STANDARD OPERATING PROCEDURES (SOPs) FOR INSTITUTIONAL ETHICS COMMITTEE (IEC) GOVERNMENT DENTAL COLLEGE & HOSPITAL, NAGPUR (IEC-GDCHN)

VERSION NO: SOP 02/V1

EFFECTIVE DATE: 01.01.2024

EFFECTIVE FROM: 01.01.2024 EFFECTIVE UP TO: 31.12.2026

PREPARED BY:

Dr. Shailesh Gondivkar	Member Secretary, IEC
Dr. Darshan Dakshindas	Ex-Member Secretary, IEC

REVIEWED BY:

Dr. Shubha Hegde	Alternate Member Secretary, IEC
Dr. Sachin Khatri	Member, IEC

APPROVED BY:

Dr. Abhay Datarkar	Dean, GDCH Nagpur
Dr. Mukta Motwani	Chairperson, IEC

The location and business address of the committee: Room No. – 25, Institutional Ethics Committee, GDCH, Nagpur Government Dental College & Hospital, GMC Campus, Medical Square, Nagpur Maharashtra, India. Pin-440003 Phone No.- 0712-2744496

Standard Operating Procedures for Institutional Ethics Committee, GDCHN (IEC-GDCHN) is a content of Compendium on scientific research and publications at GDCH, Nagpur

1- Purpose:

This Standard Operating Procedure (SOP) describes the Terms of References (TOR), for the EC and its members which provide the framework for constitution, responsibilities, and activities of the Institutional Ethics Committee (IEC).

2- Scope:

The SOP applies to all activities performed by the Institutional Ethics Committee. The objective of Standard Operating Procedures is to ensure quality and consistency in review of clinical research proposals and to follow the ICMR and national ethical guidelines for biomedical research on human subjects. The SOPs shall be updated periodically to reflect changing requirements. A copy of the latest version of SOPs shall be made available to each member and they should be trained on the SOPs.

The IEC will review scientific and ethical aspects of all types of research studies involving human participants; sponsored by Government of India, sponsored by pharmaceutical companies, and all dissertation projects (postgraduate students: MDS), PhD scholars, research projects of and Fellowship, undergraduate students (Indian Council for Medical research studentship) and investigator initiated research studies which are self-funded and those funded by Maharashtra University of Health Sciences.

Responsibility: It is the responsibility of the Institutional Ethics Committee members to read, understand, follow and respect the SOP set by the Institutional Ethics Committee.

3- Institutional Ethics Committee (IEC)

The IEC will review scientific and ethical aspects of all types of research studies involving human participants. The committee will consist of members who collectively have the qualifications and experience to review and evaluate the scientific, medical and ethical aspects of research projects involving human participants and without any known record of misconduct. In evaluating protocols and ethical issues, the IEC is aware of the diversity of laws, culture and practices governing research and medical practices in various countries around the world and especially in India. The IEC is established and functions in accordance with the relevant national law and regulations in force from time to time.

3.1 Composition of Institutional Ethics Committee

ECs should be multi-disciplinary and multi-sectoral. There should be adequate representation of age and gender. Preferably 50% of the members should be non-affiliated or from outside the institution. The number of members in an EC should preferably be between 07 and 15 and a minimum of five members should be present to meet the QUORUM requirements. The EC should have a balance between medical and non-medical members/technical and non-technical members, depending upon the needs of theinstitution.

Generally, the representation on the IEC shall be:

i. Chairperson (outside Institution- Nominated by the Dean)

ii. Member Secretary from Institute

iii. One basic medical scientist (preferably one Pharmacologist)

iv. One Clinician

v. One legal expert or retired Judge

vi. One social scientist/representative of non-governmental organization/ Philosopher/ Ethicist/ Theologian or a similar person

vii. One lay person from the community.

3.2 Membership requirements:

The Head of the Institute (HOI) is responsible for appointing new committee members. The Chairperson and IEC members can suggest names of potential members but the final decision will remain with the HOI. Members will be selected in their personal capacities based on their interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the IEC work. Members must disclose in writing any interest or involvement-financial, professional or otherwise- in a project or proposal under consideration. The IEC will decide the extent to which members that might have a conflict of interest may participate in bringing out an advice/decision.

Every EC member must:

1. Present current, signed curriculum vitae and, if relevant, training certificates on good clinical practice (GCP) and human research protection.

2. Either complete training or submit training certificates within six months of appointment (or as per institutional policy), or get training in human research protection and/or GCP at the time of appoint into the EC.

3. Be prepared to upgrade their knowledge and skills or go through training while serving as an EC member.
4. Recognize the pertinent rules and laws.
5. Read, comprehend, accept, and abide by the EC's COI policy; if applicable, announce it at the proper time.
6. Sign a confidentiality and conflict of interest agreement/s
7. Be prepared to make public her or his entire name, occupation, and EC affiliation
8. Have a strong commitment to protecting research participants and having a grasp of the need for research

Member/s should be sufficiently qualified through the experience and expertise and sensitive to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review the specific research activities, the member/s should be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards or professional conduct and practice. A member of IEC can be a part of any other IRB/IEC

A) Chairperson - (Non-affiliated) -

- A well-respected person from any background with prior experience of having served/serving in an EC.

B) Member Secretary - (Affiliated) -

- Should be a staff member of the institution
- Should have knowledge and experience in clinical research and ethics and be motivated and have good communication skills
- Should be able to devote adequate time to this activity which should be protected by the institution

C) Basic Medical Scientist(s) - (Affiliated/Non-Affiliated) -

- Non-medical or medical person with qualifications in basic medical sciences.
- In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist.

D) Clinician(s) - (Affiliated/Non-Affiliated) -

- Should be individual/s with recognized medical qualification, expertise and training.

E) Legal expert/s - (Affiliated/Non-Affiliated) -

- Should have a basic degree in Law from a recognized university, with experience
- Desirable: Training in medical law.

F) Social scientist/philosopher/ethicist/theologian - (Affiliated/Non-Affiliated) -

- Should be an individual with social/behavioural science/philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health-related activities.

G) Layperson(s) - (Non-affiliated) -

- Literate person from the public or community
- Has not pursued a medical science/Health related career in the last 5 years
- May be a representative of the community from which the participants are to be drawn
- Is aware of the local language, cultural and moral values of the community
- Desirable: involved in social and community welfare activities.

Member/s should be sufficiently qualified through the experience and expertise and sensitive to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review the specific research activities, the member/s should be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards or professional conduct and practice. A member of IEC can be a part of any other IRB/IEC.

3.3 Appointment of new members and alternate members:

The IEC members will be appointed by the Head of the Institution (HOI). New members will be appointed under the following circumstances:

1. When a regular member completes his/ her tenure.
2. If a regular member resigns before the tenure is completed.
3. If a regular member ceases to be a member for any reason including death or disqualification.
4. To fulfill the membership requirements as per section 3.2 of this SOP.

New members will be identified by the Chairperson according to the requirement (i.e., as per the composition specified in section 3.1 of this SOP), membership requirement (Section 3.2 of this

SOP) and provided the potential member fulfils the conditions of appointment. The names of new members to be appointed may be suggested by the IEC members and the Chairperson to the HOI. The final decision regarding appointment of members will be taken by the HOI.

Members to be appointed on the EC should be willing to fulfil the EC requirements as per section 3.2 of this SOP. The appointment letter issued to all members should specify the TORs. The letter issued by the HOI shall include, at the minimum (i) Role and responsibility of the member in the committee, (ii) Duration of appointment (iii) Conditions of appointment. The tenure for Members of the IEC is for a period of Three (03) Years. It can be extended to another three (03) years. Members to be appointed on the EC should be willing to fulfil the EC requirements.

Members will be selected in their personal capacities based on their interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the IEC work. Members must disclose in writing any interest or involvement-financial, professional or otherwise- in a project or proposal under consideration. The IEC will decide the extent to which members that might have a conflict of interest may participate in bringing out an advice/decision.

3.4 Tenure: Membership Duration

i. The tenure for Members of the IEC is for a period of Three (03) Years.

ii. It can be extended to another three (03) years.

iii. There will be no bar on the members serving for more than one term but it is desirable to have approximately one thirdfreshmembers.

iv. A member can be replaced in the event of long-term non-availability (three consecutive meetings). Authority to replace the member shall remain with the Chairman.

v. Members should maintain confidentiality of all discussions during the meeting and sign a confidentiality form at the start of their term. Each member of the committee will submit a declaration to maintain the confidentiality of the documents submitted to them during their membership period.

vi. Conflict of interest if any, shall be declared by members of the Institutional Ethics Committee at the beginning of every meeting.

3.5 Resignation/Replacement of members

To establish polices for removal or Resignation /Replacement of Members Chairman and Member Secretary are responsible for implementing this SOP.

Term of appointment Members of IEC will be appointed for period of 03 years initially which could be extended for another term of 03 years. Extension of membership will bebased on the recommendation of the Chairman & Member Secretary of IEC.

Policy for removal of member

- A member may be relieved or terminated of his/her membership in case of conduct not suitable for a member of the Ethics Committee.
- Inability to participate in the meetings on any grounds for more than 3 meetings of IEC
- The membership shall be reviewed by the Chairman, if the member is a regular defaulter.
- If deemed necessary, the IEC may decide to terminate the membership and recommend to the Chairman IEC for necessary action.
- In all such situations/circumstances, member secretary will serve a letter of termination to the member.
- Documentation of the termination will be recorded in the meeting minutes of the next duly constituted IEC meeting and IEC membership circular/roster will be revised.

Resignation/Replacement procedure

- The members who have resigned may be replaced at the discretion of the appointing authority for the same.
- IEC members who decide to resign must provide the Chairman & Member Secretary of IEC the written notification of their proposed resignation date at least 30 calendar days prior to the next scheduled meeting.
- In case of resignation, chairman & member secretary would appoint a new member, falling in the same category of membership ex. NGO representative with NGO representative.

3.6 Conditions of appointment

Members and Independent consultants will be appointed to the IEC if they accept the following conditions:

- Willingness to publicize his/her full name, profession and affiliation.
- Willingness to record reimbursement received for work and expenses incurred, related to the IEC assignment and make these records available to IEC and/ or general public on request.
- Willingness to sign the Confidentiality and Conflict of Interest Agreements regarding meeting, deliberations, applications, information on research participation and related matters.

3.7 Training of IEC members

i) Members should be trained in human research protection, EC functions and SOPs, and should be conversant with ethical guidelines, GCP guidelines (if applicable) and relevant regulations of the country.

ii) EC members should undergo initial and continuing training in human research protection, applicable EC SOPs andrelated regulatory requirements. All trainings should be documented.

iii) Any change in the relevant guidelines or regulatory requirements should be brought to the attention of al lEC members.

iv) EC members should be aware of local, social and cultural norms and emerging ethical issues.

4 – IEC Functions

4.1 Roles and responsibilities of the EC

i) The basic responsibility of an EC is to ensure protection of the dignity, rights, safety and well-being of the research participants.

ii) The EC must ensure ethical conduct of research by the investigator team.

iii) The EC is responsible for declaration of conflicts of interest to the Chairperson, if any, and ensuring these are recorded in the minutes.

iv) The EC should perform its function through competent initial and continuing review of all scientific, ethical, medical and social aspects of research proposals received by it in an objective, timely and independent manner by attending meetings, participation in discussion and deliberations.

v) The EC must ensure that universal ethics values and international scientific standards are followed in terms of local community values and customs.

vi) The EC should assist in the development and education of the research community in the given institute (including researchers, clinicians, students and others), responsive to local health care requirements.

vii) Responsibilities of members should be clearly defined. The SOPs should be given to EC members at the time of the appointment.

ix) The EC should ensure that privacy of the individual and confidentiality of data including the documents of EC meetings is protected.

x) The EC reviews progress reports, final reports and AE/SAE and gives needful suggestions regarding care of the participants and risk minimization procedures, if applicable.

xi) The EC should recommend appropriate compensation for research related injury, wherever required.

xii) The EC should carry out monitoring visits at study sites as and when needed.

xiii) The EC should participate in continuing education activities in research ethics and get updated on relevant guidelines and regulations.

xiv) The EC may see that conduct of same/similar research by different investigators from same institution is harmonized. 'Me too' research (replicative) should not been courage and submission of same research to different funding agencies should not be accepted.

4.2 Roles and Responsibilities of IEC members:

Chairperson:

- Conduct EC meetings, accountable for independent and efficient functioning of the committee
- Ensure active participation of all members (particularly non-affiliated, non-medical/ non-technical) in all discussions and deliberations
- Ratify minutes of the previous meetings
- In case of anticipated absence of Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson or the members present mayelect an Acting Chairperson on the day of the meeting. The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting.
- Seek COI declaration from members and ensure quorum and fair decision making.
- Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.

Member Secretary:

- Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review.
- Schedule EC meetings, prepare the agenda and minutes
- Organize EC documentation, communication and archiving

- Ensure training of EC secretariat and EC members
- Ensure SOPs are updated as and when required
- Ensure adherence of EC functioning to the SOPs
- Prepare for and respond to audits and inspections
- Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review.
- Assess the need for expedited review/exemption from review or full review.
- Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives.
- Ensure quorum during the meeting and record discussions and decisions.

Basic Medical Scientist(s):

- Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report
- For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.

Clinician(s):

- Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics
- Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report)
- Review medical care, facility and appropriateness of the principal investigator, provision for medical care, management and compensation.
- Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.

Legal expert/s:

- Ethical review of the proposal, Informed Consent Document (ICD) along with translations, Memorandum of Understanding (MOU), Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, Human Mesenchymal stem cells (HMSC) for international collaboration, compliance with guidelines etc.

- Interpret and inform EC members about new regulations if any social scientist/philosopher/ethicist/theologian
- Ethical review of the proposal, ICD along with the translations.

- Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any
- Serve as a patient/participant/societal/community representative and bring in ethical and societal concerns.

Lay person(s):

- Ethical review of the proposal, ICD along with translation(s).
- Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks.
- Serve as a patient/participant/community representative and bring in ethical and societal concerns.

- Assess on societal aspects if any.

4.3 Record Keeping and Archiving

I. Curriculum Vitae (CV) of all members of IEC.

II. Minutes of all meetings duly signed by the Chairperson. Copies of all correspondence with members, researchers and other regulatory bodies.

III. Copy of existing relevant national and international guidelines on research ethics and laws along with amendments.

IV. All study related documents (study protocols withenclosed documents, progress reports, and SAEs.) should bearchived for minimum of five years after the completion of study. A copy of filled Clinical Record Form (CRF) shall remain with the PI for minimum often years.

V. Final report of the completed projects.

5 IEC-Operations

5.1 *Meeting: Office and Conduct of the Meeting*

i. The Chairperson will conduct all meetings of the Institutional Ethics Committee. If for reasons beyond control, the Chairperson is not available, an alternate Chairperson will be elected by the members present from among themselves.

ii. The Member Secretary will be responsible for organizing the meetings, maintaining the records and communicatingwith all concerned. He/she will prepare minutes of the meetings and get them approved by the Chairperson before communicating to members and Principal Investigator.

iii. Chairman & member secretary are responsible for implementing this SOP.

iv. The Member Secretary in consultation with the chairman may convene the IEC meeting once in every year.

v. Additional review meeting can also be held with short notice as and when required.

vi. All members will receive notification of meeting schedules in advance.

vii. A minimum of five persons is required to form the quorum without which a decision regarding the research would not be taken. The quorum would have at least one representative from the following group:

1. One basic medical scientist (preferably one Pharmacologist)
2. One Clinician
3. One legal expert or retired Judge
4. One social scientist/ representative of non-governmental organization/Philosopher/Ethicist/Theologian or a similar person
5. One lay person from the community.

viii. Minutes of the IEC meetings, all the proceeding and deliberation will be documented.

ix. Applicant investigator may be invited to present the proposal or elaborate on specific issue.

The Chairperson will conduct all meetings of the Institutional Ethics Committee. If for reasons beyond control, the Chairperson is not available, an alternate Chairperson will be elected by the members present from among themselves.

5.2 Quorum Requirements

A minimum of 5 members including at least one member from the related specialty, in which presentation is due, should be present. All decisions will be taken in the meetings and not by circulation of project proposals. As per revised "Schedule Y'' of Drugs & Cosmetics Act, 1940, amended in 2005, the ethics committee approving drug trials will have in the quorum at least one representative from the following groups:

1. One basic medical scientist (preferably one pharmacologist).
2. One clinician
3. One legal expert or
4. One social scientist
5. One lay person from the community

5.3 Independent Consultants

Institutional Ethics Committee may call upon subject experts as consultants for review of selected research protocols. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities; patient groups or special interest groups e.g. cancer patients, HIV/AIDS positive persons or ethnic minorities. They will not take part in the decision-making process and shall have no voting rights.

6. Submission of documents for IEC review:

Details of documents to be submitted for EC review

1. Covering letter to the Member Secretary
2. Type of review requested
3. Application form for initial review
4. The correct version of the informed consent document (ICD) in English and the local language(s). Translation and back translation certificates (if applicable)
5. Case record form/questionnaire
6. Recruitment procedures: advertisement, notices (if applicable)
7. Patient instruction card, diary, etc. (if applicable)

8. Investigator's brochure (as applicable for drug/biologicals/device trials)

9. Details of funding agency/sponsor and fund allocation (if applicable)

10. Brief curriculum vitae of all the study researchers

11. A statement on COI, if any

12. GCP training certificate (preferably within 5 years) of investigators (clinical trials)

13. Any other research ethics/other training evidence, if applicable as per EC SOP

14. List of ongoing research studies undertaken by the principal investigator (if applicable)

15. Undertaking with signatures of investigators

16. Regulatory permissions (as applicable)

17. Relevant administrative approvals (such as HMSC approval for International trials)

18. Institutional Committee for Stem Cell Research (IC-SCR) approval (if applicable)

19. MoU in case of studies involving collaboration with other institutions (if applicable)

20. Clinical trial agreement between the sponsors, investigator and the head of the institution (s) (if applicable).

21. Documentation of clinical trial registration (preferable)

22. Insurance policy (it is preferable to have the policy and not only the insurance certificate) for study participants indicating conditions of coverage, date of commencement and date of expiry of coverage of risk (if applicable)

23. Indemnity policy, clearly indicating the conditions of coverage, date of commencement and date of expiry of coverage of risk (if applicable)

24. Any additional document(s), as required by EC (such as other EC clearances for multicentric studies)

25. Protocol

This list is subject to modifications, depending on the type of research, EC SOPs and institutional policies.

6.1 Submission & Review Procedure

Researchers should submit research proposals as soft orhard copies to the Member Secretary for review in the prescribed format and required documents as per EC SOPs.

i. All relevant documents should be enclosed with application.

ii. For projects within the GDCH, Nagpur fee will be charged as follows-

A. Undergraduate-Rs200
B. Postgraduate-Rs1000
C. PhD/Staff-Rs1500
D. Outside GDCH (within 50 km) academic or clinical protocols except Clinical trials-Rs2500

iii. For trials from outside agencies/sponsors, fee of Rs2,00,000 is to be deposited along with application form.

iv. The required number of copies of the proposal (14 for ICMR and outside funded projects and for in-house projects as specified) along with the application and documents in prescribed format duly signed by the PI and Co-investigators/Collaborators should be forwarded by the Head of the Department (Institute).

v. The Member Secretary will acknowledge the receipt of proposal and indicate any lacunae. Missing information should be replied within two weeks or as specified

vi. The date of meeting will be intimated to the PI who should be available to offer clarifications if necessary.

vii. The decision of Institutional Ethics Committee will be communicated in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication.

6.2 Review of Projects

i. Meetings of Institutional Ethics Committee shall be held at scheduled intervals as prescribed. Additional meetings will be held as and when necessary.

ii. The proposals will be sent to members at least 3 weeks in advance.

iii. The Member Secretary shall screen the proposals for the incompleteness and depending on the risk involved categorize them into three types, namely-Exemption from review, Expedited review, and Full committee review.

iv. Decisions will be taken by consensus after discussions, and voting will be done if necessary.

v. Principle Investigator should be available during the meeting and will give brief presentation of his proposal. He/She may be asked for any clarifications.

vi. Independent consultants/Experts may be invited to offer their opinion on specific research proposals.

vii. The decisions of the meeting shall be recorded in the form of minutes and shall be

confirmed during the next meeting.

6.3 Element of Review of Proposed Projects:

i. Scientific design and conduct of the study. Approval of scientific review committee/Research committee and other regulatory agencies.

ii. Assessment of predictable risks, harms and potential benefits.

iii. Procedure for selection of subjects including inclusion/exclusion, withdrawal criteria and other issues like sample size and advertisement details.

iv. Management of research related injuries, adverse events and compensation provisions.

v. Justification for placebo in control arm, if any.

vi. Availability of products to the trial subjects after the study, if applicable.

vii. Patient information sheet and informed consent form in English/Hindi and local language.

viii. Protection of privacy and confidentiality of subjects.

ix. Involvement of the community, wherever necessary.

x. Protocol and proforma of the study including the consent form.

xi. Plans for data analysis and reporting.

xii. Adherence to Regulatory requirements and applicable guidelines.

xiii. Competence of Investigators, research and supporting staff.

xiv. Facilities and infrastructure.

6.4 Review Process

i. A member shall withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises. This shall be indicated to the chairperson prior to the review of the application and recorded in the minutes.

ii. Only members will make the decision. The decisions shall be taken in the absence of Investigators, representatives of sponsors and consultants.

iii. Decision may be of approval, rejection or recommendation to revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.

iv. Revised proposals may be subjected to an expedited review.

v. All approved proposals will be subject to the laid down standard conditions. Additional conditions may be added by the Institutional Ethics Committee.

6.5 Expedited Review

Proposals which are recommended for minor revisions will be reviewed by a sub committee appointed by the Institutional Ethics Committee (IEC) for clearance and approved by the Chairperson. The approvals will be reported in the next Institutional Ethical Committee meeting by Secretary. The revised form of proposals requiring major changes will be reviewed at the next IEC meeting. Rejected proposals may be reconsidered only if a very strong background is there.

6.6 Periodic updates to be submitted to IEC

i. All amendments in protocol/ICF/IB or any new information available related to IEC approved protocols must be submitted to IEC.

ii. The investigator/Sponsor is responsible to supply ongoing safety updates, progress reports (periodic) of trial status report, re-approvals (if required) to the IRB/IEC.

iii. PI is required to inform IEC in writing after the site is initiated

iv. Half yearly progress report to be submitted in the last week of every December and June. PI's are requested to submit 2 copies of each report to IEC, one to be given back to PI, one for IEC record.

v. After receiving IEC approval, even if site is not initiated half yearly report must be submitted mentioning reasons for not initiating the site

vi. The P.I. will be required to intimate the name/s designation and nature of work/responsibilities entrusted to all the members of his/her team in the said protocol. This information will have to be submitted by the P.I. along with the submission letter addressed to the Member Secretary. Change/s in such a job/responsibility profile will be immediately intimated to the Member secretary.

vii. If an assistant whose name is not intimated is entrusted the said job/responsibility, it will be considered as a breach and the IEC will take appropriate action in the matter and this decision shall be final.

viii. The Principal Investigator and the said team shall abide by privacy and confidentiality when the study is approved by the IEC.

6.7 Communication of decision of Institutional Ethics Committee

i. Decision will be communicated to Principal Investigator (PI) by the Member Secretary in writing.

ii. Suggestions for modifications and reasons for rejection shall also be communicated to the PI.

6.8 Reporting of Serious Adverse Event (SAE)

When a subject participating in the study develops any SAE, the PI must promptly report the incident to IEC as well as concerned authorities including regulatory bodies if applicable. Following are the rules at GDCH, Nagpur.

i. In the case of site related serious adverse event, the Initial SAE report along with copy of SAE form Appendix XI (as defined by Schedule Y amendment 30 Jan 2013) is to be submitted within 24 hours.

ii. If the adverse event was anticipated in the protocol and the subject was informed about the possibility of event in the Informed Consent Form (ICF) there is no need to inform IEC unless the adverse event was unexpectedly serious, life threatening or fatal.

iii. If the adverse event was unanticipated, unexpectedly serious, life-threatening or fatal, the adverse event must bereportedtoIECthroughMemberSecretarywithin24hours.

iv. If the study is being supported by an industry sponsor, the PI is also responsible for notifying the sponsor. The sponsor must notify the regulatory authorities within 24 hours.

v. If the PI holds the “Investigational New Drug or Device” in his/her name, he/she is required to notify the regulatory authorities of the adverse event within 24 hours in addition to notifying it to IEC.

vi. Notifying to IEC does not relieve the PI from his/her responsibility to notify the sponsor or regulatory authorities.

vii. The PI must submit a written report of the adverse event or reaction to the IEC in the specified format within 10 working days.

viii. For industry sponsored research, trials of drugs or device, sponsors are required to inform investigators of adverse events that occur at other sites. When PI receives such adverse forms from other sites, he/she must notify it to IEC as early as possible.

ix. All the onsite SAEs will be reviewed by “SAE Committee” which consists of one of the IEC members, legal expert, and chairperson and member secretary. Committee will give its detailed remarks on causal relation, compensation, risk benefits assessment tc.

x. Final opinion regarding onsite SAEs will be sent to the licensing authority, duly signed by the chairperson within 21 calendar days.

6.9 Follow-up

i. IEC will follow up all studies which are cleared by it.

ii. Investigators are required to submit a 6 monthly report to IEC apart from the final report.

iii. Any AE, SAE or Suspected Unexpected Serious Adverse Reaction (SUSAR) should be reported to IEC within 24 hours of the events.

iv. The IEC reserves the right to review the study or inspect the study site during the study period. The decision can be continuation, suspension or termination of study.

v. In case of premature suspension/termination of study, the applicant must notify the IEC of the reasons for suspension/termination.

7. Financial Matters for IEC

7.1 For projects within the GDCH, Nagpur fees will be charged as follows-

7.2 Undergraduate-Rs200

7.3 Postgraduate-Rs1000

7.4 PhD/Staff-Rs1500

7.5 Outside GDCH (within 50 km) academic or clinical protocols except Clinical trials-Rs 2500

7.6 For trials from outside agencies/sponsors, fees of Rs 2,00,000 is to be deposited along with application form.

The committee may, after discussion with the Dean of the institute, decide upon/ announce/ change/amend/ alter, from time to time, announce and implement the fees for Clinical Trial/Study/Protocol/Research Proposal. The said fees are payable by the Sponsors. The fees chargeable maybe classified variously under heads such as: protocol processing fees, per amendment/follow-up study fees, and expedited review fees.

The processing fees are to be paid before approval of the protocol/amendment. An IEC approval letter will not be issued until copy of the receipt of processing fee is submitted to the Member Secretary.

There will no additional fee be charged for the review and approval of amended protocol and consent version.

7.7 Mode of Payments

Fees/Payments shall be paid by Cheque/DD drawn in favour of_____

Pan ID:_____

8 SOP's For vulnerable population

People who are considered vulnerable are those who, due to a personal disability, environmental difficulties, social injustice, a lack of power or understanding, a communication barrier, or circumstances that prohibit them from doing so, are comparatively or completely incapable of defending their own interests.

Individuals may be considered to be vulnerable if they are:

• socially, economically, or politically marginalized and, as such, vulnerable to being exploited;

• incapable of making a free, informed choice for themselves or whose autonomy is momentarily or permanently violated, such as those who are unconscious or have special needs;

• Able to give consent, but whose voluntariness or understanding is compromised due to their situational conditions; or

• Unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent. Following are some examples of vulnerable populations or groups:

• socially and economically disadvantaged (such as those who are below the poverty line, jobless, orphaned, abandoned, members of ethnic minorities, lesbian, homosexual, bisexual, and transgender (LGBT) communities, etc.);

• unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent; children (up to 18 years);

• women in special situations (pregnant or lactating women, or those who have poor decision-making powers/poor access to healthcare); tribals and marginalized communities;

• refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster situations;

• afflicted with mental illness and cognitively impaired individuals, differently-abled, mentally and physically disabled;

• terminally ill or are in search of new interventions having exhausted all therapies; suffering from stigmatizing or rare diseases; or

• have diminished autonomy due to dependency or being under a hierarchical system (students, employees, subordinates, defense services personnel, healthcare workers, institutionalized individuals, under trials and prisoners).

In order for vulnerable populations to benefit from any research findings, it is equally crucial that they are included in the study. IEC carefully weighs the study's advantages and disadvantages, looks over the rationale offered, and considers risk-reduction techniques. The protection of vulnerable subjects, including children, prisoners, fetuses/neonates, pregnant women, and those with impaired capacity to provide permission, is given particular concern by the IEC. The IEC carefully considers group characteristics, such as economic, social, physical, and environmental conditions, to ensure that the research incorporates additional safeguards measures for vulnerable subjects. If vulnerable populations are to be included in research, all stakeholders must ensure that additional safeguard measures to be strictly reviewed and approved to protect dignity, rights, safety and wellbeing of these individuals. For instance, the IEC may require that the investigator submit each signed informed consent form to the IEC, that someone from the IEC oversee the consent process, or that a waiting period be established between initial contact and enrollment to allow time for family discussion and query resolution, family discussion and questions. To the greatest extent feasible, participants must be given the authority to choose whether or not to offer assent or consent for participation. In vulnerable populations, when potential participants lack the ability to consent, a LAR should be involved in decision making. IEC expects to follow the principals laid down in the ICMR-Ethical Guidelines for Biomedical Research on Human Participant.

Additional safeguards/protection mechanisms:

- IEC takes extra precautions to avoid exploitation, retaliation, rewards, credits, etc. when it comes to selecting study participants who are vulnerable.
- The use of a vulnerable group in the study must be justified by the researchers.
- ECs must attest that they are satisfied with the explanation provided and record their confirmation in the meeting minutes.
- The ECs should carefully consider and approve any extra safety precautions.
- A thorough record of the informed consent procedure should be kept. When applicable, additional steps like documenting consent and reconsent should be taken.
- ECs should also carefully determine the benefits and risks of the study and examine the risk minimization strategies.
- Because potential participants are dependent on others, there should not be any coercion, force, pressure, undue influence, threat, or distortion of incentives for

involvement over the entire research time.

- It may be necessary to continually educate and enlighten those who are susceptible about the benefits, risks, and options related to the research.
- Research on sensitive issues such as mental health, sexual practices/preferences, HIV/ AIDS, substance abuse, etc. may present special risks to research participants.
- Researchers have to use greater caution and awareness of the potential for competing interests between LAR and the potential participant.
- In some forms of research, participants may be more vulnerable to discrimination or stigma, particularly if they are recruited from the general public or enrolled as a normal control.
- It is necessary to always protect their rights, privacy, and secrecy, both while and after the study project is finished.

- Wherever it is practical, ancillary care may be provided, such as by setting up a facility, school, or counseling center for the unsupervised children of participants.

Responsibilities of researchers:

• Recognize the participant's vulnerability and ensure that they are protected with extra security measures.
• Justify the study's decision to include or exclude vulnerable groups.
• COI issues must be addressed.
• Check if prospective participants are able to give informed consent.
• Obtain the consent of the LAR in cases where the potential participant is unable to give consent.
• Accept the participant's dissent.
• Where applicable, obtain authorization from the proper authorities (tribal communities, institutionalized individuals, etc.).
• Research should be conducted in compliance with existing regulations.

Responsibilities of Ethics Committees:

• The members of the EC bear the obligation of identifying study ideas that include vulnerable populations and making sure that these are given full board consideration. Only the full committee should do accord approval and perform initial and continuing review of proposals involving vulnerable populations.
• Examine research participants' potential for vulnerability when they are being reviewed.
• Assess the justification for including or excluding the vulnerable population.
• Make sure that the participants receive no less benefits or more harm from COI.

• Analyze participant benefits and hazards carefully, and whenever feasible, suggest risk-reduction techniques.
• Make recommendations for further safety measures, such as more regular reviews and site visits
• ECs are responsible for extra duties when study subjects are mentally ill or have cognitive impairment. They should exercise caution and insist that researchers give a rationale for any deviations from the established guidelines for research or for standardizing participation conditions. ECs must make sure that these exceptions are as low as possible and that the ICD clearly states them.

Consideration issues and protection of specific vulnerable groups:

1. Children: Before undertaking research/trial in children the investigator must ensure that:

a. Children will not be involved in research that could be carried out equally well with adults;

b. The purpose of the research is to obtain knowledge relevant to health needs of children. For clinical evaluation of a new drug the study in children should always be carried out after the phase III clinical trials in adults. It can be studied earlier only if the drug has a therapeutic value in a primary disease of the children;

c. A parent or legal guardian of each child has given proxy consent;

d. The assent of the child should be obtained to the extent of the child's capabilities such as in the case of mature minors from the age of seven years up to the age of 18 years. There is no need to document assent for children below 7 years of age. For children below 7 years, verbal/oral assent must be obtained in the presence of the parents/LAR and should be recorded.;

e. Research should be conducted in settings in which the child and parent can obtain adequate Medical and psychological support;

f. Interventions intended to provide direct diagnostic, therapeutic or preventive benefit for the individual child participant must be justified in relation to anticipated risks involved in the study and anticipated benefits to society;

g. The child's refusal to participate in research must always be respected unless there is no medically acceptable alternative to the therapy provided/ tested, provided the consent has been obtained from parents / guardian;

h. Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child participant as any available alternative interventions;

i. The risk presented by interventions not intended to benefit the individual child participant is low when compared to the importance of the knowledge that is to be gained.

2. Women in special situations: Under no circumstances should pregnant or nursing women participate in research unless the goal of the study is to learn new information about the foetus, pregnancy, and lactation, and the research poses no more than a minimum danger to the foetus or nursing infant. Women of reproductive age who are to be recruited should be made aware of the possible risks to the developing foetus in the event of a pregnancy. In addition to being informed of their options in the event that contraception fails, they ought to be asked to use an effective

contraceptive method. Research on delicate subjects, such as rape, genetic abnormalities, domestic abuse, etc., should be conducted with strong confidentiality and privacy protection in mind.

3. Research among tribal population: Only particular therapeutic, diagnostic, and preventive research that will benefit the tribal people appropriately should be done on tribal populations. In the presence of suitable witnesses and after consulting with community elders and those who are conversant in the local language or dialect of the indigenous group, informed agreement should be obtained. Before visiting tribal territories, proper authorization from capable administrative officials such as the district collector or tribal welfare commissioner should be obtained. Precautions should be made to ensure that members of especially vulnerable tribal groups—children, pregnant women, and the elderly—are not included. Any research utilizing tribal knowledge that could be commercialized should make sure that the tribe shares benefits with the group.

4. Research involving individuals with mental illness or cognitively impaired/affected individuals/psychiatric disorders:

Being mentally ill does not equate to being incapable of understanding or unable to give informed consent. Prospective participants must be made aware of the researcher's plan for handling suicidal thoughts or other risks of damage to themselves or others during the informed consent process. Interventions ought to be brief, as unrestrictive as feasible, and used only when absolutely required, in compliance with applicable relevant laws. Certain research designs that use deception to accomplish the goals of the study for the public good may lessen or breach the safeguards and rights of human participants or certain standards of informed consent.

5. Other vulnerable groups:

The economically and socially disadvantaged, the homeless, migrants, refugees, and those residing in conflict zones, riot regions, or disaster situations are some more vulnerable groups. Extra precautions need to be taken to prevent exploitation, revenge, rewards, credits, and other inducements in the event that these people are sought out to be study subjects.

- Autonomy of such individuals is already compromised and researchers have to justify their inclusion. The rationale offered for including these individuals must satisfy ECs, and they must document this in the meeting's procedures.

- The ECs must closely adhere to the additional safety precautions that were previously recommended in the guidelines.

- A thorough record of the informed consent procedure should be kept. There shouldn't be any unfair incentives or coercion to participate. If someone chooses not to participate, that decision should be recognized and not be penalized.

The EC should also carefully determine the benefits and risks of the study and examine risk minimization strategies.

Abbreviations:

- ANDA: Abbreviated New Drug Application
- BA: Bioavailability
- BE: Bioequivalence
- CDER: Centre for Drug Evaluation and Research
- CDSCO: Central Drug Standard Control Organization India
- CFR: Code of Federal Regulation, a Publication of USFDA
- CIOMS: Council for International Organization of Medical Sciences
- COA: Certificate of analysis
- COMP: For the Designation of "Orphan" Medicines for rare diseases (See EMEA)
- CPMP: Term Responsible for Medicines for Human Use (See EMEA)
- CRF: Case Record Form
- CSR: Clinical Study Report
- CTA: Certificate of Authorization
- CTC: Clinical Trial Certificate (Not in vogue due to introduction of CTA)
- CTX: Certificate of Exemption (Not in vogue due to introduction of CTA)
- CVMP: For Veterinary Medicines (See EMEA)
- DCG: Drug Controller General
- DCGI: Drug Controller General of India
- DOH: Director of Health
- DTAB: Drugs Technical Advisory Board
- EC: Ethics Committee

- EMEA: The European Agency for Evaluation of Medical Products, a decentralized body of the European union (EU) with headquarters in London. It has three committees, namely CPMP, CVMP and COMP.

- FDA: U.S.Food and Drug Administration

- GCP: Good Clinical Practice

- GEAC: Genetic Engineering Approval Committee

- GLP: Good Laboratory Practice

- GMP: Good Manufacturing Practice- HHS: Health and Human Service

- IB : Investigator's Brochure

- ICD: Informed Consent Document (=ICF: Informed Consent Form)

- ICH: International Conference on Harmonization

- ICMR: Indian Council of Medical Research

- IDE: Investigational Device Exemption

- IEC: Independent Ethics Committee

- IEC: Institutional Ethics Committee

- IND: Investigational New Drug

- IRB: Institutional Review Board. The FDA term for Ethics Committee.

- MHRA: Medicines and Health Products Regulatory Agency (U.K.) (Advised by CSM)

- NAI: No Objectionable Conditions or Practices were found during inspection.

- HMSC: Human Mesenchymal stem cells.

- MOU: Memorandum of Understanding.

Appendix I: Format for approval of Institutional Ethics Committee

Dr._____ Principal Investigator

Dear, Dr._____

Ref: your letter dated_____

The Institutional Ethics Committee reviewed and discussed your application to review the Protocol/amendment/ICF entitled'_____

_____'. IEC has reviewed and approved in principle the above-mentioned Protocol/amendment/ICF. The following below study-related documents have been reviewed in the meeting:

Sr.No	Submission Documents (For investigational site EC)	Version(s)/Date of document

The following members of the Institutional Ethics Committee were present at the meeting held on_____at time_____A.M/P.M at Government Dental College & Hospital, Nagpur.

Names	Qualification	Affiliations	IEC Designation &Role	Gender

Please note that the Principal Investigator was invited to explain the protocol. He/She and/or other study staff members did not participate in the decision making/voting procedures.

Please note that this is "Approval in Principle "The study cannot be initiated unless final approval is issued. The Final approval will be issued after completing all the pending items/documents as per regulatory requirements and IEC SOP's.

The Institutional Ethics Committee, Government Dental College & Hospital, Nagpur (IECGDCHN) follows procedures that are in compliance with the requirements of ICH (International Conference on Harmonization) guidance related to GCP (Good Clinical Practice), schedule Y and all applicable Indian regulations.

The IECGDCHN expects to be informed about the progress of the study mention frequency as per EC SOP, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

Yours sincerely, Date of Issue-

Member Secretary IECGDCHN

Institutional Ethics Committee Government Dental College & Hospital, Nagpur (2024-2026)

Appendix II - Invitation from the Dean to be a Chairman/Member Secretary/Member of Institutional Ethics Committee (Human studies)

To

_____

_____

Sub:Constitution of Institutional Ethics Committee (Human studies)

Dear Sir/Madam,

On behalf of Government Dental College & Hospital, Nagpur, I request your concurrence for possible appointment as a Chairman/Member Secretary/Member of Institutional Ethics Committee of the institute. Kindly send your written acceptance in the enclosed format and provide short curriculum vitae (C.V.) along with attested copies of educational qualifications and experience certificates along with the acceptance letter.

On receipt of your acceptance, I shall send you the formal appointment letter.

Thanking you.

DEAN

GDCH, Nagpur

Institutional Ethics Committee (Human Studies)
Government Dental College & Hospital, Nagpur (2024-2026)

Appendix III-Consent to be a Chairman/Member Secretary/Member of Institutional Ethics Committee (Human Studies)

To,

The Dean

Government Dental College & Hospital, Nagpur
440003

Sub: Consent to be a Chairman/MemberSecretary/Member of Institutional Ethics Committee (Human Studies)

Ref:Your Letter No: …….dated…/…./……

Respected Sir/Madam,

In response to your letter stated above, I give my consent to become a Chairman/Member Secretary/Member of Institutional Ethics Committee of Government Dental College & Hospital, Nagpur. I shall regularly participate in the IEC meeting to review and give my unbiased opinion regarding the ethical issues. I shall be willing for my name, profession and affiliation to be published.

I shall not keep any literature or study related document with me after the discussion and final review.

I shall maintain all the research project related information confidential and shall not reveal the same to anyone other than project related personnel.

I herewith enclose my CV and required document copies.

Thanking you,

Yours sincerely Date-
Name of the Chairman/Member Secretary/Member
Address & Contact No
Email ID-

Appendix IV: Proposal format for submission of Research Proposal

Name of College	
Department	
Name of Primary Investigator	
Name of Guide	

To,
Member Secretary,
Institutional Ethics Committee, GDCH, Nagpur.
Subject: Submission of Research Proposal titled

_____

_____

Dear Sir,

I,_____,am planning to conduct are search study and thereby enclosing the subject research proposal for your review. If you need any clarification on the same, I shall be available at the meeting convened by your committee to discuss the same.

I am herewith submitting Title & Synopsis of my research protocol titled-

Title of Synopsis-

Kindly accept the same for IEC approval.

_____
Dr.
(Name & Signature of PI)

_____
Dr.
(Name & Signature of Guide)

_____
Dr.
(Name & Signature of HOD)

Appendix IV: Proposal format for submission of Research Proposal (Checklist)

The proposal submitted herewith comprises of the following documents-

1)Study synopsis full version-Protocol	
2)Case Report form	
3)Subject (Patient/Participant) information Documents/brochure-Marathi, Hindi and English (Or other local version of the same)	
4)Informed consent form (ICF)-Marathi, Hindi, English (local version of the same) and translation/Back translation certificates	
5)Investigator brochure (IB)	
6)Subject recruiting materials-Marathi, Hindi, English and translation/Back translation certificates (local version of the same)	
7)Detail of payments to subject	
8)Details of payment to IEC	
9)CTA(Draft/Final)	
10)PI undertaking	
11)CV of Principle investigator and Co-Investigator or any other staff	
12)Permission of DCGI	
13)EC fee receipt	
14)Previous review by any other IRB/IEC-Copies of decision letter	
15)Study insurance (initial/Renewed)	

Name & Signature of PI-_____ Dt-_____

Appendix V- CERTIFICATE OF APPROVAL OF RESEARCH PROPOSAL

Research Project/Protocol no: Date:

CERTIFICATE

This is to certify that the research project/proposal no…….....entitled"…… …… ……"

Submitted by……...……has been approved by the Institutional Ethics Committee (Human Studies) in the meeting held on……., at…….…….am/pm under the following terms and conditions.

a. This approval is valid for three years or the duration of the proposal whichever less is.

b. Any serious adverse event occurring during the course of the study should be reported tothe IEC within 24 hours.

c. A half yearly progress report of the proposal has to be submitted to the IEC for review.

d. Any change in the study procedure/site/investigator should be informed to the IEC.

Member Secretary
IEC, GDCH, Nagpur
2024-2026

Appendix VI: PARTICIPANT CONSENT FORM

Date:

Participant'sname:

Address:

Title of the project:_____

The details of the study have been provided to me in writing and explained to me in my own language. I confirm that I have understood the above study and had the opportunity to ask questions. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without the medical care that willnormally be provided by the hospital being affected. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). I have been given an information sheet giving details of the study. I fully consent to participate in the above study.

Name & Signature of the participant:

Date:

Name & Signature of the witness:
Date:

Name & Signature of the investigator:
Date:

Appendix VII: CONSENT FORM (in Marathi)

सहभाग संमती फॉर्म

दिनांक:
सहभाग घेणाऱ्या व्यक्तीचे नाव:
पत्ता:
प्रकल्पाचे शीर्षक:

या अभ्यासाचा (उपक्रमाचा) तपशील मला लेखी स्वरुपात प्रदान केलेला आहे आणि मला तो स्व:ताच्या भाषेत स्पष्ट करून दिलेला आहे. मी हमी (खात्री) देतो/देते कि मला वरील उपक्रम/अभ्यास कळलेले आहे आणि मला प्रश्न विचारण्याची संधी होती. मला माहित आहे कि माझा या अभ्यासातील सहभाग ऐछिक आहेआणि मी कोणत्याही क्षणी (वेळी) माघार घेण्यासाठी कोणतेही कारण न देता मुक्त आहे. मात्र त्यामुळे मला मिळणाऱ्याकुठल्याही वैद्यकीय उपचारावर जो कि सर्व साधारणपणे एका रुग्णालयात दिला जातो त्यावर परिणाम होणार नाही. या अभासातून उत्पन्न होणारी माहिती व परिणाम जोपर्यंत फक्त वैज्ञानिक दृष्ट्या वापरली जाणार असेल तोपर्यंत मी त्यास प्रतिबंध न करण्यास सहमत आहे. वरील अभ्यासाची माहिती देणारे एक माहिती पत्रकमला देण्यात आलेले आहे. या अभ्यासासाठी सहभागी होण्याची माझी संपूर्ण संमती आहे.

सहभागी व्यक्तीची स्वाक्षरी:
दिनांक:

सक्षिदाराची स्वाक्षरी:
दिनांक:

तपासनीसची स्वाक्षरी:
दिनांक:

Appendix VII: CONSENT FORM (in Hindi)

प्रतीभागी सहमत फॉर्म

दिनांक:
प्रतीभागी का नाम:
पता:
परियोजना का शीर्षक:

इस अध्ययन (उपक्रम) का विवरण मुझे लिखित रूप में प्रदान किया गया है और मुझे मेरी अपनी भाषा में समझाया गया है। मैं आश्वासन देता हूं कि मैंने उपरोक्त गतिविधियों/अध्ययनों को समझ लिया है और मुझे प्रश्न पूछने का अवसर मिला है। मैं समझता हूं कि इस अध्ययन में मेरी भागीदारी स्वैच्छिक है और मैं बिना कोई कारण बताए किसी भी समय इससे हटने के लिए स्वतंत्र हूं।हालाँकि, यह मुझे मिलने वाले किसी भी चिकित्सा उपचार को प्रभावित नहीं करेगा जो आमतौर पर एक अस्पताल में प्रदान किया जाता है। मैं इस प्रयोग से प्राप्त जानकारी और परिणामों को तब तक प्रतिबंधित नहीं करने पर सहमत हूं जब तक उनका उपयोग केवल वैज्ञानिक रूप से किया जाता है। मुझे उपरोक्त अध्ययन का विवरण देने वाला एक सूचना पत्र दिया गया है। मैं इस अध्ययन में भाग लेने के लिए पूर्ण सहमति देता हूं।

प्रतीभागी के हस्ताक्षर:
दिनांक:

गवाहके हस्ताक्षर:
दिनांक:

परीक्षक के हस्ताक्षर:
दिनांक: