- If the study is a clinical trial a detailed explanation of the trial procedures including all invasive procedures should be included as listed below:

→The potential or direct benefits (if any) for the research participants;
→Alternative procedure(s) or treatment(s) that may be available;
→The risks, discomforts, and inconveniences associated with the study;
→Provisions for management of any adverse reactions;
→The provisions of insurance coverage for any permanent disability or death caused directly by the investigational treatment or procedure;
→Amount of the blood sample in quantity expressed in terms of teaspoonful, to be taken should be mentioned.
→Cost and source of investigations, drugs, surgery must be mentioned
Sharing the results
→The provision of including the name and address, including telephone numbers of person to be contacted in case of adverse events or for any information related to the trial.
→Self-certification should be given that translation to vernacular is accurate
Is the research sensitive to the Nepali culture and the social values? If yes explain

Statements required in the Participant Consent Form include:

→Logo of the institute
→Name and department of PI
→Title of the proposal
→Mention a statement indicating that the participant has understood all the information in the information form and is willing to volunteer / participate in the research.
→Mention a statement that the participant can withdraw from the study at any time without giving reason and without fear. Also indicate if the participant has to pay for any procedure or will be paid by PI/ Institute. Whether participant will receive any incentive for the participation or it will be voluntary.
→Please indicate who is responsible for obtaining informed consent from the participants in this research study.

- Signature/ thumb space for the research participant, a witness, and the date.

FLOW CHART SHOWING PROCEDURE FOR APPROVAL OF RESEARCH PROPOSALS