Version: 2

Standard Operating Procedure of Institutional Review Committee

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Reviewed by: Dr. Akhilesh Kumar Kasyap	Effective date: 25 August, 2024

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Preparing Standard Operating Procedures (SOPs) and Guidelines for Ethics Committees

1. Writing, Reviewing, Distributing and Amending Standard Operating Procedures for Ethics Committees

Purpose

This Standard Operating Procedure (SOP) defines the process for writing, reviewing, distributing and amending SOPs within the Grande International Hospital, IRC. The SOPs will provide clear, unambiguous instructions so that the related activities in the ethics committee are conducted in accordance with the NHRC guidelines for Institutional Review Committee (RC) and Ethical Review Board.

Scope

This SOP covers the procedures of writing, reviewing, distributing and amending SOPs within the Grande International Hospital Institutional Review Committee (GIH-IRC)

Responsibilities

It is the responsibility of the IRC to appoint the SOP Team to formulate the SOPs. The roles and responsibilities of various members of IRC are described below:

IRC Coordinator:

- Coordinates activities of writing, reviewing, distributing and amending SOPs
- Maintains the file of current SOPs and the list of SOP
- Maintains an up-to-date distribution list for each SOP distributed
- Distributes the SOPs with a receipt to all users
- Ensures all ethics committee members and involved administrative staff have access to the SOPs
- Ensures the ethics committee members, secretariat staffs and reviewers are working according to current version of SOPs

SOP team:

- Proposes required SOP
- Selects the format and coding system
- Drafts the SOP in consultation with ethics committee members and involved ERB secretariat staff
- Assesses the request(s) for SOP revision in consultation with the secretariat and Chairperson

Chair of the IRC:

- Reviews and approves the SOPs
- Signs and dates when receives the approved SOPs

Members of IRC:

- Sign and date when they receive the approved SOPs
- Maintain a file of all SOPs received
- Return all out-of-date SOPs to the ERB secretariat in charge.

2. FLOW CHART

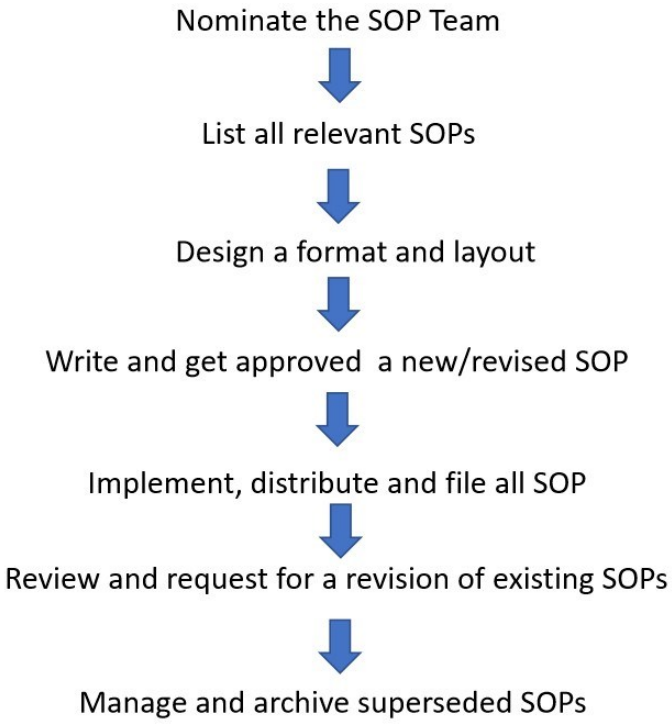


Figure 1.1 Flow Chart

The following chart depicts the actual flow of the process where an amendment is made in the SOP of GIH-IRC.

The roles and responsibilities of each SOP Team members are described in the next subsequent sections.

3. Roles and responsibilities if SOP team

The roles and responsibilities of SOP during the amendment of any section. Following members are involved in various activities to integrate the amendment in the document.

SN	Activity	Responsibility
1	Nominate the SOP Team	IRC
2	List all relevant SOPs	SOP Team
3	Design a format and layout	SOP Team
4	Write and get approved a new/revised SOP –	SOP Team and IRC Chair
5	Implement, distribute and file all SOPs	IRC co ordinator
6	Review and request for a revision of existing SOPs	IRC co ordinator
7	Manage and archive superseded SOPs	IRC co ordinator

Table 1.1 Roles and responsibilities if SOP team

4. The Procedure for the amendment

The Procedure for the amendment of SOP requires formation of SOP team and communication of the amendment followed by approval by chair person

a. Nomination of the SOP Team

The IRC appoints the appropriate individuals who have a thorough understanding of ethical review process to form the SOP writing team.

- List all relevant SOPs · Write down step by step all ERB procedures.
- Organize, divide and name each process.
- Make a list of SOPs with coding reference (Annex1:AF01-001/01.0)

b. Format and layout

- Each SOP should be given a number and a title that is self-explanatory and is easily understood.
- A unique code number with the format SOP/XXX/YY.W will be assigned to each SOP item by the coordinator.
- XXX is a three-digit number assigned specifically to the SOP.
- YY is a two-digit number identifying the version of the SOP, & W is a one-digit number identifying the version of SOP with minor changes in the SOP.
- The number of versions should be started from 01 and the W should be started with 0, for example, SOP001/01.1 is the SOP number 001 version 01 with one minor revision i.e. 01.1.

c. For Annexes:

- Each annex will be given a unique code number with the format AF/BB-XXX/YY.W. AF is the abbreviation for Annex Form.
- BB is a two-digit number identifying the number of the annex, for example AF/01-001/01.0 means Annex Form number one of the SOP/001/01.0

d. Writing and approval of SOP

- If an SOP supersedes a previous version, indicate the previous SOP version and the main changes in the historical form (Annex 2 – AF 02-001/01.0).
- When the need for a new SOP has been identified and agreed on, a draft will be written by a designated member of the SOP team.
- The draft SOP will be discussed with ethics committee members and IRC Secretariat. The SOP should be agreed upon by the people involved in that particular task. The final version will be passed to the IRC Chair for review and approval.

e. Implementation and distribution of SOPs

- The approved SOPs will be implemented from the effective date.
- The approved SOPs will be distributed to the ERB members and the relevant staff by the Secretariat according to the distribution list. (Annex 3 – AF 03-001/01.0). When a revised version is distributed, the old version will be retrieved and destroyed.
- One complete original set of current SOPs will be filed centrally in the SOP Master file (printed hard and e-copies), by the secretariat of the IRC and kept in the IRC office.

f. **Request for a revision of an existing SOP**

- Any member of the ERB and secretariat who notices an inconsistency between two SOPs or has any suggestions on how to improve a procedure should use the form in Annex to make a request
- If the SOP team agrees with the request, an appropriate team will be designated to proceed with the revision process. If the committee does not agree, the ERB chair will inform the person who made the request of the decision.
- Revision of the SOPs will be reviewed and approved in the same manner as new SOPs. The coordinator is expected to review the SOPs at least every 2 years and record the dates of review on the SOP Master file or whenever there is a request from NHRC to update any changes in the NHRC guidelines.
- Any new changes will be carried out after filling the form in Annex 4 (AF 04/001/1.0)

g. Manage and archive superseded SOPs

Superseded SOPs should be retained and clearly marked **"superseded"** and archived in the historical file by the IRC coordinator.

h. Glossary

SOP (Standard Operating Procedure): A Detailed, written instructions, describing all activities and actions undertaken by an organization to achieve uniformity of the performance of a specific function. The aim of the SOPs and their accompanying checklists and forms is to simplify the organization and documentation of operation, whilst maintaining high standards of Good Clinical Practice.

IRC member: An individual serving as regular members of IRC. The boards are constituted in accordance with the IRC membership requirements set in the guideline.

SOP Team: A selected committee of the ERB members and secretariat staff who oversee the creation, preparation, review and periodic revision of the SOPs.

Master SOP files: An official collection of the standard operating procedures (SOP) accessible to ERB secretariat staff, ERB members, auditors and government inspectors as a paper copy with an official stamp on each page and the approval signatures. Photocopies made from these official paper versions of the SOP cannot be considered current or official.
SOP historical files.

A collection of previous official versions of a SOP, table of contents, relevant information regarding changes and all preplanned deviations.

i. References:

- WHO Operational Guidelines for Ethical Review Committee That Review Biomedical Research (Geneva 2000 www.who.int/tdr/publications/publications/ - accessed 11 February 2005)

- ICH E6: GCP 1996

Preparation of Guidelines

National Ethical Guidelines for Health Research in Nepal 2022 is used as the guiding document in preparing the SOP.

1. Constituting an Ethics Committee

Ethical Review Process GIH-IRC established as per the guidelines for Institutional Review Committees (IRCs) for Health Research in Nepal section 2016, is mandated to review, approve, and monitor the research involving human participants and ensure the social and scientific value of the study and its ethical conduct. The IRC and the institution have the responsibility to ensure that the conduct of all health-related research approved by the IRC be monitored and supervised by procedures and/or by using existing appropriate mechanisms within the institution. (section 11, Requirement of approval to do health-related research)

Suppose any person or organization does research work without obtaining approval pursuant to Section 11 or does not observe the direction given by the Council in doing research work after obtaining approval. In that case, the Council may warn such a person or organization or restrict such research work for a certain period of time (NHRC Act section 12, "Special powers of Council").

2. Constituting an IRC

a. Objectives:

- To work within the framework of the highest possible ethical and scientific standards in biomedical research.
- To be independent, autonomous and multidisciplinary in nature.
- To develop a mechanism to ensure clear and efficient communication, harmonization of standards, networking and cooperation between the IRC and ERB of NHRC.
- To be familiar with the different methodologies and ethical considerations that apply to each type of proposed research.
- To establish a clear procedure for the effective review of health-related research proposals.
- To develop and establish a mechanism to train its members in order to maintain a high ethical and scientific standard.
- To propose administrative and financial support from the institute.
- To outline a clear registration process and fee for reviewing a research proposal.

(Note: An IRC may implement its own procedure to interact with other IRCs regarding matters of common interest as necessary. Such interactions enable IRCs to learn about prior decisions by other IRCs or the ERB of NHRC that may be relevant to proposed research under review)

b. Responsibilities

Responsibilities for developing mechanism for the establishment of an IRC and for the selection of the members to the IRC will done in following manners:

GIH Executive Committee is responsible for nominating IRC Chairperson and then approved by the Medical director. The Chairperson who will be then responsible for forming a 7 to 15 member committee which will be then approved by the Medical Director.

Following are the criteria required for the formation of GIH-IRC:

Criteria 1: The committee is multidisciplinary, pluralistic, gender, age and discipline balanced.

Criteria 2: The committee should include at least one member who is not affiliated with the institution.

Criteria 3: The committee should include at least one person from the administration representing a general population (The voting member of IRC).

Criteria 4: If any IRC includes a member from NHRC, the member from NHRC should not be a voting member of the IRC.

Criteria 5: A person is considered eligible for the membership of IRC, if s/he has a postgraduate qualification in health-related sciences (basic and biomedical/clinical/public health/ Epidemiology / Biostatistics /nursing) with knowledge and experience in the ethical conduct of the health research.

The recommended member are within the expertise in the following disciplines

- Public health/epidemiology/research methodology
- Biomedical/laboratory science
- Clinical science
- Nursing
- Behavioral and social sciences
- Biostatistics
- Pharmacy/Pharmacologist
- Law/ Teaching/ Journalism/ Community Leadership

In addition, a person with a postgraduate degree in law and legal expertise in the health sector and a sociology/anthropology post-graduate with experience related to social health research can also be eligible to be an ERB member. Each member should be self-motivated to maintain basic ethical principles (beneficence, non-maleficence, autonomy an justice).

All IRC members should hold an appropriate educational degree, training and research experience in health-related research processes. These members should be given an initial orientation on basic principles of research ethics and the proposal approval process adopted by the IRC. The member secretary appoints an expert consultant on an ad-hoc basis to the IRC, but the consultant should *not be considered as a voting member* of the IRC.

3. Terms and Conditions of Appointment

Appointments should be made for tenure of three years, with a provision for re-appointment. A rotational system for membership should be considered that allows for continuity, the development and maintenance of expertise within the IRC, and the regular input of fresh ideas and approaches. Institutions should plan in such a way that not more than 50% of the members retire at once, in order to facilitate or ensure continuity of the IRC. Also, no 2 members can resign at once.

Conditions of Appointment IRC members shall be appointed under the following conditions:

- If he/she entirely agrees to make his/her profile public, as a member of IRC
- If he/she is able to read meticulously, understand what constitutes a conflict of interest for IRC members, and declare Conflict of Interest, if any
- If he/she signs a confidentiality agreement regarding IRC meetings, discussions, and research proposals applied for ethical review.
- If he/she agrees that the remunerations paid to him/her in the course of IRC work will be recorded and made available to the public on request.
- If he/she provides a recent CV and relevant training certificate related to health research ethics, GCP, GCLP, etc. (as applicable).
- If he/she is aware and ready to abide by relevant national laws, NHRC guidelines, and regulations.

The conditions of appointment to the IRC should state provisions available for IRC members to receive introductory training in the work of the IRC as well as ongoing opportunities for enhancing their capacity for ethical review. List of Introductory training:

- Basic Research Ethics
- Good Clinical Practice
- Standard Operating Procedure

4. IRC Office:

The institution can setup an IRC Office with necessary administrative support. It should clearly designate the Chairperson, Member-Secretary and Members. The list of the name of IRC members should be displayed in front of the IRC office. There should be at least one administrative staff provided by the institution for the IRC office otherwise such tasks should be delegated to one of the officers of the institution.

Duties & responsibilities of each IRC member should be clearly stated. All working procedures must be in writing; for example, agenda, minutes, notification of decisions, monitoring and supervision etc.

5. Quorum Requirements

The presence of at least 51% members of the total number of IRC members shall be deemed to constitute quorum or the meeting of IRC. At least one female member and one legal or non-affiliated member must be present to make decisions about any proposed research. A voting member must be present to approve the final decision.

Invited experts/consultants *should not be counted in meeting quorum requirement.*

6. Provision for Panel of Experts/Consultants

The IRC can prepare a list of potential experts who are capable and interested in reviewing research proposals. These experts/consultants can be specialists in specific diseases, particular health problems/ conditions, health systems, health research methodologies, legal or ethical aspects, or members of special interest/minority groups who can provide special expertise to the IRC on proposed research protocols. It is strongly recommended that the IRC should develop terms of reference for all independent consultants.

Terms of reference for all independent consultants should include following points:

- If he/she is able to read meticulously, understand what constitutes a conflict of interest
- Declare Conflict of Interest, if any
- If he/she signs a confidentiality agreement regarding IRC meetings, discussions, and research proposals applied for ethical review.
- If he/she agrees that the remunerations paid to him/her in the course of IRC work will be recorded and made available to the public on request;
- If he/she is aware and ready to abide by relevant national laws, NHRC guidelines, and regulations.

7. Procedures for reappointment, resignation, and discontinuation of appointment (such as for non-attendance)

The reappointment of a old IRC member will follow the same procedure as appointment of a new member. Resignation will be accepted via an Email to IRC and decision is made in the IRC meeting and memo will be submitted to the hospital administration after approval of the Medical Director.

The discontinuation of appointment will be as per the decision of the Committee and the decision will be submitted in a form of memo and approved by the Medical Director along with a reason such as non-attendance or any other valid reason

8. Duties and Responsibilities of IRC Members

a. Chairperson

- Nominating the members for IRC
- Reviewing and Approving the SOP
- Signing when receive the approved SOP
- To approve the decisions made by the committee

b. Member Secretary

- Reviewing and Approving the SOP
- Signing when receive the approved SOP
- To approve the decisions made by the committee

c. Members

- Reviewing research proposals to ensure adherence to ethical guidelines.
- Monitoring ongoing research projects to safeguard the welfare of research participants.
- Providing guidance and recommendations on ethical considerations related to research activities.

d. IRC Coordinator

- Plan meeting and meeting agenda
- Communicate decisions and archive documents
- Monitoring and Evaluation

9. Quorum Requirements:

The presence of at least 51% members of the total number of IRC members shall be deemed to constitute quorum or the meeting of IRC. At least one female member and one legal or non-affiliated member must be present to make decisions about any proposed research. Footnote Invited experts/ consultants should not be counted in meeting quorum requirements.

10. Provision for Panel of Experts/Consultants:

The IRC can prepare a list of potential experts who are capable and interested in reviewing research proposals. These experts/consultants can be specialists in specific diseases, particular health problems/ conditions, health systems, health research methodologies, legal or ethical aspects, or members of special interest/minority groups who can provide special expertise to the IRC on proposed research protocols. It is strongly recommended that the IRC should develop terms of reference for all independent consultants.

Terms of reference for all independent consultants should include following points:

- If he/she is able to read meticulously, understand what constitutes a conflict of interest
- Declare CoI, if any
- If he/she signs a confidentiality agreement regarding IRC meetings, discussions, and research proposals applied for ethical review.
- If he/she agrees that the remunerations paid to him/her in the course of IRC work will be recorded and made available to the public on request; that he/she is aware and ready to abide by relevant national laws, NHRC guidelines, and regulations

11. Training Personnel and IRC Members

Training of the IRC member is carried out on request of NHRC that includes mandatory training and additional training. The evidence of this training is kept in the IRC office.

12. Selection of Independent Subject Experts

Independent Subject Experts are after the joint review of protocol/proposal are conducted and the decision of IRC is approved. The Independent Subject Expert will be provided an invitation letter who will then provide his/her CV and include them in the subsequent meetings until the proposal is accepted.

Confidentiality / Conflict of Interest Agreements and Mitigation Measures

1. Privacy and Confidentiality

Researchers ensure participants' privacy during the research. The identity and records of the participants should be kept confidential, and access to such information should be limited to authorized individuals only. However, the privacy of certain information such as suicidal ideation, homicidal tendency, and risky behavior of participants with a positive status of infectious diseases (HIV, TB, Influenza, COVID-19, etc.) can be breached only in consultation with the IRC and ERB-NHRC (if necessary). In other words, breach of privacy and confidentiality is justified only when supported by valid scientific or legal reasons. Individuals' right to life is considered more important than the research participants‟ right to privacy and confidentiality. Also the privacy of the reviewers should be maintained by other members of IRC.

The IRC Coordinator assigns Reviewer's Code to the is implemented during review process. Reviews Code is a Unique two digit code assigned to each reviewers of IRC.

2. Identifying, Mitigating and Managing Conflict of Interest

a. **At the level of researchers:** The researcher identifies and disclose any financial and/or non-financial conflict of interest between the researcher and the bodies representing the ethical oversight. The researcher should also express his/her commitment to time and resource investment in conducting the research.
b. **At the level of reviewers:** The reviewer declares CoI during the review process if any of his/her close friends, family members, and/or students have submitted the research proposal to obtain research grants and approval. The reviewer declares CoI if any of his/her close friends, family members, and/or students are directly or indirectly involved in the research study.
c. **At the level of a research institution:** The institution communicates and declares CoI with transparency during the research process (and develops SOP to manage and mitigate said CoI. CoI should not interfere in any process of the ethical review, implementation, monitoring, data analysis, and recommendation. The process of managing CoI should be clearly documented in the SOP.)
d. **At the level of ECs:** IRC members must declare their CoI (if any) and take appropriate actions to recuse themselves from the review and decision-making process on the protocol(s) related to their CoI and follow directives from the IRC.

Procedures to manage COIs

Disclosure Forms: Require IRB members, researchers, and any other relevant individuals to complete detailed disclosure forms. These forms should be updated regularly. The COI disclosure form should contains following information:

Date of Disclosure:

Personal Information

Name:
Position/Title:
Department/Division:
Institution/Organization:
Contact Information (Email/Phone):
Type of Disclosure: (e.g., Financial, Personal, Professional, Institutional)

Description of Potential Conflicts

Provide detailed information about the potential conflicts:

I. Financial Conflicts: (Such as Direct Financial Interests) Examples of such Financial conflicts are Ownership of stocks, equity, or financial stakes in companies that could benefit from the research outcomes.

It includes the consulting fees, Grants and Contracts and Royalties. They are described as below:

a. **Consulting fees:** The Payments or honoraria received for consulting services from organizations that could be affected by the research.

b. **Grants and Contracts:** Financial support from funding sources with interests in the research outcomes or applications.

c. **Royalties:** Payments received from patents, copyrights, or other intellectual property that may be impacted by the research.

d. **Amount/Value:** (Provide approximate values if applicable)

II. Personal Relationships

a. **Family:** Financial or personal relationships with family members who could benefit from the research outcomes.

b. **Friends:** Close friendships with individuals who have a stake in the research results.

c. **Romantic Relationships:** Romantic or intimate relationships with individuals who have an interest in the research.

d. Professional Relationship

Collaborators: Professional collaborations with individuals or organizations that have a vested interest in the research results.

Mentors: Relationships with mentors who may have conflicting interests or expectations regarding the research.

Supervisors: Supervisory relationships that might affect the objectivity of the research process or decisions.

III. Institutional Conflicts

Institutional Investments: Financial interests held by the institution in companies or sectors related to the research.

Partnerships and Alliances: Institutional collaborations or partnerships that could influence research outcomes or the review process.

Submission of Proposal in more than one IRC at the same time for a single center study.

IV. Intellectual and Academic Conflicts

Academic Rivalries: Conflicts stemming from competition or rivalry with other researchers or institutions.

Publication Bias: Influence from the desire to publish results that align with previous work or institutional goals.

Professional Advancement: Personal ambitions related to career advancement or reputation that could bias research decisions.

V. Research-Specific Conflicts

Study Design: Bias in study design that could affect the outcomes, such as selective reporting or methodological flaws.

Data Management: Manipulation or selective presentation of data to support a desired outcome.

Peer Review: Potential biases in peer review processes due to personal or professional relationships.

VI. Regulatory and Compliance Conflicts

Compliance Issues: Conflicts arising from the need to meet regulatory or compliance requirements that might influence research design or outcomes.

Conflict with Ethical Standards: Situations where personal or institutional interests may conflict with ethical standards or guidelines for research.

VII. Other Miscellaneous Conflicts

Personal Gain: Any personal benefit or gain (e.g., awards, recognition) that might influence research objectivity.

Political or Social Influences: External pressures or interests from political, social, or advocacy groups that could affect research decisions.

Impact Assessment

Impact Assessment of a proposed research work must include

Potential Impact: (Describe how the conflict might affect the research, decision-making, or the integrity of the review process)

Mitigation Measures: (Detail any proposed measures to mitigate the conflict, such as recusal, role modification, or independent review)

Declaration

Acknowledgment of Understanding: (Confirm that you understand the institution's COI policies and the importance of full disclosure)

Signature of Disclosure:

Date:

Footnote:

Routine updates are required to ensure disclosures are updated regularly and whenever there are changes in relationships or financial interests.

Mitigation Measures

Managing or mitigating conflicts of interest (COIs) effectively involves implementing strategies that ensure decisions are unbiased and maintain the integrity of the research process. Here are key strategies to manage or mitigate identified COIs:

- **Recusal and Abstention Recusal from Decision-Making:** Require the individual with the COI to recuse themselves from participating in discussions or decision-making related to the research where the conflict exists. Abstention from Voting: Ensure that the conflicted member abstains from voting on proposals or issues where they have a conflict.
- **Independent Review External Reviewers:** Engage independent reviewers or experts who are free from the conflict to assess and make recommendations on the research proposal. Third-Party Oversight: Utilize a third-party committee (NHRC-ERB) to oversee the research process when there is a significant conflict that cannot be managed internally.
- **Role Modification Adjust Responsibilities:** Modify the conflicted individual's role to limit their involvement in the aspects of the research affected by the COI. Separate Duties: Ensure that tasks and responsibilities that could be influenced by the COI are handled by other members who are free from such conflicts.
- **Increased Transparency Disclosure Statements:** Require public disclosure of the COI in any reports, publications, or presentations related to the research. Document and publicly share how COIs are managed to maintain transparency and trust in the research process.
- **Monitoring and Reporting Regular Monitoring:** Implement ongoing monitoring to ensure that COI management strategies are being followed and are effective.
- **Reporting Mechanisms:** Establish clear procedures for reporting and addressing any issues that arise related to COIs during the course of the research.
- **Disclosure and Communication Mandatory Disclosure:** Require detailed disclosure of all potential COIs before any involvement in the review process.
- **Open Communication:** Foster an environment where members feel comfortable disclosing conflicts and discussing how they will be managed.

Initial Review Procedures

1. Submission of proposal by researcher

IRC co ordniator is responsible for managing proposal submission, review, feedback, and approval through an email and maintaining the archival database. Investigators planning to conduct health research in Grande International Hospital should submit their research proposals through the Email (ircgrande@gmail.com) for ethical review and approval.

2. Initial Review of Submitted Proposal

Principal Investigator or an assigned team member should submit the proposal and attach all the administrative and technical documents mentioned below. The administrative and technical documents to be submitted:

a. Proposal with the format provided in the website of Grande International Hospital Form A, Form B and Form C; for Single Center Study, Multi Centric Study and Thesis.
b. Informed Consent Document (ICD) in both English and Nepali language.
c. Document with clear information on any compensation to be given to the research participant (e.g., any transportation costs, food, free health care or insurance coverage, etc.).
d. Sponsors grant agreement.
e. IRB approval from other collaborating institutes if it is a multi-national and multicentric study.
f. A signed statement by the researcher stating that he/she will abide by the ethical principles of research; and
g. A declaration of the CoI and its mitigation measures, as applicable. Only those applications fulfilling the requirements will be accepted for review and further process. Incomplete submission will not be processed further. Upon successful completion of submission of the required documents, including the proposal. For any additional documents required during the review process, the researcher will be notified by the IRC secretariat. Process and list of documents and ethical review processing fee required for application is accessed in Annex – II

3. IRC/GIH reviewing process

IRC/GIH decides the process for review for a particular proposal. The review process could involve one reviewer or involve more than one reviewer or Joint Review.
If only a few proposals (two to three) need to be reviewed at a time, it would be advisable for all IRC members to review the full set including all associated documents. If a large number of proposals need to be reviewed at each meeting, one IRC member (principal reviewer) is to undertake an in-depth review including all forms, questionnaires etc., and prepare a summary containing essential details for other members to review via email.

4. Conduct of Meetings:

Meetings are conducted on a regular basis at once a month or two. The frequency of meetings shall depend on the number of applications that need reviewing. Minimum of 2 proposals are expected in a meeting. The tentative date of next meeting are circulated to all staff so that they can apply their proposal on time The number of agenda items should be reasonable so that sufficient time can be given to each item for proper discussion.

Members are provided 1 week time to peruse the applications prior to the meeting. The principal reviewers in particular should have had adequate time to review the applications assigned to them, and to consult with applicants if necessary. Depending upon the nature of the research proposal, the IRC can invite the applicant to present the proposal to the panel of experts and IRC members. This will help the IRC to understand the proposal better and guide the researcher appropriately. This procedure should be followed if an independent (expert) reviewer is invited to advise on any particular topic. Minutes of IRC meetings should be maintained in a confidential manner in a standard format.

5. Communicating a Decision:

A decision is communicated via email to the applicant according to the IRC procedures. The communication of the decision should include, but not be limited to, the following: • The exact title of the research proposal reviewed • The name and title of the research applicant.

- The name of the site(s) for the research
- The date and place of the decision
- A clear statement of the decision reached
- Any suggestions by the IRC concerning the research The name and title of the authorized representative of the IRC or the institution involved should include their signature in the letterhead of the correspondence. The date should be mentioned after the signature. In the case of a conditional decision, any requirements by the IRC, including suggestions for revision, and details of the procedure for having the application re-reviewed should be clearly stated.

Footnotes

- Potential risk to participants should reasonably be less than anticipated benefits.
- Selection of participants should be equitable. If the research involves vulnerable populations, additional safeguards should be included in the research protocol to protect the rights of these people.
- Informed consent should be obtained in an appropriate language understandable by the participant. The informed consent should be signed by the participant or a witness. The participant should be allowed to withdraw from the research at any time without explanation.
- There should be adequate provisions to protect the privacy of participants and maintain confidentiality of data.
- The research plan should make adequate provisions for monitoring during data collection to ensure the safety of participants. The mechanism for compensation in case of injury should be well documented.
- The expected duration of research should be specified prior to approval. In case of amendments, prior approval needs to be given before implementation of amended research activities.
- The IRC should receive final reports from researchers, a copy of which needs to be submitted to GIH-IRC.

6. Exemption from Review

Researchers can apply for exemption from review in certain situations. Based on the risk categorization, the ERB secretariat will put forward the proposal to the Expedited Review Subcommittee meeting for the necessary decision.

1. Quality assurance and quality control audit in the institution.
2. Observation of pubic/staff behavior when information is recorded without any link and disclosure of the person under observation.

Expedited Review of the proposals

GIH-IRC has the provision for the expedited review process whereby proposals can be reviewed and approved by one member of the IRC/GIH without convening a meeting of the GIH-IRC. The expedited review can also be used to review minor changes in a previously approved research.

Footnote Expedited Review

For expedited review, the IRC has established the procedures for the expedited review of research involving minimal risks to participants. These procedures has specified the following: The nature of the applications are expected to be the proposals approved By NHRC, The other amendments and considerations that will be eligible for expedited review.

The types of research which are eligible for expedited review procedure also include the proposals of research that are related to Quality Improvement Measures. The Member-Secretary acts as a focal person for the Expedited Review along with Chairman, a female member and a voting member.

The delegation of tasks to sub-committees thus formed by 3 members and 1 voting member. The status of decisions (e.g. subject to confirmation by the full IRC or not will be done by the Expedite Review Subcommittee). The decisions by the Sub Committee or the Full Committee is approved by the chairperson.

Research with potential for physical or psychological harm should generally not be considered for expedited review. This includes drug trials, research involving invasive physical procedures and research exploring sensitive personal or cultural issues.

Review of Proposals related to Clinical Trials
(Drug, Vaccine, Diagnostics, Device, Surgical procedure & other intervention (s))

The proposal related to Clinical Trials (Drug, Vaccine, Diagnostics, Device, Surgical procedure & other intervention (s)) will be forwarded to NHRC secretary along with a request conducting a Joint Review.

A copy of proposal will be provided to IRC by the researcher in a format provided in the website (Please refer Form B in https://grandehospital.com/irc-institutional-review-committee/) along with the approval letter of NHRC. CV of all the researchers et all will be submitted along with the proposal.

Protocol Amendments, Continuing Review, and End of Study

1. Review of Resubmitted Protocols

For proposals requiring major revision, researchers may re-submit the proposals according to the decision of the IRC. The re-submitted proposal with significant revisions will follow the same process which is used for a new proposal. The proposal that has not been approved within a year has to be submitted to GIH-IRC.

2. Review of Proposal Amendment

The researcher should submit a request for amendment through an email (ircgrande@gmail.com) 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 process; however, major revisions shall be reviewed by the full board and may require resubmission.

3. Continuing Review of Proposals

Investigators are required to conduct their studies in ways that are consistent with the protocol they have described in their proposal, and any divergences from protocol ("protocol deviations") must be reported to the IRC office. At GIH-IRC, approval of studies expires after one year, and so continuing studies must request renewal, and studies that have been completed must be formally closed.

Investigators are also asked to maintain complete records of their study's documents and provide to GIH-IRC when needed.

4. Review of Final Reports

The researcher should submit his/her final report upon completion of the study through the email. The report will be reviewed by the reviewer, or any member of the IRC, or the subject expert (as applicable).

Monitoring Protocol Implementation

Monitoring mechanism is developed tailored to the research design and documentation is done by the IRC coordinator and kept in the IRC office. A checklist is developed based on the research proposal and documented and approved by The Chairperson/ The Member secretary.

Non-Compliance/Violation Any non compliance/violation during the monitoring phase can lead to termination of the requested research where corrective action cannot be taken. The decision is made during the IRC meeting and approved by the The Chairperson/ The Member secretary.

Response to Request The IRC office responds to any request within the ethical standard of NHRC. The Principle Investigator queries in the IRC email for the same purpose which is discussed with the reviewer.

Management of Study Termination

The IRC office issues a letter regarding the termination of a study due to the reasons mentioned in the letter. The original copy is provided to the Principal investigator and a copy is retained in the office.

Preparation of Review Meeting Agenda and Communication Records

The IRC coordinator is responsible for the preparation of the agenda meeting after discussion with the member secretary. The meeting preparation consists of a list of proposals and remarks and the assigned reviewer. Other agenda apart from the proposal review is discussed at the end of the session. The agenda of the meeting is attached in the invitation email. The meeting minutes are maintained in the meeting register along with the attendance of the meeting. The communication with the primary investigator will take in a form of email sent to the respective email address.

Archival and Retrieval of Documents

The documents available in the IRC consist of Request letters, CV and approval letter. The copy request letters that are received or sent are provided in the administration and IRC office. The Soft Copy of CV and proposals are stored and protected in the IRC office. The IRC office retains the original copy of the approval letter and provides the copy of the letter to the principal investigator. The submitted published articles are kept in the IRC office for reference.

Annexure 1

List of SOPs

Sn	Title	SOP Number
1	Preparing Standard Operating Procedures (SOPs) and Guidelines for Ethics Committees	SOP/001/1.0
2	Preparation of Guidelines	SOP/002/1.0
3	Confidentiality / Conflict of Interest Agreements and Mitigation Measures	SOP/003/1.0
4	Initial Review Procedures	SOP/004/1.0
5	Expedited Review of the proposals	SOP/005/1.0
6	Review of Proposals related to Clinical Trials *(Drug, Vaccine, Diagnostics, Device, Surgical procedure & other intervention(s))*	SOP/006/1.0
7	Protocol Amendments, Continuing Review, and End of Study	SOP/007/1.0
8	Monitoring Protocol Implementation & Management of Study Termination	SOP/008/1.0
9	Preparation of Review Meeting Agenda & Communication Records	SOP/009/1.0
10	Archival and Retrieval of Documents	SOP/010/1.0

Annexure 2

Document History

Author –	Version	Date	Describe the main change
Dr. Sworup Shrestha	0.2	*25-07-024*	first draft
Dr. Sworup Shrestha	2.0	*25-08-024*	final version

Annexure 3

Log of SOP Recipients

No.	Name of Recipients	SOP	No. of Copies	Signature	Date
1	Dr. Akhilesh Kumar Kasyap (Chairperson)	All SOPs	1		
2	Dr. Bibhuti Nath Mishra (Member Secretary)	All SOPs	1		
3	Dr. Sworup Shrestha-IRC office	All SOPs	1		

Annexure 4

Request for Revision of a SOP

(Please complete this form whenever a problem or a deficiency in an SOP is identified and maintained with the SOP until an authorized replacement is in place)

SOP Code:		
Title:		
Details of problems or deficiency in the SOP:		
Identified by:	Date (DD/MM/YY):	
Discussed with:	☐	☐
SOP revision required:	Yes	No
If yes, to be carried out by whom?		
If no, why not?		
Date SOP re-finalized:		
Date SOP approved:		
Date SOP becomes effective:		

Annexure 5

Fee Structure

Regarding the Research Fee, the applicants has to pay certain fee as per below categories while fee for the internal applicants (Staff of Grande International Hospital) can be waived off at discretion of the management.

S. No.	Degree	Research Fee (NPR)
1.	Bachelor's Degree	5,000
2.	Master's Degree and above	10,000