N.K.P. Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital

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NKPSIMS & RC and LMH/ IEC / 7 / 2023 Date: 1/6/2023

STANDARD OPERATING PROCEDURE

Version No : **3.3**

Effective date : **1 June 2023**

Superseded Version : **3.2**

Prepared by : **Dr. R A SIDDIQUI**
Member Secretary

Dr. R.A Siddiqui
Member Secretary IEC
N.K.P. Salve Institute of Medical Science & RC
And Lata Mangeshkar Hospital, Nagpur.
Digdoh hills, Hingna Road, Nagpur-440019
Ethics Committee Re-Registration No.
ECR/88/Inst/MH/2013/RR/19

Reviewed by : **IEC Members**

Approved by : **Dr. Shriram Karandikar**
Chairman

Dr. S. C. Karandikar
Chairperson IEC
N.K.P. Salve Institute of Medical Sciences & RC
AND Lata Mangeshkar Hospital, Nagpur-440019
Ethics Committee Re-Registration No.
ECR/88/Inst/MH/2013RR/19

N.K.P. Salve Institute of Medical Science & RC And Lata Mangeshkar Hospital, Nagpur-440019 ★ Approved Ethics Committee Re-Registration No. ECR/88/Inst/MH/2013/RR/19

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NKPSIMS & RC and LMH/ IEC / 7 / 2023 Date: 1/6/2023

INDEX

N.K.P. Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital

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1.0 Introduction:

The objective of this SOP is to contribute to the effective functioning of the IEC at the NKP Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital, Nagpur so that a quality and consistent ethical review mechanism for health and biomedical research is put in place to all proposals dealt by the Committee.

The objective of this SOP is to contribute to the effective functioning of the IEC at the NKP Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital, Nagpur so that a quality and consistent ethical review mechanism for health and biomedical research is put in place to all proposals dealt by the Committee.

2.0 Term of reference of Ethics Committee

2.1 Authority under which Ethics Committee constituted

The Institutional Ethics Committee will be constituted under Dean, NKP Salve Institute of Medical Sciences & Lata Mangeshkar Hospital, Digdoh Hills, Hingna road, Nagpur, Maharashtra 440019.

The functioning and decision making of Ethics Committee would be completely independent. Neither Institute nor any authority of institute will be hindrance to the ethics committee which impacts its functioning or decisions.

2.2 Composition of Ethics Committee:

Institutional ethics committee shall be multidisciplinary and multi-sector in composition.

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NKPSIMS & RC and LMH/ IEC / 7 / 2023 Date: 1/6/2023

The ethics committee shall have a minimum of 7, and maximum of 11 members. The members are selected to have an equitable representation of all specialties and gender. It includes scientific and non-scientific persons, clinicians and non-clinicians, pharmacologist, persons of the community, a legal expert, a social worker/layperson/patient representative to represent different point of view. Members are expected to be aware of local, social and cultural norms, as this is the most important social control mechanism.

To maintain the independence of ethics committee 50% of members should be appointed from outside the institute (not affiliated with NKP Salve Institute).

The composition should be as follows:-

1. Chairperson (not-affiliated to Institute)

2. Member secretary (affiliated to Institute)

3. two to four clinicians (Affiliated/ not affiliated to institute)

4. Pharmacologist (Affiliated/not affiliated to Institute)

5. Legal expert (Affiliated/not affiliated to Institute)

6. Social scientist/representative of NGO (not affiliated to Institute)

7. Lay person from the community (not affiliated to Institute &non scientific)

Subject Expert: An EC may invite nonmembers with expertise in special areas for assistance.

Quorum: The EC meeting will only be deliberated if quorum of minimum 5 members along with Chairperson & Member Secretary are present which include Pharmacologist, Clinician, Legal Expert, Lay person and Social scientist.

N.K.P. Salve Institute of Medical Science & RC And Lata Mangeshkar Hospital, Nagpur-440019 ★ Approved Ethics Committee Re-Registration No. ECR/88/Inst/MH/2013/RR/19

N.K.P. Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital

Digdoh Hills, Hingna Road, Nagpur – 440 019

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2.3 Conditions of appointment

The Institutional Ethics Committee is constituted by Dean NKP Salve Institute of Medical Sciences & Lata Mangeshkar Hospital, Nagpur

2.3.1 Appointment of Chairperson

a. The Chairperson will be selected and appointed by the Dean.

b. The Chairperson will be independent of the institution.

c. The Chairperson will be responsible for conducting all committee meetings and will lead all discussions and deliberations pertinent to the review of research proposals.

d. The Chairperson will preside over all elections and administrative matters pertinent to the committee's functions.

e. In case of anticipated absence, the Chairperson will nominate a committee member, who is independent of the institution as Acting Chairperson. The Acting Chairperson will have all the powers of the Chairperson for that meeting.

f. The chairperson in consultation with secretary and committee members can make amendments to SOP, if necessary on the basis of changes in national and international ethical, social and legal guidelines.

2.3.2 Appointment of Members

a. The members will be selected and appointed by the Dean, provided they are willing to work as an Institutional Ethics Committee member.

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b. Members are selected on their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, experience in domain field and profile.

c. Conflict of interest shall be avoided when making appointments, but where unavoidable, there shall be transparency with regard to such interests.

d. New members shall be identified according to the requirement i.e. as per the composition specified in the SOP.

The following qualities are sought in IEC members:

- Interest and motivation
- Time and effort
- Commitment and availability
- Experience and education
- Respect for divergent opinions

The member should submit their detail CV in annexure-01 format and evidence of qualification & experience to the Ethics Committee office. A formal letter of appointment shall be given to the Member mentioning his/her role and responsibilities and duration of membership.

2.3.3 Appointment of Member Secretary

a. The Member Secretary from institute shall be appointed by Dean.

b. In consultation with the Chairperson, the Member Secretary shall oversee following functions with the help of Ethics Committee Coordinator.

i. Receiving all research proposals.

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ii. Numbering the proposals.

iii. Forwarding all proposals to committee members for review.

iv. Establishing time limits for receipt of reviewers' comments.

v. Preparation of agenda for all committee meetings.

vi. Inviting experts from relevant therapeutic areas to the scheduled meetings or getting their expert opinions.

vii. Notification of review outcome to investigators of research proposals.

viii. Preparation and circulation of minutes (within 14 days to 28 days of the meeting).

ix. Retention and safekeeping of all records and documentation.

x. Performance of other duties assigned by the Chairperson.

c. If Member Secretary is a part of any study, he will not take part in decision making process and approval letter of that study shall be signed by chairman.

2.3.4 Tenure of Membership

a. A member will be a regular member for a period of up to Five (5) years.

b. The membership can be continued for not more than three consecutive terms.

c. Extension of membership will be determined by a vote of two-thirds of the members present in a quorum at a regular committee meeting.

N.K.P. Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital

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d. New members will be appointed to replace members who are unable to continue due to any reason.

2.4 Roles and Responsibilities of Ethics Committee Members:

Sr. No.	Designation	Role & Responsibility
1	Chairperson	1. Conduct IEC meeting and accountable for functioning of the IEC 2. Assure active participation of all members in review, discussion and decision making process of IEC 3. Grievance handling from different stake holders 4. Review and ratify ethics committee meeting minutes 5. Review and assess SAE reports and assure timely reporting to DCGI.
2	Member Secretary	1. A member from institute who is office bearer of Ethics committee and has sole responsibility of ethics committee functioning as per SOP. 2. In consultation with the Chairperson, the Member Secretary shall oversee following functions with the help of Administrative manager and Institutional Ethics Committee Clerk. i. Receiving all research proposals. ii. Numbering the proposals. iii. Forwarding all proposals to committee members for review.

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NKPSIMS & RC and LMH/ IEC / 7 / 2023 Date: 1/6/2023

		iv. Establishing time limits for receipt of reviewers' comments. v. Preparation of agenda for all committee meetings. vi. Inviting experts from relevant therapeutic areas to the scheduled meetings or getting their expert opinions. vii. Notification of review outcome to investigators of research proposals. viii. Preparation and circulation of minutes ix. Retention and safekeeping of all records and documentation. x. Performance of other duties assigned by the Chairperson. 3. Arrange trainings of IEC members and ensure proper documentation of each activity as per SOP. 4. Prepare and respond to Audits and inspections 5. Correspondence with all stake holders (Investigator/ Sponsor/CRO/Trial participants)
3	Basic medical scientist	1. An individual with scientific qualification, preferably pharmacologist. 2. To confirm the safety and efficacy of investigational drug from previous studies. 3. Confirm that study is scientifically sound to safeguard right safety and wellbeing of trial participant. 4. Check relatedness of AE/SAE and compensation calculation.
4	Clinician	1. Medically qualified personnel to review medical management part of study. 2. To validate protocol and confirm that patient should get

N.K.P. Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital

Digdoh Hills, Hingna Road, Nagpur – 440 019

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		standard of care treatment at least. 3. Review AE/SAE management, causality assessment and opinion.
5	Legal Expert	1. A law graduate to look in to medico legal part of clinical trial. 2. Confirm participants rights, safety and wellbeing by reviewing insurance and other legal documents 3. Confirm and make sure that study budget is influencing trial participant and investigator. 4. Make sure that trial participants get proper compensation and remunerations for their participation in clinical trial.
6	Social scientist/philosopher/ ethicist	1. A scientific/ non scientific literate person from community who can actively present his/her opinion from patient point of view. 2. Should read and understand informed consent documents, their translations and other patient related material. 3. Look in to the social benefit of proposed clinical trial.
7	Lay Person	1. A non scientific literate person from community who can actively present his/her opinion from patient perspective. 2. Should read and understand informed consent documents, their translations and other patient related material and confirm that it is feasible for study participant to understand and make unbiased decision of participation.

N.K.P. Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital

Digdoh Hills, Hingna Road, Nagpur – 440 019

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2.5 Resignation of members

All members have their right to continue or resign from ethics committee at any point of time by giving a written notification of resignation with reason to the Chairman of EC or Dean of the Institute at least 1 month before leaving.

If a regular member resigns, or ceases to be a member due to disqualification, or death, a new member shall be appointed for the remaining term as per the Conditions of appointment stated in SOP.

2.6 Termination of Membership

An EC member may be relieved or terminated of membership in case of conduct unbecoming for a member of the Ethics Committee or inability to participate in the consecutive 3 meetings without any valid reason.

In some conditions if deemed necessary, the IEC may decide to terminate the membership and recommend to Dean, through the Chairperson for necessary replacement.

In all such situations/circumstances, Head of Institute (Dean) shall send a letter of termination to the member. Documentation of the termination shall be recorded in the meeting minutes of the next duly constituted IEC meeting and IEC membership circular/roster shall be revised and notified to regulatory authority as per procedure. EC Membership list shall be updated in EC SOP Annexure-02.

3.0 Training of Ethics Committee Members & Self-Assessment

All the members of Institutional Ethics Committee shall follow Standard Operating Procedures and Good Clinical Practice guidelines and other regulatory requirements to safeguard right, safety and wellbeing of trial subjects.

Every member of ethics committee shall be required to undergo such training and development programs as may be specified by central licensing authority from time to time.

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Digdoh Hills, Hingna Road, Nagpur – 440 019

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3.1 Training of New Members:

All Ethics committee members must be trained on following essential trainings before attending full board meeting. Training can be obtained directly from Chairman, online study material or by any external agency.

1) Role and Responsibilities of Ethics Committee Members
2) Good Clinical Practice
3) IEC SOP (Current version).
4) New Drug and Clinical Trial Regulations 2019
5) ICMR Guidelines (Current edition)

3.2 Training of Existing Members:

Member Secretary with permission of chairman and Dean of Institute can plan training of ethics committee members every six months to update on current regulatory and GCP guidelines and circulars.

Following training materials are available in Ethics committee office for reference.

1) ICH GCP Guidelines
2) Schedule Y
3) New Drug and Clinical Trial Regulations 2019
4) CDSCOs guidance document for Institutional EC reviewing clinical trials.
5) ICMR Guidelines (Current edition)

It is mandatory for all ethics committee members to attend the training organized by IEC or Institute. Training will be documentation and maintained by Member Secretary in Annexure 03-training log.

Training Plan:

Member Secretary and Chairman will decide training topics as per self-assessment of ethics committee. The training plan will be executed under supervision of chairman in given timeline.

N.K.P. Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital

Digdoh Hills, Hingna Road, Nagpur – 440 019

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Pre-Assessment:

Trainer who is going to conduct training on given topic shall circulate pre-assessment questionnaire to trainee which help to know the present knowledge of members about topic to be discussed.

Post Assessment:

Post assessment questionnaire shall be completed from attendees to check the knowledge update by training.

3.3 Self-Assessment:

Ethics Committee members should perform self-assessment once in a year to evaluate their knowledge update. IEC member shall complete Annexure 04-self assessment form for evaluation and submit it to secretary.

Chairman shall review self-assessment form and suggest improvement and also can plan training if required.

Pre and post training assessment will be done by trainer and feedback shall be conveyed to the head of institute.

3.4 Maintenance of training records:

The IEC coordinator should maintain the training attendance log and copy of training certificates in ethics committee office. Training certificates copies would be filed in individual members file.

A copy of training material will be kept in IEC office for future references.

4.0 Confidentiality and Conflict of Interest Agreements

Member secretary is responsible to maintain the confidentiality of submitted proposals and get Annexure 5- confidentiality agreement &Annexure 6- conflict of interest agreement signed from each member/person attending the IEC meeting and reviewing documents.

N.K.P. Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital

Digdoh Hills, Hingna Road, Nagpur – 440 019

Phone (07104) 665000,244291, Fax:(07104) 306111- mail: nkpsims1@rediffmail.com/website : www.nkpsims.in

It is mandatory to maintain the confidentiality of study protocols, IEC documents, and correspondence with experts, it is the responsibility of all appointed members of Institutional Ethics Committee to read, understand, accept and sign the agreement contained in the Confidentiality / Conflict of Interest form before beginning their ethical review tasks with the IEC to protect the rights of study participants. Every member including the Chairperson, the alternate Chairperson and the alternate members should declare conflict of interest before meeting start and sign the Confidentiality/Conflict of Interest Agreement and submit to chairman and it should be documented in meeting minutes. Even though the member discontinues being a part of the NKP SIMS IEC, he/she will have to maintain confidentiality which will be valid for all the protocol related information for which he/she had access to.

Conflict of interest occurs when:

An individual's private interest differs from his or her professional obligations to the institute.

Member is directly or indirectly benefited from Investigator/Institute or Sponsor such as:

- Member or his/her spouse is Shareholder of Sponsor Company more than 30%.
- Member or his/her spouse is a part of study team.
- Member's personal/ academic or political involvement in study.

A conflict depends upon situation and not on the character or actions of the individual. Potential conflicts of interest must be disclosed by respective member before meeting.

Guest Attendees

Permission to observe the Institutional Ethics Committee meetings/ visit will be given only after a formal written request addressed to the Chairperson/ Member Secretary.

Approved
Ethics Committee Re-Registration No.
ECR/88/Inst/MH/2013/RR/19

N.K.P. Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital

Digdoh Hills, Hingna Road, Nagpur – 440 019

Phone (07104) 665000,244291, Fax:(07104) 306111- mail: nkpsims1@rediffmail.com/website : www.nkpsims.in

Permission will be granted for academic purposes and other reasons at the discretion of the Chairperson / Member Secretary.

Guest shall be requested to sign Annexure07: Confidentiality and Conflict of interest Agreement Form for Guest Attendees.

They will be escorted by staff of the Ethics Committee.

Care will be taken to see only the necessary documents are given access to while proposals will be stored under lock and key.

Agreement signing process:

Read the text carefully and thoroughly:

Newly appointed members should obtain two copies of the Confidentiality Agreement Form& Conflict of Interest Agreement Form

The member is expected to read through the text of the form very carefully and fill in their names and their office on the blanks.

Ask questions, if any:

The signee may direct questions to the Secretary, if any part or sentences is not clear.

Member Secretary explains or clarifies the contents of the document.

Sign with consent:

Sign and date both copies of the document before chairperson. Give both the forms chairperson to sign and date. The member secretary shall keep one copy in IEC office & another copy given to member for their record.

Member Responsibility:

N.K.P. Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital

Digdoh Hills, Hingna Road, Nagpur – 440 019

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If any of the member by any means fall in to conflict of interest for submitted study protocol, should declare that before meeting proceeding and submit conflict of interest agreement signed and dated on that day.

This member shall not participate in decision making process of that particular study he/she involved in.

5.0 Ethics Committee Meeting & Meeting Minutes

Schedule and conduct of the Ethics Committee meeting is responsibility of chairperson. Deliberation and maintaining meeting minutes is responsibility of member secretary. All EC members should attend the meetings regularly and actively participate in discussion and decision making.

The ethics committee shall schedule a meeting once a month as per availability of quorum. When there is no agenda for full board review, the meeting may be held less frequently, but not less than once every twelve (12) weeks.

Member Secretary shall finalize meeting date after discussion with Chairperson &members. Scheduled date will be informed to all IEC members and Investigators/researcher at least one week in advance to meeting date.

If required, the subject expert may be invited for the meeting & the protocol and relevant documents shared for his/her assessment and opinion of the research proposal.

Representatives from specific patient groups such as those suffering from HIV/AIDS or genetic disorders may also be invited for the meeting based on the requirement.

In case of special case like, SAE review and opinion expedited meeting can be scheduled by Member secretary and call members for meeting.

Agenda Preparation:

Member secretary shall prepare ethics committee meeting agenda after discussion with chairman. Following order of topics shall be followed for agenda preparation and discussion during meeting:

N.K.P. Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital

Digdoh Hills, Hingna Road, Nagpur – 440 019

Phone (07104) 665000,244291, Fax:(07104) 306111- mail: nkpsims1@rediffmail.com/website : www.nkpsims.in

i) Serious Adverse Event(s)

ii) New study Protocol

iii) Protocol Amendment(s)

iv) Safety alerts (CIOMS) of ongoing studies.

v) Protocol Deviations and other Notifications.

Member secretary shall prepare and circulate meeting agenda to all EC members and Investigators in Annexure 08 format at least 1 week before meeting date.

Distribution of Dossier to Members:

Soft copy of submitted documents will be circulated by email to each individual member. A hard copy of protocol synopsis shall be circulated at the time of meeting. The committee members should review shared documents before the meeting and come with preparation to ask query if they have any during discussion.

Conduct of meeting:

- All members should gather IEC meeting room on scheduled date and time
- Attendance will be taken by member secretary
- Chairperson to determine the quorum requirement is met before initiating meeting.
- The Chairperson should ask for declaration of conflict of interest (if applicable).
- If an IEC member has conflict of interest involving a project then he/she should declare the same, before the meeting commences and do not participate the discussion & opinion process of the same. This should be recorded in the minutes.
- The Member Secretary should table the minutes of the previous meeting and present the current meeting agenda for discussion.
- The meeting proceeds in the sequential order of the agenda; however the Chairperson may change the order, if the situation so demands.

Approved
Ethics Committee Re-Registration No.
ECR/88/Inst/MH/2013/RR/19

N.K.P. Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital

Digdoh Hills, Hingna Road, Nagpur – 440 019

Phone (07104) 665000,244291, Fax:(07104) 306111- mail: nkpsims1@rediffmail.com/website : www.nkpsims.in

- Investigator or Co-Investigator should present protocol(s) or SAE in EC meeting, and provide satisfactory answer to queries raised by EC members
- Meeting minutes will be recorded by EC staff during meeting proceeding.

Decision making

i. Decision for each proposal shall be by voting.
ii. All members present in meeting will vote on the submitted research proposal.
iii. Absent members will not vote.
iv. A majority vote (more than 50%) is required for approval, disapproval and request for modifications, suspension or termination of a research proposal or an ongoing study.
v. Member(s) of the committee who is/are listed as investigator(s) on a research proposal will opt out from all deliberations on the proposal and will not vote on the proposal.
vi. An investigator or study team member invited for the meeting will not vote or participate in the decision making procedures of the committee.
vii. Specific person/ groups invited for the meeting will not vote or participate in the decision making procedures of the committee

After meeting:

The Member Secretary will be responsible for coordination and recording of the proceedings of the meeting. The proceedings of the meetings shall be recorded in English and in the form of minutes in Annexure 09. The minutes shall be approved by the chairperson and will be circulated to all the members.

Member secretary shall complete the proceedings and give vote of thanks to all members present.

Member secretary will communicate the EC opinion to concerned stake holder with formal letter within 10 working days.

N.K.P. Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital

Digdoh Hills, Hingna Road, Nagpur – 440 019

Phone (07104) 665000,244291, Fax:(07104) 306111- mail: nkpsims1@rediffmail.com/website : www.nkpsims.in

6.0 Receipt, review and decision making of clinical trial proposals

6.1 Submission of Application:

The researcher/ Investigator should submit an appropriate application to the IEC in a prescribed format as per schedule Y along with the study protocol at least 3 (three) weeks in advance to scheduled meeting date. Each set shall contain the documents on A 4 size paper properly indexed and labelled 2 hard copies and 1 soft copy in CD.

Each set shall contain the documents arranged in a file in the order mentioned below:

i. Covering letter from Principal Investigator

ii. The recent version of protocol which include the clear research objectives and rationale for undertaking the investigation in human subjects in the light of existing knowledge

iii. Principal investigators current Abbreviated Curriculum vitae & GCP training

iv. Investigator's Declaration form.

v. Investigator's undertaking

vi. Informed Consent Documents (ICD): Study Specific Patients Information Sheet (PIS) and Informed Consent Form (ICF) and its translations in Hindi, Marathi and other languages as applicable.

vii. Case record form/Questionnaire/Patient Diary.

viii. Special subject recruitment procedures along with consent or matter. (E.g. advertisement/letters to doctors/posters if any)

N.K.P. Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital

Digdoh Hills, Hingna Road, Nagpur – 440 019

Phone (07104) 665000,244291, Fax:(07104) 306111- mail: nkpsims1@rediffmail.com/website : www.nkpsims.in

ix. Investigator Brochure (for sponsored projects). This should give details of the study drug, toxicology studies, phase I, II, III data wherever available, safety information etc.

x. Ethics Committee clearance of other centers (if multicenter study).

xi. Insurance policy

xii. DCGI clearance [for regulatory studies]

xiii. Investigator's agreement with sponsor

xiv. Health Ministry Screening Committee (HMSC) / Bhabha Atomic Research Centre (BARC) / Genetic Engineering Advisory Committee (GEAC) / Director General of Foreign Trade (DGFT) clearance wherever applicable

xv. Food and Drug Administration (FDA) marketing/manufacturing license for drugs.

Submission of Thesis and Academic study:

The researcher should submit 3 set of Thesis/ protocol along with IEC Application form available in IEC office. The IEC review fees is not applicable for this submission.

6.2 Receipt of proposal

The Investigator should submit the study proposal in writing to the chairperson/member secretary of Institutional Ethics Committee.

The project proposals in the prescribed format will be accepted in office of the IEC between 10.00 A.M to 5:00 PM (Monday- Friday).

N.K.P.Salve Institute of Medical Science & RC And Lata Mangeshkar Hospital, Nagpur-440019 ★ Approved Ethics Committee Re-Registration No. ECR/88/Inst/MH/2013/RR/19

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Phone (07104) 665000,244291, Fax:(07104) 306111- mail: nkpsims1@rediffmail.com/website : www.nkpsims.in

The Member Secretary or EC staff should screen the proposals for their completeness before putting at the IEC meeting for review by completing the checklist Annexure 10. The submission letter shall be acknowledged by member secretary/EC member or EC staff as per availability and provide inward number on acknowledged copy to applicant as per inward register.

The entry of all submissions and/or notifications to EC should be recorded in INWARD register with sequential inward number and date of receipt. All proposals including new protocol, amendment(s), Protocol Deviations, Safety alerts (SAE) and Notifications submitted by Investigator(s) after previous meeting will be considered for review in upcoming scheduled meeting. The soft copy of documents submitted will be circulated to EC members by email at least 1 week before meeting date. The hard copy of documents should be given to chairperson & Member secretary for review which will be kept in EC meeting during discussion for reference to EC members.

6.3 Elements of Review

The clinical trial proposals will be taken for review and discussion as per meeting agenda. While reviewing initial submission dossier, EC member shall evaluate the scientific validity of the protocol, risk to subjects, expected benefit and ethical standards as per applicable rules and regulations. The Basic Medical Scientist should do risk and benefit assessment and document the same with the help of Annexure 11.

Scientific design and conduct of the study

- The appropriateness of the study design in relation to the objectives of the study.
- The statistical methodology (including sample size calculation), and the potential for reaching sound conclusions with the smallest number of research participants
- The justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities.
- The justification for the use of control arms; criteria for prematurely withdrawing research participants.
- Criteria for suspending or terminating the research as a whole.

N.K.P. Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital

Digdoh Hills, Hingna Road, Nagpur – 440 019

Phone (07104) 665000,244291, Fax:(07104) 306111- mail: nkpsims1@rediffmail.com/website : www.nkpsims.in

- The adequacy of provisions made for monitoring and auditing the conduct of the research, the adequacy of the site, including the supporting staff, available facilities, and emergency procedures.

6.4 Care and protection of research participants

- Suitability of the investigators qualifications and experience for the proposed study.
- Any plans to withdraw or withhold standard therapies for the purpose of the research, and the justification for such action.
- Medical care to be provided to research participants during and after the course of the research.
- Confirm the facility of emergency handling and infrastructure at study site.
- Adequacy of medical supervision and psycho-social support for the research participants
- Steps to be taken if research participants voluntarily withdraw during the course of the research.
- Criteria for extended access to, the emergency use of, and/or the compassionate use of study products.
- Arrangements, if appropriate, for informing the research participant's general practitioner or family doctor, including procedures for seeking the participant's consent to do so.
- Description of any plans to make the study product available to the research participants following the research; a description of any financial costs to research participants
- Rewards and compensations for research participants (including money, services, and/or gifts).
- Provisions for compensation/treatment in the case of the injury/disability/death of a research participant attributable to participation in the research. (As per DCGI Guidelines on compensation).
- Insurance and indemnity arrangements.

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6.5 Community considerations

- Impact and relevance of the research on the local community and on the concerned communities from which the research participants are drawn.
- Steps taken to consult with the concerned communities during the course of designing the research.
- Influence of the community on the consent of individuals.
- Proposed community consultation during the course of the research.
- Extent to which the research contributes to capacity building, such as the enhancement of local healthcare, research, and the ability to respond to public health needs.
- A description of the availability and affordability of any successful study product to the concerned communities following the research.

6.6 Recruitment of research participants

- The characteristics of the population from which the research participants shall be drawn (including gender, age, literacy, culture, economic status, and ethnicity)
- The means by which initial contact and recruitment is to be conducted.
- The means by which full information is to be conveyed to potential research participants or their representatives.
- Inclusion criteria & Exclusion criteria for research participants.
- Make sure that students or staff will not be enrolled in research.

6.7 Review of budget & indemnity:

The legal experts shall review the legal documents like Financial Agreement and insurance and confirm that contract and budget is evaluated, Indemnity of investigator and institute, compensation to the subject for study participation. The legal expert should make sure that participant travel reimbursement cost overcomes expense of travel and daily wages of average population in the vicinity. Legal expert shall use Annexure 12- CTA checklist for documenting the review and opinion on CTA & insurance.

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6.8 Decision making process:

Investigator/ Applicant shall be invited to the ethics committee meeting to present protocol submitted by him/her for review & opinion. Ethics Committee members can interrogate the investigator during or after protocol presentation related to the study protocol and procedures. Investigator shall leave meeting room after protocol presentation and question answers.

Decision may only be taken after sufficient time has been allowed for review and discussion of an application in the absence of non-members (e.g., the investigator, representative of the sponsor, observer, and independent consultant) in meeting, with the exception of EC staff (coordinator). Only IEC members who attend the meeting shall participate in the decision making process. Chairman after discussion with all members present in meeting shall confirm EC opinion by completing Annexure 13 - Study assessment form

A member must voluntarily withdraw from the EC meeting while making a decision on an application which evokes a conflict of interest which should be indicated in writing to the chairperson prior to the review and should be recorded so in the minutes.

If one of the members has her/his own proposal for review, then the member should not participate when the project is discussed. The member who is a part of study team, he/she shall not participate in voting process but he/she can be a part of quorum.

The decision must be taken by a broad consensus after the quorum requirements are fulfilled to recommend / reject / suggest modification for a repeat review or advice appropriate steps.

Decisions shall be arrived at through consensus. If opinion not in harmony, then voting will be done. In case of tie the chairperson can have a casting vote.

If the full board approves a research proposal subject to minor modifications or submission of supporting documents, the revised project proposal submitted by the PI shall be reviewed and approved by the Member Secretary, on behalf of the full board and shall inform the decisions to all members in next EC meeting. In case of major changes, the revised documents shall be discussed in full board meeting.

If the DCGI permission is awaited, a letter of provisional approval from IEC may be issued and final EC approval will be given after a copy of DCGI permission is submitted. A study cannot begin until the final letter of permission is issued by the IEC.

A negative decision on an application shall be supported by clearly stated reasons. If the investigator wishes to appeal against the decision, he/she may do so by contacting the member secretary.

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Subject expert/s may be invited as consultant to offer their views, but should not participate in the decision making process. However, his/her opinion must be recorded.

The ethics committee decision will be conveyed to respective applicant/ stake holders in writing by member secretary.

Meeting minute shall be documented which should be reviewed by Member secretary and approved by the Chairperson

All documentation and communication of an IEC are to be dated, filed and preserved according to written procedures.

The approval given by IEC shall be valid for one year from date of approval. PI may file for extension with proper renewal document and annual review fees.

6.9 Expedited Review Procedures

a. The committee may use expedited review procedure in case of minor changes/ amendments in the previously approved / new research proposal that appear to involve no more than minimal risk to the study subjects.

b. Under an expedited review procedure, the review may be carried out by the Chairperson or member secretory of the committee, or by one or more experienced reviewers designated by the chairperson from among the members of the committee. The reviewers may exercise all of the authorities of the committee except that the reviewers may not disapprove the research.

c. The committee will keep all members of the committee informed of these approvals under the expedited review procedure.

d. Only the Chairperson or member secretory shall make the decision to allow an expedited review.

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7.0 Review of Resubmitted and Amended Protocols and Protocol-related Documents

Any amendment to protocol or study related document requiring regulatory and ethics committee approval before implementation should be submitted to EC in 2 hard copies and 1 soft copy along with review fees.

The Secretary shall confirm the request for Amendment Memorandum of the Protocol/Protocol related documents from the Principal Investigator on an existing and previously approved Protocol/Protocol related documents.

The memorandum should:

1. State/describe the amendment
2. Provide the reason for the amendment
3. State any untoward effects with original protocol
4. State expected untoward effects because of the amendment

In case of resubmitted protocol, the member secretary shall verify if the PI has replied to EC within 180 days of receipt of the letter of comments from EC.

The Secretary will check for completeness of document checklist for the contents of protocol amendment submission package.

The Secretariat will confirm the presence of the following documents:

a. The amended version of the protocol and related documents
b. The changes or modifications should be underlined or highlighted.

Notify the Chairperson of the IEC.

Upon receipt of the resubmission or amendment dossier, the EC coordinator will inform the Chairperson and Member Secretary and share submitted documents.

Determine whether expedited or full review.

After review of the documents, the Chairperson and Secretary will determine whether the protocol requires expedited review or full board review.

The amended protocol/ protocol related document will require Full Board review if any of the following criteria are met:

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Phone (07104) 665000,244291, Fax:(07104) 306111- mail: nkpsims1@rediffmail.com/website : www.nkpsims.in

The Protocol amendment which increases risk to study participants, as judged by the Chairperson and Secretary, such as a change in study design, which may include but is not limited to:

a. additional treatments or the deletion of treatments any changes in inclusion/exclusion criteria.

b. change in method of dosage formulation, such as, oral changed to intravenous

c. significant change in the number of subjects if the decrease/increase in the number of subjects alters the fundamental characteristics of the study, it is significant

d. significant decrease or increase in dosage amount

Distribution to IEC members

The following documents are distributed to each IEC member if full board review:

- Amended document
- Summary of changes from previous version.

The Secretary places the protocol amendment request on the agenda for the next convened meeting.

Protocol Amendment Review Process

The EC member will utilize the process outlined in EC SOP for Initial Review of Submitted Protocol to review amended protocols and protocol-related documents.

The Chairperson / EC members performing the expedited/full board review shall provide their opinion in meeting.

IEC Decision

The Secretary will read the decision of EC on the amended protocol/study related documents in the full Board/Expedited meeting.

- Approve the protocol amendment

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Digdoh Hills, Hingna Road, Nagpur – 440 019

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- Require a modification to the proposed amendment or informed consent documents, stating the reason and action required to sustain the study with a follow-up full IEC review / expedited IEC review.
- Not approve the amendment request, stating the reason – but allow the study to continue as previously approved.
- Disapproved by giving reason.

Member Secretary shall convey decision to the Investigator in writing.

8.0 Procedure to be followed for vulnerable population

Vulnerable Subjects: Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, and patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests.

The description of vulnerable population is not just limited to mentioned in SOP, Kindly refer to the ICMR guidelines for detail of vulnerable group like pregnant woman, children, terminally ill patients, etc.

EC members are responsible for conducting appropriate review of research planned for vulnerable populations, including an assessment of potential for coercion, in consultation with any appropriate experts and resources as described in the SOP.

Effort may be made to ensure that individuals or communities invited for research be selected in such a way that the burdens and benefits of the research are equally distributed.

N.K.P. Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital

Digdoh Hills, Hingna Road, Nagpur – 440 019

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Reviewing the protocol with vulnerable population

The protocol should be reviewed as per section 6.0 of SOP.

Additionally, the protocol should be reviewed to assess if the following points are addressed:

- Can the research be performed in any other non-vulnerable participants?
- Is there justification to use vulnerable population
- Do the benefits justify the risks.
- Are the participants selected equitably.
- Have the measures to protect Autonomy of the vulnerable population been described

EC members dealing with such protocols should be well versed with the potential harm or risk of such population participating in the study.

The review must address all points in the checklists for different vulnerable populations (Annexure 14-18).

The Member Secretary/Chairperson might appoint two or more members of the EC who have a thorough understanding of the ethical review process and experience in the field of research to review such type of protocols.

The reviewers should be familiar and trained in the concept of vulnerability and protections for participants with diminished autonomy.

- EC Members will review the protocol and the informed consent document or assent form.
- The suggestions that are agreed upon by the IEC members present at the meeting will be discussed and the comments will be sent to the PI.
- The discussion will be recorded in the respective meeting minutes
- The consent process of such individuals must be AV recorded by the investigator for reference to regulatory authority.

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Digdoh Hills, Hingna Road, Nagpur – 440 019

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Obligations/duties of stakeholders

All stakeholders have different responsibilities to protect vulnerable participants as follows

Stake holder	Obligations/ Duties
Researcher/ Investigator	• Recognize the vulnerability of the participant and ensure additional safeguards are in place for their protection. • Justify inclusion/exclusion of vulnerable populations in the study • COI issues must be addressed • Have well defined procedures (SOPs) to ensure a balanced benefit-risk ratio. • Ensure that prospective participants are competent to give informed consent • Take consent of the LAR when a prospective participant lacks the capacity to consent • Respect dissent from the participant • Seek permission of the appropriate authorities where relevant, such as for institutionalized individuals, tribal communities, etc • Research should be conducted within the purview of existing relevant guidelines/regulations
Ethics Committees	• During review, determine whether the prospective participants for a particular research are vulnerable. • Examine whether inclusion/exclusion of the vulnerable population is justified. • Ensure that COI do not increase harm or lessen benefits to the participants. • Carefully determine the benefits and risks to the participants and advise risk minimization strategies wherever possible. • Suggest additional safeguards, such as more frequent review and monitoring, including site visits. • Only the full committee should do initial and continuing review of such proposals. It is desirable to have empowered representatives from the specific populations during deliberations. • ECs have special responsibilities when research is conducted on participants who are suffering from mental illness and/or cognitive impairment. They should exercise caution and require researchers to justify cases for exceptions to the usual requirements of participation or essentiality of departure from the guidelines governing research. ECs should ensure that these exceptions are as minimal as possible and are clearly spelt out in the ICD. • ECs should have SOPs for handling proposals involving vulnerable populations.
Sponsors	• The sponsor, whether a government, an institution or a pharmaceutical company, should justify the inclusion of vulnerable groups in the protocol and make provisions for protecting their safety. • The sponsor must enable monitoring and ensure that procedures are in place for quality assurance (QA) and quality control (QC). • The sponsor should ensure protection of the participants and research team if the research is on sensitive topics.

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Digdoh Hills, Hingna Road, Nagpur – 440 019

Phone (07104) 665000,244291, Fax:(07104) 306111- mail: nkpsims1@rediffmail.com/website : www.nkpsims.in

9.0 Periodic review and Monitoring of trial

Patient enrollment in study should be started only after IEC approval, DCGI approval and CTRI registration.

The principal investigator should inform ethics committee about site initiation by sponsor/ CRO and enrollment of first patient in study approved by ethics committee.

Investigator should submit the study progress report to the ethics committee on each anniversary of EC approval date.

9.1 Monitoring of ongoing trials at site.

- Ongoing protocols should be monitored every year with advance intimation to PI and EC.
- The IEC staff will look through the master chart of projects approved by the Ethics Committee for the due date of Monitoring.
- The Member Secretary will plan for monitoring of approved study progress and discuss in the forthcoming Ethics Committee meeting at least one month ahead and as close as possible to the due date or anniversary completion of the date of original approval of the protocol.
- During full board meeting, chairman and member secretary shall appoint a subcommittee of 3-4 members who will visit the site for monitoring of scheduled clinical trial, fix a date and communicate the monitoring date to the Investigator.
- The subcommittee shall review confirm the following points are followed during trial conduct.
    1. Patient enrollment started after all essential approvals and CTRI registration.
    2. Investigator's involvement in consent process.
    3. Equitable selection of subjects from all socioeconomic levels and both genders.

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Digdoh Hills, Hingna Road, Nagpur – 440 019

Phone (07104) 665000,244291, Fax:(07104) 306111- mail: nkpsims1@rediffmail.com/website : www.nkpsims.in

4. Patient travel reimbursement confirmation from PI and subject.
5. Trial participant feedback about conduct of trial and treatment given to him during trial related procedures.
6. Action items in Sponsor/CRO post monitoring and audit report and its resolution from PI/ study coordinator.
7. Number of protocol deviations, violations and Corrective and Preventive Action (CAPA) taken by PI or responsible authority.
8. Protocol knowledge and compliance by investigator and study team.

- The subcommittee shall refer and complete study monitoring checklist Annexure 19.
- The subcommittee shall submit report to chairman which is discussed in upcoming full board meeting.
- Appropriate action will be taken for significant findings.

The Member Secretary will inform the ethics committee opinion to Principal Investigator and office copy will be filed in study file.

9.2 For cause assessment

If more than expected SAE/ Protocol deviations/ Violations reported or observed in any ongoing study, the ethics committee member secretary with approval of chairman can plan the for cause assessment of that particular study. Chairman will appoint a subcommittee of 3 members who will visit the PI and site and perform for cause assessment visit and note down the discrepancies and corrective and preventive actions taken by PI. Subcommittee shall submit for cause assessment report to EC. For cause assessment report will be discussed in next full board meeting.

IEC shall share a copy of for cause assessment report & (corrective & Preventive Action) CAPA with Investigator after duly signed by Member Secretary & Chairman.

N.K.P. Salve Institute of Medical Science & RC And Lata Mangeshkar Hospital Nagpur-440019 ★ Approved Ethics Committee Re-Registration No. ECR/88/Inst/MH/2013/RR/19

N.K.P. Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital

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Phone (07104) 665000,244291, Fax:(07104) 306111- mail: nkpsims1@rediffmail.com/website : www.nkpsims.in

10. Review of informed Consent Document (subject information sheet and informed consent form) and informed consent process

Informed consent protects the individual's freedom of choice and respect for individual's autonomy and is given voluntarily to participate in research or not.

While reviewing Informed consent documents, EC members should confirm if following essential elements are covered in ICF or not with the help of check list Annexure 20.

Adequate information about the research is given in a simple and easily understandable definite language in a document known as the Patient Information Sheet (PIS) and Informed Consent Form (ICF).

ICFs must cover all required points as per appendix V of schedule Y. ICF along with translations in regional languages (Hindi, Marathi & English) is mandatory.

Following information should be collected in ICF for all clinical trial participants.

- Date of birth/ Age
- Qualification
- Occupation
- Annual income of subject
- Name and address of nominee and his/her relation to subject

Possible risk and adequate benefits of trial must be mentioned in patient information sheet.

ICF should have well defined compensation details and travel allowances to study participants.

Contact details of PI/Co-I and IEC with name and designation should be mentioned in ICF.

If Audio Video consent applicable to study as per DCGI regulation/ circular, AV recording consent to be obtained from study participant before starting AV consent process.

ICF should be amended in timely manner to include all protocol amendments or revisions in Gazette rule or amendments in schedule Y or any other regulatory notifications.

ICF amendments ideally submitted for EC review and approval. However administrative changes or typographical errors/ grammatical corrections can be submitted for notification provided that basic ICF were reviewed and approved by IEC earlier.

N.K.P. Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital

Digdoh Hills, Hingna Road, Nagpur – 440 019

Phone (07104) 665000,244291, Fax:(07104) 306111- mail: nkpsims1@rediffmail.com/website : www.nkpsims.in

ICF Process review:

When reviewing ICF process, Ethics committee member should ensure that PI/Co-I followed ICH GCP guideline while taking consent.

A copy of the participant/patient information sheet is given to the participant for her/his record. The informed consent should be brief in content highlighting that it is given of free will or voluntarily after understanding the implications of risks and benefits and he/she could withdraw without loss of routine care benefits. Assurance is given that confidentiality would be maintained and all the investigations/ interventions would be carried out only after consent is obtained. Sufficient time and opportunity provided to patient/ participant to ask questions which are answered to his/her satisfaction.

Voluntarily signed consent taken from subject/ Legally Acceptable Representative/ Impartial witness as per situations.

Waiver of consent Voluntary informed consent is always a requirement for every research proposal. However, this can be waived if it is justified that the research involves not more than minimal risk or when the participant and the researcher do not come into contact or when it is necessitated in emergency situations. If such studies have protections in place for both privacy and confidentiality, and do not violate the rights of the participants then IECs may waive off the requirement for informed consent in following instances:

i. When it is impractical to conduct research since confidentiality of personally identifiable information has to be maintained throughout research as may be required by the sensitivity of the research objective, e.g., study on disease burden of HIV/AIDS.
ii. Research on publicly available information, documents, records, works, performances, reviews, quality assurance studies, archival materials or third party interviews, service programs for benefit of public having a bearing on public health programs, and consumer acceptance studies.
iii. Research on anonymous biological samples from deceased individuals, left over samples after clinical investigation, cell lines or cell free derivatives like viral

Approved
Ethics Committee Re-Registration No.
ECR/88/Inst/MH/2013/RR/19

N.K.P. Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital

Digdoh Hills, Hingna Road, Nagpur – 440 019

Phone (07104) 665000,244291, Fax:(07104) 306111- mail: nkpsims1@rediffmail.com/website : www.nkpsims.in

isolates, DNA or RNA from recognized institutions or qualified investigators, samples or data from repositories or registries etc. iv. In emergency situations when no surrogates consent can be taken.

Participant is paid for the inconvenience and time spent, and should be reimbursed for expenses incurred, in connection with their participation in research. They may also receive free medical services. During the period of research if the participant requires treatment for complaints other than the one being studied necessary free ancillary care or appropriate referrals may be provided.

10.1 Rights and responsibilities of research participants

Rights of research participant:

If you are asked to consent to be a subject in a research study, you have the following rights:

- To have enough time to decide whether or not to be in the research study, and to make that decision without any pressure from the people who are conducting the research.
- To refuse to be in the study at all, or to stop participating at any time after you begin the study. If you decide to stop participating in the study, you have a right to continued, necessary medical treatment.
- To be told what the study is trying to find out, what will happen to you, what drug/device will be used and what you will be asked to do if you are participating in study?
- To be told about the reasonably foreseeable risks of being in the study.
- To be told about the possible benefits of being in the study.
- To be told whether there are any costs associated with being in the study and whether you will be compensated for participating in the study.
- To be told who will have access to information collected about you and how your confidentiality will be protected.
- To be told whom to contact with questions about the research, about research-related injury, and about your rights as a research subject.
- If the study involves treatment or therapy:
    - To be told about the other non-research treatment choices you have.
    - To be told where treatment is available should you have a research-related injury, and who will pay for research-related injury treatment?
- To receive a copy of the consent form that you will sign.
- To ask any questions you may have.
- To discuss & take opinion of your primary care physician or family physician.

N.K.P. Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital

Digdoh Hills, Hingna Road, Nagpur – 440 019

Phone (07104) 665000,244291, Fax:(07104) 306111- mail: nkpsims1@rediffmail.com/website : www.nkpsims.in

Responsibilities of Research Participant

- Completely read the consent form and ask the Principal Investigator (PI) any questions you may have. You should understand what will happen to you during the study before you agree to participate.
- Know the dates when your study participation starts and ends.
- Carefully weigh the possible benefits (if any) and risks of being in the study.
- Talk to the Principal Investigator (PI; the person in charge of the study) if you want to stop being part of the research study.
- Contact the PI and/or the Institutional Ethics Committee (IEC) with complaints or concerns about your participation in the study.
- Provide truthful answer to questions asked during screening regarding your medical history and socio-economic details.
- Follow direction for proper use, dosing and storage of self-administered study medications, providing biological sample, and preparing for test, procedure or examinations
- Report to the PI immediately any and all problems you may be having with the study drug/procedure/device.
- Fulfill the responsibilities of participation as described on the consent forms unless you are stopping your participation in the study.
- Tell the PI or the person you are working with on the study when you have received the compensation you were promised for participating in the study.
- Ask for the results of the study, if you want them.
- Keep a copy of the consent form for your records.
- Keep research staff informed when your contact information changes.
- Follow directions for taking non-study-related medications

11.0 Obtaining & Documenting Informed Consent Process

Responsibility of Ethics Committee:

- Verify that the ICF has all the essential elements as required by ICH GCP and local regulations (reference ICH-GCP section 4.8.10 and Schedule Y (Appendix V)
- Review and approve current version and translations in local languages if it is appropriate.

N.K.P. Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital

Digdoh Hills, Hingna Road, Nagpur – 440 019

Phone (07104) 665000,244291, Fax:(07104) 306111- mail: nkpsims1@rediffmail.com/website : www.nkpsims.in

Responsibility of Investigator:

- Ensure that current version of ICF approved by ethics committee is used.
- Explain the content of ICF to a potential subject and /or to subject's legally acceptable representative (LAR) in presence of an impartial witness (IW) and verify that the content of ICF is understood by subject and/or LAR if applicable
- Verify that the subject signs and dates (if applicable) the ICF
- Sign the ICF as staff /investigator obtaining informed consent (where applicable) and sign off the informed consent documentation in source notes
- Provide a photocopy of the signed ICF to the subject or subject's LAR as applicable

11.1 Obtaining Informed consent:

- Consent of subject for audio video recording:

If the study involves vulnerable population or new chemical entity as a study drug requiring audio visual recording of consent process as per CDSCO guidelines, audio visual recording of consent process should be done. Prior consent of the subject should be taken for audio-visual recording of informed consent process and the same should be documented by Investigator. Only those subjects who give consent for AV recording shall be included in the clinical trial.

- Procedure of Audio Visual recording:

Before beginning AV recording process, Investigator should confirm the language feasible to the subject/LAR/IW and confirm that the informed consent form provided to subject is in that language. The ICF given is current version and is approved by ethics committee.

In order to identify the subject/LAR/IW his/her photo ID may be documented.

The video camera for the audio visual recording should be of adequate capability to simultaneously capture the facial details of subject, LAR/IW (if any), Investigator/authorized person present during the consent process. The audio visual recording should be conducted in a room conductive to recording of disturbance free audio and video of the consent process. During videography process, care should be taken not to include unrelated persons/ patients at the hospital within the field of vision.

N.K.P. Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital

Digdoh Hills, Hingna Road, Nagpur – 440 019

Phone (07104) 665000,244291, Fax:(07104) 306111- mail: nkpsims1@rediffmail.com/website : www.nkpsims.in

- **Quality of Audio visual recording:**

The video recording of informed consent may not serve the intended purpose if the quality of the recording fails to meet a minimum standard required for the purpose. The video recording should be done using video camera of appropriate resolution and in a room free from any disturbance to ensure that the image is recognizable and the audio is clearly audible.

- **Information to be given to prospective study subject:**

Investigator must provide the individual with the following information in a language that is non-technical and understandable by the study subjects and same shall be recorded through audio visual means.

Essential elements:

1. Statement that the study involves research and explanation of the purpose of research.
2. Expected duration of the subject's participation
3. Description of the procedures to be followed, including all invasive procedures
4. Description of any reasonably foreseeable risk or discomforts to the subject.
5. Description of any benefit to the subject or others reasonably expected from research. If no benefit is expected subject should made aware of this.
6. Disclosure of specific appropriate alternative procedures or therapies available to the subject.
7. Statement describing the extent to which confidentiality of records identifying the subject will be maintained and who will have access to subject's medical records.
8. Trial treatment schedule and the probability for random assignment to each treatment (for randomized trials)
9. Statement describing the financial compensation and medical management as per regulatory guidelines.
10. Information about whom to contact for trial related queries, rights of subjects and in the event of any injury.
11. The anticipated prorated payment if any to the subject for participating in the trial.
12. Subject's responsibilities on participation in the trial.
13. Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the subject is otherwise entitled.
14. Any other pertinent information.

N.K.P. Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital

Digdoh Hills, Hingna Road, Nagpur – 440 019

Phone (07104) 665000,244291, Fax:(07104) 306111- mail: nkpsims1@rediffmail.com/website : www.nkpsims.in

Additional Elements which may be required:

1. Statement of foreseeable circumstances under which the subject's participation may be terminated by the investigator without the subject's consent.
2. Additional cost to the subject that may result from participation in the study.
3. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by subject.

Where a subject is not able to give informed consent (e.g. an unconscious person or a minor or those suffering from severe mental illness or disability) the above information should be provided to the legally acceptable representative (LAR). If the subject or his/her LAR is unable to read/write- an impartial witness (IW) should be present during the entire informed consent process.

There should not be any restriction on subject's right to ask any questions related to the study. Details of such questions if any, asked by the subject/LAR/IW and his/her understanding on consent are also to be recorded through audio visual means and documented as well.

The process of signing/putting thumb impression by the subject/LAR/IW and Investigator should be video recorded.

- **Protection of Privacy and confidentiality of study participant:**

During the complete study period and at the time of audio visual recording of consent process, the identity and records of the trial participants are as far as kept confidential. Investigator and other study staff should not disclose details about identity of said subjects without valid scientific and legal reasons which may be essential for the purpose of therapeutics or other interventions, without the valid scientific consent in writing of the subject concerned or someone authorized on their behalf and after ensuring that the said subject does not suffer from any form of hardship, discrimination or stigmatization as a consequence of having participated in the trial.

The investigator must safeguard the confidentiality of trial data, which might lead to the identification of the individual subjects. Data of individual subjects can be disclosed only in a court of law under the orders of the presiding judge or in some cases may be required to communicate to Drug regulatory/ Health authority of India.

In order to maintain the confidentiality, the videographer should be engaged as part of the study team and allocate the activities of audio video recording of informed consent process to the respective person. The investigator shall maintain the details of person whom he/she has delegated the duties of audio video recording.

All study documents & AV recordings which may have identification of subject should be kept in lock and key cupboards at access restricted area in the institute premises.

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11.2 Storage and archival of audio visual recordings:

Audio visual recording of informed consent process and other related documents should be preserved safely after the completion/ termination of the study for at least a period of 5 years.

The recording can be stored in CD or External Hard Drive as per availability of resources at institute's defined archival place.

Photocopy of filled, signed and dated informed consent form should be given to the participant for his/her reference and record.

12. Reporting, Analysis of SAE and making opinion on compensation

Serious Adverse Event: Any untoward medical occurrence that at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect.

Adverse Event an AE is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.

12.1 Receipt of AE/SAE report

The IEC will receive the following documents pertaining to AE/ SAE experienced by the research participants for research proposals approved by the IEC:

1. On site SAE report or the unexpected adverse event report to be submitted by the Principal Investigator to IEC within 24 hours of their occurrence as per the format specified in Appendix XI of Schedule Y. In case of holidays or office close, Investigator can email SAE report to official email ID of IEC mentioned in SOP copying to member secretary.
2. The SAE report must fulfill the data elements mentioned in Appendix XI of schedule Y, Also can refer to Annexure 21.

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3. In the case of SAE, the report with due analysis will be submitted by the Principal investigator within 14 calendar days also by the sponsor within 21 calendar days along with the supporting documents if any.

5. The follow up reports of all on site SAE / unexpected AE reports till the event is resolved.

6. On site AE reports to be submitted by the Principal Investigator annually. In view of the risk assessment of a given research proposal the IEC can request adverse events to be reported earlier, if deemed necessary at specified timelines in the project approval letter.

The IEC Secretary/Coordinator will verify that the report is complete in all respects and is signed and dated by the Principal Investigator (PI) and that it has been received at the EC office within the specified timelines above. If the report has been received beyond the specified time, this will be considered as violation.

The Member Secretary/ Coordinator after verification of the report will sign and write the date on which the report is received.

• For all the onsite AE/ SAE reports received at the EC office, the member secretary will inform and send reports to the chairperson within two working days.

12.2 Review of AE, SAE Reports

AE, SAE reports submitted to the IEC will be reviewed by the ethics committee members in full board meeting.

In case of the SAEs at the site to be discussed at the full board meeting, the member secretary will also provide the relevant information including updates on SAE that have occurred earlier at the site. After reading and reviewing the report, the Chairperson will invite members to voice their opinions and ensure free and frank discussion.

12.3 Review procedures and Actions to be taken at SAE meeting

• The SAE will be reviewed completely by all members of the IEC with a special focus on relatedness to the clinical trial, medical management and financial compensation to be given to the research participant as per Schedule Y.

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• Ethics Committee may solicit opinion of the legal Expert who is member of the IEC during its meetings

• Appropriate to the discussions, the decision regarding a specific action or combination of actions to be taken will be arrived by consensus at the meeting.

A) Assessment of relationship of AE/SAE to clinical trial:

The Causality assessment is a systematic review of the data to determine the likelihood of a causal association between the event and the investigational product. The information about the event may be adequate or inadequate. Even with the adequate information, precision of causality is largely determined by the expertise, experience and skills of reviewer.

IEC members can refer to the WHO-UMC causality categories for reference as follows:

Causality Term	Assessment criteria
Certain	1. Event or laboratory test abnormality, with plausible time relationship to drug intake. 2. Cannot be explained by disease or other drug 3. Response to withdrawal plausible (Pharmacologically, pathologically) 4. Event definitive a recognized pharmacological phenomenon 5. Re-challenge satisfactory, if necessary
Probable/ likely	1. Event or laboratory test abnormality, with reasonable time relationship to drug intake. 2. Unlikely to be attributed to disease or other drugs

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	3. Response to withdrawal clinically reasonable 4. Re-challenge not required
Possible	1. Event or laboratory test abnormality, with reasonable time relationship to drug intake 2. Could also be explained by disease or other drugs 3. Information on drug withdrawal may be lacking or unclear
Unlikely	1. Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) 2. Disease or other drugs provide plausible explanations

B) Compensation or Medical Management

IEC shall follow CDSCO guidelines and formula to calculate the compensation to be provided.

The following decisions/Actions including the following but not limited to, are listed below:

1. Note the information about the SAE in records for future reference
2. Ethics Committee should ask sponsor to reimburse the medical management cost till the time it is proven that event is not related to study procedure or drug.
3. Opine on the whether the research participant is entitled for financial compensation and calculate the amount of compensation with the help of formula as per Rule 122DAB of D&C act 1945.
4. Request further follow up information and/ or additional details on causality of the event, provision of medical treatment till SAE is resolved and financial compensation

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Digdoh Hills, Hingna Road, Nagpur – 440 019

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5. Provide periodic follow-up of the research participant till SAE is resolved. In case of pregnancy as SAE to send follow up reports of the fetus and post-delivery of the baby till 1 year.

12.4 Preparation of the minutes and their approval

The decision taken while reviewing SAE reports will be recorded in the minutes of the meeting.

The minutes (to be prepared within 5 working days of the meeting) will be prepared by the Member Secretary with the help of the EC Coordinator.

12.5 Inform Investigator

The Member secretary will draft a formal letter to the concerned Principal Investigator and inform him/ her about the EC decision. The IEC secretariat will file a copy of the letter in the study file.

The principal investigator will be requested to reply to the query letter on the SAE report within 7 working days. If no response is received (within 7days of dispatch of EC query letter) from the investigator regarding the query raised on the given SAE, a reminder letter will be sent to the investigator stating that the response to the query letter must be sent within 5 working days of the dispatch of reminder letter. If no response is received to the reminder letter, this should be discussed in the full board IEC meeting and decision will be taken on case to case basis.

- The principal investigator will be requested to forward follow-up reports after due analysis of the SAE/unexpected AE report to the IRB within 10 calendar days of the occurrence of the SAE/unexpected AE report.

12.6Inform Licensing authority (DCGI)

The Member Secretary of the IEC will forward the letter stating the decision taken on the given SAE report along with the opinion on financial compensation, reply forwarded by the PI (if available) to the Licensing authority (DCGI) within 30 calendar days of the occurrence of the SAE/ unexpected adverse event.

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If the SAE is death then the Member Secretary of IEC will forward the letter stating the decision taken on the given SAE report-death, along with the opinion on financial compensation, reply forwarded by the PI (if available) to the Chairperson of the Expert Committee constituted by the Licensing authority (DCGI) and also a copy to DCGI within 30 calendar days of the occurrence of the SAE-death.

The IEC staff will file a copy of these letters in the study file along with Courier receipt.

12.7 SAEs occurring at other sites:

The investigator will need to submit the SAEs occurring at other sites (CIOMS/SUSARS and Appendix XI) along with the appropriate covering letter (hard copy) mentioning the total number of reports and its details in the following format:

Sr. No.	Country	MFR Control No.	Type of Report (initial/FU)	SAE event	Date of ADR report	Patient Number & Site

The SAEs occurring at other sites will be reviewed by the Ethics committee members in the forthcoming scheduled meeting. The agenda and minutes of the meeting will include the information on SAEs at other sites

• If appropriate to the discussions the issue can be re-discussed and decision can be arrived at by consensus.

Actions are listed below:

- Suggest changes/ amendments in protocol, Patient Information Sheet/ Informed Consent Document/ Investigators' Brochure/ any other study-related documents
- Suspend enrollment of new participants;
- Direct the Investigator to inform participants already enrolled in the study about the AEs and if required obtain their consent again (re-consent) regarding continuation in the research trial

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If the recommendation from the IEC includes, suspension of the study or suspension of any one or more of the study-related procedures or activities, amendments in the protocol or other study-related documents (excluding Investigators' brochure), re-consenting of research participants, the decision will be conveyed to the Principal Investigator through telephone, fax or email within 24 hours. Such a communication will be documented by the EC Member-Secretary in the study file. A formal letter to the Principal Investigator informing about the EC recommendations in such situations will be sent within 5 working days of the IEC meeting having taken place.

13. Handling issues related to non-compliances, protocol violation, complaints by the participants and other stakeholders

Non compliance:

A) Investigators: The common lapse in investigator may include unreported changes in protocol, misuse or unused of the informed consent document, failure to submit protocol to IEC in timely manner may be because of miscommunication. Occasionally an investigator will either avoid or ignore IEC. Such cases present a more serious challenge to EC. Regardless of investigator intent unapproved research involving human subjects places those subjects at an unacceptable risk.
   Action taken by EC: In such circumstances an institutional ethics committee and Institute should act promptly to act research, assure corrective action. The EC is required to inform the head of the Institute and the licensing authority immediately of noncompliance by the investigator and harming the subjects.

B) Site/ Institute: Institutional noncompliance is more broadly described as systemic failure of institute to implement practice and procedures. Prime examples are the failure of institution to ensure that the EC is appropriately constituted and function in accordance with the regulations and investigator meet their obligations to the EC.

C) Institutional EC: Ethics Committee noncompliance occurs whenever the EC deviates from the duties imposed on it by the regulations. Ethics Committee may also breach their responsibilities by failing to maintain adequate records of ethics committee business.

Protocol Deviation/Violation:

Identification, reporting, and evaluation of protocol violations during a clinical trial are integral in adding value to the study data. Preventable errors in study conduct may lead to avoidable patient harm and may result in false negative trial results. Hence designing a plan to prevent/minimize and effectively manage the protocol violations would save time and resources whilst adding quality to

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the collected data. Any protocol deviation or violation observed during trial conduct should be reported to the Institutional Ethics Committee as per Annexure 22. The IEC may ask for detail information and supportive documents for protocol deviation or violation.

The Ethics Committee shall review the following points

- Nature of Deviation/ Violation (Intention behind act)
- Frequency of deviations/ violation
- Overall deviations/violations reported by same PI/co-I in past.

If the protocol violation is serious the ethics committee may withhold study recruitment and schedule audit to find root cause of act. Institutional Ethics Committee shall report continuing noncompliance to Head of Institute and regulatory authorities in writing.

Handling complaints by the study participants and other stakeholders

Study participants are provided with Ethics Committee contact details to reach us in for their rights and safety. Study participant/their relatives or any one from community who care about wellbeing of participants can drop a complaint/suggestion to ethics committee office.

Any request, complaint, query shall be accepted by IEC staff and forwarded to Member Secretary and Chairman. The member secretary can also directly receive complain and put forward and if required keep the issue in full board meeting for discussion and grievance resolution. The final decision will be conveyed to applicant and PI by the member secretary. Corrective action will be taken by EC to safeguard rights of research participants.

The details of Grievance should be recorded and filed in relevant study file as per Annexure 23.

14. Ethics Committee Fees and financial disbursement

The Institutional ethics committee review fees is as follows:

Type of submission	EC fees (in INR)
Sponsored clinical trial protocol submission for initial review	Rs. 90,000
Protocol or any other document amendments requiring EC review & opinion	Rs. 30,000
Expedited review	Rs.95,000
Academic/ investigator initiated study	No fees
Sponsored observational studies	Rs. 20,000

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Digdoh Hills, Hingna Road, Nagpur – 440 019

Phone (07104) 665000,244291, Fax:(07104) 306111- mail: nkpsims1@rediffmail.com/website : www.nkpsims.in

NKPSIMS & RC and LMH/ IEC / 7 / 2023 Date: 1/6/2023

All the payments in form of Cheque / DD should be drawn in favour of **"Ethics committee, NKP Salve Institute of Medical Sciences & Research centre"**

PAN Number: AAATV0836H

All the payments have to be sent to Institutional Ethics Committee office along with the documents to be reviewed. In case of delay in the receipt of the payment, Institutional Ethics Committee shall review the documents; however, would not communicate the decision on the proposal to the investigators until receipt of payment.

In respect to the time and effort given by ethics committee members, as a token of gratefulness to members honorarium shall be given as follows:

Chairperson – 10000

Members (Clinical/non clinical) – 2000/ per EC Meeting

Subject Expert (Invited) – 2500/ per EC Meeting

15. Communication with different stake holders

Institutional Ethics Committee has a defined process of communication with different stake holders like Investigator, Regulatory Authorities, Sponsor and their representatives.

Stake holders can communicate with IEC through written or email as per the contact details given below.

Office staff will maintain the Inward and outward register indicating date of receipt and issue of letter along with name and subject of letter or document. Member Secretary is office bearer; therefore all communications will be addressed and responded by Member Secretary.

Address for Communication:

Institutional Ethics Committee

NKP Salve Institute of Medical Sciences & research centre and Lata Mangeshkar Hospital

Digdoh Hills, Hingna Road, Nagpur-440019

Phone: 07104-665000

Fax No.:07104-306111

Email ID: **iec.nkpsimslmh2022@gmail.com**

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Phone (07104) 665000,244291, Fax:(07104) 306111- mail: nkpsims1@rediffmail.com/website : www.nkpsims.in

15.1 Communication with Investigator:

Investigator and Ethics Committee can directly communicate with each other in writing or email regarding but not limited to following activities
Submission and notification of study related documents
Notification of ongoing study related activities like study update status, deviations or violations.
Acknowledgement of document submitted from Ethics committee office.
Receipt of circulars from ethics committee office
Ethics committee can ask for essential study related documents
Communication regarding AE and SAE reporting

15.2 Communication with DCGI (regulatory authority)

It is basic responsibility of Ethics committee chairman to confirm if proper communication done with regulatory authorities through proper channel.

Common subjects for communication are:

Ethics committee SOP or Member list amendment

Study transition from one investigator to another

SAE causality and analysis reporting in given timelines.

Notification of Fraud or Misconduct

15.3 Communication with study participants and their care taker

Study participant or their care taker can directly communicate with ethics committee in writing.

If any written complaint received from subject, it will be discussed in full board meeting and response given by member secretary in writing.

15.4 Communication with Sponsor or their representative.

Usually investigator acts as a site representative of sponsor and can communicate on behalf of sponsor to Ethics Committee in writing. Ethics committee also communicates with Investigator if any information or document required from sponsor.

Safety reports (SUSAR) can be sent by sponsor/ representative directly to the Ethics Committee.

N.K.P. Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital

Digdoh Hills, Hingna Road, Nagpur – 440 019

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15.5 Administrative support

Ethics committee is provided with a dedicated support staff who is responsible to perform administrative work like

- Correspondence with IEC members and external experts
- Assisting member secretary in drafting Agenda, meeting minutes and approval letter
- Record keeping
- Assist member secretary in arranging and conducting meeting.
- Receiving and dispatching office letters and documents

16. Storage and Archival of the study files and administrative documents

Member Secretary is office bearer and responsible to maintain the administrative documents and study files.

Documents of Ongoing Trials:

Trial Master File (TMF) shall be allotted to each individual study approved by IEC. The master file comprises of all essential documents including correspondences.

Administrative staff is responsible to maintain the Trial Master file. All active files shall be kept in a secured file cabinet with controlled access till study completion or closure. Inward and Outward register shall be maintained to keep the record of incoming and outgoing documents.

Study Closure

Study is declared closed and the file as inactive by the IEC and will be sent to archive for 5 years in the following conditions:

Review and notification of Study Completion Report

Review and notification of Premature Study Termination Report

No response from the PI to the query letter sent by the EC while reviewing protocol for initial review within 90 working days.

N.K.P. Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital

Digdoh Hills, Hingna Road, Nagpur – 440 019

Phone (07104) 665000,244291, Fax:(07104) 306111- mail: nkpsims1@rediffmail.com/website : www.nkpsims.in

NKPSIMS & RC and LMH/ IEC / 7 / 2023 Date: 1/6/2023

The IEC staff should perform following activities after study close out.

- Remove the contents of the entire file from the active study filing area.
- Verify that all documents are present in an organized manner.
- Shift it to a cupboard where in all files to be archived are placed.
- The Secretariat will hold the files of multi-center studies, until all the study sites are closed.
- Place the files in the cupboard at a given area together.
- Perform inventories of miscellaneous administrative documents
- Send it to the archival facility so that it may be easily retrieved bearing a label with the archival date.
- The projects transferred to the archival cupboard will be entered in the Project Archival Register
- Projects will be archived for 5 years from completion or closure.
- After 5 years of Completion of archival period the file containing all the documents will be shred using the shredding machine and document the same.

Documents will be archived in archival steel cupboard at Institutional Ethics Committee

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Digdoh Hills, Hingna Road, Nagpur-440019

Retrieving Documents

- Retrieval of documents can only be done with a request form- Annexure 24 signed and dated by the Chairperson or Member secretary.
- The Secretariat retrieves archived documents and returns the file back to its place.
- The Secretariat will also record, sign and date when the document has been returned and kept.

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NKPSIMS & RC and LMH/ IEC / 7 / 2023 Date: 1/6/2023

Annexures

Annexure 01- CV Format

CURRICULUM VITAE			
Full Name:			
Permanent / Residence Address		Affiliation & office address	
Telephone/ Mobile Number :		Email Address:	
ACADEMIC QUALIFICATIONS			
Institution, Address	Year of completion	Degree/ Specialization	
Medical / Any Legal Registration Number (MMC)			
CURRENT AND PREVIOUS POSITIONS			
Start and End Date	Designation/Affiliation	Institution or Company with Address	

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NKPSIMS & RC and LMH/ IEC / 7 / 2023 Date: 1/6/2023

GCP Trained? Yes or No If Yes please provide the recent date of training	
Experience Working as an Institutional EC Member? (If Yes please provide details below.)	

Declaration:

I undersigned declare that, information provided by me is true and updated to the best of my knowledge.

I am aware that this information would be used for Ethics Committee purpose only.

SIGNATURE	DATE

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Approved
Ethics Committee Re-Registration No.
ECR/88/Inst/MH/2013/RR/19

N.K.P. Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital

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NKPSIMS & RC and LMH/ IEC / 7 / 2023 Date: 1/6/2023

Annexure 2 - EC Membership list

Sr. N	Name & Designation	Highest Qualification	Tel./ Fax Number	Email ID	Mailing address	Affiliation
1	Dr. S. C. Karandikar (Chairperson)	MBBS; MS(Ophth)	07122246720 / 9422835652	Karandikar.eye@gmail.com	69, Shankar Nagar, West High Court Road, Nagpur 440010	Not affiliated to Institute
2	Dr. R. A. Siddiqui (Member Secretary)	MBBS; MD (Pharmacology)	9326724322	riyaz19752008@gmail.com	Pharmacology Dept, NKP Salve Institute of Medical Sciences, Digdoh Hills, Hingna Road, Nagpur	Professor & Head, Pharmacology, NKP Salve Institute of Medical Sciences, Nagpur
3	Dr. Shadma H Quazi (Basic Medical Scientist)	MBBS; MD (Pharmacology)	9545557802	quazi18shad@gmail.com	Pharmacology Dept, NKP Salve Institute of Medical Sciences, Digdoh Hills, Hingna Road, Nagpur	Assistant Professor, Pharmacology, NKP Salve Institute of Medical Sciences, Nagpur
4	Dr. Sushil Pande (Clinician)	MBBS; MD(Skin & VD)	9323511245	drsushilpande@gmail.com	Pharmacology Dept, NKP Salve Institute of Medical Sciences, Digdoh Hills, Hingna Road, Nagpur	Professor, Dermatology, NKP Salve Institute of Medical Sciences, Nagpur
5	Dr. Ajeet Saoji (Clinician)	MBBS; MD(community Medicine)	9822715189	ajeetsaoji@gmail.com	Community Medicine Dept, NKP Salve Institute of Medical Sciences, Digdoh Hills, Hingna Road, Nagpur	Professor and Head, Community Medicine, NKP Salve Institute of Medical Sciences, Nagpur
6	Adv. Rajesh. S. Nagpure (Legal Expert)	B Com; LLB	9923122111 Fax: 07104232905	adv_raj_nagpure66@yahoo.com	Plot no 34, Gawande Layout, Khamla road, Nagpur 440015	Not affiliated to Institute
7	Mrs. Vaishali Nitin Dhangare (Social Worker)	BA; MSW	7887374186	vaishaliband2018@gmail.com	6, Bandu Soni Layout, Sambhaji Nagar, Nagpur 440022	Not affiliated to Institute
8	Mrs. Shalini. B. Thakre (Lay Person)	BA	8149847742	sbthakare@gmail.com	Plot No 9, Police Nagar, Digdoh Hills, Hingna road, Nagpur	Not affiliated to Institute

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Approved
Ethics Committee Re-Registration No. ECR/88/Inst/MH/2013/RR/19

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NKPSIMS & RC and LMH/ IEC / 7 / 2023 Date: 1/6/2023

Annexure 03 : Training log

Ethics Committee Training log Training Date: Training Topic: Trainer name : Sign & Date by Trainer:		
Sr. No	Attendees Name	Signature & date

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NKPSIMS & RC and LMH/ IEC / 7 / 2023 Date: 1/6/2023

Annexure 04- Self Assessment

Institutional Ethics Committee (IEC) Member Self-Assessment

Name:_____ Date:_____

Using a 5 point scale where 5 means excellent and 1 means very poor, please rate your performance on the EC by writing an [√] in the appropriate cell following each question.

Following this, please note any areas for improvement and outline a plan for improvement. This form is for your personal development as a member of the EC and does not need to be shared with anyone else.

1. **My attendance at the EC meetings was**

5=Excellent	4=Good	3=Fair	2=Poor	1=Very Poor

2. **My participation at the EC meetings was**

5=Excellent	4=Good	3=Fair	2=Poor	1=Very Poor

3. **My preparation for the EC meetings in terms of reading materials, performing tasks, and so on was.**

5=Excellent	4=Good	3=Fair	2=Poor	1=Very Poor

4. **My involvement with the EC's tasks and functions was**

5=Excellent	4=Good	3=Fair	2=Poor	1=Very Poor

5. **I would rate my overall performance on the EC as..**

5=Excellent	4=Good	3=Fair	2=Poor	1=Very Poor

6. **I can improve in the following areas:**

7. **My plan for improvement is as follows**

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N.K.P. Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital

Digdoh Hills, Hingna Road, Nagpur – 440 019

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NKPSIMS & RC and LMH/ IEC / 7 / 2023 Date: 1/6/2023

Annexure 05:

Confidentiality Agreement Form for Ethics Committee members

In recognition of the fact, that I/we_____(member's name), and my affiliation_____herein referred to as the "Undersigned", have been appointed as a member of the Institutional Ethics Committee for Clinical Studies has been asked to assess research studies involving human subjects in order to ensure that they are conducted in a humane and ethical manner, with the highest standards of care according to the applied national, local regulations, institutional policies and guidelines; Whereas, the appointment of the undersigned as a member of the Institutional Ethics Committee for Clinical Studies is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest; Whereas, the fundamental duty of an Institutional Ethics Committee member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review; Whereas, the Institutional Ethics Committee for Clinical Studies must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects; The undersigned, as a member of the Institutional Ethics Committee for Clinical Studies, is expected to meet the same high standards of ethical behavior to carry out its mandate. This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the Institutional Ethics Committee. Any written information provided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly. As such, the undersigned agrees to hold all confidential information/ data in trust or confidence and agrees that it shall be used only for contemplated purposes, shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the Institutional Ethics Committee.

The undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that his/her performance of this agreement is consistent with the institute's policies and any contractual obligations they may have to third parties. Confidential information includes any information submitted by the Scientists in connection with Ethics Committee review, whether written or oral, including, but not limited to technical, scientific, financial, strategic, marketing or product information. It also includes, but is not limited to, information concerning EC's computer processes, programs and codes, financial information, pending projects and proposals, standard operating procedures, legal and regulatory affairs. Confidential and proprietary information includes the above information even when it is not marked as such. "Confidential information" does

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not include information that: (a) was already in my possession, as evidenced by written records; (b) becomes publicly available through no fault of my own; or (c) is lawfully and in good faith made available to me by a third party. Where I am required by law, regulation, or court order to disclose confidential and proprietary information, I will provide EC with a notice of such request(s) immediately, but in no event later than two (2) business days after receipt of such request. I agree to cooperate with Ethics Committee if Ethics Committee wishes to seek a protective order.

Agreement on Confidentiality

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 Institutional Ethics Committee. A copy will be given to you for your records. In the course of my activities as a member of the Committee, I may be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information; subject to applicable legislation, including the Access to Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Committee duties) to the Chairperson upon termination of my functions as a Committee member. I also understand that as a member I will be given copies of the study proposals/necessary documents to be evaluated. These will be duly returned by me to the Institutional Ethics Committee during the meetings/as and when requested for. I also understand that these documents are confidential; hence every effort will be taken to prevent access to any other person other than me or the office staff of the Institutional Ethics Committee. At times documents/proposal in soft copy format will be given/send to me. I will assure that these documents/proposals will be access controlled. I ....., have read and accept the aforementioned terms and conditions as explained in this Agreement

Undersigned Signature Date .....

Chairperson's signature Date .....

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Annexure 06:

Conflict of Interest Agreement Form for Ethics committee members

It is recognized that the potential for conflict of interest will always exist but has faith in the Institutional Ethics Committee 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 Institutional Ethics Committee 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 Institutional Ethics Committee for Clinical Studies. The Undersigned will immediately disclose to the Chairperson of the Institutional Ethics Committee 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 in respect of such proposals. While signing the attendance register, the member documents the proposal for which he/she has Conflict of Interest when a member has a conflict of interest, the member should notify the Chairperson and may not participate in the Institutional Ethics Committee review or approval except to provide information requested by the Committee. Examples of conflict of interest cases may be any of the following:

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive
- Any kind of advantage.

A member's personal biases may interfere with his or her impartial judgment 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 Institutional Ethics Committee. A copy will be given to you for your records. Whenever I have a conflict of interest, I shall immediately inform the Chairperson not to count me towards a quorum for voting.

I, ..., have read and accept the aforementioned terms and conditions as explained in this Agreement. I shall abstain from any participation in discussions or recommendations in respect of such proposals.

_____

Undersigned Signature Date

_____

Chairperson's signature Date

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Annexure 07:

Confidentiality and Conflict of interest Agreement Form for Guest Attendees

To IEthics Committee,

I,.....from .....

understand that I am allowed to attend the Institutional Ethics Committee meeting as a guest or an observer. In the course of the meeting of the Institutional Ethics Committee, some confidential information may be disclosed or discussed. Upon signing this form, I agree to take reasonable measures to keep the information as confidential. Indicate the details (date) of the Institutional Ethics Committee Meeting attended: _____

I also confirm that I do not have conflict of interest with study taken for review in today's EC meeting.

Whenever I have a conflict of interest, I shall immediately inform the Chairperson.

_____

_____

Signature of the Guest or Observer

_____

_____

Member Secretary
Institutional Ethics Committee

_____

_____

Signature of the Chairperson

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Annexure 08 - Meeting Agenda

Meeting Date:

Time:

Venue:

Sr. No	Study/Protocol No	Investigator Name	Topic
1	ABCD/123	XYZ	1. 2.
2	XYZ/456	ABC	1. 2.

Agenda and related documents circulated to following members of IEC:

Name of Members	Designation	Signature

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Annexure 09- Minutes of Meeting

Meeting Date		
Start Time		
End time		
Chairperson		
Meeting attendance taken by Chairman. Quorum is complete. Conflict of interest checked. Meeting started. Following members are present.		
Sr. no	Name	Designation
Sr. No 1	Study ID/Protocol Number	
Discussion		
Sr. No 2	Study ID/ Protocol Number:	
Discussion:		
Common Discussion of EC members (if any):		
Meeting Minutes Prepared by:		
Reviewed by:		
Approved by:		

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NKPSIMS & RC and LMH/ IEC / 7 / 2023 Date: 1/6/2023

Annexure 10: Submission documents checklist

Two (2) hard Copies + 1 soft copy of Ethics Committee Dossier (as per GCP guidelines) should be enclosed.

Sr. No.	Document	Available: (Yes/ No/ Not Applicable)
1	Final Protocol with all amendments	
2	Investigator's Brochure and any other safety- related information available	
3	Details of Informed Consent Form.	
4	Patient Information Sheet in English and the relevant translated languages and their back-translations with appropriate translation certificates	
5	Case Record form	
6	Current CV of the Principal Investigator	
7	Proposed methods for patient recruitment including advertisement(s) etc. proposed to be used for the purpose	
8	Insurance Policy/Compensation for participation and for serious adverse events occurring during the study participation	
9	Investigator's agreement with the Sponsor.(CTA)	
10	Letter of permission of DCGI for clinical trials if applicable	
11	Investigator's undertaking	
12	CTRI Registration	
13	Any other relevant information	

Checklist completed by: _____ Sign & Date: _____

Checklist reviewed by: _____ Sign & Date: _____

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Annexure 11: Risk benefit assessment tool

A) High risk/ Low Benefit

Risk:	Benefits
• Completely new drug/ formulation • Highly toxic substance • Safety/Efficacy not established through earlier studies • Inadequate or no risk AE handling mechanisms • High data disclosure and data leakage possibilities • Affects large number of participants • Violation of legal regulations • Inadequate project documentation • Inadequate PI/ staff expertise • New procedure	• Cost of treatment/ drug borne by participant • Replaces current drugs with no extra benefits either treatment wise or cost wise. • Short term relief as oppose to long term action • No post trial alternatives.

B) High Risk/ High Benefit

Risk:	Benefits:
• Completely new drug/ formulation • Highly toxic substance • Safety/Efficacy not established through earlier studies • High incidence of SAEs/ ADR in preliminary studies. • High data disclosure and data leakage possibilities • Affects large number of participants • Violation of legal regulations • Inadequate project documentation • Inadequate PI/ staff expertise • New procedure	• Completely new results • Preventive for life e.g. vaccine • Significant improvement over existing treatments • Minimal side effects as compared to existing treatment. • Significant reduction in treatment cost • Extension of benefit/ availability of treatment post trial • Benefit large number of participants.

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C) Low Risk/High Benefit

Risk:	Benefits:
• Proven acceptable toxicity • Proven Safety/Efficacy • Drug/formulation a variation of approved drugs/ class of drugs • Minor/ acceptable adverse events • No drug but only data analysis • Following regulations	• Completely new results • Preventive for life e.g. vaccine • Significant improvement over existing treatments • Minimal side effects as compared to existing treatment. • Significant reduction in treatment cost • Extension of benefit/ availability of treatment post trial • Benefit large number of participants.

D) Low Risk/ Low Benefits

Risk:	Benefits:
• Proven acceptable toxicity • Proven Safety/Efficacy • Drug/formulation a variation of approved drugs/ class of drugs • Minor/ acceptable adverse events • No drug but only data analysis • Following regulations • Standard of care given	• Cost of treatment/ drug borne by participant • Replaces current drugs with no extra benefits either treatment wise or cost wise. • Short term relief as oppose to long term action • No post trial alternatives.

Protocol Number: _____

Risk benefit assessment Category: _____

Risk benefit assessment done by: _____

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Approved
Ethics Committee Re-Registration No. ECR/88/Inst/MH/2013/RR/19

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Annexure 12: Clinical Trial Agreement Checklist

Study Number: _____ Investigator Name: _____

Sr. N	Clause in Agreement	Y	N	NA
1	Organization has a written agreement with the sponsor that the Organization will use procedures that protect research participants.			
2	Before initiating research, the Organization has a written agreement with the sponsor about plans for disseminating findings from the research and the roles that investigators and sponsors will play in publication or disclosure of results.			
3	The organization has a written agreement with the sponsor that addresses medical care for research participants with a research-related injury.			
4	Instituteis one of the party involved in agreement			
5	Responsibilities of Sponsor, Investigator and Institute are defined			
6	Sponsor or their representative is ready to supply study drug as per protocol requirement. Process of study drug accountability and destruction is clearly mentioned.			
7	Compliance with legal and regulatory requirements.			
8	Intellectual property rights, confidentiality and publication rights are clearly mentioned.			
9	Sponsor has made adequate arrangement of Insurance and Indemnity of Investigator and Institute.			
10	Financial transparency and Conflict of interest declared.			
11	Term & Termination of Agreement			
12	Institutional Overhead charges are clearly mentioned			
13	Provision of reimbursement of study participant expenses for travelling and daily wages is sufficient.			
14	Provision for SAE management hospitalization cost reimbursement			
15	Study budget is appropriate and agreed by the Investigator			
16	CTA accepted by the Investigator and Institute.			

CTA & Insurance reviewed by: _____ Comments: _____ Sign & Date: _____

N.K.P.Salve Institute of Medical Science & RC And Lata Mangeshkar Hospital Nagpur
Approved
Ethics Committee Re Registration No.
ECR/88/Inst/MH/2013/RR/19

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Annexure 13: Study assessment form

Protocol Number: _____

Investigator Name: _____

Document review date:

Name of EC Member: _____

Designation: _____

Sr. No.	Criteria	Comment Acceptable / Not acceptable
1	Documents submitted are complete as per regulatory requirement	
2	Protocol presentation given by Investigator	
3	Knowledge & Experience of investigator to conduct the clinical trial of submitted therapeutic indication.	
4	Investigator given satisfactory answer to the questions asked.	
5	The proposed clinical trial is ethically and scientifically sound.	
6	All essential approvals obtained by the Investigator/ Sponsor	
7	Any discrepancy in essential documents like Protocol, ICF, Insurance, etc.	

Final Opinion for proposal: Approved/ Not approved/ Conditional approved

Comments if not approved: _____

Comments for Conditional approval:

_____

Sign & Date: _____

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Annexure 14: Checklist for Research Involving Children

Investigator Name:			
Study Title:			
Criteria	Yes	No	NA
Does the research pose greater than minimal risk to children?			
If yes: Are convincing scientific and ethical justification given			
If yes: Are adequate safeguard in place to minimize these risks			
Does the study involve normal volunteers?			
If yes, Is inclusion of normal volunteers justified			
Have appropriate studies been conducted on animals and adults justified			
If No: is there lack of appropriate studies been conducted on animals and adults justified			
Will older children be enrolled before younger ones			
Is permission of both parents is necessary			
If yes, is condition under which one of the parents may be considered: not reasonably available, described?			
Will efforts be made ensure that parents' permission to involve their children in research studies is free from coercion, exploitation, and /or unrealistic promises?			
Are provisions made to obtain the assent of children over 7yrs and, where appropriate, honoring their dissent?			
Are provisions made to protect subjects' privacy and the confidentially of information regarding procedures?			
Are there special problems that call for the presence of a monitor			

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or IEC member during consent procedures?			
Are special needs of adolescents such as counseling and confidentiality accounted for in the research design?			
Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?			
Does the research involve a which has implications for member ?(for example, genetic risk , HIV infection ,Hepatitis C)			
If Yes: Are adequate mechanisms in place to deal with other members of the family?			
Should parents be required to be present during the conduct of the research? (Are proposed subjects to be very young ? Are the procedures involved painful? Must subject stay overnight in the hospital when they otherwise would not have to?)			

Reviewer's Comments

_____

_____

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NKPSIMS & RC and LMH/ IEC / 7 / 2023 Date: 1/6/2023

Annexure 15: Checklist for Research Involving Pregnant Women & Fetuses

Section 1: Research Involving Pregnant Women or fetuses prior to delivery

Check points	Yes	No	NA
Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses			
The risk to the fetus is not greater than minimal, or any risk to the fetus which is greater than minimal is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus			
Any risk is the least possible for achieving the objectives of the research			
The woman's consent or the consent of her legally authorized representative is obtained in accord with the informed consent provisions , unless altered or waived in accord with ICMR guidelines			
The woman or her legally authorized representative, as appropriate, is fully informed regarding the reasonably foreseeable impact of the research on the fetus or resultant child			
If the research involves children who are not born, assent and permission will be obtained in accord with Schedule Y			
No inducements, monetary or otherwise, will be offered to terminate a pregnancy			
Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy			
Individuals engaged in the research will have no part in determining the viability of a fetus			

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Section 2: Research involving fetuses after delivery

Check points	Yes	No	NA
Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to fetuses			
The individual(s) providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or resultant child			
No inducements, monetary or otherwise, will be offered to terminate a pregnancy			
Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate pregnancy			
Individuals engaged in the research will have no part in determining the viability of a fetus			
A. Fetuses of uncertain viability			
Does the research hold out the prospect of enhancing the probability of survival of the particular fetus to the point of viability, and any risk is the least possible for achieving the objectives of the research;			
OR, The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no risk to the fetus resulting from the research			
The legally effective informed consent of either parent of the fetus or , if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained			
B. Nonviable fetuses			
Vital functions of the fetus will not be artificially maintained			
There will be no risk to the fetus resulting from the research			
The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means;			
The legally effective informed consent of both parents of the fetus will be obtained in accord with the subpart A of 45 CFR 46. However if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable fetus will suffice to meet the requirements of this paragraph. The consent of a legally authorized representative of either or both of the parents of a nonviable fetus will not suffice to meet the requirements.			

Comments: .....

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Approved
Ethics Committee Re-Registration No. ECR/88/Inst/MH/2013/RR/19

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Annexure 16: Checklist for Research Involving Cognitively Impaired Adults

1. **Research Involving Cognitively Impaired Adults in which there is Anticipated Direct Benefit to the subject** (All items must be "Yes")

The risk to the subjects is presented by an intervention or procedure that holds out prospect of direct benefit for the individual subject. More than minimal risk to subjects is presented by monitoring procedure that is likely to contribute to the subjects well being.	□ Yes	□ No
The risk is justified by the anticipated benefit to the subjects.	□ Yes	□ No
The relation of anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches	□ Yes	□ No
The proposed plan for the assessment of the capacity to consent is adequate	□ Yes	□ No
The consent document includes a signature line for a legally authorized representative.	□ Yes	□ No

2. Research Involving Cognitively Impaired Adults in which there is No Anticipated Direct Benefit to the subject (All items must be "Yes")

The proposed plan for the assessment of the capacity to consent is adequate	□ Yes	□ No
The objectives of the trial cannot be met by means of study of subjects who can give consent personally	□ Yes	□ No
The foreseeable risks to the subjects are low	□ Yes	□ No
The negative impact on the subject's well-being is minimized and low.	□ Yes	□ No
The trial is not prohibited by law.	□ Yes	□ No
Subjects have a disease or condition for which the procedures in the research are intended.	□ Yes	□ No
Subjects will be particularly closely monitored	□ Yes	□ No
Subjects will be withdrawn if they appear to be unduly distressed.	□ Yes	□ No
The proposed plan for the assessment of the capacity to consent is adequate.	□ Yes	□ No
The consent document includes a signature line for a legally authorized representative.	□ Yes	□ No

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NKPSIMS & RC and LMH/ IEC / 7 / 2023 Date: 1/6/2023

Annexure 17: Checklist for Research Involving Students, Employees or Residents

Does the employer or supervisor of the research subject need to be aware of the research project?	□ Yes	□ No
Is there a letter of support and/ or internal services checklist?	□ Yes	□ No
Have the subjects been assured that their status (education, employment, and/or promotion) will not be affected by any decision to participate or not?	□ Yes	□ No
Have the risks to subjects been minimized?	□ Yes	□ No
Have subjects been assured that participation is voluntary (no signs of coercion)?	□ Yes	□ No
Have subjects been assured that confidentiality will be protected or maintained	□ Yes	□ No

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NKPSIMS & RC and LMH/ IEC / 7 / 2023 Date: 1/6/2023

Annexure 18: Checklist for Genetic Research

Will the samples be made anonymous to maintain confidentiality? If yes, stop here	□ Yes	□ No
Has the investigator established clear guidelines for disclosure of information, including interim or inconclusive research result?	□ Yes	□ No
Has the appropriateness of the various strategies for recruiting subjects and their family members been considered?	□ Yes	□ No
Does the proposed study population comprise family members?	□ Yes	□ No
Will family members be implicated in the studies without consent?	□ Yes	□ No
Will the samples be destroyed in the future?	□ Yes	□ No
Is genetic counseling being offered?	□ Yes	□ No

Comments: _____

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NKPSIMS & RC and LMH/ IEC / 7 / 2023 Date: 1/6/2023

Annexure 19: Study monitoring checklist

Protocol Number :	Date of Visit:
Study Title	
Name of Principal Investigator	
Type of study	Sponsored / Investigator oriented/ Academic/ ICMR/ Other (Specify)
Date of EC Approval	
Date of study initiation	
Study duration	
Reason for Monitoring	Routine/ For cause/ SAE reporting/ Protocol violation or deviations
Project status	□ Ongoing □ Completed □ Recruitment completed □ follow up extension □ Suspended □ Terminated
Recruitment status	Total screened _____ Enrolled _____ Screen failure _____

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	Withdrawn _____ Reason_____ Discontinued _____ Reason _____ Completed _____ Active _____
Are study team members qualified and experienced for study protocol	Comment
Are site facility appropriate	Comment
Is recent version of ICF after EC approval used for consent process	Comment
Is appropriate vernacular language used for consent	Comment
Any issues related to ICF process?	Comment
Recent protocol version used approved by EC	Comment
All patient enrolled fulfilled inclusion/ exclusion criteria?	Comment
Any AE found and notified to EC?	Comment
Whether SAE informed to EC & CDSCO in timeline?	Comment
Compensation paid for study related injury?	Comment
Are there any protocol non-compliance/ Deviations? If yes informed to EC?	
Storage of documents and investigational product in lock & key?	

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Discussion with investigator and study team members done?	
Name of EC member who attended monitoring	
Checklist completed by :	Signature: Date:

Final decision in IEC meeting held on _____

_____

Signature of Chairperson

Date

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Annexure 20: ICF checklist

Protocol Number: _____

Investigator Name: _____

S.N	Description of Element	Present Y/N/NA/ Comment
1	The identity of the Researcher	
2	The identity of the Sponsor	
3	The study title	
4	A statement that the participant is being invited to participate in research	
5	Subject's participation and withdrawal from the trial is voluntary.	
6	Information concerning the presence of any real, potential or perceived conflicts of interest on the part of the researchers, their institutions or the research sponsors	
7	A statement of the research purpose in plain language	
8	A description of available alternative procedures or courses of treatment that are available outside of the research project	
9	The approximate number of research participants	
10	The probability of randomization to each intervention	
11	A description of the research intervention and procedures to be used, including clear indication of those aspects that are experimental	
12	Separate consent/ statement for Pharmacogenetic or Pharmacokinetic sample required subject voluntary consent.	
13	The nature of participation	
14	Participants are informed of any therapy that will be withdrawn or withheld for the purposes of the research, and the anticipated	

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	consequences of withholding or withdrawing therapy.	
15	The measures employed to protect the privacy and minimize risks to participants	
16	The researchers' plan for handling results and findings, including clinically relevant information and incidental findings	
17	An explanation of the responsibilities of the participant	
18	The expected duration of participation	
19	Information on stopping rules and when researcher may remove participants from the clinical trial without the participant's consent	
20	A plain language description of all reasonably foreseeable risks or inconveniences, to participants, and in general, that may arise from research participation	
21	Description about the associated and unforeseen risks and benefits of the trial.	
22	An indication of what information will be collected about participants and for what purpose	
23	An indication of who will have access to information collected about the identify of participants, including specification that the monitor(s), auditor(s), the IEC and the regulatory authority(ies) will be granted direct access to the participant's original medical records for verification of clinical trial procedures and data	
24	A description of how confidentiality will be protected and, to the extent permitted by the applicable laws and regulations, records identifying the participant will not be made publicly available.	
25	A description of the anticipated uses of data	
26	Information indicating who may have a duty to disclose information collected, and to whom such disclosures could be made	
27	Any anticipated expenses associated with participation in the clinical trial	
28	A description of the compensation, if any, that will be provided to the participant in the event that he/she is injured during the research	

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Ethics Committee Re-Registration No.
ECR/88/Inst/MH/2013/RR/19

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29	Information about any payments, including incentives for participants and reimbursement for participation related expenses	
30	An assurance that participants will be given, in a timely manner throughout the course of the research project, information that is relevant to their decision to continue or withdraw from participation.	
31	The identity and contact information for a qualified individual who can explain the scientific or scholarly aspects of the clinical trial (e.g., PI or Sub-I)	
32	The identity and contact information for an appropriate individual outside the research team whom participants may contact regarding possible ethical issues in the research (e.g., IEC)	
33	The person to contact in the event of research-related injuries	
34	Signature and date of signature of the participant (or their substitute decision-maker/legally authorized representative, if applicable)	
35	Signature and date of the Investigator	
36	Signature and date of person assisting in the consent discussion (Impartial witness)	

ICF Checklist completed by: _____

Comments: _____ Sign & Date: _____

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Annexure 21: Data elements for reporting Serious Adverse Event occurring in clinical trial.

1. Patient Details :	
Initials & other relevant identifier (hospital/OPD record number etc.):	
Gender :	
Age and/or date of birth:	
Weight :	
Height :	
Socioeconomic Background of Subject:	
2. Suspected Drug(s) :	
Generic name of the drug:	
Indication(s) for which suspect drug was prescribed or tested:	
Dosage form:	
Daily dose and regimen and strength (specify units - e.g., mg, ml, mg/kg):	
Route of administration:	
Starting date and time of day:	
Stopping date and time, or duration of treatment:	
3. Other Treatment(s):	
Provide the same information for concomitant drugs (including non-prescription/OTC drugs) and non-drug therapies, as for the suspected drug(s):	

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NKPSIMS & RC and LMH/ IEC / 7 / 2023 Date: 1/6/2023

Sr. No	Generic name of the drug/ device	Indication(s)	Dosage Form and strength/ Dosage regimen	Route of Administration	Starting date & time of day	Stopping date, time & duration of treatment

4. Details of Suspected Adverse Drug Reaction(s):	
Full description of reaction(s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction:	
Start date (and time) of onset of reaction:	
Stop date (and time) or duration of reaction:	
Dechallenge and rechallenge information:	
Setting (e.g., hospital, out-patient clinic, home, nursing home):	
Relationship to Study Drug: (Related / Not Related)	
Reasoning for Relatedness / Un-Relatedness by PI:	
5. Outcome :	
Information on recovery and any sequelae; results of specific	

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tests and/or treatment that may have been conducted.	
For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; any post-mortem findings:	
Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc.	
6. Details about the Investigator :	
Center Number :	
Name:	
Address:	
Telephone number / Email:	
Profession (speciality):	
Date of reporting the event to Licensing Authority:	
Date of reporting the event to Ethics Committee overseeing the site:	
Date of reporting the event to Sponsor / CRO:	
Was the reporting done in 24 hours of occurrence? If no, please mention the reason for delay:	
Signature of the Investigator:	

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NKPSIMS & RC and LMH/ IEC / 7 / 2023 Date: 1/6/2023

Annexure 22:

Format for Notification of Protocol Deviation / Violation

Date:

To

The IEC

Protocol Number:

Protocol Title:

Subject: Notification of Protocol Deviation/ Violation

Subject Number:

Description of Deviation/ Violation with its impact on study subject:

Corrective Action taken by PI/ related authority:

Preventive actions to be taken:

Reported by

Sign & Date

Enclosure:

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Annexure 23 – Grievance redressal form

Date	
Complaint received by	
Complaint/ Suggestion received through	Telephone No. Report Date: Walk in Date & Time: Other, Specify
Reference Study No./ Title	
Study Participant Name	
Contact details of applicant	
Information requested/ Complaint/ Suggestion	
Reviewed by	
Final Decision	
Action Taken	
Signing Authority	Signature & Date

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Annexure 24: Document Request Form for Archived file

Name of Document requested:	Protocol No:
Requested by:	Date:
☐ Chairperson ☐ Secretariat ☐ IEC Member	
☐ EC staff ☐ Authority ☐ Others.....	
Purpose of the request:	

_____

Sign & date of Requester

_____

Sign & date of IEC Chairperson/ Member Secretary