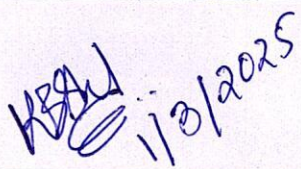
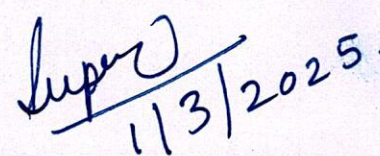
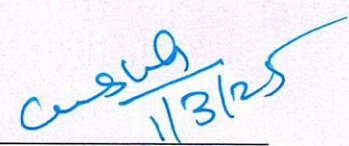




Standard Operating Procedures (SOP)
For
NHL Institutional Ethics Committee
(NHLIEC)
Version: 8.3
Effective From: 01.03.2025

NHLIEC SOP Version 8.3 Effective From: 01.03.2025

Validity: Three years or Release of next version (whichever is earlier)

Prepared by: Dr. Karan Shah Assistant Professor, Department of Pharmacology Smt. NHL Municipal Medical College, Ahmedabad.	 Signature with date
Reviewed by: Dr. Supriya Malhotra Professor & Head, Department of Pharmacology Smt. NHL Municipal Medical College, Ahmedabad.	 Signature with date
Approved by: Dr. Cherry K. Shah Dean (Institutional Head), Smt. NHL Municipal Medical College, Ahmedabad.	 Signature with date
Complete Name of the Ethics Committee	Institutional Ethics Committee, Smt. NHL Municipal Medical College, Ahmedabad (NHLIEC)
Complete address of the office of the Ethics Committee	Department of Pharmacology, First floor, Smt. NHL Municipal Medical College, Ellisbridge, Ahmedabad- 380006
Hospitals attached to the Institution and the Institutional Ethics Committee	• SVP Institute of Medical Sciences & Research, Ellisbridge, Ahmedabad • SCL General Hospital, Saraspur Ahmedabad • Shri C.H. Nagri Municipal Eye Hospital, Ellisbridge, Ahmedabad
Frequency of Ethics Committee Meeting	As per the requirement, [around 6 in a year]
Date of Next/ immediate Ethics Committee meeting	As decided by the Member secretary after consultation with Chairperson
Lead time required by the Ethics Committee before which they discuss documents submitted to them	15 days



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INSTITUTIONAL ETHICS COMMITTEE

Registration No. ECR/245/Inst/GJ/2013/RR-24

Purpose

The purpose of this Standard Operating Procedure (SOP) is to outline the

- Composition, roles and responsibilities of Members of NHLIEC
- Application process for review of submitted clinical trials by NHLIEC
- Review guidelines for NHLIEC members
- Decision-making by the NHLIEC and notification to the applicant
- Ongoing review of the conduct, progress, efficacy and safety of a clinical trial.
- Special consideration for vulnerable population

The SOP provides clear, unambiguous instructions so that the related activities of the committee are conducted in accordance with Indian laws and relevant, National and International Guidelines

Objective

The Institutional Ethics Committee of the Smt. NHL Municipal Medical College (NHLIEC), Ellisbridge, Ahmedabad-380006, India in the western zone of Ahmedabad, is established with an objective that all clinical trials/studies on patients of all affiliated hospitals (S.V.P. Institute of Medical Science and Research, Smt. S.C.L. General Hospital, C.H. Nagri Eye Hospital) are being conducted as per ICH and GCP guidelines and the safety & wellbeing of the patients are properly maintained.

The NHLIEC essentially targets patient care and ethical aspects of research & education, being undertaken in the affiliated hospitals and college departments. It safeguards the rights, safety and wellbeing of all trial subjects. Special attention will be paid to trials that may include vulnerable subjects. The Committee will ensure that clinical trials are conducted in accordance with the ethical principles laid down in the Declaration of Helsinki, ICMR guidelines, Schedule Y of Drugs & Cosmetics Act and abide by the New Drugs & Clinical Trials Rules, 2019 as well as “National Guidelines for Ethics Committees Reviewing Biomedical & Health Research during COVID 19 pandemic” April 2020 along with ICH & GCP guidelines.



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Scope

Each trial, under the GCP principle, should be conducted in compliance with the protocol that has received prior EC approval/favourable opinion. This SOP covers all clinical trials from Phase I to Phase IV. This includes the investigator-initiated research as well as parent or other organization or pharmaceutical company sponsored trials that are submitted to NHLIEC.

Role

The NHLIEC will review and approve all types of research proposals involving human participants with a view to safeguard the dignity, right, safety and wellbeing of all actual and potential research participants. The goals of research, however important, would never be permitted to override the health and wellbeing of the research subjects.

The NHLIEC will take care that all the cardinal principles of research viz. Autonomy, Beneficence, Non-maleficence and justice are taken care of in planning, conduct and reporting of the proposed research. For their purpose, the NHLIEC will look into the aspects of informed consent process, risk benefit ratio whenever required.

The NHLIEC will review the proposals before start of the study as well as monitor the research throughout the study until and after completion of the study. The NHLIEC will also examine compliance with all regulatory requirement, applicable guidelines and laws.

Composition

- The NHLIEC has been constituted under the authority of the ex officio Dean, Smt. NHL Municipal Medical College, Ellisbridge, Ahmedabad-380006 and shall comprise of 10-15 members [to allow a quorum of at least 5 members at each review meeting in order to provide collective expertise ensuring a comprehensive review (scientific and ethical) of the projects submitted to it.]
- The Dean in office can be a part of the committee.
- NHLIEC shall be multi-disciplinary and multi-sectoral.
- There shall be adequate representation of age and gender.
- At least 50% of the members shall be non-affiliated or from outside the institution.



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The composition may be as follows: -

- 1) Chairperson
 - 2) 1-2 basic medical/non-medical scientist
 - 3) 1-2 clinicians from each specialty
 - 4) One legal expert or retired judge
 - 5) One social scientist / representative of non-governmental voluntary agency/
philosopher / ethicist
 - 6) One lay person from the community
 - 7) Member Secretary
 - 8) Co-Member Secretary can be appointed with due permission of the Dean
- f) The dean in office should appoint, from among its members, a chairperson (who is from outside the institution) and nominate a Member Secretary
- g) The member secretary would belong to the same institution and would conduct the business of the committee.
- h) There will be adequate representation of age, gender, community, etc. in the NHLIEC to safeguard the interests and welfare of all sections of the community / society.
- i) Members should be aware of local, social and cultural norms, as this is the most important social control mechanism.
- j) The committee will comprise a diverse working group without any gender bias.
- k) The following qualities are sought in the NHLIEC members:
- ✓ interest and motivation,
 - ✓ commitment and availability,
 - ✓ experience or education,
 - ✓ respect for divergent opinions,
 - ✓ interest in committee work,
 - ✓ integrity, and
 - ✓ diplomacy

Quorum

For review of each protocol, the quorum of NHLIEC should be at least 5 members with the following representations as per ICMR guidelines and NDCT Rules-2019:

- a) Basic medical scientist (preferably one pharmacologist).



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- b) Clinician
- c) Legal expert
- d) Social scientist/ representation of non-governmental voluntary agency / philosopher / ethicist / theologian or similar person
- e) Lay person

In any case, for the appropriate quorum, the NHLIEC must include at least one member whose primary area of interest/ specialization is non-scientific and at least one member who is independent of the institution / trial site preferably, the Chairperson.

In absence of Chairperson, one of the members from outside the institution may be appointed as Acting Chairperson for the particular meeting by the Dean.

At least one female member should remain present

If required, Subject experts may be invited to offer their views.

Further, based on the requirement of research area, e.g. HIV AIDS, genetic disorders etc. specific patient groups may also be represented in the NHLIEC as far as possible. Only those NHLIEC members who are independent of the clinical trial and the Sponsor of the trial should vote / provide opinion in matters related to the study.

Terms of Appointment

- a) The members including the member secretary will be nominated & appointed by the Dean in office, who would be a mix of medical, non-medical scientific and non-scientific persons including lay public to reflect differed viewpoints.
- b) The members will be selected to have an equitable representation of all specialties. It includes scientists, clinicians, members of the community, a lawyer /expert in ethics, a social worker.
- c) Duration: The members will be appointed for duration of 5 years.
- d) Renewal: The membership may be renewed after the stated term again, for a period of 3 years.

Replacement/Removal procedure

- a) The members may be replaced/ removed at the discretion of the committee members



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when a majority vote is obtained.

- b) A member may be relieved of his/her membership when he/she remains absent from the meeting frequently without prior information to the member secretary.
- c) A member may also be relieved of his/her membership in case of a conduct unbecoming for a member of the Ethics Committee.
- d) In case of any dispute in the same, the institutional head (dean) will be the final authority

Resignation procedure

The member can resign from the committee after discussion to the Dean in office.

Updating NHLIEC members

All relevant new guidelines should be brought to the attention of the members. Members should be encouraged to attend national and international training programs in research ethics for maintaining quality in ethical review and to be aware of the latest developments in this area.

Archiving/Record keeping

- a) The constitution and composition of the Ethics Committee
- b) Curriculum Vitae (CV) of all members of Ethics Committee
- c) Standard Operating Procedures followed by the Ethics Committee
- d) Hard/soft copy of National and International Guidelines followed by the Ethics Committee
- e) Copy of all study protocols with enclosed documents, annual reports, side-effects/ADRs etc.
- f) The studies which are completed shall be archived and later on destroyed at the end of five years. Those studies which are not initiated, are rejected or terminated midway by sponsor shall be archived and later on destroyed at the end of three years
- g) Minutes of all meetings with due signature of Chairperson and Member Secretary.
- h) Hard/soft Copy of all correspondence of the study
- i) The final report of the completed projects



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Voting status

Voting is done at the end of protocol presentation. Particular emphasis is on voting in matters where unanimity is not possible. All members including the member secretary have the right to vote. Chairperson will cast a deciding vote in case of a tie.

Conflict of Interest

Definition: A situation in which a person, such as a public official, an employee, or a professional, has a private or personal interest sufficient to appear to influence the objective exercise of his or her official duties.

There are three key elements in this definition: financial interest, official duties, and professional interest.

A conflict of interest occurs when:

- An individual's private interest differs from his or her professional obligations to the institute.
- Professional actions or decisions occur that an independent observer might reasonably question.
- A conflict depends upon situation and not on the character or actions of the individual.
- Potential conflicts of interest must be disclosed and managed as per policy.

Measures to monitor or prevent Conflict of Interest for NHLIEC Members:

At the beginning of the tenure and before he/she commences to review research projects submitted to NHLIEC and before he/she starts to function as an NHLIEC member and before he/she starts attending NHLIEC meetings will read the Confidentiality and Conflict of Interest Agreement Form carefully and thoroughly and will sign and date the document before the Member Secretary. The signed form shall remain with the office of the Committee and a photocopy shall be handed over to each member. [The appropriate Confidentiality and Conflict of Interest Agreement Form will be provided to the NHLIEC members annexed as Annexure 2]

Whenever such situation arises e.g. any NHLIEC member being one of the investigators in the proposed research, he/she would not participate in the proceedings of the meeting



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related to the referred proposal. His/her participation if needed will be only limited to the clarifications sought by the other members related to the referred research proposal in which he/she is one of the investigators.

In other situations, decision will be jointly taken by all the members.

It is recognized that the potential for conflict of interest will always exist but institution has faith in the NHLIEC members and in its chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects.

It is the policy of the NHLIEC is that no member may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the NHLIEC

The Member Secretary will immediately disclose to the Chairperson of the NHLIEC any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Committee, and to abstain from any participation in discussions or recommendations or decision making in respect of such proposals.

If an applicant submitting a protocol believes that an NHLIEC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol. The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the NHLIEC member(s) in question. The Committee may elect to investigate the applicant's claim of the potential conflict.

When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the NHLIEC review or approval except to provide information requested by the Committee.

Training of the NHLIEC Members in Research Ethics

- ✓ An individual selected as a new member of the NHLIEC will be required to attend one meeting as an 'Observer' before being inducted as a member.
- ✓ Member-secretary or an NHLIEC member will provide an introductory training to the new member.

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SAE Reporting

- The Investigator must report all onsite SAE's as per regulatory timelines for Data Elements of SAE. The Investigator shall submit SAE reports received from the Sponsor to the EC. The Investigator forwards summary reports of all onsite SAEs to the EC at the time of continuing review within the specific timeframe.
- The SAEs will be discussed during the next scheduled EC meeting or emergency meeting as required after the receipt of SAE reports.
- EC shall review all SAE reports (occurring at the trial sites approved by EC) in accordance with the regulatory requirements. If the SAE is related to the clinical trial or study conduct, and death or injury occurs at the trial site, EC shall determine and recommend financial compensation for the clinical trial subject as per current regulations (The New Drugs and Clinical Trials Rules 2019). Compensation calculation shall follow the Compensation Formula as decided by CDSCO. The SAE review will be documented in minutes of the meeting.
- EC shall forward its review report on SAE(s) (occurring at the trial sites under a given EC), along with its opinion on financial compensation (if any), to the regulatory authority.
- EC shall forward their opinion on SAE to DCGI within 30 calendar days of the occurrence of the SAE.
- The Investigator shall notify the EC if medical management or compensation has been provided to the clinical trial subject as decided by the local regulatory authority.

SAE Analysis, Calculation of Compensation, and Communication to DCGI

- The Investigator/Sponsor shall submit the SAE details as per (Refer Annexure VIII - Table 5 as per New Drug and Clinical Trial Rules 2019) with the WHO-UMC causality template within 24 hours of occurrence of SAE with available supporting documents. (Refer Annexure IX - WHO-UMC Causality Template)
- The Sponsor & Investigator shall forward their due reports on SAE cases after analysis to the EC, Head of Institution within 14 days of the knowledge of occurrence of SAE injury cases or death.
- The Ethics Committee shall forward their reports on SAE injury cases after due analyses, along with their opinion on financial compensation, to the regulatory



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authority within 30 days of receiving the report of the serious adverse event from the investigator.

- The Expert Committee shall provide their recommendations within 30 days of receiving the report of SAE of injury cases or death.
 - The Central Licensing Authority (CLA) shall pass orders to the Sponsor within 30 days of receiving the Expert Committee's report regarding compensation for SAE injury cases or death.
 - The Sponsor or its representative shall make payment within 30 days of receipt of such an order from the CLA.
 - In the case of an Adverse Event, the EC will deliberate on the same and form an opinion regarding financial compensation (if any) to be paid to the affected participant in the event of a death or non-death injury using the prescribed compensation formula (Refer Internal Document 03).
 - The final SAE report shall be submitted to the IEC in the format specified by the rules issued by CDSCO.
 - The SAE review will be carried out by the EC at the subsequently scheduled EC meeting. Based on the results of SAE analysis, the IEC may request clarifications from the PI and take further action by means of suspending/terminating the trial if it is found to affect the safety and well-being of participants.
 - The Ethics Committee shall forward its report (assessment of causality) on the serious adverse event along with its suggested opinion on the quantum of financial compensation (if any) to be paid by the sponsor or its representative to the Licensing Authority, DCGI, within thirty calendar days of the occurrence of the serious adverse event.
- h) All members should maintain in absolute confidentiality of all discussions during the meeting. They have no rights to participate if they are principal investigator.
- i) The member secretary/Co-member secretary/designee, will record the minutes during each meeting



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- j) Correspondence between the Institutional Ethics Committee (NHLIEC) and the principal investigator / study team and other relevant records (response letter, minutes of meetings, membership list composition etc.) will be retained for a minimum period of 5 years after completion of the trial.
- k) In order to ensure timely disposal of cases, the monitoring of its own conduct, functioning and records of NHLIEC is done. For this the committee will maintain a list of projects submitted, approved / disapproved and the outcome of each project, relevant correspondence and all study related documents
- l) In one calendar year, any principal investigator shall be allowed to handle between 2-3 clinical/research trials in his field of work in the institution.

Procedure

The applicant of the proposal generally the principal investigator is required to submit his/her application letter and 1 copy of a dossier (in hard format) as well as a **soft copy of the submission** comprising of following documents, at least 15 days before a scheduled meeting:

- The application for the request of review of the proposed Clinical Trial duly signed by the principal investigator. The application should also contain the names of the co-investigator/s included in the study. The application should be addressed to the Chairperson/Member Secretary and should be forwarded by the Head of the Department of the principal investigator.
- Research protocol.
- Protocol Amendment, if any.
- Investigator's Brochure.
- Case Report Form
- Informed consent form, [English]
- Informed consent form, [English to Gujarati translation].
- Informed consent form, [Gujarati to English back translation].
 - including translation certificate
- Informed consent form, [English to Hindi translation].
- Informed consent form, [Hindi to English back translation].



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- including translation certificate
 - Patient/ volunteer information Leaflet [English]
 - Patient/ volunteer information Leaflet [English to Gujarati translation].
 - Patient/ volunteer information Leaflet [Gujarati to English back translation].
- including translation certificate
 - Patient/ volunteer information Leaflet [English to Hindi translation].
 - Patient/ volunteer information Leaflet [Hindi to English back translation].
- including translation certificate
 - Safety Reports
 - DCGI Submission/Approval/Notification Letter
 - Insurance Policy
 - Import license, where applicable
 - Investigator's undertaking
 - Registration number with Clinical Trial Registry of India (CTRI)
 - Curriculum vitae of Principal Investigator & Co Investigator/s
 - Copy of Medical Council Registration certificate of Principal Investigator & Co Investigator/s
 - "Good Clinical Practices" training certificate of Principal Investigator & Co Investigator/s

Clinical Trial Agreement (CTA) & Payments

As per the existing rules of the Institution, as on the date of submission of the protocol-. A tri-partite or four-party clinical trial agreement [CTA] will be done, including "Dean, Smt. NHL Municipal Medical College" as one of the parties. All payments proposed to be made to the Principal Investigator or Institute (i.e. Institutional Overheads and any other relevant institutional payments) by the sponsor, for the study shall be made to the institution directly and shall be then disbursed by the institution with the consent of the Dean and the Principal Investigator.

Following is the account details for the aforementioned payments:

Payee Name	INST. ETHICS COM. SMT. NHL MEDI. COLLEGE
Bank	ICICI Bank
Branch	JMC House, Opp. Parimal garden Ahmedabad
Bank A.C. No.	002401047404



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Bank IFSC Code	ICIC0000024
PAN No.	AAAAI9107K
TAN No.	AHMI02258E
GST No.	Not Available

When a Contract Research Organization (CRO)/Site Management Organization (SMO) is involved, proper bifurcation of the amount/budget must be specified in the CTA with two payees. One payee must be the aforementioned institutional account to receive all the payments proposed to be made to the Principal Investigator (PI charges) and Institute (i.e. Institutional Overheads and any other relevant institutional payments) by the sponsor.

All the other payments which are to be paid to the CRO/SMO (All reimbursement and other charges with proper bifurcation of the said amount) should be paid to the second payee specified by the CRO/SMO in the CTA.

The NHLIEC is to be notified of any payments proposed to be made to study patients towards reimbursement of incidental expenses.

The total fees for review/consideration of the protocol/clinical study in question which includes Ethics Committee Members Conveyance Allowance will be **Rs.82,500**. The fees for any protocol &/or other amendment/s as well as for serious adverse event (SAE) review meeting in the study shall also be **Rs.82,500** and should be in the form of electronic transfer into the abovementioned account of "Institutional Ethics Committee, Smt. NHL Municipal Medical College"

If a Site Management Organization (SMO) is involved in a study and a meeting is required for the review, but the payment from the sponsor/CRO is delayed, the SMO may make the payment for the review fee on behalf of the sponsor/CRO to NHLIEC. Once the sponsor/CRO completes the payment, the same amount will be reimbursed to the SMO.

Each member of the NHLIEC shall be paid Conveyance Allowance for the meetings attended. The Conveyance Allowance shall be decided /revised as per instructions of the Dean.

It will be the responsibility of PI & SPONSOR/CRO/SMO (Whatever applicable) to acknowledge the Dean & NHLIEC regarding any changes in the Financial Transactions

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from the SPONSOR/CRO/SMO (Whatever applicable) within 15 workings days.



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- i) The Investigator is called to the meeting to present the study or answer specific queries. However, he / she will not participate in the decision making / voting process of that study even if he / she is a regular member of the NHLIEC.
- j) A meeting may be conducted once the submission to the DCGI has been made and the response or approval is still awaited from the DCGI. In such cases, the IEC will conduct only an ethical review of the study, and no approval will be issued. Instead, the applicant will be provided with an "Ethical Clearance in Principle", which will explicitly state that this does not constitute an approval. The final approval to initiate the trial will be granted only after the DCGI approval is received and submitted to the NHLIEC.
- k) A Study Team member including the Principal Investigator will be deemed an interested party with regard to the review.
- l) The decision of the committee will be taken by a majority vote after the quorum requirements are fulfilled to recommend / reject / suggest modifications for a repeat review or advise appropriate steps.
- m) In cases where NHLIEC revokes its approval accorded to a trial protocol, it must record the reasons for doing so and at once communicate such a decision to the Investigator.
- n) Should an amendment to a study related document be administrative in nature and not involving study design or safety criteria, it may be provisionally approved in writing, by the Chairperson and member-secretary of the NHLIEC without calling a full meeting.
- o) The Chairperson/member-secretary will inform other members of the NHLIEC of amendment and his / her decision during the subsequent regular meeting of the committee and the decision will be ratified. After the review meeting, the member-secretary will convey the decision of the committee to the Principal Investigator in writing by a response letter.
- p) The NHLIEC shall also carry out ongoing review/monitoring of the trials at appropriate intervals as per regulatory requirements for safeguarding the rights,



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safety and wellbeing of the trial subjects.

Note: In special situations like the pandemic- COVID 19 and other such situations, the NHLIEC can conduct virtual meetings and shall continue to do so until required. The permission of the chairperson as well as institutional head should be obtained. Site Monitoring visits may not be possible in pandemic conditions.

Response/Decision Letter

The response/decision letter shall contain following information:

- a) Date, place and time of NHLIEC meeting.
- b) Names and designations of the members who attended the meeting.
- c) Title of the Research proposal
- d) Name of the Principal investigator
- e) List of documents (with date and version number wherever possible) reviewed by the Institutional Ethics Committee (NHLIEC)
- f) A clear Statement of the Decision Reached.
- g) Any advice (non-binding) by the Institutional Ethics Committee (NHLIEC)
- h) In the case of Negative decision, reasons for not approving the proposal must be mentioned
- i) In the case of "approval" decision, the responsibilities of the principal investigator shall be communicated
- j) The response letter shall contain the signature with date of the NHLIEC Member Secretary or Acting Member Secretary (if appointed for the meeting) and NHLIEC Chairperson or Acting Chairperson (if appointed for the meeting).

The NHLIEC expects the principal investigator to inform the following to NHLIEC:

- a) The randomization of the first patient,
- b) The progress of the study by monthly reports should be submitted for regular review.
- c) Any serious side effects, adverse drug reactions occurring in the course of the study and the interventions undertaken are to be intimated within 24 hrs. of their occurring as per the New Drugs & Clinical Trials Rules, 2019, and a new Appendix in Schedule 'Y' along with other amendments
- d) Any changes in the protocol and patient information /informed consent documents, Amendments/revisions to any study-related document as well as patient safety related



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Ellisbridge, Ahmedabad-380006.

GUJARAT STATE (INDIA)

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information, etc prior to their implementation, should be approved at the NHLIEC meeting.

- e) Any new information related to the study should be communicated
- f) Study completion and discontinuation with reasons
- g) Justification for approval to restart studies discontinued earlier
- h) The final report of the study shall be submitted to the NHLIEC in all cases, even when the study abandoned for any reason (s).

Vulnerable Population

Vulnerable populations refer to individuals who may not be able to safeguard their own rights and interests due to various limitations. These could be personal disabilities, financial hardships, lack of knowledge, communication barriers, or other circumstances that restrict their ability to make independent decisions.

Identifying Vulnerability

A person may be considered vulnerable if they:

- a) Experience social, economic, or political disadvantages, making them more prone to exploitation.
- b) Lack the ability to provide informed consent due to cognitive impairment, unconsciousness, or other factors affecting their autonomy.
- c) Can technically consent but are influenced by external pressures or limited understanding of the research.
- d) Feel compelled to participate due to expectations of benefits or fear of negative consequences if they refuse.

Ethical Safeguards

- a) When conducting research involving vulnerable individuals, it is crucial to implement additional protections to ensure their rights and well-being are not compromised.
- b) If a study exclusively targets a vulnerable group, it must be designed to address their specific health concerns and provide meaningful benefits.
- c) If participants are unable to make decisions independently, a legally authorized



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representative (LAR) should be involved in the consent process.

- d) Confidentiality must be strictly maintained, as any breach may lead to discrimination, stigma, or legal consequences.

Categories of Vulnerable Groups

Vulnerable individuals may include, but are not limited to:

1. Economically disadvantaged individuals, orphans, marginalized ethnic groups, and LGBTQ+ communities.
2. Individuals who may feel pressured to participate due to expectations of rewards or fear of repercussions.
3. Pregnant and lactating women, especially those with limited healthcare access.
4. Socially excluded or disadvantaged communities.
5. Refugees, migrants, homeless individuals, and those living in conflict zones or affected by natural disasters.
6. Individuals with mental health conditions, cognitive impairments, or physical disabilities.
7. Patients with terminal illnesses who have exhausted all standard treatment options.
8. Individuals suffering from rare or stigmatized diseases.
9. Those in dependent or hierarchical structures, such as students, employees, defense personnel, healthcare workers, institutionalized individuals, prisoners, or undertrials.

Justification for Inclusion

- a) Researchers must provide valid reasons for including vulnerable participants in a study.
- b) The Ethics Committee (EC) should critically assess the justification and ensure that participation is truly beneficial for the group in question.

Informed Consent and Risk Evaluation

- a) The consent process must be well-structured, ensuring that participants (or their representatives) fully understand the study's implications. If applicable, assent and re-consent should be documented appropriately.
- b) The EC must evaluate potential risks and benefits and ensure that all necessary precautions are taken to minimize harm.



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- c) Both researchers and EC members must remain vigilant in preventing conflicts of interest and ensuring participant welfare remains the top priority.



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Annexure:1 Confidentiality Agreement Form for NHLIEC Members

It is recognized that the potential for conflict of interest will always exist but has faith in the NHLIEC and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects.

It is the policy of the NHLIEC that no member may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the NHLIEC.

The Undersigned should protect the secrecy and respect the Confidentiality of the data submitted by the sponsors, and will not divulge the contents to any party.

The Undersigned will immediately disclose to the Chairperson of the NHLIEC any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Committee, and to abstain from any participation in discussions or recommendations or decision making in respect of such proposals.

If an applicant submitting a protocol believes that an NHLIEC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the EC member(s) in question. The Committee may elect to investigate the applicant's claim of the potential conflict.

When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the NHLIEC review or approval except to provide information requested by the Committee.



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Agreement on Conflict of Interest

Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the NHLIEC. A copy will be given to you for your records.

I, (Name), acknowledge my responsibility as a member of the **NHL Institutional Ethics Committee (NHLIEC)** to uphold the highest ethical and professional standards in reviewing research proposals.

I understand that any actual or potential conflict of interest—whether personal, financial, or professional—must be disclosed immediately to the Chairperson. In such cases, I shall refrain from participating in the discussion, deliberation, and decision-making process for the concerned proposal.

By signing this agreement, I confirm that I have read, understood, and agree to abide by the terms and conditions stated herein.

Signatures:

Member's Name: _____

Signature: _____

Date: _____

Chairperson's Name: _____

Chairperson's Signature: _____

Date: _____

I acknowledge receipt of a signed copy of this Agreement for my records.

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consent as per regulatory requirements.

- Investigational Product (IP) Handling: Inspect the storage, temperature control, and record maintenance of study drugs/products.
- Random Document Review: Perform spot-checks on trial documentation, participant records, and case report forms (CRFs).
- Adherence to Protocols: Ensure that all study procedures are followed as per approved protocol.

Special Monitoring Visits

- Post-SAEs: Conduct additional visits following the reporting of a Serious Adverse Event (SAE) to assess corrective and preventive actions.
- High-Risk Studies: More frequent monitoring may be required for studies involving vulnerable populations or high-risk interventions.

Virtual Monitoring (if applicable)

- In exceptional circumstances (e.g., pandemics like COVID-19), virtual monitoring may replace physical site visits to ensure continuity of oversight.

Reporting and Documentation

- A monitoring report shall be submitted to the EC after each visit.
- Any non-compliance issues shall be reported to the EC with recommendations for corrective action.
- The EC may decide on further actions, including protocol modifications, additional monitoring, or trial suspension if necessary.