MADHESH INSTITUTE OF HEALTH SCIENCES

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STANDARD OPERATING PROCEDURE (SOP)
FOR
MADHESH INSTITUTE OF HEALTH SCIENCES
INSTITUTIONAL REVIEW COMMITTEE (MIHS-IRC)

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1.1. Purpose

1.1.1. To review and make appropriate decision on research proposals submitted to MIHS-IRC
1.1.2. To maintain the dignity, rights, safety and well-being of research participants
1.1.3. To promote scientific and ethical health research

1.2. Scope

1.2.1. The SOP is a valuable guideline for student researchers, faculties and external researchers who wish to do research in MIHS

1.3. Functions of the MIHS-IRC

1.3.1. To support and facilitate UG and PG academic research (Thesis) in different academic programs
1.3.2. To review research proposals submitted to MIHS
1.3.3. To supervise or monitor the implementation of health research projects approved by MIHS-IRC
1.3.4. To organize health research workshop/trainings.
1.3.5. To organize orientation program for new members and reviewers of IRC on the ethical review process
1.3.6. To conduct continuing education on research and reviewing for existing members.

1.4. Composition of MIHS-IRC

1.4.1. The MIHS-IRC will be formed with members from diverse background. Potential candidates should be sought from among the senior health professional possessing at least postgraduate qualification in a related scientific discipline, preferably having received training in ethics and the ethical review process.
1.4.2. The committee consists of minimum 7 to maximum 15 members paying an attention to age, gender and discipline balance.
1.4.3. The committee should include at least one member which is layperson and not affiliated to the institution.

1.5. Persons with expertise in following disciplines will be eligible for MIHS-IRC member

1.5.1. Public Health/Epidemiology/Research Methodology
1.5.2. Biomedical and Laboratory Sciences
1.5.3. Clinical Sciences
1.5.4. Basic Sciences
1.5.5. Nursing
1.5.6. Community Medicine
1.5.7. Behavioral and Social Sciences
1.5.8. Biostatistics
1.5.9. Pharmacy and Pharmacology

1.5.10. Law/Teaching/Journalism/Community Leaders

1.6. Appointment of Members of MIHS-IRC

1.6.1. The academic committee of MIHS will appoint a MIHS-IRC Chairperson, affiliated and non-affiliated members.

1.6.2. The academic committee has the right to replace the MIHS-IRC chair/members in case of their resignation/disqualification. Such an appointment should be done as early as possible and not later than three months.

1.6.3. Members should sign the acceptance of appointment and confidentiality agreement regarding the meeting deliberation, applicant's information's on research participants and related matters. The MIHS-IRC administration staff should also sign the confidential agreement.

1.7. Duration of appointment

1.7.1. The duration of appointment should be made for tenure of three years, with a provision of reappointment based on his/her performance.

1.7.2. The tenure could be extended for one more term based on the performance and needs of the organization. However, the tenure will not be extended for a third consecutive term.

1.7.3. While revising the MIHS-IRC members, at least 50% of the members of the existing IRC members will be retained in order to ensure continuity of experience. Not more than 50% of the members retire at a time in order to allow smooth continuity of MIHS-IRC.

1.7.4. The appointment letter of MIHS-IRC chair/member should specify the following:

a. Subject area representing specific roles and responsibilities for each member of the committee

b. Duration of appointment

c. Conditions of appointment

1.8. Resignation of membership

1.8.1. A MIHS-IRC chair/member who does not want to continue as member of the MIHS - IRC, he/she can submit resignation to the academic committee of MIHS or to the member secretary (the member secretary will forward this to the academic committee of MIHS).

1.8.2. Membership on the IRC will cease when resignation is accepted.

1.8.3. Replacement of the vacant membership will be initiated by the academic committee of MIHS.

1.8.4. For any voluntary resignation a prior notice of at least one month should be given to the academic committee of MIHS.

1.9. The membership will automatically expire if the member:

1.9.1. Continuously absent in the meeting for more than 3 times without valid reasons

1.9.2. Deviates from the norms and standards of the committee

1.9.3. Non-compliance or resignation from the position
1.9.4. Is convicted by a court of law for a criminal offence

1.10. Responsibilities of the MIHS-IRC

1.10.1. Responsibilities of MIHS-IRC towards NHRC

1.10.1.1. The MIHS-IRC will be effective immediately after the approval of NHRC's Executive Board.
1.10.1.2. The MIHS-IRC will be supervised, monitored and evaluated by the NHRC's Ethical Review Board.

1.10.2. The MIHS-IRC will submit the following information to NHRC:

1.10.2.1. List of all the approved research proposals.
1.10.2.2. Progress report (six monthly) on all health research being conducted under the IRC's.

1.10.3. The MIHS-IRC will forward the following research proposals to NHRC for approval.

- Research proposed at the national or international levels.
- Research conducted in multiple centers.
- Externally sponsored/funded research.
- Clinical trials.

1.10.4. NHRC will be notified of any approved health research projects that was subsequently suspended or terminated.

1.10.5. The MIHS-IRC will report annually to NHRC information relevant to its procedures including:

- Membership/Membership changes
- Numbers of meetings
- The number of protocols presented, the number approved, and the number rejected
- Monitoring procedures in place and any problems encountered; and
- Complaint's procedures and number of complaints handled.

1.10.6. Responsibilities of members of MIHS-IRC

1.10.6.1. Chairperson

- The chairperson will be responsible for conducting committee meetings
- Lead all discussions and deliberations pertinent to the review of research proposals
- The chairperson signs documents and communication related to IRC functioning

- In case of anticipated absence, the chairperson may appoint an IRC member as acting Chairperson or oldest member as acting chairperson.
- If chair is the applicant for obtaining the approval from MIHS-IRC, he/she should not be present in the meeting and the decision letter should be signed by the MIHS-IRC member secretary.
- If MIHS authority is the applicant for obtaining the ethical approval from MIHS-IRC, a decision letter should be signed by the MIHS-IRC chair.

1.10.6.2. Member Secretary

- To accept research study/project proposals
- To prepare, maintain and distribute the study files
- To schedule and organize IRC meetings after Consultation with the Chairperson
- To prepare and maintain meeting agenda and minutes.
- To maintain IRC record and archive them
- To communicate with IRC members and investigators
- To notify the PI regarding IRC decisions
- To arrange the trainings of personnel and IRC members
- To organize the preparations, review, revision and distributions of SOPs and guidelines
- To ensure adherence of IRC functioning as per SOPs
- If member secretary is the applicant for obtaining the approval from MIHS-IRC, he/she should not be present in the meeting and the decision letter should be signed by the MIHS-IRC chair

1.10.6.3. IRC members

- To attend IRC meetings and participate in discussions and deliberations for appropriate decisions.
- To review, discuss and consider research proposals submitted for evaluation.
- To monitor Serious Adverse Event reports and recommend appropriate action(s)
- To review the progress reports and monitor ongoing studies.
- To maintain confidentiality of the documents and deliberations of IRC meetings.
- To declare any conflict of interest, if any.
- To participate in continuing education activities in biomedical ethics

1.10.6.4. Clinician

- To provide medical inputs on protocol: Informed consent forms and other aspects like standard of care, Placebo use, Sample size, dosing, Concomitant medications, prohibited medications, risk & benefit to patients.
- To provide suggestion regarding inclusion & exclusion criteria

1.10.6.5. Basic Medical Scientist

- To provide scientific aspects of the study: Investigator's brochure, safety of drug, Pharmacodynamics and pharmacokinetics of drug, lab procedures, study design, sample size, use of biological samples
- To see: preclinical data and whether protocol adequately addresses issue of all this matter or not, Qualification of PI and GCP training certificate, Details of SAEs and reporting time limit from PI, All ethics issues and other procedures involved in the study

1.10.6.6. Legal Expert

- To review Clinical Trial Agreement (CTA): Parties involved, scope of agreement, responsibilities of parties and payment details
- To review incidence of SAE included or not
- To see whether any clause is violating the norm, Confidentiality, dispute resolution,
- Updated with regulatory requirements and interpretation of the same

1.10.6.6.1. **Social Scientist / NGO representative / Philosopher / Ethicist**

- To see Community perspective, Informed consent process, Compensation, Design of trial whether it is discomfort to subjects, Number of blood samples, Post-trial access to involved community, Confidentiality, Vulnerable population, Recruitment process.

1.10.6.6.2. Layperson

- Participate in IRC meetings
- Review, discuss and consider the ethical merits of the informed consent form and process of research proposals/protocols submitted for evaluation
- Declare any conflict of interest

MIHS-IRC secretariat

- The IRC secretariat should work in close coordination with the IRC chair, IRC member-secretary, and academic committee of MIHS and is responsible to:
- Develop a roster of subject-specific expert reviewers with approval from MIHS-IRC;
- Collect and archive CVs, confidentiality agreements, and CoI from MIHS-IRC chair, member-secretary, members, and reviewers;
- Validate the financial section of the proposal in line with the grant agreement for payment of the ethical review processing fee;
- Maintain the electronic database of the proposals, archiving and tracking procedures, including preliminary screening and verification of the submitted proposals as per the checklist;
- Prepare, maintain, and distribute proposals to primary and technical reviewers. Communicate with the reviewers and investigators for

clarifications, and responses; revise until the final approved proposal is archived;

- Prepare the meeting agenda in consultation with MIHS-IRC Chair and member-secretary, communicate with the MIHS-IRC chair/member secretary/members and coordinate/organize ERB, and expedited review committee meetings regularly;
- Prepare and present the summary of the proposals (Title, PI, Sponsor, Site, Risk assessment Matrix, etc.) for discussion in the MIHS-IRC and expedited review sub-committee meetings;
- Draft the meeting minutes, share with members, member-secretary, and chair for review/revision/editing and final approval. The final minute should be signed by the Chief of the MIHS-IRC secretariat, Member Secretary, and ERB Chair before further communication;
- Prepare the decision letter according to the approved minute. Obtain signature from member secretary/ MIHS-IRC chair.
- Organize MIHS-IRC documentation, communication, and archiving;
- Plan and organize monitoring site visits of the ongoing studies;
- Update and share relevant and contemporary ethical issues to the MIHS-IRC;
- Facilitate to organize meetings/workshops/training related to research ethics capacity building and IRC periodic review;
- Carry out the additional responsibilities given by MIHS-IRC chair/member-secretary and academic committee of MIHS;
- Organize IRC accreditation sub-committee meetings and inspection visits for accreditation of IRCs; and
- Organize the complaint handling meeting and communicate with members and concerned stakeholders.

1.10.7. Office Management

- The list of the name of IRC members should be displayed in front of the IRC office
- It will have a separate MIHS-IRC secretariat provided by institute to carry out regular administrative work.
- It will be equipped with filing cabinet (which will be labelled properly), locker for confidential documents, computer, printer and communication facilities (internet, telephone- STD/ISO and fax).
- A fully furnished seminar room with T/L equipment such as LCD projector should be made available for research related review meetings, education and training.

1.10.8. Qualification of IRC members

- All IRC members should hold an appropriate educational degree, trainings and research experience in health-related research process.

- It is mandatory that the IRC members should receive introductory training on the ethics in health research.

1.10.9. Fund management

- It will have its own fund management process, separate account and fund disbursement mechanism. Despite the 'research fund ' granted by the institute, revenue will be generated through research proposals registration and review process. An institutional overhead charge of up to 5% of MIHS-IRC ethical review process charge can be levied on researches involving human subjects and hospital data base.
- Each proposal submitted to MIHS-IRC will not be charged for ethical review process as per the MIHS-IRC rule.
- External donations, university grants could also be the source of revenue.
- At the onset, seed money of NPR 500 ,000 will be established as a research fund.

1.11. Capacity building of MIHS-IRC and its Secretariat

- The academic committee of MIHS will conduct regular training programs related to research ethics to MIHS-IRC members at least twice a year. This is essential for a hands-on experience of reviewing the research proposals and responsible conduct of research. Additionally, all the members of MIHS-IRC will be oriented with the ethics-related guidelines and SOPs upon appointment and each time there is any update/revision.

2. Ethical clearance application and review process (MIHS-IRC-SOP-00-08-2024)

2.1. Submission of application for ethical clearance

2.1.1. A researcher, who wants to do study/data collection /research in MIHS, must get ethical clearance from MIHS-IRC.

2.1.2. Principal investigator or correspondent researcher should submit the application on behalf of whole research team with given standard format. Application should be addressed to member-Secretary of MIHS-IRC in a prescribed format. (See Annexure I). Researchers of other institutions must submit Ethical clearance of parent institution/NHRC along with application and proposal in a given standard format.

2.1.3. Applicant should submit one electronic and one hard copy of research proposal along with application.

2.1.4. Only two copies of proposal (initial hard copy and approved hard copy) will be archived by MIHS-IRC. All the review process will be done electronically in track change form. Each stage of track change format will be archived and labelled properly in the computer.

2.1.5. Only those applications fulfilling all requirements will be accepted for review.

2.1.6. Deficits in the application should be informed to the applicants within one weeks of submission. Incomplete applications should be resubmitted duly completed.

2.1.7. If corrections are made in the proposal that is already submitted and approved, the researcher must submit in writing the changes made with reasoning to the committee. The proposal will be reviewed again in the IRC, taking the corrections into consideration during the re-approval process.

2.1.8. Application should include the Informed Consent Form as a separate copy which is to be used while undertaking the research. In addition, this may include a translation copy, in a local language if applicable.

2.2. Documents required for the ethical clearance application

2.2.1. Filled application form with signature and date in MIHS-IRC format.

2.2.2. Current version of curriculum vitae of principal investigator and co-investigators with academic qualification and work experiences.

2.2.3. The protocol of the proposed research in the given format with the supporting documents. (A copy of valid and reliable research tools, questionnaires etc)

2.2.4. A copy of informed consent with detailed description of the process of giving the information to the research participant and its content, process of obtaining the consent, the person responsible for obtaining the informed consent and documentation of the signature of the researcher/research participant and /witness if applicable.

2.2.5. A signed statement by the researcher stating that he or she will abide by the ethical principles of research.

2.2.6. Ethical clearance letter from the parent institution/NHRC if the researcher is from other institution.

2.3. Panel of Experts

2.3.1. MIHS-IRC will prepare a list of potential experts who are capable and interested to review the research proposals. These experts could be a specialist in specific diseases, in health systems, health research methodologies or legal or ethical aspects or member of special interest groups so that they can provide special expertise in the review and finalization process to the research proposals submitted to MIHS-IRC.

2.4. Identification of reviewer

2.4.1. It is mandatory to present thesis proposal for all Post Graduate Students to MIHS-IRC to get ethical approval. The committee might approve the proposal of faculty, staffs or external researcher, also thesis of undergraduate students based on proposal submitted. However, the MIHS-IRC committee can ask for presentation if required to get ethical approval.

2.4.2. The MIHS-IRC Chairperson/Member-Secretary will decide the reviewer for a particular proposal. Depending upon the nature of the proposal, it can be reviewed by more than one reviewer.

2.4.3. The reviewer(s) may exercise all the authorities except disapproval. Research may only be disapproved following review by the full committee. The review committee will adopt a method of keeping all members advised of research studies that have been approved by the expedited review process.

2.4.4. A checklist will be sent to the reviewer in order to maintain the consistency and objectivity of the review process.

2.4.5. Depending upon the nature of research proposal, the committee can invite the researcher to present the proposal to the panel of experts and its members. This will help the committee to understand the proposal in a better way and guide the researcher appropriately.

2.5. Ethical concerns during the review process

2.5.1. Potential research related risks to the participants are reasonable in relation to the anticipated benefits that might be expected from participating in research study and to the importance of the knowledge that may result. An attempt will be made to minimize those risks.

2.5.2. Selection of participants will be equitable. If the research involves vulnerable population, additional safeguards should be included in the research to protect the rights of these people.

2.5.3. Informed consent will be sought. The informed consent format is in a language understandable by the participant. The participants can withdraw from the research at any time without explanation.

2.5.4. There will be adequate provisions to protect the privacy of participants and confidentiality of data will be maintained.

2.5.5. The research plan makes adequate provisions for monitoring the data collected to ensure the safety of participants.

2.5.6. The mechanism for compensation in case of injury will be well documented.

2.5.7. The MIHS-IRC will receive periodic and final report on the research and will make a copy of this available to the NHRC-IERB.
2.5.8. The financing process will be transparent.
2.5.9. A written approval from the hospital directors/department heads stating access to data base has to be taken into consideration.

Exempt from review

- Researchers can apply for exemption from review in certain situations. Based on the risk categorization, the MIHS-IRC secretariat will put forward the proposal to the MIHS-IRC meeting for the necessary decision.

Conditions for exemption from the review:

a) Research that involves accessing and analyzing data available in the public domain;
b) Research on anonymous or non-identified data/samples;
c) Observation of public behavior when information is recorded without any link and disclosure of the person under observation; and
d) Quality assurance and quality control audit in the institution.

Flow Chart

	Activity	Responsibility
Step 1	Receive the submitted documents and forward to the chair immediately for initial review	Secretariat
Step 2	Review and determine per criteria that the protocol is exempt from IRC review within 5 days.	Chair
Step 3	Prepare a letter of exemption to the PI indicating the protocol is exempted from IRC review	Secretariat
Step 4	Keep copies of all related documents and compiles them in their respective protocol files	Secretariat
Step 5	Update the IRC database	Secretariat

Description of detailed procedures:

- The secretariat receives the submitted documents and forwards them to chair immediately for initial review.
- The application documents received from investigator submission are checked using the protocol checklist (Annex-1) as guide. After checking the documents are complete, the secretariat signs a copy of the application form

to acknowledge the receipt of the documents and return a copy to the PI or duly designated representatives.

- The chair reviews and determines per criteria that the protocol is exempted from IRC review within 5 days.
- The IRC secretariat prepares a letter of exemption to the PI indicating the protocol is exempted from IRC review.

Expedited review

- The Academic Chief of the MIHS will form an expedited Review Sub-committee (consisting of affiliated and non-affiliated members).
- MIHS-IRC chair will be the coordinator and others will be the sub-committee members. Emphasis will be laid on balancing gender and discipline while forming the Expedited Review Sub-committee.
- The Expedited Review Sub-committee's recommendations are presented to MIHS-IRC for final approval.
- Expedited Review Sub-committee only reviews proposals that are grouped into 'less than minimal', 'minimal risk', and 'low risk' categories. Proposals, which are grouped into the 'higher risk' category, are sent to MIHS-IRC to decide upon further actions on the approval process as per SOP.
- Urgent implementation of the protocols during public health emergencies and disasters, requiring fast-track approval may also be considered for expedited review as per the following procedure:

a) Secretariat prepares the list of proposals for Expedited Review Sub-Committee meeting in consultation with Member Secretary and Expedited Review Sub-Committee Coordinator.
b) Secretariat prepares and presents the summary of the proposals (Title, PI, Sponsor, Site, Risk assessment, etc.) for discussion in the Expedited Review Sub-committee meetings.
c) Secretariat drafts meeting minutes and submits them for review/editing and approval by Expedited Review Sub-Committee coordinator.
d) Secretariat prepares a list of proposals approved by the Expedited Review Sub-Committee meeting and forwards them to MIHS-IRC full board meeting for endorsement.

Process flow

	Activity	Responsibility
Step 1	Receive the submitted documents for initial review and forward them to Chair for assessment	Secretariat
Step 2	Determine that the protocol is for expedited review and assigns reviewers	Chair

Step 3	Forward the copies of protocols and related documents for expedited review to the assigned primary reviewers the next working day	Secretariat
Step 4	Do the expedited review and submit the decision to the Secretariat	Reviewers
Step 5	Communicate the decision for approval or revision to the Principal investigator through a letter of notification within the last 2 weeks of the month	Secretariat
Step 6	If modifications are required, revise the protocol or related documents and submit to the MIHS-IRC	Principal Investigator
Step 7	Review revisions and recommend if for approval	Reviewers
Step 8	Prepare an approval letter to be signed by the chair/secretariat and sent to the Principal Investigator	Secretariat
Step 9	Report results of expedited review to full board as part of the meeting agenda	Secretariat
Step 10	Keep copies of all related documents and complies them in their respective protocol files	Secretariat
Step 11	Update the MIHS-IRC database	Secretariat

Description of detailed procedure

- The secretariat receives the submitted documents for initial review and forwards them to the chair for assessment. The application documents received from investigator submission are checked using the protocol checklist as guide. After checking the documents are complete, the Secretariat sign a copy of the application form to acknowledge receipt of the documents and return a copy of submission receipt to the PI or duly designated representatives.
- The chair determines that the protocol is for expedited review and assigns reviewers.
- The Secretariat forward the copies of protocols and related documents for expedited review to the assigned primary reviewers the next working day.
- Reviewers do the expedited review and submit the decision to the Secretariat.
- Secretariat communicates the decision for approval or revision to the principal investigator through a letter of notification within the last 2 weeks of the month.
- If modifications are required, Principal Investigator revises the protocol or related documents and submit to the IRC-MIHS.
- Reviewers review revisions and recommend it for approval.
- Secretariat prepares an approval letter to be signed by the chair/secretariat and sent to the Principal Investigator.

- Secretariat report results of expedited review to full board as part of the meeting agenda.
- Secretariat keep copies of all related documents and complies them in their respective protocol files.
- Secretariat update the MIHS-IRC database

Full board review

- This applies to the review and approval of study protocols or amendments with medium to high risk to study participants and major revisions in the protocol or informed consent.
- It is responsibility of the Secretariat to manage the document submission, send protocol documents to the primary reviewers, refer the protocol to full board meeting for discussion and decision, communicate the review results to the Principal Investigator, keep copies of the documents in the protocol files and update the protocol entry.

Criteria for full board review

- Major revisions of the protocols and informed consent after initial review.
- Amendment that involves major changes from previously approved protocol or consent form
- Major amendments that change the risk /benefit assessment
- Progress/ final reports that deviate from approval given by IRC.

Process Flow

	Activity	Responsibility
Step 1	Receive the submitted documents for initial review and forward them to Chair for assessment	Secretariat
Step 2	Determine that the protocol qualifies for full board review and assigns reviewers	Chair
Step 3	Forward the copies of protocols and related documents a week before the meeting to be reviewed within last 2 weeks of month.	Secretariat
Step 4	Do the review of the protocol as well as the reports deemed for full board review	Reviewers
Step 5	Include the protocol in the meeting agenda for discussion to arrive at a decision through full board	Secretariat
Step 6	If modifications are required, revise the protocol or related documents and submit to the IRC-MIHS	Principal Investigator

Step 7	Prepare an approval letter to be signed by the chair/secretariat and sent to the Principal Investigator	Secretariat
Step 8	Keep copies of all related documents and complies them in their respective protocol files	Secretariat
Step 9	Update the MIHS-IRC database	Secretariat

Description of detailed procedure

- The secretariat receives the submitted documents for initial review and forwards them to the chair for assessment.
- The application documents received from investigator submission are checked using the protocol checklist as guide. After checking the documents are complete, the Secretariat sign a copy of the application form to acknowledge receipt of the documents and return a copy to the PI or duly designated representatives.
- The chair determines that the protocol is qualified for full board review and assigns reviewers.
- The Secretariat forward the copies of protocols and related documents a week before the meeting to be reviewed within 2 weeks of the month.
- Reviewers do the review of the protocol and related documents as well as the reports deemed for full board review.
- Secretariat includes the protocol in the meeting agenda for discussion to arrive at a decision through full board.
- After reviewing the protocol and the documents the reviewer recommends a decision via consensus.
- Record the decision by marking the appropriate block in the assessment form: Approved, minor revision, major revision for resubmission or disapproved
- Includes comments and reasons for disapproval.
- If modifications are required, Principal Investigator revises the protocol or related documents and submit to the IRC-MIHS.
- Secretariat prepares an approval letter to be signed by the chair/secretariat and sent to the Principal Investigator.
- Secretariat keep copies of all related documents and complies them in their respective protocol files.
- Secretariat update the MIHS-IRC database

Re-submitted Proposal Review

- For proposals requiring major revision, researchers may re-submit the proposals according to the decision of the MIHS-IRC. The re-submitted proposal with significant revisions will follow the same process which is used for a new proposal.

Review of Amendment of the Approved Proposal

- The researcher should submit a request for amendment through an online portal of MIHS-IRC and get approval within a valid timeline before implementation.
- The rationale and justification for the amendment should be scientifically strong, without deviating much from the main objective and methodology of the approved proposal.
- Minor revisions on the approved proposal shall be cleared through the Expedited Review Sub-Committee meeting process; however, major revisions shall be reviewed by the full board.

Review of the Final Report

- The researcher should submit his/her final report upon completion of the study through the online MIHS-IRC portal. The report will be reviewed by the relevant Secretariat staff, an expert member of the MIHS-IRC, or the subject expert (as applicable), before issuing an acknowledgment letter.

1.1. Review process for research involving animals.

1.1.1. The welfare of animals used in research is very important. Good scientific practice is inextricably related to the wellbeing of animals. Research findings may be affected if an animal is in distress or under stress. There are good ethical, scientific, legal and economic reasons for making sure that animals are looked after properly and used in minimum numbers. Therefore, housing animals in optimal conditions and ensuring they receive the finest care from knowledgeable and experienced caregivers makes sense from a scientific standpoint. Scientists are researching the settings that various animals enjoy since what animals actually need is sometimes different from what humans believe they need.

1.2. Animals are only used in research when there is no other option and the possible advantages of the study outweigh the anticipated risks. The principles that uphold the humane use of animals in scientific research are known as the three Rs. Before utilizing animals for research, scientists must show that there is no other choice and describe how they intend to reduce the number of animals used and their suffering.

1.3. The 3 R s are:

1.3.1. Replacement: replace animals with a non-animal alternative when possible.

1.3.1.1. Replacement strategies include:

- Tissue culture
- Perfused organs
- Tissue slices
- Cellular fractions
- Subcellular fractions

1.3.2. Reduction: reduce the number of animals used to the minimum possible.

1.3.2.1. Reduction strategies include:

- Right choice of strategies in the planning and performance of whole lines of research.
- Controlling variation amongst the animals used in studies,
- Careful design and analysis of studies.
- Avoiding unnecessary replication
- Use of modern imaging techniques in conjunction with new statistical analysis methods also allow reductions in the numbers of animals used.

1.3.3. Refinement: refine methodology to minimise or eliminate impact of the research on animals.

1.3.3.1. Refinement techniques may include

- Non-invasive techniques
- Appropriate anaesthetic and analgesic regimes for pain relief
- Training animals to voluntarily co-operate with procedures (e.g. blood sampling) so that they have greater control over the procedure reduce distress
- Provision of species-appropriate housing and environmental enrichment which meet the animals' physical and behavioural needs (e.g. providing opportunities for nesting for rodents)

1.4. There is a steady decrease in the use of animals in medical research, and attempts are being made to substitute other laboratory procedures for animal testing. However, if there is an urgent necessity, the NHRC/ERB may approve the use of animals in health research as long as the researcher follows the "Ethical Guidelines for the Use of Animals in Health Research in Nepal-2005."

1.5. *The fundamental principles in animal experimentation for health research:*

- Ensure that the number, type, species, etc., of animals selected for the health research, are appropriate and justified.
- When designing the research protocol, the number of animals used should reflect the minimum necessary to yield valid answers to the research hypothesis.
- Ensure that the animals used for the health research are not purchased from illegal sources.
- Ensure that the researchers involved in the use of animals in health research are qualified, responsible, and respectful of animals' worth and rights.
- Ensure that the use of animals in health research is justified.
- The species chosen for study should be best suited to answer the question(s) posed, taking into account their biological characteristics, including behavior, genetic constitution, and nutritional, microbiological, and general health status.
- Necessary steps should be taken to ensure that the animals used in health research are well sheltered (with the provision of food, water, etc.) and protected (from abuse, cruelty, exposure to contamination, etc.);
- Proper care should be taken to minimize animals' discomfort, distress, and pain;

- Before using animals for research purposes, a detailed proposal illustrating the research plan, design, and procedures should be submitted to the concerned authority. The researcher should also be clear as to why the use of animals in the research is indispensable.
- Upon completing research involving animals (that cannot be rehabilitated or returned back to their natural habitat), the researcher is obliged to euthanize animals. The decision to not euthanize animals should be backed by valid scientific reasons. If the researcher decides not to kill animals, it is the researcher's responsibility to take care of the experimental animals.
- Use of wild/endangered/threatened animals is generally restricted. However, for research of essential value, the use of such restricted animals must abide by the law and policies for wildlife conservation. Wild animals for experimentation shall be acquired under the National Parks and Wildlife Conservation Act 2029 BS (1977 AD) (3) and the Wildlife Farming, Breeding and Research Policy 2059 BS (2002 AD), Convention on International Trade in Endangered Species of Wild Flora & Fauna, Animal Health and Livestock Service Act 2055 BS (1999 AD) (4) and rules 2057 BS (2001 AD) (5).
- Experimental animals should be housed safely in adequate spaces with the appropriate temperature, ventilation, and stress-free housing, without exposure to extreme environments. Transfer delivery boxes should be strong and well secured to avoid escape.
- The researcher should be adequately qualified, and have knowledge of the behavioral characteristics of the animal subjects to be aware of normal, species-specific behaviors and unusual behaviors that could forewarn the researcher of potential health problems.
- Animals used in health research should be housed in a separate location away from public housing. In addition, animals involved in research should not be exposed to dust, smoke, noise, rodents, insects, and birds. In order to avoid infection and stress, animal facilities must be equipped with systems that can control infection, temperature, humidity, ventilation, lighting, and sound to suit the needs of each species.
- Animal facilities should be developed and maintained following nationally approved standards, particularly in terms of maintaining biosafety and biosecurity.
- Since experimental animals are at high risk of being exposed to pathogens and/or hazardous agents, the researcher needs to adopt safety measures in line with biosafety and biosecurity guidelines to reduce the risk of spreading animal-related diseases/infections.
- Procedures subjecting animals to pain, stress, misery or death should be used only when an acceptable alternative procedure is unavailable.
- Ensure that the animals involved in research are taken good care of, have a well-managed house, and is not subject to cruelty. safe
- Animal housing should be managed in such a way that it reflects the effective involvement/supervision/accountability of a qualified and trained veterinarian.

- Animals should be fed palatable, non-contaminated, and nutritionally adequate food daily or according to their requirements unless the protocol in which they are being used requires otherwise.
- Cages for animals should be made of suitable material and size. Cages should also have adequate space to avoid any injury to animals. Since bedding can affect animals' well-being as well as the research outcomes, the researcher should provide clean and comfortable bedding for the animals involved in the research. For comfortable bedding, the researcher (in consultation with the veterinarian) should select bedding materials suitable for animals.
- All transportation of animals should be planned to minimize transit time and the risk of zoonosis, protect against environmental extremes, avoid overcrowding, provide food and water when indicated and protect against physical trauma. Each shipment of animals should be inspected for compliance. A health certificate for the animal should be obtained at the point of transportation origin and destination. Newly received animals should be given a period for physiologic, psychological, and nutritional stabilization before their use.
- Same experimental animals should not be used in more than one study, either in the same or different projects, without the approval of the ERB.
- Animals cannot be subjected to successive surgical procedures unless required by the nature of the research, the nature of the surgery, or for the well-being of the animal. Multiple surgeries on the same animal must receive special approval from the ERB, NHRC.
- Releasing captivated animals back to their natural habitat can pose substantial risks both to the captivated animals and other animals in the wild. Animals that are not suitable for rehabilitation must be euthanized upon the completion of the research. However, the selection and use of methods of euthanasia on animals should ensure less suffering and immediate death. Death should be confirmed by the person who can recognize and certify the cessation of vital signs in the species. A registered veterinarian should closely monitor the method of euthanasia.
- It is important for the investigators to maintain records of the animals in research. These records should include the type of species, birth profile, sex, identifier, behavior profile, etc. Animals' records should also be kept simple and comprehensive. All animals used in health research must regularly be monitored and have updated records.

3. Monitoring of health research (MIHS-IRC-SOP-00-08-2024)

3.1. Responsibility:

3.1.1. The Madhesh Institute of Health Sciences management and the MIHS-IRC has the responsibility to ensure that the conduct of all research approved by MIHS-IRC is carried out with the given ethical and technical standard. The MIHS-IRC will establish a follow-up procedure for monitoring the progress of all research activities since the time of approval to its termination. The member secretary in consultation with Chairman will identify and designate one or more IRC members/Independent monitor from IRC to conduct site monitoring of the study sites of relevant projects. The secretariat will inform the PI in writing about the date/time of monitoring visit and request for confirmation from the PI or Co-investigator to be available for the monitoring visit. The identified members of Site monitoring committee (SMC) will declare in writing conflict of interest, if any prior to visit the site. The report should be submitted by them to IRC by 7 days in the specified visit report format.

3.2. Flow Chart

Step 1	Designate IRC members or appoint an independent monitor along with IRC members to monitor the project	Chairman+ Member secretary
Step 2	Inform PI in writing about the date/time of monitoring visit	Member secretary
Step 3	Declaration of conflict of interest prior to visit the site	SMC
Step 4	Visit the site and Report should be submitted to IRC by 7 days in the specified visit format	SMC
Step 5	Submit the complete site monitoring visit report to the IRC secretariat within 14 days of conducting a site monitoring visit	SMC
Step 6	Review reports submitted and Decide on appropriate course of action	IRC meeting
Step 7	Communicate the IRC decision to the PI	Member Secretary
Step 8	Store original documents and decisions taken by IRC in project file	Member Secretary

3.3. Detailed instructions

3.3.1. During the visit

3.3.1.1. MIHS-IRC will inspect the study site. Key focus areas during oversight are listed below

3.3.1.2. Protocol understanding of the site team

3.3.1.3. Approved protocols, informed consent, Audio-visual recording of consent, case record forms and subject diaries and make sure that the site is using the most recent version.

3.3.1.4. Randomly selected participant's files to ensure that the participants are signing the correct informed consent.

3.3.1.5. Laboratory and other facilities necessary for the study at site.

3.3.1.6. Source documents

3.3.1.7. Verify the investigator is enrolling only eligible subjects.

3.3.1.8. Availability of study specific logs and forms

3.3.1.9. Views of study participants, if possible

3.3.1.10. SAEs are appropriately reported within the time as per the applicable

3.3.2. **After the visit**:

3.3.2.1. The IRC member/Independent monitor will submit the complete site monitoring visit report to the IRC secretariat within 14 days of conducting a site monitoring visit.

3.3.2.2. The report should describe the findings of the monitoring visit.

3.3.2.3. On basis of the information and comments received from the IRC members /Independent monitor, the IRC will take appropriate action by voting or combination of actions, some of which are listed below, but are not limited to:

3.3.2.4. Continuation of the project with or without changes

3.3.2.5. Restriction on enrollment

3.3.2.6. Recommendations for additional training

3.3.2.7. Recruiting additional members in the study team

3.3.2.8. Revising the protocol

3.3.2.9. Termination of the study

4. Meeting (MIHS-IRC-SOP-00-08-2024)

4.1. Responsibility

4.1.1. Member Secretary of MIHS-IRC will prepare the agenda for the meeting in consultation with the Chairperson of MIHS - IRC. The Member Secretary will be assisted in his or her tasks by an administrative secretary.

4.2. Preparation of agenda

4.2.1. It is responsibility of the IRC secretariat to prepare the agenda for IRC meetings and to ensure proper recording and dissemination of minutes after the meeting is over. Members interested in posting some agenda for the forthcoming meeting may send it to the office of Member Secretary one day prior to scheduled period.

4.3. Conduction of meeting

4.3.1. The MIHS- IRC will organize a regular meeting on 1st Friday of each month.

4.3.2. The meeting shall start with welcoming members by chairman.

4.3.3. The chairman/Member Secretary shall determine the quorum is maintained

4.3.4. The member secretary will discuss the minutes of the previous meetings of IRC and present the agenda for the current meetings.

4.3.5. The Secretariat will obtain the signature of all the IRC members on the attendance register. If any IRC member has conflict of interest involving a project, he/she should declare the same, before the meeting commences and leave the meeting room before the discussion on the same. This will be recorded in the minutes.

4.3.6. If the chairperson has conflict of interest involving a project, he/she should declare the same and the eldest member should be the chairperson for the meeting.

4.3.7. The IRC members will discuss and clarify the comments and suggestions. The member secretary shall record the decision.

4.3.8. Applications should be submitted to the IRC secretariat at least two weeks before the next upcoming scheduled meeting that the applicants want their applications to be reviewed.

4.3.9. The meeting can be called if number of proposals submitted to MIHS-IRC are five or more.

4.4. Quorum requirement

4.4.1. The minimum number of members required to compose a quorum will be more than 51 percent of the total. Invited experts will not be considered for quorum requirement.

4.4.2. At least one female member to be present in the meeting.

4.4.3. At least one legal or non-affiliated member must be present in the meeting.

4.5. Ad hoc/ Extraordinary meeting

4.5.1. Ad hoc/extraordinary review meeting should be held if there is an urgent issue or issues that do not qualify for expedited review but require a full review committee meeting.

4.5.2. The secretariat should circulate notice giving the date, venue, time and agenda of the ad

4.5.3. hoc/extraordinary meeting at least 48 hours before the day of the meeting.

4.6. Decision on ethical application

4.6.1. Making decision

4.6.1.1. The committee members will consider the following before making the decision:

4.6.1.2. Withdrawal from the process if there is a 'conflict of interest'.

4.6.1.3. Decisions can only be made by a meeting that has a proper quorum.

4.6.1.4. All relevant documents must be present before a decision is made.

4.6.1.5. Only members who participate in the review should be involved in the decision.

4.6.1.6. The committee members should arrive at a pre-defined method for arriving at a decision on the basis of evidence.

4.6.1.7. The IRC will respond with one of the following decisions to the research applicant:

4.6.1.7.1. **Approved**: either with or without comments or questions addressed to the applicant; any reply to a committee 's comments or questions to be forwarded in due course;

4.6.1.7.2. **Approved subject to conditions**: subject to recommended revisions of the proposal and/or satisfactory answers to questions asked from the applicant. The applicant's reply and/or revised proposal will be forwarded to consider the revisions that have been made and to provide final approval;

4.6.1.7.3. **Approval deferred**: pending substantial revisions of the proposal/study and/or satisfactory answers to questions asked from the applicant. The applicant's reply and/or revised proposal will be forwarded to the committee for reconsideration and final approval, and

4.6.1.7.4. **Approval declined**: reasons for declining approval to be forwarded to the applicant, either with or without an invitation to submit a substantially revised protocol for reconsideration.

4.7. Meeting minutes

4.7.1. The member secretary will record the minutes of the meeting and disseminate the same to the members within a week of the meeting for their signed approval.

4.7.2. The minutes of the IRC meeting will be ratified in the subsequent IRC meetings.

4.7.3. In the record section of IRC Secretariat, approved minutes will be maintained by the coordinating staff with confidentiality for a minimum period of five years both as soft and hard copies.

5. Communication (MIHS-IRC-SOP-00-08-2024)

5.1. Responsibilities

5.1.1. A decision will be communicated in writing to the applicant according to the MIHS-IRC procedures. IRC Secretariat communicates decision to the PI/CoI regarding the status of submitted protocol, before and after monitoring.

5.1.2. IRC Secretariat may communicate with various stakeholder regarding the project.

5.2. Initial Submission of project to IRC

5.2.1. The PI/ CoI should submit all study related documents to the IEC, no fewer than fourteen (15) days before the scheduled meeting.

5.2.2. The PI/CoI should complete the IRC submission form and PI must sign and date in the form wherever required.

5.2.3. PI/Co-I must check the submissions as per the IRC checklist to ensure that all mandatory forms and documents are enclosed.

5.3. Communicating a decision

5.3.1. A decision should be communicated in writing to the applicant within a reasonable time (within a month of submission) in the format of IRC MIHS with following quotation:

5.3.1.1. **Approved**: The study is approved in its present form. When committee approves the study, the certificate will be issued within a period of 15 days.

5.3.1.2. **Approved with modifications**: This is a conditional approval. The revisions are required. If revisions are found satisfactory, approval will be granted.

5.3.1.3. Resubmit: When extensive revisions are necessary

5.3.1.4. **Not approved**: The study is not approved in its current form. The required modifications will be suggested during the meeting with reasons.

5.3.1.5. **Defer**: The decision cannot be arrived at present and therefore postpone to next meeting.

5.3.2. Approval will be given for one/two/three years at a time depending on the type and level of proposal. Projects, which have not been commenced within specified time of original approval, must be resubmitted to MIHS - IRC. If the project is not completed within specified validation period, the researcher will be required to write to MIHS-IRC requesting an extension of approval or will need to reapply. The communication of the decision should include, but is not limited to the following:

5.3.2.1. The exact title of the research proposal reviewed.

5.3.2.2. The potential research participant information sheet/material and informed consent form.

5.3.2.3. The name and title of the research applicant.

5.3.2.4. The name of the site(s) for the research.

5.3.2.5. The date and place of the decision.

5.3.2.6. The name of the MIHS-IRC taking the decision.

5.3.2.7. A clear statement of the decision reached.

5.3.2.8. Any advice by the MIHS-IRC concerning the research study.

5.3.2.9. In the case of a conditional decision, the requirements by the MIHS-IRC, including suggestions for revision and the procedure for having the application re-reviewed.

5.3.2.10. In the case of a positive decision (approved), a statement of the responsibility of the applicant, the need to notify the MIHS-IRC in case of protocol amendments , the need to notify the MIHS-IRC in the case of amendments to the recruitment of participants , or the informed consent form , the need to report serious and unexpected adverse events related to the conduct of the study, the need to report unforeseen circumstances, the termination of the study and the information the MIHS-IRC expects to receive in order to perform ongoing review; the final summary or final report.

5.3.2.11. The schedule/plan for the ongoing review by the MIHS-IRC

5.3.2.12. In the case of a negative decision, clearly stated reason(s) for the negative decision should be mentioned.

5.3.2.13. Signature and date of the authorized person of the MIHS-IRC

5.3.3. Suspension or discontinuation of research

5.3.3.1. When the MIHS-IRC is satisfied that circumstances have arisen such that a research project is not being or cannot be conducted in accordance with the approved protocol and that, as a result, the welfare and rights of participants are not or will not be protected, the IRC will take the following steps:

5.3.3.1.1. Withdraw approval

5.3.3.1.2. Recommend that the research project be discontinued, suspended, or that other necessary steps be taken

5.3.3.1.3. Research must not continue if ethical approval has been withdrawn and the researches didn't comply with any special condition required by the MIHS-IRC.

5.3.4. Right to Appeal/Complaint

5.3.4.1. An investigator who receives an unfavorable review by the committee has the right of appeal.

5.3.4.2. This appeal is initiated by filing a notice of appeal in writing to the head of the institution with in thirty (30) days from the date of notice he/she received.

5.3.4.3. Any research participants involved in a research project have the right to raise complaints or concerns directly either to the chairperson of the IRC or head of the institution. The head of the institution may request the MIHS-IRC for re-review of the proposal if he/she gets an appeal for the same.

5.3.4.4. The MIHS-IRC shall notify the investigator for rehearing, and the investigator shall have the right to appear at the rehearing to defend the proposal.

5.3.5. In the case of approval of the study, the communication should include:

5.3.5.1. The need to notify the IRC in the case of amendments

5.3.5.2. The need to report serious and unexpected adverse events related to the conduct of study
5.3.5.3. The need to report unforeseen circumstances, the termination of the study
5.3.5.4. The final report and any research articles published in scientific journal.

6. Recording and Reporting/Documentation and Archiving (MIHS-IRC-SOP-00-08-2024)

6.1. Responsibility

6.1.1. It is the responsibility of the IRC secretariat to ensure that all study files are prepared, maintained, circulated and kept securely for the specified period of time under a proper system that ensures confidentiality and facilitates retrieval at any time.

6.2. Organize the active study files

6.2.1. IRC secretariat will organize the contents of the active study files and maintain the active study files

6.2.2. The study files will comprise all essential documents and correspondence related to the protocol.

6.2.3. The submitted hard copy protocols and the related documents will be labeled and stored in the cupboard with lock and key in separate cupboard.

6.2.4. Maintain the study files

6.2.5. Collect and file related documents of the approved study appropriately

6.2.6. Attach an identity label to the set of documents

6.2.7. Keep all active study documents in secured place.

6.2.8. Soft copies of active files stored in computer which are password protected and will be accessible to only the IRC secretariat

6.2.9. Annual subscription of appropriate anti-virus and malware protector will be availed for soft copy submission.

6.2.10. Remove the contents (hard and soft copies) of the entire files from the active study cupboard to the archived study cupboard. The cupboard where hard copies of the archived study files will be kept in a lock and key and will have controlled access only to the secretariat.

6.2.11. The coordinating staff will maintain the confidentiality for control and archiving of the records by signing the confidentiality agreement.

6.2.12. The Chairperson/Member-Secretary and the person(s) authorized by him can have access and retrieval of the various documents, files and archives.

6.2.13. Records will be kept at least for ten years even after the completion of the research. The records shall be accessible for inspection and copying by authorized representatives of the institutions.

6.3. For multi-center research proposals, the MIHS-IRC will also record information provided by the researcher:

6.3.1. Details of other centers involved.

6.3.2. The approval status of the study at each center, and

6.3.3. Details of any amendments required at other centers

6.3.4. Documents that should be filed and archived include

6.3.5. The constitution, written standard operating procedures (SOP) of the MIHS-IRC, and regular
6.3.6. (Annual) Reports.
6.3.7. The CV of all the MIHS-IRC members.
6.3.8. A record of all expenses (including allowances and reimbursements) of the MIHS-IRC.
6.3.9. Agenda of the MIHS-IRC meetings.
6.3.10. The minutes of the MIHS-IRC meetings.
6.3.11. Copy of all research proposal documents.
6.3.12. All correspondence of the MIHS-IRC.
6.3.13. A copy of all decisions and advice given by the MIHS-IRC
6.3.14. Notification of the completion, premature suspension or termination or all research proposals.
6.3.15. Final summary or final report of all research studies.
6.3.16. Records of continuing review activities.
6.3.17. Copies of all correspondence between the IRC and investigators.
6.3.18. A list of all members, reviewers and experts.

6.4. Research proposal will be achieved as

6.4.1. Name and responsible institution or organization or group or individual
6.4.2. Project identification number(s)
6.4.3. Principal researcher(s)
6.4.4. Title of the project
6.4.5. Ethical approval or non-approval with date
6.4.6. Approval or non-approval of any changes to the protocol
6.4.7. The terms and conditions, if any, of approval of any protocol
6.4.8. Whether approval was by expedited review
6.4.9. Action to be taken by the MIHS-IRC to monitor/supervise the conduct of the research

7. Writing and Revision of SOP (MIHS-IRC-SOP-00-08-2024)

7.1. This SOP document is subject to continuous change, review and update in accordance with constitutional, national and international perspective. It is responsibility of the chair of MIHS-IRC to appoint an SOP Team to formulate or revise the SOPs of the MIHS-IRC. The Chair designates the members of the team which composed of at least 3 members together with IRC Secretariat, initiates approval processing of final version of SOPs. The Secretariat is responsible for coordinating the writing and revising of SOPs, maintaining current SOPs with a complete SOP list, ensuring that all MIHS-IRC members have access to the SOPs and are working according to the current version of the SOPs. The Head of Institute is responsible for the final approval of all SOPs.

7.2. Writing SOPs

7.3. Process Flow for New SOP

Activity	Responsibility	
Step 1	Designate an SOP Team	Chair
Step 2	Design the format, layout, identifier of SOP	SOP Team
Step 3	Write a new SOP and submit it to the chair	SOP Team
Step 4	Review and approve new SOP draft in a full board meeting to the head of institute	Chair/IRC members
Step 5	File and distribute approved SOP	Secretariat

7.4. An SOP is written according to the following format:

7.4.1. Purpose of the activity
7.4.2. Scope and coverage of the SOP
7.4.3. Division of responsibility
7.4.4. Flowchart
7.4.5. Detailed instructions
7.4.6. Glossary
7.4.7. References
7.4.8. Annexes: formats and checklists
7.4.9. Assign an identifier to the SOP
7.4.10. Each SOP chapter is given a code and a little that is self-explanatory and is easily understood. For the MIHS-IRC SOPs the following format is used: MIHS-IRC-SOP XX/YY-W-ZZZZ where XX is a two-digit number corresponding to the chapter, YY is a two digit number identifying the version of SOP (version starts from 01), W is a one-digit number identifying the version of SOP with minor changes in the SOP (it starts with 0), and ZZZZ is a four –digit number identifying the year of SOP was drafted or revised
7.4.11. The SOP Team writes a new SOP and submits it to the chair.
7.4.12. The SOP Team makes a draft of the SOP based on the design and format detailed above.
7.4.13. The SOP team submits completed draft to the chair.

7.4.14. The IRC chair and members review and approve new SOP draft in a full board meeting and submits to the head of the Institute.
7.4.15. The IRC chair submits the draft to full board review where IRC members deliberate on the draft.
7.4.16. Upon full board approval, the chair submits the approved draft to the head of Institute for final approval.
7.4.17. The approved SOPs will be implemented from the date of approval by the head of the Institute.
7.4.18. The IRC Secretariat file and distribute approved SOPs.

7.5. Revising SOPs

7.5.1. Process Flow

Activity	Responsibility	
Step 1	Propose to revise the SOP	IRC members
Step 2	Review, discuss and approve the SOP draft revision in a full board meeting	IRC members
Step 3	Approve and sign the SOP revision	Head of the institute
Step 4	File and distribute the revised SOP	Secretariat
Step 5	Archive the Superseded SOP	Secretariat

7.5.2. As the IRC sees fit, an existing SOP may be revised.
7.5.3. The SOP may be reviewed regularly by the SOP Team every two years
7.5.4. The SOP Team or any member of the board may propose for the revision of the SOPs and submit a written proposal to SOP Team.
7.5.5. Any proposal for revision must be written and submitted by the SOP team to the board for review, approval, coding and inclusion into the documents.
7.5.6. The IRC members review, discuss and approve the SOP draft revision in a full board meeting
7.5.7. When the need for a revision of SOP has been identified and agreed on, a draft will be written by a designated member of the MIHS-IRC. A draft of the revised SOPs will be discussed by the IRC members. The draft version will be reviewed by the chair who will submit it to the Head of the Institute.
7.5.8. The IRC chair and the Head of the institute shall approve and sign the SOP revision.
7.5.9. The chair submits the approved draft to the head of the institute for the final approval.
7.5.10. The approved revised SOP will be implemented from the date of approval by head of the institute.
7.5.11. The IRC Secretariat files and distributes the revised SOP.
7.5.12. Upon approval by head of the institute, the Secretariat distributes the printed revised SOP to MIHS-IRC members, updates the electronic SOP manual, and publishes the SOP through the hospital website.
7.5.13. The IRC Secretariat maintains the originally signed updated SOP manual in the MIHS-IRC office and retains one copy of originally signed outdated versions.

7.5.14. The IRC secretariat collects the old SOP manuals in exchange of the revised manual.
7.5.15. The IRC Secretariat includes the revised SOP in the SOPs manual that is currently used.
7.5.16. The IRC Secretariat archives the superseded SOP
7.5.17. The secretariat archives the superseded version of the SOP in the historical file
7.5.18. Superseded SOPs are clearly marked “superseded” with the year of archiving stamp in the cover page.
7.5.19. Outdated SOPs are considered a permanent file.

8. Abbreviations and glossary

IRC-MIHS	Institutional Review Committee of Madhesh Institute of Health Sciences
NHRC	Nepal Health Research Council
SOP	Standard Operating Procedure
TOR	Terms of References
PI	Principal Investigator
SAE	Serious Adverse Event
COI	Conflict of Interest
GCP	Good Clinical Practise
SMC	Site Monitoring Committee
CoI	Co-Investigator
Protocol	A document which states the background, rationale and objectives of a research project and describes its design, methodology including statistical considerations, and the condition under which it is to be performed and managed.
Quorum	It is the minimum number of members that must be present to constitute a valid meeting where decisions can be taken concerning submissions put forward for ethical review. A meeting is quorate when a quorum is present
Agenda	A list of things to be done; a program of business for the meeting
Active study file	Any approved protocol, supporting documents, records containing communications and reports that correspond to each currently approved study

9. References

1. **National Ethical Guidelines for Health Research in Nepal: Published by Nepal Health Research Council (NHRC) 2022**
2. **Guidelines for Institutional Review Committees (IRCs) for Health Research in Nepal: Published by Nepal Health Research Council (NHRC) 2016**
3. **National Ethical Guidelines for Health Research in Nepal and Standard Operating Procedure, Nepal Health Research Council,2011**
4. **Ethics Review Committee Guidelines: A Guide for Developing Standard Operating Procedures for Committees that Review Biomedical Research Proposal, Forum of Ethics Review Committees, Sri Lanka, 2007.**
5. **WHO Operating Guidelines for Ethical Review Board that Review Biomedical Research (2000), https://www.who.int/tdr/publications/documents/ethics.pdf**
6. **World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, Geneva, 2000**
7. **WHO (International agency for Research in Cancer)IARC Ethics Committee (IEC) Standard Operating Procedures (SOPs) https://ethics.iarc.who.int/procedures/iec-sops-2021.pdf**
8. **SOP Guidelines for writer https://hub.ucsf.edu/sops**
9. **SOP (Version-1, 2023), Institutional Review Committee (IRC), National Medical Collage, Birgunj, Nepal**
10. **https://www.nal.usda.gov/animal-health-and-welfare/animal-use-alternatives#:~:text=The%20%E2%80%9C3Rs%20alternatives%E2%80%9D%20refers%20to,Principles%20of%20Humane%20Experimental%20Technique%22.**
11. **https://nc3rs.org.uk/who-we-are/3rs**

10. Appendix

1. 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	

2. 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:

3. Approval letter format

Madhesh Institute of Health Sciences
Janakpurdham, Madhesh Province, Nepal
Madhesh Institute of Health Sciences - Institutional Review Committee (MIHS-IRC)

Ref: Date:

……(PI)
Madhesh Institute of Health Sciences

Ref: Ethical Approval of Research Proposal

Protocol Registration No/ Submitted Date			**Sponsor Protocol No**	
Principal Investigator/s			**Sponsor Institution**	
Title				
Protocol Version No			**Version Date**	
Other Documents			**Risk Category**	
Co-Investigator/s				
Study Site				
Type of review	**Expedited**		**Date of approval**	**Frequency of continuing review**
	Full Board			
	Meeting Date:			
Total budget of research				
Ethical approval processing fee				

Investigator Responsibilities

- Any amendments shall be approved from the MIHS-IRC before implementing them
- Submit progress report every 6 months
- Submit final report after completion of protocol procedures at the study site
- Report protocol deviation / violation within 7 days
- Comply with all relevant international and NHRC guidelines
- Abide by the principles of Good Clinical Practice and ethical conduct of the research

If you have any questions, please contact MIHS-IRC.

Thanking you
……
Dr. ……
MIHS-IRC Chair/Member-Secretary
Institutional Review Committee (MIHS-IRC)

MIHS-IRC is Approved by ERB of Nepal Health Research Council (NHRC), Government of Nepal
Email: mihs irc email irc.secretary@mihs.edu.np Phone: …… Fax: …… Website: https://mihs.edu.np/

4. Visit report format

IRC Ref. No:

Title of study:

Principal Invesigator:

1. Date of IRC approval:
2. Date of start of study:
3. Date of study completion:
4. Provide details of:
   a) Total number of study participants approved by the IRC for recruitment:
   b) Total number of study participants recruited till date:
   c) Total number of participants withdrawn from the study (if any): Provide the reasons for withdrawal of participants:
5. Describe any ethical issue encountered:
6. State the number of Deviations/violations/Amendments made to the study protocol during the study period(if any):
7. Number of SAEs that occurred in the study:
8. Is medical management or compensation for SAE provided to the participants? Yes/No If yes , provide details
9. Have any participating investigators been added or withdrawn since last review? Yes /No If yes, provide the details
10. Is report of interim data analysis available? Yes/No If yes ,provide the details
11. Is report of the data safety and monitoring board available? Yes/No If yes, provide details
12. Remarks, if any

Signature of Site Monitoring Committee: Date:

Signature of PI

5. Health Research Monitoring Checklist

Madhesh Institute of Health Sciences

Institutional Review Committee (IRC)

Janakpurdham, Madhesh Province, Nepal

Health Research Monitoring Checklist

IRC ref. no:

Study title: Name of PI:

Date of visit: Date of start of study

Time of visit: Date of IRC approval:

SN	Components	Yes	No	N/A
Before conducting the research				
1	The proposed research address pertinent question (s) and is designed either to add to existing knowledge about the subject in question			
2	The research design appropriate for the questions being asked			
3	It is possible to have access to all the necessary skills and resources to conduct the research			
4	A risk assessment has been conducted to- • determine whether there are any ethical issues or not • determine potential risks to the organization, health, safety and wellbeing of the researcher and the research participants			
5	All the conflict of interest relating to the research have been identified , declared and addressed			
6	Aware of the guidance from the applicable organization on misconduct in research			
7	Availability of the adequate number of samples			
8	Feasibility of the research to conduct (man, money and material)			
When conducting the research				
1	The agreed research design has been used			
2	Informed the research participants about the research and its purposes			
3	Written informed consent has been taken			
4	Allocation of the participants groups has been done			
5	Followed the sampling strategy			
6	Payments to participants for visit			
7	List of study participants enrolled in the study			
8	Followed the best practice for collection, storage and management of data			
After completing the research				
1	The research and its findings will be reported accurately, honestly and within a reasonable time frame			
2	All the contributors of the research will be acknowledged			
3	The research data will be retained in a secure and accessible form and for the required duration			
4	The research study complies with all legal, ethical and contractual requirements.			
5	Disseminating the research findings			

Remarks:

Recommendations, if any

Name and signature of the monitoring members team

6. Review form

MADHESH INSTITUTE OF HEALTH SCIENCES-INSTITUTIONAL REVIEW COMMITTEE (MIHS-IRC)

REVIEWER'S EVALUATION TOOL

Student:_____

This instrument must be used in conjunction with the templates developed for quantitative research proposals

The criteria do not reflect the chronological order as indicated in the templates

	Rubrics Unsatisfactory: Missing/Unclear Developing: Conditionally satisfactory / Requires minimal changes Accomplished: Achieved level of competency	**Unsatisfactory**	**Developing**	**Accomplished**
Abstract	Comments/Suggestions			
Title	Comments/Suggestions			
Introduction / Background / Literature review	Comments/Suggestions			
Rationale	Comments/Suggestions			
Problem statement	Comments/Suggestions			
Assumptions and delineations/ delimitations	Comments/Suggestions			

Criterion As indicated in template	Rubrics Unsatisfactory: Missing/Unclear Developing: Conditionally satisfactory / Requires minimal changes Accomplished: Achieved level of competency	Unsatisfactory	Developing	Accomplished
Research question(s), aim and objectives, or hypothesis	Comments/Suggestions			
Significance / Importance, Benefits	Comments/Suggestions			
Concept clarification	Comments/Suggestions			
Methodology — **Research design**	Comments/Suggestions			
Context / Setting	Comments/Suggestions			
Population / Unit of analysis Sampling	Comments/Suggestions			
Data collection and instrument(s)	Comments/Suggestions			

Criterion As indicated in template	Rubrics Unsatisfactory: Missing/Unclear Developing: Conditionally satisfactory / Requires minimal changes Accomplished: Achieved level of competency	Unsatisfactory	Developing	Accomplished

	Pilot study **(Only for quantitative studies)**	Comments/Suggestions			
	Data analysis	Comments/Suggestions			
Rigour		Comments/Suggestions			
Ethical considerations Participant Information Leaflet **Consent**		Comments/Suggestions			
Logistical planning *Budget, timeframe, dissemination*		Comments/Suggestions			
Referencing		Comments/Suggestions			
Language, style and technical care of the document		Comments/Suggestions			

Annexures	Comments/Suggestions			

Final comments:_____

_____

_____

_____

_____

Recommendation	
Approved **Approved with minor changes** **Re-submit**	

_____

_____

Name of reviewer **Signature of reviewer**

Date: _____

7. Letter of notification

Letter of Notification after review

Madhesh Institute of Health Sciences

Institutional Review Committee (IRC)

Janakpurdham, Madhesh Province, Nepal

Title of the research reviewed

Name of the applicant :

Site for the research:

The Date of the decision:

The place of the decision:

Decision regarding research proposal:

- **Approved**
- **Approved with modification**
- **Resubmit**
- **Not approved**
- **Defer**

Suggestions by the IRC:

Signature Member Secretary

8. Submission form research Proposal

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

10. **Research Title:** **Financial Information**

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: ……

Check List

For all applicants

1. Covering letter addressed to the Member secretary indicating the submission of the approval of proposal.
2. Proposal will only be accepted if submitted in MIHS-IRC format.
3. Both printed and electronic version of the proposal should be submitted.
4. Curriculum Vitae of the Principal Investigator & Co-Principal Investigator of the study team should be submitted.
5. If the Principal Investigator is a non- Nepali citizen, at least one Co- investigator should be a Nepali citizen.
6. Submission of the application processing fee to MIHS-IRC if free for local researchers
7. Source of funding for the proposed project.
8. The proposal should have institutional ethical clearance from his/her own country if submitted from academic and related institution.
9. If the research study is to be conducted in any hospitals/organization or institution/community, a letter of approval from the related hospital/organization or institution/district authority should be provided.
10. Consent form should be in Nepali & local language (if necessary).
11. Data collection tools should be in Nepali & local language (if necessary) including interview guideline, observation checklist, questionnaires etc.
12. Style of referencing should be in Vancouver style.
13. List of abbreviations / acronyms should be provided.

For students' applicants

1. Approval letter from concern Institute/University.
2. Recommendation letter from Academic Supervisor.

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**:

9. Participant Information sheet, Consent form and ascent form sample (Nepali and English)

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: ……

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

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 दिंदै 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: .....

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

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: _____

अभिभावकीय सहमति फारम

अनुसन्धानको शीर्षक: [अनुसन्धानको शीर्षक यहाँ राख्नुहोस्]
प्रमुख अनुसन्धानकर्ता: **संस्था**:
सम्पर्क जानकारी: [तपाईंको सम्पर्क जानकारी] **मिति**:

परिचय

हामी तपाईंको बच्चालाई "[अनुसन्धानको शीर्षक यहाँ राख्नुहोस्]" नामक अनुसन्धान अध्ययनमा भाग लिन आमन्त्रित गर्दैछौं। यस फारमले अध्ययनको बारेमा जानकारी प्रदान गर्दछ र तपाईंको बच्चालाई भाग लिन अनुमति दिनको लागि तपाईंलाई सोध्छ। कृपया यस फारमलाई ध्यानपूर्वक पढ्नुहोस् र निर्णय गर्नु अघि कुनै पनि प्रश्न सोध्न नहिचकिचाउनुहोस्।

अध्ययनको उद्देश्य: **यो अध्ययनको उद्देश्य सजिलो शब्दमा अनुसन्धानको उद्देश्यको संक्षिप्त विवरण] हो।**

अध्ययनमा के हुनेछ: **यदि तपाईं आफ्नो बच्चालाई भाग लिन अनुमति दिनुहुन्छ भने, तपाईंको बच्चा [बच्चा के गर्नुपर्नेछ, कति समय लाग्छ, र अन्य कुनै पनि सान्दर्भिक प्रक्रियाहरू स्पष्ट, सरल भाषामा व्याख्या गर्नुहोस्]।**

जोखिम र लाभहरू: **जोखिमहरू**: **यस अध्ययनमा भाग लिने सम्भावित जोखिमहरू वा असुविधाहरू [कुनै पनि सम्भावित जोखिमहरूको वर्णन गर्नुहोस्, वा यदि कुनै छैन भने, "न्युनतम देखि कुनै पनि छैन" भन्नुहोस्]।**

लाभहरू: **यस अध्ययनमा भाग लिने सम्भावित लाभहरूमा [कुनै पनि प्रत्यक्ष वा अप्रत्यक्ष लाभहरूको वर्णन गर्नुहोस्] समावेश छ।**

गोपनीयता: **यो अध्ययनमा सङ्कलन गरिएको सबै जानकारी गोपनीय राखिनेछ। तपाईंको बच्चाको पहिचान कुनै पनि रिपोर्ट वा प्रकाशनहरूमा प्रकट गरिने छैन। डेटा सुरक्षित रूपमा भण्डारण गरिनेछ र अनुसन्धान टोलीले मात्र पहुँच गर्न सक्छ।**

स्वैच्छिक सहभागिता: **यो अध्ययनमा सहभागिता पूर्ण रूपमा स्वैच्छिक छ। तपाईं र तपाईंको बच्चालाई कुनै पनि समय बिना दण्ड वा तपाईंले अन्यथा पाउन योग्य लाभहरू गुमाउन अध्ययनबाट बाहिर निस्कने अधिकार छ।**

सहमति र सहमति

यो फारममा हस्ताक्षर गरेर, तपाईं सहमत हुनुहुन्छ?:

अभिभावक/अभिभावकको नाम: _____
हस्ताक्षर: _____
मिति: _____
बच्चाको नाम: _____
बच्चाको हस्ताक्षर (लागू भएमा): _____
मिति: _____
अन्वेषकको नाम: _____
हस्ताक्षर: _____
मिति: _____

मधेश स्वास्थ्य विज्ञान प्रतिष्ठान
जनकपुरधाम, मधेस प्रदेश, नेपाल

सहभागीक सूचना पत्र

नमस्कार,
हम ....., वर्तमानमे .....मे ..... विभागमे ..... पदपर कार्यरत छी । एहि अनुसन्धानक उद्देश्य ..... विषयमे अध्ययन करब अछि । हम अपनेके एहि विषयमे जानकारी दैत, अपनेके एहि अध्ययनमे सहभागी होएबाक लेल आग्रह करैत छी । जौं लिखल बात बुझबामे कठिनाई होइत अछि त अपने हमरासँ पूछि सकैत छी, तखन हम अपनेके विस्तारसँ बुझाएब ।

अनुसन्धानक शीर्षकः .....
अनुसन्धानक उद्देश्यः .....
अनुसन्धानमे कएल जाएवला कार्यक जानकारी (Write in accordance with your study) : एहि अध्ययन तीन भागमे विभाजित अछि, पहिल भागमे सामाजिक आ व्यक्तिगत स्वास्थ्य सम्बन्धी प्रश्नावली, दोसर भागमे ..... सम्बन्धित प्रश्नावली आ तेसर भागमे .....। अनुसन्धानकर्ता द्वारा समस्त प्रश्न सुनाएल जायत आ अपनेके उचित उत्तरकेँ सामने टिक चिन्ह लगाओल जायत ।

भेंटघाट आ समय : एहि अध्ययनमे अपनेके एकबेर मात्र सहभागी हाएबाक आवश्यकता अछि आ समय मात्र ..... मिनट लागत ।

उपलब्धि : यद्यपि एहि अध्ययनसँ अपनेके सीधा लाभ नहि हाएत, मुदा एकत्रित जानकारीसँ जनचेतना कार्यक्रमक विकासमे सहायता होएत ।

जोखिम : एहि अनुसन्धानमे सहभागी होएबाक क्रममे अपनेके स्वास्थ्य आ व्यक्तिगत स्तर पर कोनो प्रकारक जोखिम नहि हाएत ।

दस्तुर : एहि अनुसन्धानमे सहभागी होएबाक लेल अपनेके कोनो प्रकारक शुल्क देबाक आवश्यकता नहि अछि ।

सहभागिता : एहि अध्ययनमे अहाँक सहभागिता पूर्णतः स्वैच्छिक अछि । अपने कोनो समय अध्ययन छोड़ि सकैत छी, आ एहि कारण अहाँपर कोनो नकारात्मक प्रभाव नहि पड़त ।

जानकारीक उपयोग : अपने द्वारा प्रदान कएल गेल समस्त जानकारी गोप्य राखल जाएत आ मात्र एहि अध्ययनक उद्देश्यक हेतु उपयोग हाएत ।

सम्पर्क जानकारीः
प्रमुख अनुसन्धानकर्ताः .....
सम्पर्क मोबाइल नंः .....
मधेश स्वास्थ्य विज्ञान प्रतिष्ठानः +९७७ .....
वेबसाइटः .....
सहयोगः ..... धन्यवाद ।

क्रमांकः ..... **मितिः .....**

मन्जूरी पत्र

अनुसन्धानक शीर्षकः .....
अनुसन्धानक उद्देश्यः .....

हमरा ई जानकारी देल गेल अछि जे हम ..... नामक अनुसन्धानात्मक अध्ययनमे सहभागी बनल छी ।

हम एहि अनुसन्धानमे पूरे सहभागि होएबाक करबाक लेल सहमत छी । अध्ययनक समस्त बातकेँ हम स्पष्ट रूपेँ बुझि लेने छी आ एहिमे भाग लेबाक लेल हम स्वयं राजी छी । अनुसन्धानक क्रममे पूछल गेल प्रश्नक सटीक उत्तर देबाक लेल हम तैयार छी, आ हमरा ई विश्वास अछि जे हमरा द्वारा देल गेल जानकारी पूर्ण रूपसँ गोपनीय राखल जाएत । हम एहि अनुसन्धानमे बीना कोनो दबाव आ स्वयं इच्छासँ भाग लेबए चाहैत छी । हमरा ई जानकारी देल गेल अछि जे यदि हमरा कोनो कारणसँ अध्ययनमे रुचि नहि होइत अछि तँ हम कोनो समय बाहर भऽ सकैत छी । संगहि हमरा एहि अनुसन्धानमे कोनो प्रकारक शुल्क नहि देबाक बातक जानकारी सेहो अछि ।

यदि हमरा एहि अध्ययनसँ सम्बन्धित कोनो प्रकारक प्रश्न होइत अछि, तँ हम .....मे कार्यरत ..... (.....)सँ सम्पर्क करब ।

सहभागीक नाम आ हस्ताक्षरः .....

प्रमुख अनुसंधानकर्ताः
.....
.....
मधेश स्वास्थ्य विज्ञान प्रतिष्ठान
जनकपुरधाम, मधेस प्रदेश, नेपाल

अभिभावकीय सहमति फारम

अनुसन्धानक शीर्षकः (अनुसन्धानक शीर्षक एतए राखू)
प्रमुख अनुसंधानकर्ता संस्थाः
संपर्क जानकारीः (अपनेके सम्पर्क जानकारी एतए राखी) मितिः
हम अपनेके बच्चाके ("अनुसन्धानक शीर्षक एतए राखू") नामक अनुसन्धानमे सहभागी होएबाक लेल आमन्त्रित करैत छी । ई फार्म अध्ययनक विषयमे जानकारी प्रदान करैत अछि आ अपनेके बच्चाकेँ सहभागी होएबाक अनुमति लेल पूछैत अछि । कृपया ध्यानसँ एहि फार्म पढ़ू आ कोनो निर्णयसँ पहिने अपन सवाल अवश्य पूछी ।

अध्ययनक उद्देश्य

एहि अध्ययनक उद्देश्य सहज भाषामे अनुसन्धानक उद्देश्यक संक्षिप्त विवरणे अछि ।

अध्ययनमे की होएत

यदि अपने अपन बच्चाकेँ सहभागी होएबाक अनुमति दैत छी, तँ हुनका बच्चाकेँ की कएल जाएत, समय आ प्रक्रिया साफ-साफ बुझावए पड़त ।

जोखिम आ लाभ

जोखिमः ई अध्ययनमे सम्भावित जोखिम वा असुविधा जोखिमक वर्णन करू, यदि कोनो नहि अछि तँ 'न्यूनतमसँ कोनो नहि' लिखू ।

लाभः ई अध्ययनमे भाग लेबाक लाभमे प्रत्यक्ष वा अप्रत्यक्ष लाभक वर्णन करू सामिल अछि ।

गोपनीयताः ई अध्ययनसँ प्राप्त समस्त जानकारी पूर्ण रूपसँ गोपनीय राखल जाएत । अहाँक बच्चाक नाम आ पहिचान कोनो रिपोर्ट वा प्रकाशनमे नहि देखाएल जाएत । डेटा सुरक्षित रूपसँ राखल जाएत आ मात्र अनुसन्धानक टीमद्वारा उपयोग कएल जाएत ।

स्वैच्छिक सहभागिता : ई अध्ययनमे सहभागिता पूर्णतः स्वैच्छिक अछि । अपने आ अपनेके बच्चा कोनो समय बीना कोनो दबाव आ कोनो प्रकारक दण्डक डरसँ अध्ययन छोड़ि सकैत छी ।

सहमति आ अनुमति:

ई फार्म पर हस्ताक्षर कऽ अहाँ स्वीकार कऽ रहल छी :

अभिभावकक नामः .....
हस्ताक्षरः .....
मितिः .....
बच्चाक नामः .....
हस्ताक्षर (लागू होइत अछि) .....
मितिः .....
अनुसन्धानकर्ताक नामः .....
हस्ताक्षरः .....
मितिः .....