Covering letter

Date:

To

Member Secretary

Madhesh Institute of Health Sciences

Institutional Review Committee (MIHS-IRC)

Subject: Application for ethical approval

I am / We are going to conduct a research project entitled [Write your title here] at [Mention your study site here] . I am / we are fully aware about the ethical concerns regarding this research and will maintain them throughout the course of study.

I/We wish to submit the above proposed project for ethical review by MIHS-IRC. I/we have enclosed all the required documents mentioned in the checklist.

Thanking you with anticipation of your early response.

Yours Sincerely,

Signature:

Name of the Applicant:

Date:

Ethical Approval Research Proposal Form

Research Proposal Approval Format

Research Title:

MADHESH INSTITUTE OF HEALTH SCIENCES

INSTITUTIONAL REVIEW COMMITTEE (MIHS-IRC)
Janakpurdham, Madhesh Province, Nepal
Email: irc.secretary@mihs.edu.np , Website: https://mihs.edu.np/

For Official Use Only

(Please see the check list before Registration of the application form)

Registration No.:
Registration Date:
Approved Date:
Name of PI:
Total Budget of the Project:
MIHS-IRC Processing Fee:
Research Site:
Tentative Date of Initiating the Project:
Duration of the Research Project:
Name of Internal Reviewer:

Protocol submission checklist

S.N	Documents enclosed (when applicable, in a separate file)	Y/N/NA
1	Cover Letter to MIHS–IRC for Ethical Clearance	
2	Declaration by the Principal Investigator	
3	Declaration by the Departmental Head/ Hospital Director	
4	If setting is other institution/community, acceptance letter from that institution/concerned authority	
5	Full proposal signed by candidate, guide, co-guide	
6	Timeline/work plan/Gantt Chart	
7	Estimated budget	
8	Approval letter from department/institution (as per need)	
9	Consent form (as per MIHS- IRC format)	
10	Information sheet (as per MIHS-IRC format)	
11	Questionnaires/tools	
12	Other documents as per need	

Part – I

Passport size photograph

Administrative Information

1. Research Title:

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

   Nationality:

   Citizenship Number with district name from where it was obtained (only for Nepali)

   Passport Number (only for non-Nepali citizen):

   Signature: Date:

   Postal Address:

   Telephone No.:

   Mobile No.:

   Fax No.:

   e-mail:

   Alternate e-mail:

3. Full name of the Institution associated with the Principal Investigator (if applicable) :

   Designation:

   Postal Address (if different from the address given above):

Telephone No.:

Fax No.:

e-mail:

Website:

4. Declaration of the head of the Institution (if applicable)

   If the proposed research is approved, we will allow him/her to conduct the research in this institution.

   Signature: Date:

   Last (Surname) Middle (if any) First name Designation:

   Name of the Institution

   Contact/Postal Address:

   Telephone No.:

   Fax No.:

   Institutional e-mail:

   Website:

5. Name and Title of Co-investigators responsible for the proposed research (Use the similar format if more than one):

   Passport size photograph

   Last (Surname) Middle (if any) First name Nationality:

   Citizenship Number with district name from where it was obtained (only for Nepali)

   Passport Number (only for non Nepali citizen): Affiliated Institution (if applicable):

Designation:

Signature: Date:

Postal Address (if different from the address given above):

Telephone No.:
Fax No.:

e-mail:

(Use additional sheet if necessary)

6. List the name(s) and institutional affiliation to the researcher(s) (other than co-investigator) to assist your project in Nepal and abroad (if any)

Name *Institution and Address*

(a)

(b)

(Use additional sheet if necessary)

7. List the name(s) of Nepali researcher(s) (other than co-investigator) or Nepalese Institution/hospital/NGO(s) etc. from whom you may seek co- operation (if any)

(a)

(b)

(Use additional sheet if necessary)

8. List major equipment(s) in relation to your research project you plan to bring/import to Nepal (If applicable)

(a)

(b) .....

(Use additional sheet if necessary)

8.1 List details of all specimen(s) (if any) that you may transport from Nepal in relation to your research.

(a)

(b)

(c)

(d)

8.2 Country of Destination:

Name of Institution:

8.3 Mode of Transportation of Specimen

8.4 How will you ensure duplicate specimens remain in the country?

.....

(If necessary use additional sheet)

9. Is this research part of your

Thesis?

Yes/No……..

If yes,

For what degree and in which subject? From which university? From which country?

Part II

Financial Information

10. **Research Title:**

11. **Name of the funding organization:**

Contact information of funding organization or agency:

Postal Address:

Telephone No.:

Fax No.:

e-mail:

Contact person at the funding organization or agency:

Last (Surname) Middle (if any) First name Designation:

Total amount of funds (in NRs / US $) allocated for the proposed research project:

Itemized budget (in detail) and justify the resources required for the proposed research work (*use additional sheet*)

Part – III

Research Proposal Description

12. Research Title:

13. Proposal Summary (maximum 500 words):

14. Introduction:

14.1 Background of Study (maximum 500 words):

14.2 Statement of the Problem and Rationale / Justification (maximum 500 words)

14.3 Conceptual framework

14.4 Research Objectives / purpose / aim of the study: General

Specific

15. Research Design and Methodology Research Method

Qualitative Quantitative Combined

Variables:

Type of Study (Specify):

Study Site and Its Justification:

Study Population (Specify):

Study Unit:

Sampling Methods / Techniques (Specify):

Sample size (with justification):

Criteria for Sample Selection:

Data Collection Technique / Methods (Specify):

Data Collection Tools: (please attached in annex) Pre-testing the Data Collection

Tools (if applicable):

Validity and Reliability of the Study Tools:

Potential Biases (if applicable):

Limitation of the Study:

16. Plan for Supervision and Monitoring:

17. Plan for Data Management and Analysis:

18. Expected Outcome of the Research:

19. Plan for Dissemination of Research Results:

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

    How is the research project going to strengthen the research capability of the host institution: Nepali Researcher (if submitted from aboard):

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

Part – IV

Ethical Consideration

22. Regarding the human participants:

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

Yes (*provide justification*) No

How many participants are required for the research? Explain.

What is the frequency of the participant's involvement in the research? Explain.

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

Are vulnerable members of the population required for this research? If yes, provide justification.

Are there any risks involved for 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.

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

23. Informed Consent Form / Ethical Issues:

Statements required in the Informed Consent Form include:

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 the study.

A statement guaranteeing the confidentiality of the research participants.

If required, a statement on any compensation that might be given to the research participant and or their community.

A statement indicating that the participants has understood all the information in the consent form and is willing to volunteer / participate in the research.

Signature space for the research participants, a witness, and the date.

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

Obtaining the Consent

How informed consent is obtained from the research participants?

Verbal Written

Please indicate who is responsible for obtaining informed consent from the participants in this research study?

……..……

Is there anything being withheld from the research participants at the time the informed consent is being sought?

If yes, explain

……

Is the research sensitive to the Nepali culture and the social values?

Yes No Explain.

……

Is health insurance *(if applicable)* being made available to the research participants? If yes, please provide the necessary insurance data.

……

(Include in consent form)

Part – V

ACCEPTANCE OF GENERAL CONDITIONS AND DECLARATION BY THE PRINCIPAL INVESTIGATOR

I hereby certify that the above-mentioned statements are true, I have read and understood the regulation of the Madhesh Institute of Health Sciences Institutional Review Committee (MIHS-IRC) on the approval of research proposal and will act in conformity with the said regulation in all respects.

If the research is terminated, for any reason, I will notify MIHS-IRC of this decision and provide the reasons for such actions. I will provide MIHS-IRC with a written notice upon the completion of the research as well as a final summary/full report of the research study. If I publish the results in a journal, I shall acknowledge the MIHS-IRC and shall provide the Institute with three copies of any such articles.

……

Signature of Applicant Date: ……

ANNEXURE A: Participants Information Sheet (Both English and Nepali Language)

ANNEXURE B: Research Instruments/Tool (both Nepali and English Language as indicated)

ANNEXURE C: Informed consent form (Should be in both Nepali and English language. A generic consent form, add similar assent form where applicable is given below)

ANNEXURE D: Letters of approval

ANNEXURE E: **Other Documents as Needed**:

Madhesh Institute of Health Sciences

Janakpurdham, Madhesh Province, Nepal

Participant Information Sheet

Namaskar

I am ……., presently working at …….. of …… as a …….. The main purpose of this research is to study …….. I would like to give you some information of this study and I humbly request you to participate in this study. If in any place you find it difficult to understand, please stop me so that I can explain in detail.

Title: …….

Purpose of study: To study ……

Methods: (Write in accordance with your study) There are three parts of the study. The first part will deal with your sociodemographic details, the second part will be related to information regarding ……. while in the third part we will investigate the ……. You will be asked few questions related to study and the investigator will tick on the response you have said.

Expected duration of the participation and frequency of contact: You will have to be present only once for ……. minutes during the study.

Benefits: There will not be direct benefit for you but the information obtained will be helpful for future awareness programme.

Risks: There will not be any risk to you during and after participation.

Payment: Participation in the study is totally voluntarily. You may withdraw from the study in the middle too.

Use of data: The information obtained from you will be stored properly and will not be used in other studies.

Contact details:

Principal Investigator: ……

……..

Mobile No: ……

MIHS, +977 ……

Website: www……..

Financial support: ……

मधेश स्वास्थ्य विज्ञान प्रतिष्ठान

जनकपुरधाम, मधेस प्रदेश, नेपाल

सहभागीको सूचना पत्र

नमस्कार

म ....., हाल .....मा .....बिभागमा ..... पदमा कार्यरत छु। यस अनुसन्धानको उदेश्य ..... बारेमा अध्ययन गर्नु हो। म यसको जानकारी दिँदै यहाँहरुलाई यस अध्ययनमा सहभागी हुन आग्रह गर्दछु। यसमा लेखिएका कुरा बुझ्न गार्हो भएमा मलाई रोकेर सोध्नुहोला र म यहाँलाई त्येसको वारेमा अझ बिस्तृत रुपमा बताउने छु।

अनुसन्धानको शीर्षक: .....

अनुसन्धानको उदेश्य: .....

अनुसन्धानमा गरिने कार्यको जानकारी: (Write in accordance with your study) यस अध्ययनमा ३ भाग छन्। पहिलो भागमा सामाजिक तथा व्यक्तिगत स्वस्थ सम्बन्धि प्रश्नावली, दोस्रो भागमा .....सँग सम्बन्धि प्रश्नावली र तेस्रो भागमा ....। अनुसन्धानकर्ताले सम्पूर्ण प्रश्नहरु पढेर सुनाउने छ र दिइएको सुहाउदो जवाफमा यहाँहरु कै अगाडी टिक लगाउने छ।

भेटघाट र लाग्ने समय: यस अनुसन्धानमा यहाँ को एकपल्ट मात्रै सहभागिता हुनु पर्ने छ र यसको समय सिर्फ ..... मिनेट हुने छ ।

फाइदा: यस अध्ययनले यहाँलाई प्रत्यक्ष्य रुपमा फाइदा नपुर्याएता पनि यसबाट प्राप्त जानकारीले जनचेतनामुलक कार्यक्रमको लागी सहयोग पुग्नेछ ।

जोखिम: यस अनुसन्धानमा सहभागी हुँदा यहाँको स्वस्थलाई अनि व्यक्तिगत रुपमा कुनै जोखिम हुनेछैन ।

दस्तुर- यस अनुसन्धानमा सहभागी हुँदा यहाँले कुनै प्रकारको रकम दिनु पर्ने छैन ।

सहभागिता: यस अध्ययनमा यहाँको सहभागिता स्वैच्छिक हुनेछ। यहाँ कुनै पनि समय यस अध्ययनलाई छोड्न सक्नु हुने छ र यहाँलाई कुनै पनि नकारात्मक असर पर्ने छैन।

जानकारीको प्रयोग: यहाँले दिनु भएको सम्पूर्ण जानकारीहरु गोप्य राखिनेछ र यस अध्ययनको प्रयोजन को लागी मात्रै प्रयोग हुनेछ।

<u>सम्पर्क</u>

प्रमुख अनुसन्धानकर्ता: .....

सम्पर्क मोबाइल नो: .....

मधेश स्वास्थ्य विज्ञान प्रतिष्ठान, +977 .....

www.....

सहयोग: .....

(Write in accordance with your study) :

\+

SNo

Date: ………………………..

Informed Consent

Title of this project: ……

BACKGROUND AND PURPOSE: The purpose of this research project is to……
……..

The general nature of this study entitled " ……." conducted by …….. has been well explained to me. I understand that my responses will be confidential or that anonymity will be preserved and that my name will not be associated with any results of this study. Potential risks resulting from my participation in this project have been described to me. I know that I may refuse to answer any question asked and that I may discontinue participation at any time. I have also been informed that I need not have to pay in this study participation.

SIGNATURE: I confirm that the purpose of the research, the study procedures, the possible risks and discomforts as well as benefits have been explained to the me and I agree to participate in the study.

_____ _____

Date Signature

Principle Investigator: Mr/Ms/Dr ……..

……..

Telephone No.: ……..

MIHS, Janakpurdham, Madhesh Province, Nepal

क्रमसंख्या..... मिति.....

मंजुरिनामा पत्र

अनुसन्धानको शिर्षक: .....

अनुसन्धानको उदेश्य: .....

मलाई यस '' .....'' नामको अनुसन्धानात्मक अध्ययनमा संग्लग्न गराईएको कुरा मलाई जानकारी छ।

म यस अनुसन्धानको लागि पूर्ण सहभागिता जनाउदछु । उक्त अध्ययनको बारेमा मैले राम्ररी बुझेको छु र यसमा भाग लिन म राजीखुशी छु। यस अध्ययन को लागि सोधिएका प्रश्नहरुको सहि उत्तर दिन तयार छु र मैले दिएका विवरणहरु गोपनिय राखिने कुरामा विस्वस्त छु । त्यसैले कसैको दबाब बिना म आफ्नो स्वइच्छाले यस कार्यक्रममा आफ्नो सहभागिता जनाउन चाहान्छु । यस अध्ययनबाट आफुलाई रुचि नलागेको खण्डमा कुनैपनि बेला बाहिरिन सकिने कुरा पनि मलाई जानकारी गराईएको छ। साथै येस्मा मैले कुनै प्रकारको रकम दिनु नपर्ने बारेमा पनि थाह छ|

यदि मलाई यस अध्ययन सम्बन्धि केहि जिज्ञासा भएको खण्डमा मैले .....मा कार्यरत .....लाई (.....) सम्पर्क गर्नेछु ।

सहभागीको नाम र हस्ताक्षर .....

प्रमुख अनुसन्धानकर्ता

.....

.....

मधेश स्वास्थ्य विज्ञान प्रतिष्ठान

जनकपुरधाम, मधेस प्रदेश, नेपाल

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Assent Form for Parental Consent

Title of Research: [Insert Research Title Here]
Principal Investigator:
Institution:
Contact Information: [Your Contact Information]
Date:

Introduction: We are inviting your child to participate in a research study entitled "[Insert Research Title Here]." This form provides information about the study and asks for your permission for your child to take part. Please read this form carefully and feel free to ask any questions before making your decision.
Purpose of the Study: The purpose of this study is to [Briefly describe the purpose of the research in simple terms].
What Will Happen in the Study: If you agree to allow your child to participate, your child will [Explain what the child will be asked to do, how long it will take, and any other relevant procedures in clear, simple language].
Risks and Benefits: Risks: The potential risks or discomforts of participation in this study are [Describe any potential risks, or if there are none, state "minimal to none"].
Benefits: The potential benefits of participating in this study include [Describe any direct or indirect benefits].
Confidentiality: All information collected in this study will be kept confidential. Your child's identity will not be revealed in any reports or publications. The data will be stored securely and only accessible to the research team.
Voluntary Participation: Participation in this study is completely voluntary. You and your child have the right to withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled.
Consent and Assent
By signing this form, you agree that:
You have read and understood the information provided in this form.
You have had the opportunity to ask questions and have them answered.
You give your permission for your child to participate in this study.

If you agree, please sign below.

Parent/Guardian's Name: _____
Signature: _____
Date: _____
Child's Name: _____
Signature of Child (if applicable): _____
Date: _____
Investigator’s Name: _____
Signature: _____
Date: _____

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