Standard Operating Procedures (SOP)

(Version-1, 2023)

Institutional Review Committee (IRC)

National Medical College

Birgunj, Nepal

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1. Writing and revising Standard Operating Procedures(SOPs) [NMCTH-IRC-SOP-01/01-0-2023]

1.1 Purpose

To define the process for writing and revising Standard Operating Procedures (SOPs) used by National Medical College Teaching Hospital Institutional Review Committee

1.2 Scope

This SOP provides instructions on how the NMCTH-IRC SOPs are prepared, approved and distributed.

1.3 Division of Responsibility

It is responsibility of the chair of NMCTH-IRC to appoint an SOP Team to formulate or revise the SOPs of the NMCTH-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 NMCTH-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.

1.4 Writing SOPs

1.4.1 Process Flow for New SOP

	Activity	Responsiblity
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

1.4.2 Description of detailed procedures:

- The Chair designates an SOP Team.
    - The Chair assigns members and non-members, as needed, to be part of the SOP team
    - The SOP team receives an orientation from the chair regarding duties and responsibilities
    - The chair can organize SOP Team workshop to facilitate and drafting of SOPs
- The SOP Team designs the format, layout, identifier of the SOP.

- An SOP is written according to the following format:
    - Purpose of the activity
    - Scope and coverage of the SOP
    - Division of responsibility
    - Flowchart
    - Detailed instructions
    - Glossary
    - References
    - Annexe: formats and checklists
- Assign an identifier to the SOP

  Each SOP chapter is given a code and a little that is self explanatory and is easily understood. For the NMCTH-IRC SOPs the following format is used: NMCTH-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

- The SOP Team writes a new SOP and submits it to the chair.
    - The SOP Team makes a draft of the SOP based on the design and format detailed above.
    - The SOP team submits completed draft to the chair.
- The IRC chair and members review and approve new SOP draft in a full board meeting and submits to the head of the Institute.
    - The IRC chair submits the draft to full board review where IRC members deliberate on the draft.
    - Upon full board approval, the chair submits the approved draft to the head of Institute for final approval.
    - The approved SOPs will be implemented from the date of approval by the head of the Institute.
- The IRC Secretariat file and distribute approved SOPs.

1.5 Revising SOPs

1.5.1 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	Chair/Head of the institute
Step 4	File and distribute the revised SOP	Secretariat
Step 5	Archive the Superseded SOP	Secretariat

1.5.2 Detailed Instructions

- IRC member/s proposes to revise the SOP.

- As the IRC sees fit, an existing SOP may be revised.
- The SOP may be reviewed regularly by the SOP Team every two years
- 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.
- 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.

- The IRC members review, discuss and approve the SOP draft revision in a full board meeting
    - 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 NMCTH-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.
- The IRC chair and the Head of the institute shall approve and sign the SOP revision.
    - The chair submits the approved draft to the head of the institute for the final approval.
    - The approved revised SOP will be implemented from the date of approval by head of the institute.
- The IRC Secretariat files and distributes the revised SOP.
    - Upon approval by head of the institute, the Secretariat distributes the printed revised SOP to NMCTH-IRC members, updates the electronic SOP manual, and publishes the SOP through the hospital website.
    - The IRC Secretariat maintains the originally signed updated SOP manual in the NMCTH-IRC office and retains one copy of originally signed outdated versions.
    - The IRC secretariat collects the old SOP manuals in exchange of the revised manual.
    - The IRC Secretariat includes the revised SOP in the SOPs manual that is currently used.
- The IRC Secretariat archives the superseded SOP
    - The secretariat archives the superseded version of the SOP in the historical file
    - Superseded SOPs are clearly marked “superseded” with the year of archiving stamp in the cover page.
    - Outdated SOPs are considered a permanent file.

2. Forming IRC, NMCTH [NMCTH-IRC-SOP-02/01-0-2023]

2.1 Purpose

The purpose of this SOP is to define the Terms of References (TOR) which provide the framework for constitution, responsibilities and activities of IRC-NMCTH.

2.2 Scope

This SOP applies to the activities performed by the IRC-NMCTH

2.3 Responsibility

It is responsibility of the IRC members and Secretariat to read, understand, follow and respect the SOP set by IRC-NMCTH.

2.4 Detailed instructions:

2.4.1 Composition of IRC:

- IRC, NMCTH is multidisciplinary and pluralistic in composition and will have Minimum 7 to maximum of 15 members with an attention to gender, age and discipline balance.
- The committee should include at least one member who is not affiliated with the institution

2.4.2 Appointment of IRC members

- Chairperson is appointed by the head of the institution
- Other members including member-secretary, will be appointed by the chairperson.
- Appointments should be made for tenure of three years, with a provision for re-appointment.
- Not more than 50% of the members should retire at once.

2.4.3 Tenure of Membership:

The appointment of the members would be for a period of three years; after which they may be either replaced or reappointed with a fresh appointment letter prior to the end of tenure of members by IRC Chairman/Head of the Institution.

2.4.4 Resignation

A member can resign by submitting the resignation letter addressing to IRC-Chairperson and email delivered to Member Secretary. The member secretary will inform the appointing authority for formal acceptance and to initiate the necessary replacement/recruitment procedure for filling up the vacancy.

2.4.5 Responsibility of IRC

2.4.5.1 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.

2.4.5.2 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 sign documents and communication related to IRC functioning
- 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 preperations, review, revision and distributions of SOPs and guidelines
- To ensure adherence of IRC functioning as per SOPs

2.4.5.3 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 and

2.4.5.4 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

2.4.5.5 Basic Medical Scientist:

- To provide scientist 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

2.4.5.6 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

2.4.5.7 Social Scientist / NGO representative / Philosopher / Ethicist:

- o 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.

2.4.5.8 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
- Evaluate final reports
- Declare any conflict of interest

2.4.6. IRC office

- The list of the name of IRC members should be displayed in front of the IRC office
- There should be at least one administrataive or clerical support staff provided by the institution for the IRC.
- IRC NMCTH is provided with a computer, a printer, a projector , almira, tables, chairs and with necessary administrative support.

2.4.7Qualification 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.

3 Review procedures [NMCTH-IRC-SOP-02/01-0-2023]

3.1 Exempt from review

3.1.1. Purpose:

To describe the process of review of protocols that qualify for exempted from review

To describe the IRC-NMCTH protocol review requirements and submission process from the time of receipt of the protocol and relaed documents.

3.1.2 Scope:

This SOP applies to exemption for review of protocols that do not need to undergo either full or expedited review as decided upon by chair of the IRC

The IRC-NMCTH accepts the protocols for researches done in National Medical College to review. This SOP applies to review and approval of study protocols submitted to the IRC-NMCTH.

3.1.3. Responsiblities:

It is the responsibility of the chair to assess whether the study protocol may be exempted from review of the IRC.

The IRC-NMCTH Secretariat manages and ensures completion of all protocol submissions , send protocol documents

3.1.4. 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

3.1.5. Description of detailed procedures:

3.1.5.1 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 (Annex-2) to acknowledge the receipt of the documents and return a copy to the PI or duly designated representatives.

3.1.5.2 The chair reviews and determines per criteria that the protocol is exempted from IRC review within 5 days.

3.1.5.3 The IRC secretariat prepares a letter of exemption to the PI indicating the protocol is exepted from IRC review.

3.2 Expedited review

3.2.1 Purpose

To describe the process of review of protocols that qualify for expedited review.

3.2.2. Scope

This SOP applies to the review and approval of the study protocol or amendments with minimal risks to the study participants and minor revision in the protocol or informed consent.

3.2.3. Responsibility

Expedited review is the responsibility of primary reviewers appointed to assess and make recommendations for appropriate reaction any protocol that qualifies for the expedited process.

3.2.4. 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 IRC-NMCTH	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 IRC-NMCTH database	Secretariat

3.2.5.Description of detailed procedure

3.2.5.1 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 (Annex-1) 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(Annex-2) to the PI or duly designated reprensatives.

3.2.5.2 The chair determines that the protocol is for expedited review and assigns reviewers.

3.2.5.3 The Secretariat forward the copies of protocols and related documents for expedited review to the assigned primary reviewers the next working day.

3.2.5.4 Reviewers do the expedited review and submit the decision to the Secretariat.

3.2.5.5 Secretariat communicates the decision for approval or revision to the Principal investigator through a letter of notification (Annex-3) within the last 2 weeks of the month.

3.2.5.6 If modifications are required, Principal Investigator revises the protocol or related documents and submit to the IRC-NMCTH.

3.2.5.7 Reviewers review revisions and recommend if for approval.

3.2.5.8 Secretariat prepares an approval letter to be signed by the chair/secretariat and sent to the Principal Investigator.

3.2.5.9 Secretariat report results of expedited review to full board as part of the meeting agenda.

3.2.5.10 Secretariat keep copies of all related documents and complies them in their respective protocol files.

3.2.5.11 Secretariat update the IRC-NMCTH database

3.3 Full board review

3.3.1 Purpose

To describe the process when protocol submission are classified for full board review.

3.3.2 Scope

The SOP 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.

3.3.3 Responsibility

3.3.3.1 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.

3.3.3.2 Criteria for full board review

- Major revisions of the protocols and informed consent after initial review.
- Amendment that involve 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.

3.3.4 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	Reviewers

	reports deemed for full board review.	
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-NMCTH	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 IRC-NMCTH database	Secretariat

3.3.5.Description of detailed procedure

3.3.5.1 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 reprensatives.

3.3.5.2 The chair determines that the protocol is qualified for full board review and assigns reviewers.

3.3.5.3 The Secretariat forward the copies of protocols and related documents a week before the meeting to be reviewed within 2 weeks of the month.

3.3.5.4 Reviewers do the review of the protocol and related documents as well as the reports deemed for full board review .

3.3.5.5 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.

3.3.5.6 If modifications are required, Principal Investigator revises the protocol or related documents and submit to the IRC-NMCTH.

3.3.5.7 Secretariat prepares an approval letter to be signed by the chair/secretariat and sent to the Principal Investigator.

3.3.5.8 Secretariat keep copies of all related documents and complies them in their respective protocol files.

3.3.5.9 Secretariat update the IRC-NMCTH database

4. Monitoring procudere [NMCTH-IRC-SOP-04/01-0-2023]

4.1 Purpose

The purpse of this SOP is to provide the procedure to select a site for monitoring and how the site will be monitored.

4.2 Scope

It covers the procedure applies to any visit and/or monitoring of any study sites as stated in the institutional review committee(IRC) approved study protocols.

4.3 Responsibility:

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 .

4.4 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

4.5 Detailed instructions:

4.5.1 Before the visit:

The chairman/member secretary will designate an IRC members or appoint an Independent monitor who along with IRC members will perform the task of monitoring. The selected members will be provided the information with an appointment letter in this regard. 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 IRC 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 .

4.5.2 During the visit:

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

- Protocol understanding of the site team
- 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.
- Randomly selected participant's files to ensure that the participants are signing the correct informed consent.
- Laboratory and other facilities necessary for the study at site.
- Source documents
- Verify the investigator is enrolling only eligible subjects.
- Availability of study specific logs and forms
- Views of study participants, if possible
- SAEs are appropriately reported within the time as per the applicable

4.5.3 After the visit:

The IRC member/Independent monitor will submit the complete site monitoring visit report (Annex-6) to the IRC secretariat within 14 days of conducting a site monitoring visit.

The report should describe the findings of the monitoring visit.

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:

- Continuation of the project with or without changes

- Restriction on enrollment
- Recommendations for additional training
- Recruiting additional members in the study team
- Revising the protocol
- Termination of the study

5.Meeting preparation and Meeting Minutes [NMCTH-IRC-SOP-05/01-0-2023]

5.1 Purpose

The purpose of this SOP is to describe the administrative process and provide instructions for the preparation of agenda, invitation, distribution, review , approval , minutes and action to be taken by IRC

5.2 Scope

It covers the procedure applies to administrative processes concerning the preparation of agenda , meeting procedure for all full board IRC meetings.

5.3 Responsibility:

It is the responsibility of the secretariat to prepare the agenda for IRC meetings and to ensure proper recording and distribution of the minutes after the meeting is over. The chairman and Member Secretary will review and approve the agenda and the minutes sent to him/her.

5.4 Detailed instructions:

5.4.1 Agenda

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.

Meeting venue:

IRC meeting will be held in IRC office.

5.4.2 Conduct of meeting:

- The committee would meet twice in every month or wherever it is necessary
- The meeting shall start with welcoming members by chairman.
- The chairman/Member Secretary shall determine the quorum is mainained
- The member secretary will discuss the minutes of the previous meetings of IRC and present the agenda for the current meetings.
- 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.
- The IRC members will discuss and clarify the comments and suggestions. The member secretary shall record the decision.

5.4.3 Decision Making Process:

- IRC member will withdraw from the meeting for the decision procedure concerning the study where conflict of interest exists.
- If any IRC member has his/her own proposals for IRC review he/she will not participate in the IRC discussion or vote on that particular project.
- Decisions will only be made at meetings where a quorum is present.

Types of decision:

- 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.
- Approved with modifications: This is a conditional approval. The revisions are required. If revisions are found satisfactory, approval will be granted.
- Resubmit: When extensive revisions are necessary
- Not approved: The study is not approved in its current form. The required modifications will be suggested during the meeting with reasons.
- Defer: The decision cannot be arrived at present and therefore postpone to next meeting.

5.4.4 Preparing and recording minutes:

- The member secretary will record the minutes of the meetng and disseminate the same to the members within a week of the meeting for their signed approval.
- The minutes of the IRC meeting will be ratified in the subsequent IRC meetings.
- 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.

6. Communication [NMCTH-IRC-SOP-06/01-0-2023]

6.1 Purpose

To describe the procedures related to communication with the IRC during the entire study duration right from study initiation to completion, and to describe what documents should be retained to reflect interaction with the IRC.

6.2 Scope

This SOP will apply to all studies being conducted at NMCTH.

6.3 Responsibility

Interactions with the Institutional Review Committee (IRC) continue throughout the duration of a research study. Establishing effective ongoing IRC communication and reporting procedures are essential to the successful management of research studies. An effective working relationship with the IRC strengthens the team approach to the protection of participant safety in addition to enhancing compliance with applicable SOPs, guidelines and regulations governing research studies.PI/CoI communicate with IRC during submission. IRC Secretariat communicates decision to the PI/CoI regarding the status of submitted protocol, before and after monitoring. IRC Secretariat may communicate with various stakeholder regarding the project.

6.3.1 Detailed description

6.3.1.1 Initial Submission of project to IRC

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

The PI/CoI should complete the IRC submission form (Annex-8) and PI must sign and date in the form wherever required.

PI/Co-I must check the submissions as per the IRC checklist (Annex-1) to ensure that all mandatory forms and documents are enclosed.

6.3.1.2Communicating a decision:

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

- 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.
- Approved with modifications: This is a conditional approval. The revisions are required. If revisions are found satisfactory, approval will be granted.
- Resubmit: When extensive revisions are necessary
- Not approved: The study is not approved in its current form. The required modifications will be suggested during the meeting with reasons.
- Defer: The decision cannot be arrived at present and therefore postpone to next meeting.

➢ **Right of appeal and complaints:**

- A researcher who receives an unfavorable decision by the IRC has the right to appeal.
- This appeal is initiated by filing a notice of appeal in writing to the head of institution within thirty days of the date that he/she received notice of IRC decision.
- 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

➢ In the case of approval of the study, the communication should include:

- The need to notify the IRC in the case of amendments
- The need to report serious and unexpected adverse events related to the conduct of study
- The need to report unforeseen circumstances, the termination of the study
- The final report and any research articles published in scientific journal.

7.Management of study files and Archiving [NMCTH-IRC-SOP-07/01-0-2023]

7.1 Purpose:

The purpose of this SOP is to provide instructions for preparation, circulation and maintenance of active study files and related documents approved by the IRC

1.2 Scope

It covers the policies applies to all active study files and their relate documents that are maintained in the IRC office.

1.3 Responsibility:

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 retrival at any time.

1.4 Flowchart

1.5 Detailed instruction:

1.5.1 Organize the active study files

- IRC secretariat will organize the contents of the active study files and maintain the active study files
- The study files will comprise all essential documents and correspondence realted to the protocol.
- The submitted hard copy protocols and the related documents will be labeled and stored in the cupboard with lock and key in separate cupboard.

1.5.2 Maintain the study files

- Collect and file related documents of the approved study appropriately
- Attach an identity label to the set of documents
- Keep all active study documents in secured place.
- Soft copies of active files stored in computer which are password protected and will be accessible to only the IRC secretariat
- Annual subscription of appropriate anti-virus and malvare protector will be availed for soft copy submission.

1.5.3 Archiving

- 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 are kept will be kept in a lock and key and will have controlled access only to the secretariat.
- The coordinating staff will maintain the confidentiality for control and archiving of the records by signing the confidentiality agreement.

Abbreviation & Glossary

IRC-NMCTH	Institutional Review Committee of National Medical College Teaching Hospital
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

Minutes	An official record of proceedings at a meeting

References:

1. **Guidelines for Institutional Review Committees(IRCs) for Health Research in Nepal: Published by Nepal Health Research Council(NHRC) 2016**
2. **National Ethical Guidelines for Health Research in Nepal and Standard Operating Procedure, Nepal Health Research Council,2011**
3. **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.**
4. **WHO Operating Guidelines for Ethical Review Board that Review Biomedical Research (2000), https://www.who.int/tdr/publications/documents/ethics.pdf**
5. **Standard Operating Procedure,version-2,2021, Institutional Ethics Committee, Narayana Medical College, India**
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**

Annex-1

Checklist for submission of proposal(IRC-NMCTH)

Birgunj, Parsa

1.	Covering letter		Yes/No
2.	Proposal Submission form (Including) a) Research proposal discussion b) Ethical Consideration c) Financial Consideration d) Declaration	1. Research title	Yes/No
		2. Description of Author	Yes/No
		3. List of Abbreviation	Yes/No
		4. Introduction(Background/statement of problems)	Yes/No
		5. General and specific objectives	Yes/No
		6. Research question(If Relevants)	Yes/No
		7. Research hypothesis	Yes/No
		8. Literature Review	Yes/No
		9. Conceptual Framework	Yes/No
		10. Research design & Methodology	Yes/No
		-Research Method	Yes/No
		-Type of study	Yes/No
		-Study population	Yes/No
		-Study site and Justification	Yes/No
		-Sampling method	Yes/No
		-Sample size & its determination	Yes/No
		-Selection criteria	Yes/No
		-Tools and technique for data collection	Yes/No
		-validity of tools	Yes/No
		-Pretesting of Data collecting tools(If	Yes/No

		possible)	
		-Plan for data analysis	Yes/No
		-Biases and limitations	Yes/No
		-Plan for dissemination of research results	Yes/No
		11. References	Yes/No
		12.Proforma	Yes/No
3.	Photocopy of appointment letter		Yes/No
4.	Approval letter from respective and concerened department		Yes/No
5.	Updated CV of PI/CoI		Yes/No

Annex-2

Cover letter for research protocol submission

Date:

To,

The Chairperson/Member secretary

The Institutional Review Committee

National Medical College

Birgunj, Nepal

Subject: Research proposal submission.

Dear Sir,

I would like to inform you that I Mr./Dr..... Faculty of Department....., National Medical College have planned to conduct research entitled "(Research title)". Please find the thesis proposal attached herewith. I have understood the regulation of IRC-NMCTH regarding the the review of research proposal. Thank you .

Thanking You

……..

Name of PI
Designation
Name of the Department
National Medical College
Birgunj, Nepal

Annex-3

Institutional Review Committee

(IRC)

Date: …….

Name of PI
Designation
Department …….
National Medical College

Ref: Ethical Approval of Research Proposal

Dear ……..,

Thank you for the submission of your research proposal entitled **"Title…….. .(Ref. No……)"** to the Institutional Review Committee, National Medical College. The proposal was ethically reviewed by IRC. We are pleased to inform you that the above mentioned research proposal has been approved from ethical point of view by IRC of National Medical College on ……...

Approval is given for three years. Project which have not commenced within two years of original approval must be re-submitted to IRC. You must inform IRC when the research has been completed. If you are unable to complete your research within three years validation period, you will be required to write to IRC to request an extension or you will need to re-apply.

Any serious adverse events or significant change which occurs in connection with this study and/or which may alter its ethical consideration must be reported to IRC, and an Ethical amendment Form submitted where appropriate. You are requested to follow the ethical principles for the health and biomedical research.

Thanking you,

……
Member secretary
IRC, NMC-TH
Birgunj, Nepal

Annex-4 Visit report format(IRC-NMCTH)

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

Annex-5

National Medical College Teaching Hospital

Birgunj, Parsa

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

Annex-6 Reviewer Form

Institutional Review Committee (IRC)

National Medical College, Birgunj

Please provide your comments on the proposal in specific headings given below. You can add extra pages as required:

Title:

Summary:

Introduction:

Research gap or rationale:

Research hypothesis/question

Literature Review:

Research objectives:

Research Design and Methodology:

Ethical consideration:

Consent:

References:

Other comments (if any):

Opinion of reviewer (please bold and underline one option):

a. Accepted
b. Accepted with minor revisions
c. Major revisions required
d. Rejected

Annex-7

Letter of Notification after review

Institutional Review Committee (IRC)

National Medical College, Birgunj

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 Secretiat:

Annex-8

Submission form research proposal

College logo

Research title

Submitted to:

Institute review committee (IRC)
National medical college
Birgunj, Nepal
Email: irc@nmcbir.edu.np

Submitted by:

Name:

Qualification:

Designation:

Department:

Contact no.:

Email:

Detail information of the researchers

Principal Investigator

SN.	Full name	Details	Signature
1		Qualification: Designation: Department: Contact no.: Email:	

Co-investigators

(Please also indicate as Guides and Co-guides under the full names for thesis proposal)

SN.	Full name	Details	Signature
1		Qualification: Designation: Department: Contact no.: Email:	
2		Qualification: Designation: Department: Contact no.: Email:	

3		Qualification: Designation: Department: Contact no.: Email:	

(Please add the columns if needed)

Departments involved

1.

2.

Other information

Supervisor: For medical and post graduate students

Guide: For thesis purpose

Co-guides: For thesis purpose

Name and address of the sponsor/funder if any

Recently updated Curriculum Vitae of Principal Investigator & Co-investigators

Format for

CURRICULUM VITAE OF THE INVESTIGATOR(S)

1. Name:
2. Designation:
3. Address for correspondence:
4. Date of birth:
5. Educational qualifications:
6. Research experience in the related field (if any)
7. List of important recent publications related to the subject of the present project (if any).

Other documents

- Cover letter
- Letter of approval from Head of Department
- Letter of approval for other department heads if any
- Consent form
    - English
    - Nepali
- Pro forma

NOTE:

- *Please read the instructions carefully and complete all the sections (that implies to your research)*
- *Type all the entries in English- Times New Roman Font, size 12 without bold/ Italics.*
- *Submit the completed application at IRC office and mail it to irc@nmcbir.edu.np*

1. **Research title**
   (Should indicate the subject and scope of the study accurately. Use words that gives a positive impact. Use current nomenclature, and avoid abbreviations. Do not include "study of," "analysis of" or similar constructions. Title should not be more than 10 – 15 words.)

2. **Summary**(within 250 words)
   (It should summarize all the aspects of the study like rationale, objectives, methods, study population, duration, site of study and expected outcomes. The language should be simple and understandable and should be able (to describe the whole project)

3. **Introduction** (about 1000 words)

(Aim of the study, set some background. Describe the magnitude, frequency, affected areas, gender consideration, and ethnic view etc of the problem. Literature review: recent published related articles that support your study.)

4. **Statement of problem/ Rationale of the study**
   (Should demonstrate the literature gap. Need to do the study. Should answer what and why of the problem. How will the study fill the gap?)

5. **Objectives**
   (The objective should be SMART(Specific, Measurable, Achievable, Relevant and Time-bound))

6. **General objective**
   (General statement of what is to be accomplished)

7. **Specific objectives**
   (The breakdown of general objective that measures specific construct within the general objective)
   To identify

   To define

   To estimate

   To determine

   To measure

8. **Research question/hypothesis**

   Question should be in a PICO format **P**opulation, **I**ntervention/exposure of **i**nterest **C**omparison/**C**ontrol **O**utcome

   Research hypothesis translates a research question into a prediction of expected outcomes

   Write either research question or hypothesis

9. **Conceptual Framework**
   (A written or visual presentation that explains either graphically or in narrative form)

10. **Research design and methodology**
    (Should explain what do we need to meet the research objective? How do we collect these data?)

10.1 Research method
   a. Quantitative b. Qualitative c. Combined

10.2 Type of study:
   a. Observational (Analytical/Descriptive) b. Experimental/Interventional

10.3 Study population:

10.4 Study site:

10.5 Sampling method:

a. Probability b. Non probability

10.6 Sample size:

(Sample size should be calculated using standard formula for the type of study being done. Single formula does not help to determine the sample size. Reference can be taken from similar study or a pilot study done by the researcher)

10.7 Inclusion and exclusion criteria

10.8 Study variable

(Dependent and independent variable has to be determined and included in the proposal)

10.9 Time and duration of study

10.10 Tools and techniques of the study

(Tools has to be listed and procedure has to be well explained in tabulated form)

11. **Plan for data management and statistical analysis**

Software that will be used for data entry and analysis. Statistical tests: (Specify the most probable statistical tests that will be used to analyze the data depending on the predicted nature of data)

12. **Biases**

13. **Limitations of the study**

14. **Safety considerations**

(Safety aspects of the research should always be kept in mind and information should be provided in the protocol on how the safety of research participants will be ensured.)

15. **Plan for supervision and monitoring**

16. **Expected outcome of the research**

(Indicate how the study will contribute to advancement of knowledge. This includes how the results will affect health care, health systems, or health policies.)

17. **Plan for dissemination of research results**

18. **Plan for utilization of the research finding**

19. **Work plan**

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

Work	**Duration/ Date**
Protocol writing	
Anticipated time of proposal approval	
Clinical trial registry (in case of clinical trial)	
Data collection and data entry	

Data analysis	
Manuscript/ thesis book preparation	
Submission to journal/ dissemination	

20. **Ethical clearance**

Regarding the human participants:

- Are human participants required in this research? If yes, provide justification.
- What is the frequency of the participants' involvement in the research? Explain.
- What is the follow up schedule?
- Clearly indicate the participant's responsibilities in the research. What is expected of the research participants during the research?
- Does your study involve vulnerable members like – pregnant women / newborn / children below 12 years / physically or mentally challenged / persons with HIV / AIDS / IV drug users? If yes, provide justification.
- Are there any risks involved to the participants? If yes, identify clearly what are the expected risks for the human participants in the research and provide a justification for these risks.
- Are there any benefits involved to the participants? If yes, identify clearly what are the expected benefits for the participants

21. **Informed consent**

Should include, how will the consent be obtained? Who will obtain the consent? Who will give the consent? Is any information being held from the participants, justify?

22. **Budget**

(Should include financial provision necessary for carrying out the research up to dissemination of research findings.)

Budget table
Budget justification
Source of budget
Sponsor, if any

23. **Reference**

(Should include all cited references in chronological order in Vancouver style)

24. **Annex**

List of abbreviations
Pro forma
Data collection tools and questionnaire
Information to participants
Informed consent

Acceptance and Declaration by the Principal Investigator

I, hereby, certify that the above mentioned statements are true to the best of my knowledge; I have read and understood the regulation of Institutional Review Committee of National Medical College regarding the review of research proposal and will act in conformity with the said regulations in all respects. I agree to accept responsibility for the scientific conduct of the research project.

If the research is terminated, for any reason, I will notify IRC of this decision and provide the reasons for such actions. I will notify IRC if any changes are needed in study design. In addition, I will notify IRC in written upon completion of the research.

……..……
Signature of the Principal Investigator
Name:
Date:

Annex-9 **Department of……..**

National Medical College

Birgunj, Nepal

Research title

Consent form

1	I confirm that I have read and understood the information sheet and consent form dated ___	☐
2	I have had the opportunity to ask questions.	☐
3	My participation in this study is voluntary	☐
4	I can leave the study at any time during the study without having to face any consequence, medical or legal.	☐
5	I understand that the researchers and the IRC and other regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial.	☐
6	I understand that my identity will not be revealed in any information released to third parties or published.	☐
7	I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s)	☐
8	I agree to participate in this research	☐

Please do the initials in the box

Name of subject:

Age:

Signature or thumb:

Date:

Name of witness:

Signature of witness or thumb:

Date:

Name of legal guardian:

Signature or thumb:

Date:

Name of investigator: Date:

Signature:

Department of

National Medical College
Birgunj, Nepal

Research title

सुसूचितमन्जुरीनामा

कृपया बक्समा टिक गर्नुहोस्

- म पुष्टि गर्छु कि मैले मिति कोजानकारी पाना र सहमति फारम पढेर मैले प्रश्नहरू सोध्ने मौका पाएँ ☐
- यस अध्ययनमा मेरो सहभागिता स्वैच्छिक हो ☐
- म अध्ययनको कुनै पनि समयमा अध्ययन छोड्न सक्छु मैले कुनै पनि परिणाम, मेडिकल वा कानूनी, सामना नगरी छोड्न सक्छु। ☐
- म बुझ्छु कि अन्वेषकहरू र आईआरसी र अन्य नियामक प्राधिकरणहरूलाई हालको अध्ययन र यस सम्बन्धमा हुने कुनै पनि अनुसन्धानको सम्बन्धमा मेरो स्वास्थ्य रेकर्ड हेर्नको लागि मेरो अनुमतिको आवश्यक पर्दैन, यदि म परीक्षणबाट फिर्ता भए पनि। । ☐
- मँ बुझ्छु कि मेरो पहिचान कुनै पनि जानकारीमा प्रकट हुँदैन ☐
- यस अध्ययनबाट उत्पन्न कुनै डाटा वा नतिजाको प्रयोग प्रतिबन्ध नगर्न म सहमत गर्छु ☐
- यसकोप्रयोग केवल वैज्ञानिक उद्देश्यहो लागि को (हरू) ☐
- म यस अनुसन्धानमा भाग लिन सहमत छु ☐

सहभागीकोसही_____
सहभागीकोनामथर _____

सहभागीको उमेर_____
मिति२०७ / /
साक्षीकोसही_____
साक्षीकोनामथर _____
मिति२० / /
अनुसन्धानकर्ताकोनामथर_____
अनुसन्धानकर्ताकोसही_____
मिति२०७ / /