Scheer Memorial Adventist Hospital

Institutional Review Committee

Application for Ethical Approval of Research Proposal

Title:

Registration Form (For Official Use Only)

Registration No.:
Registration Date:
Approved Date:
Name of PI:
Total Budget of the Project:
IRC Processing Fee:
Research Site:
Tentative Date of Initiating the Project:
Duration of the Research Project:
Name of Reviewers:
Signature and Seal of IRC:

NOTE:

- Please read the instructions carefully and complete all the sections (that apply to your research)
- Type all the entries in English, Times New Roman Font, size 12.
- Submit the completed application at IRC office, Scheer Memorial Adventist Hospital.

Research Proposal Description

Do you have funding for your project? (Circle the answer)

a. Yes

b. No

What collaboration have you done for this research project?

1. Summary of the Proposed Research Protocol (Up to 200 words)

2. INTRODUCTION:

2.1. Background:

(Relevant to the topic, preferably recent evidences to indicate the need of the study)

2.2. Statement of the Problem / Rationale / Need for the study:

Statement of the problem

Rationale for the study

Need for the study

2.3. Research Hypothesis / Research Question:

2.4. Objectives of the Research:

Primary Objective (General):

Secondary Objective (Specific):

2. 5 Variables of the Study

2. 6 Conceptual Framework

2.7 Operational Definition

2.8 Delimitation of the study

3. METHODS/ METHODOLOGY

3.1. Research design

3.2. Study Site with Rationale

(Explain where the research will be conducted (e.g.: hospital ward, outpatient department or community, with rationale for site selection)

3.3. Population and Sampling

Target population, Sample size, sample unit

3.4. Sampling Technique

Inclusion Criteria

Exclusion Criteria

3. 5. Instrumentation/Data collection tools

Validity

Reliability

3.6. Data Collection Procedure/s

3.7. Plan for data analysis

3.8. Plan for Supervision and Monitoring:

3.9. Plan for dissemination of the research

4. Work Plan (include study duration, tentative date of starting the project and work schedule)

Work	**Duration/ Date**	**Remarks**
Protocol writing		
Anticipated time of protocol approval		
Clinical trial registry (if appropriate)		
Data collection and data entry		
Data analysis		
Manuscript / Thesis book preparation		
Submission to journal / Dissemination		

5. ETHICAL CONSIDERATION

(Ethical principles are based on Declaration of Helsinki. Please refer to explanations of the ethical consideration in the Declaration of Helsinki)

10.1. Ethical issues	**Yes/ No**	**Justification if yes**
a. Are human participants included in the study?		
b. Are **vulnerable members** of the population required for this research? (includes age under 18, pregnant women etc)		
c. What risks are involved for participants? Clearly identify expected risks for human participants in the research. Provide justification for these risks.		
d. What benefits may be involved for participants? Clearly identify expected benefits for the participants.		(e.g.: If participants lack knowledge, they will be taught about immunizations after the interview.

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

5.3. <u>Obtaining the Consent:</u>

5.3.a. How will the informed consent be obtained from the research participants?

5.3.b. Who will obtain the consent from the study participants?

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5.3.c. Is there anything being withheld from the research participants at the time the informed consent is being sought? Mention "YES" or "NO"

Yes

No

INFORMED CONSENT FORM / ETHICAL ISSUES:

Statements required in the Informed Consent Form include:

i. Clear **purpose of the research**
ii. **Voluntary participation**
iii. **Rights to withdraw** from the study: A statement that the human participants can withdraw from the study at any time without giving reason and without fear.
iv. Statement to **assure confidentiality** of the participant's details.
v. Statement **of compensation** that might be given to the research participant and or their community (if any).
vi. Risk of participation
vii. Benefits of the participation
viii. A statement indicating that the participants have **understood** all the information in the consent form and are willing to volunteer / participate in the research.
ix. Signature space for the research participants, a witness signature and the date.

Note- Informed Consent form should be submitted in English language and in the language appropriate to the research participants, example- Nepali.

6. BUDGET PLAN (Include the details of anticipated budget for your research. Only few examples of the items are listed, you may add items based on the nature of your research. Please note that the figures in the table are just examples)

SN	Items	Unit	Unit cost (NRs)	Total (NRs)
1	Ethical clearance			
2	Cost for printing/ photocopy			
3	Transportation			
4	Laboratory cost			
5	Payment to research assistant			
6	Others			
	Total			

Annexes

2. Annexes should include
    i. References
    ii. Data Collection Instruments including data collection forms, self-reports outcome measures, questionnaires etc
    iii. Information Sheet and Informed Consent Form (Should be in English and also in the language of participants)
    iv. List of abbreviations
    v. Recently updated Curriculum Vitae of Principal investigator and Co-investigators.
    vi. For Students, approval letter from the Academic Supervisor
    vii. Agreement letter to submit a hard and soft copy of your final research paper to the IRC of SMAH.