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MGM Medical College Institutional Ethics Committee, Navi Mumbai

STANDARD OPERATING PROCEDURES

Version- 01

September 2021

Secretary
Institutional Ethics
Committee (IEC)

Dean.
M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

STANDARD OPERATING PROCEDURES

MGM Medical College Institutional Ethics Committee, Navi Mumbai

(MGMMC-IEC, Navi Mumbai)

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Date	:	14 September 2021
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Introduction

The first International statement on the ethics in medical research using human subjects, the Nuremberg Code was formulated in 1947 and it laid emphasis on consent and voluntariness. In 1964, the eighteenth World Medical Assembly at Helsinki, Finland adopted a code of ethics for the guidance of doctors involved in clinical research. This is popularly known as the "Declaration of Helsinki."

In 1980, the Indian Council of Medical Research released a 'Policy Statement on Ethical Considerations involved in Research in Human Subjects' for the benefit of all those involved in clinical research in India. This year the Vice Chancellor of MGMUHS has asked for a formal SOPs of Ethics committee for its constituent Institutions and Hospital, to review the ethics of any human research project conducted at our institutes. Guidelines were laid down for submitting a research project for ethics committee approval.

In the last few years, clinical research activities in our institutes have increased, and these are expected to increase even further in future. Moreover in 1996, the International Conference on Harmonization (ICH) published a tripartite guideline for Good Clinical Practice (GCP) to harmonise technical requirements for registration of pharmaceutical products in three regions namely the United States, the European Union and Japan). Today, the ICH GCP guideline is followed globally for clinical research. This guideline elaborates the composition and functioning of an Institutional Ethics Committee to review clinical research proposals.

It was thus felt necessary to establish an Ethics Committee consistent with the ICH GCP Guideline so as to facilitate the ethical review of any human research project in our institutes and also be an asset to the sponsors of such projects, the subjects participating in them, the relevant statutory authorities, and the society at large. In June 1999, the committee was reformulated so that the chairperson was no longer the Head of the Institute. A unanimous decision was taken to change the name the committee to, 'Ethics Committee for Research on Human Subjects'. Standard Operating procedures were drafted and the first version was printed in May 2000.

On 20th January 2005, the Ministry of Health and Family Welfare, after consultation with the Drugs Technical Advisory Board, amended the Schedule Y of Drugs and Cosmetics Rules, 1945. In addition to requirements concerning clinical trials the new Schedule Y also outlines requirements of Institutional Ethics Committees. It was therefore mandatory to carry out minor amendments in the already existing Standard Operating Procedures in order to make them compatible with the latest Schedule Y.

The Institutional Ethics Committee for Aademic Research presently functions according to the requirements laid down in Schedule Y (20th January 2005) and is guided by the ICH GCP guidelines for Good Clinical Practice, ethical principles set forth in the Declaration of Helsinki and the Ethical Guidelines for Biomedical Research on Human Subjects laid down by the Indian Council of Medical Research (National Ethical Guidelines For Biomedical And Health Research Involving Human Participants, 2017) and New Drugs Clinical Trials Rules, 2019.

Standard Operating Procedures

1. Name

This committee will be known as the MGM Medical College Institutional Ethics Committee, Navi Mumbai (MGMMC-IEC, Navi Mumbai). This name will remain unchanged until the members choose to change it by a vote of three-fourths of the current strength.

2. Purpose

The primary purpose of this committee will be:

1. To ensure the protection of the rights, safety, dignity and well-being of human subjects involved in a research project.
2. To provide public assurance of that protection.
3. To ensure that universal ethical values and scientific standards are followed in terms of local community values and customs

3. Membership

The committee will consist of multi-disciplinary and multi-sectoral members who collectively have the experience and expertise to review and evaluate the scientific, medical and ethical aspects of a proposed research project. A list of committee members, their qualifications and their affiliations (hospitals, colleges etc.) described in section 13 of this document will be maintained in the committee's records.

3.1 Composition of the Committee

a. The regular members of the committee will include at least 7 and a maximum of 15 individuals as follows :
   i. Medical scientists and clinicians with expertise in diverse health care specialities.
   ii. A legal expert.
   iii. A social worker/representative of a non-governmental organisation/theologian.
   iv. A lay person from the community.
b. The committee will have adequate representation of age and gender.
c. Preferably 50% of the members will be non-affiliated or from outside the institution.
d. At least one of the non-scientific members will be independent of the institution.
e. A minimum of five members will be required to meet the quorum requirements.
f. The EC will have a balance between medical and non-medical members/technical and non-technical members, depending upon the needs of the institution

3.2 Chairperson

a. The Chairperson will be selected and appointed by the Head of the Institute.
b. The Chairperson will be independent and non-affiliated to 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.

3.3 Members

a. The members will be selected and appointed by the Head of Institute (in consultation with Chairperson), provided they are willing to work as an Ethics Committee member.
b. A member shall be willing to publicise his/her full name, profession and affiliation.
c. A member will sign a confidentiality agreement described in Page 14.6 of this document before every meeting.
d. A member will have been trained in ethical issues or shall be willing to undergo GCP training in ethical issues.

3.4 Member Secretary

a. The Head of Institute (in consultation with Chairperson), will elect a Member Secretary
b. In consultation with the Chairperson, the Member Secretary will be responsible for the following functions:
    i. Receiving all research proposals.
    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.
    vii. Notification of review outcome to investigators of research proposals.
    viii. Preparation and circulation of minutes (within 14 days of the meeting).
    ix. Retention and safekeeping of all records and documentation.
    x. Performance of other duties assigned by the Chairperson.

3.5 Tenure of Membership

a. A member will be a regular member for a period of up to five (5) years.
b. Extension of membership will be determined by a vote of two-thirds of the members present in a quorum at a regular committee meeting.
c. There is no limit to the number of times that the membership can be extended.
d. New members will be appointed to replace members according to the process described in Page 3.8 of this document.

3.6 Resignation of Members

Members may resign before completing their terms by writing their intention to the chairperson.

3.7 Termination of Membership

The membership will stand to be terminated under the following circumstances:

a. if a member resigns from the committee

b. If a member remains absent for 3 consecutive meetings without informing or giving a valid reason.
c. if a member is incapable of performing his/her duty as an ethics committee member
d. if a member retires from the institute voluntarily or by superannuation
e. in case of demise of a member.

3.8 Appointment of New Members

a. New members will be selected and appointed under the following circumstances:
   i. When a regular member completes his tenure and does not wish to continue his/her membership.
   ii. If a regular member resigns.
   iii. In case of the termination of membership of a regular member
c. A new member will be preferably but not necessarily nominated from the same category as that of the member being replaced.

4. Responsibilities of the Committee and Members

4.1 Responsibilities of the Committee

a. The committee's primary responsibility will be the protection of safety, dignity, rights, well-being and confidentiality of the research subjects.
b. The EC will 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.
c. The EC must ensure ethical conduct of research by the investigator team.
d. The committee will review all research proposals submitted to it within specified time limits.
e. The committee will keep all information submitted to them confidential especially the proprietary information.
f. The committee will maintain concise but clear documentations of its views on the research proposal.
g. The committee will review the progress of each research project at appropriate and specified intervals, but not less than once a year.
h. The committee will review the qualifications of all investigators participating in the proposed research study.
i. The committee will ensure that universal ethical values and scientific standards are followed in terms of local community values and customs
j. The EC is responsible for declaration of conflicts of interest to the Chairperson, if any, at each meeting and ensuring these are recorded in the minutes
k. Responsibilities of members are defined (Details in Table 4.2). The SOPs will be given to EC members at the time of their appointment.
l. The Secretariat/clerk should support the Member Secretary and Alternate Member Secretary (if applicable) in all their functions and should be trained in documentation and filing procedures under confidentiality agreement.

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

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

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

p. The EC will carry out monitoring visits at study sites as and when needed.

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

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

4.2 Definition and Responsibilities of the Committee and Members

S. No	Members of EC	Definition/description
1	Chairperson/ Vice Chairperson (optional) Non-affiliated Qualifications - A well-respected person from any background with prior experience of having served/ serving in an EC	• Conduct EC meetings and be 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 both Chairperson and Vice Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson or the members present may elect 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.
2	Member Secretary/ Alternate Member Secretary (optional) Affiliated Qualifications – • Should be a staff member of the	• Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review • Schedule EC meetings, prepare the agenda and

	institution • Should have knowledge and experience in clinical research and ethics, be motivated and have good communication skills	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. • Should be able to devote adequate time to this activity which should be protected by the institution • 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
3	Basic Medical Scientist(s) Affiliated/ non-affiliated Qualifications – • 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	• 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.
4	Clinician(s) Affiliated/ non-affiliated Qualifications – • Should be individual/s with recognized medical qualification, expertise and training	• 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 car, management and compensation. • Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
5	Legal expert/s Affiliated/ non-affiliated Qualifications –	• Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA),

	• Should have a basic degree in Law from a recognized university, with experience • Desirable: Training in medical law	regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines etc. • Interpret and inform EC members about new regulations if any
6	Social scientist/ philosopher/ ethicist/theologian Affiliated/ non-affiliated Qualifications – • 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	• 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.
7	Lay person(s) Non-affiliated Qualifications – • 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	• 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

5. Functions and Operations

5.1 Submission of the Research Proposal

a. All Biomedical and Health Research Academic Projects : Prospective, retrospective studies (on drugs, investigational techniques as well as devices or any other procedure), case reports/case series involving human volunteers or patients to be conducted at MGM Medical College & MGM Hospital, shall have MGMMC-IEC, Navi Mumbai permission before commencing such a study.

b. Each project along with a duly completed v application form shall be submitted in duplicate. The MGMMC-IEC application form will be available at the office of the MGMMC-IEC between 1.30 p.m. to 3.30 p.m on week days. The information to be given on the application form shall be preferably typed or filled in legible handwriting. It shall have the designation and signatures of Principal Investigator, all the co-investigators and the Head of the concerned department. If the study involves more than one department, then respective collaborator/co-investigator and head of the collaborating department shall also sign the form.

c. Studies which plan to undertake an academic trial shall submit along with the MGMMC-IEC application form, requisite documents and regulatory approval letter if applicable.

d. In case a clinical study is planned on an "alternative system of medicine" a co-investigator from that system will be required on that study. For ayurvedic or herbal drugs, which are not marketed, a copy of the marketing/manufacturing licence issued by FDA to the company shall be submitted.

e. A user fee of Rs. 10,000/- will be charged for all sponsored or collaborative projects with outside Institutes. Government sponsored projects will be charged Rs.5000/- and projects (Original research study), which are not sponsored, will be charged Rs 1000/-. And Case Study/Series will be charged Rs 500/- The fees shall be collected at the time of submission of the project. The amount to be collected, as processing fee will be reviewed at the end of 1 year.

f. The project proposal shall be submitted in duplicate. Each set shall contain the documents on A 4 size paper arranged in a file in the order mentioned below:
   i. MGMMC-IEC application form duly filled.
   ii. Protocol and any amendments to it, with version and date
   iii. The informed consent document (ICD), including any amendments / addenda and its translation(s) into regional language(s). The ICD should be customised for the study according to the format given in ICMR Guidelines
   iv. Case Record Form
   v. Scales/Questionnaire.
   vi. Principal investigators current Curriculum vitae and GCP training certificate in case of Trial .
   vii. Subject recruitment procedures (e.g. advertisements/letters to doctors/posters) if applicable
   viii. Investigator Brochure (for sponsored and trial projects). This should give details of the study drug, toxicology studies, phase I, II, III data wherever available, safety information etc if applicable
   ix. Ethics Committee clearance of other centres (if multicentre study).
   x. Insurance policy if applicable
   xi. DCGI/Regulatory clearance, if applicable

xii. Investigator's agreement with sponsor if applicable

xiii. Investigator's undertaking for conduct of Study as per ICMR Guidelines

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 herbal drugs wherever applicable.

The guidelines for submission of a research proposal are as described and the checklist for documents to be submitted is as described in Section 14.

5.2 Procedures

a. All communications with the committee shall be in writing.

b. The project proposals in the format mentioned in Section 5.1 will be accepted in office of the MGMMC-IEC on or before the 20th of every month.

c. The projects submitted by the 20th of a month will be circulated to all committee members and the proposal shall be reviewed for elements described in section 5.3.

d. A meeting, as described in section 5.4, of all members will be held where each proposal will be discussed and decisions arrived at.

5.3 Elements of Review

The submitted proposal shall be reviewed both for scientific content and ethical principles.

The committee members shall review the proposal with reference to the following:

a. Scientific design of the study
b. Justification/Rationale of the study
c. Selection criteria for subjects
d. Justification for use of placebo, if any
e. Potential benefits to the study subjects
f. Predictable risks to the study subjects
g. Criteria for discontinuation/withdrawal of subjects
h. Monitoring of serious adverse events
i. Compensation to subjects for participating in the study
j. Subject recruitment procedures
k. Patient retention activities.
l. Compensation for study related injury
m. Post Study/ trial benefits
n. Protection of privacy and confidentiality
o. Statistical analysis
p. Informed consent document in English and regional languages
q. Competence of investigators, supporting staff and infrastructure facility
r. Approval of regulatory authorities wherever applicable

5.4 Meetings

a. The committee will hold a regular meeting, minimum of once every three months preferably on the second or third Tuesday of that month. When there are no research proposals to review, the meeting may be held less frequently, but not less than once every sixteen (16) weeks.

b. Regular meetings may not be held in the months of May and October/November when the college closes for vacation.

c. All members will receive notification of meeting schedules at least 1-2 weeks in advance.

d. The committee members will review all the proposals before the meeting.

e. The proposal may be sent to a subject expert for his/her assessment and opinion of the research proposal. The subject expert may be invited for the meeting.

f. The investigator and/ or co-investigator may be invited to the meeting to provide clarifications on the study protocol.

g. Specific patient groups such as those suffering from HIV/AIDS or genetic disorders may also be invited for the meeting based on the requirement of the research area.

h. In cases of emergency situations or in pandemic situations, an online meeting of ethics committee will be held to review research projects which will be accordance to the SOP as per the latest ICMR guidelines for ethics committee

i. Quorum

Meetings will be held as scheduled provided there is a quorum. In accordance with National Ethical Guidelines for Biomedical and Health Research Involving Human Participants), the quorum of the MGMMC-IEC

- A minimum of five members will be present in the meeting room.
- The quorum will include both medical, non-medical or technical or/and non-technical members.
- Minimum one non-affiliated member will be part of the quorum.
- Preferably the lay person will be part of the quorum.
- No decision is valid without fulfilment of the quorum.

j. Hierarchy

i. There will be one Chairperson and one Member Secretary.

ii. The Chairman will be the head of the Ethic committee.

iii. The Member Secretary will be the guardian of all documents in the committee's possession.

iv. All other members will be regular committee members with equal ranking.

k. Minutes

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. The minutes shall be approved by the chairperson.

l. Decision making

i. Decision for each proposal shall be by voting.
ii. A majority vote for approval, disapproval, request for modifications, suspension or termination of a research proposal or an ongoing study is defined as one-half of the members who have reviewed the project.
iii. All members present at the MGMMC-IEC meeting will vote on the research proposal.
iv. Absent members will not have a vote.
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/expert or study team member invited for the meeting will not vote or participate in the decision making procedures of the committee.
vii. Specific patient groups invited for the meeting will not vote or participate in the decision making procedures of the committee.

5.5 Review Outcome

The committee will document its view on the following:

a. Final Approval
b. Provisional approval subject to regulatory approval
c. Provisional approval subject to minor modifications
d. Request for major modification giving reasons/ resubmit protocol with desired major modifications
e. Request for additional information/documents
f. Clear disapproval giving reasons.
g. Termination/suspension of an ongoing study giving reasons

5.6 Notification of Review Outcome

The outcome of committee's review shall be communicated to the investigator within 10-14 working days of the meeting.

5.7 Approval

Research projects will be given approval for a period of one year from the date of the meeting on which the project was approved. In case of PG Thesis/Dissertation projects, the period of approval will be 2 years to cover the tenure of the course. The approval shall be in the format described in section 14

5.8 Review of the Modified Proposal

a. When modifications to the proposal, as recommended by the committee, are minor, the revised documents may not be re-circulated. The revised proposal shall be reviewed by either the Chairperson of the committee, the Member Secretary of the committee, or by one or more experienced reviewers designed by the chairperson from among the members of the committee. An approval may then be issued if the revised documents satisfactory. The committee will keep all members of the committee informed of these approvals.

b. When modifications to the proposal, as recommended by the committee, are major, the revised proposal will be re-circulated and discussed again at next meeting.

5.9 Procedures for Appeal

For research proposals rejected/disapproved by the committee, the applicant may appeal for a repeat review, within four (4) weeks of the receipt of the committee's decision. While doing so, the applicant shall give justification relevant to the issues/objections raised by the committee.

5.10 Review of Amendments to the Approved Research Proposal

a. All amendments to the approved research proposal shall be submitted to the committee immediately for its review.

b. No changes in the protocol, case record form and /or ICD shall be initiated without prior written approval from the committee, except when necessary to eliminate immediate hazards to the subject, or when the change(s) involve only logistical or administrative aspects of the trial (e.g. change of monitor(s), telephone number(s).

5.11 Expedited Review Procedures

a. The committee may use expedited review procedure in case of minor changes/ amendments in the previously approved 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 of the committee, or by one or more experienced reviewers designed 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. An ongoing research activity may be disapproved only after review in accordance with non-expedited review procedure as mentioned in section 5.2

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

e. Only the Chairperson shall make the decision to allow an expedited review

5.12 Review of Subject Recruitment Procedures

All advertisements, letters to doctors, posters, notices to be used for recruitment of subjects wherever applicable shall be reviewed and approved by the committee prior to their implementation in the study.

5.13 Review of On-going Studies

a. The committee will conduct a continuing review of each on-going study by reviewing the reports described in section 6.

b. The committee may also ask for a status report from the investigator at earlier intervals as is felt appropriate to the degree or risk to the human subjects.

c. On the basis of the review, the committee shall recommend temporary suspension or termination of ongoing clinical trials for reasons such as patient safety.

5.14 Site monitoring

a. The Ethics Committee will monitor the approved study/site until completion of the research to check for compliance or improvement.

b. Monitoring can be routine or "for cause" and must be decided at a full committee meeting. For research that involves higher risk or vulnerable participants or if there is any other reason for concern, the EC at the time of initial review or continuing review can suggest that routine monitoring may be conducted at more frequent intervals.

6 Reports Required of Research Investigators

The research investigator shall submit the following reports to the committee:

a. Annual progress/status report: For studies whose duration is more than a year, the first report shall be submitted at least thirty (30) days before the completion of the year following the date of the first approval.

b. Subsequent reports shall be submitted at one-year intervals following the first report.

c. In addition, the investigator shall also promptly report the following to the committee:
   i. Deviations from/changes to the protocol to eliminate immediate hazards to trial subjects.
   ii. Changes that may increase the risk to subjects and /or affect the conduct of the trial.
   iii. All adverse events that are both serious and unexpected within seven working days of the occurrence of the adverse event.
   iv. New information that may affect adversely the safety of the subjects or the conduct of the trial.

d. Study completion report: A brief report of the study shall be submitted to the committee at the end of the study.

7 Extension of Approval

For studies whose duration is more than one year (Except PG Thesis/Dissertation) , an extension of approval shall be given after the status report and all other relevant reports mentioned under § 6 are reviewed and approved by the committee. The approval for extension for study will be given for a period of one year.

8 On-going Training of Members

a. The Chairperson will identify the training requirements of the committee members.

b. The Chairperson and the Member Secretary will organize workshops or training programmes for the committee members.
c. The type of programmes, areas for training and mentors for these workshop or training programs will be decided by the committee members at a scheduled meeting.
d. Members shall also be deputed by the chairperson to attend workshops to train ethics committee members.

9 **Records Retention**

The committee will archive the following records for a period of at least five (5) years

a. Standard operating procedures (SOPs) of the committee
b. Guidelines for submission established by the committee.
c. Annual reports of the committee
d. Membership list
e. Curriculum Vitae of the members
f. Agenda of meetings
g. Minutes of meetings

The committee will also archive the following records for a period of at least three (3) years following the completion of a study

a. One copy of all research protocol and documents submitted by a research investigator
b. All correspondence by the committee with the research investigator regarding application, decision and follow –up
c. A copy of the decision and any advice or requirements sent to an applicant
d. All written documentation received during the study
e. The notification of the completion, premature suspension or premature termination of a study
f. A summary of the final report of the study

The records shall be made available to relevant statutory authorities upon request.

10 **Reports to the Relevant Regulatory Authorities in case of SAE**

The ethics committee and pharmacoviglilance committee will report any SAE to the Competent Authority as per the prescribed guidelines

11 **Location and Business Address:**

The location and business address of the committee is as follows:

MGM Medical College Institutional Ethics Committee, Navi Mumbai
Department of Pharmacology
2nd Floor
MGM Medical College,
Kamothe, Navi Mumbai

12 Amendments to the Standard Operating Procedures

a. Amendments to the Standard Operating Procedures of the MGM Medical College Institutional Ethics Committee, Navi Mumbai (MGMMC-IEC, Navi Mumbai) of MGM Medical College & MGM Hospital shall be proposed in writing.

b. The proposal for amendment shall be submitted to the Member Secretary.

c. The proposal for amendment shall be presented to the regular members at a scheduled committee meeting.

d. Only regular members shall vote to accept or reject the proposed amendment.

e. A proposed amendment shall be approved by a vote of three-fourths of the members present in a quorum at a scheduled committee meeting, rounded to the next whole number.

f. If the changes on a final version are minor the version will be indicated as Version 1.1, version 1.2 etc. If there are major amendments, the version will be indicated as Version 2,3

13 List of committee members with their affiliations and qualifications

The present composition of the MGM Medical College Institutional Ethics Committee, Navi Mumbai is listed below in table

No	Name	Position on ethics Committee	Designation & Affiliation	Qualification	Gender
1	Dr Pramila Yadav	Chairperson	Professor, Pharmacology, DY Patil Medical College, Nerul, Navi Mumbai , DY Patil Medical College, Nerul, Navi Mumbai, 400706	MBBS, MD (Pharmacology)	F
2	Dr. Padmaja Kanchi	Member/ (Chairperson)	Associate Professor & HOD PSM Dept of Terna Medical College, Navi Mumbai, 400706	MBBS, MD (Community Medicine)	F
3	Dr. Pradeep Jadhav	Member Secretary (Pharmacologist)	Assoc. Prof, Pharmacology, MGM Medical College, Kamothe, Navi Mumbai, Maharashtra 410209	MBBS, MD (Pharmacology)	M
4	Dr. Ipseeta Ray	Member (Basic Medical Scientist)	Prof, Pharmacology, MGM Medical College, Kamothe, Navi Mumbai, Maharashtra 410209	PhD (Pharmacology)	F
5	Dr. R.S. Inamdar	Member (Basic Medical Scientist)	Prof & HOD, Physiology, MGM Medical College, Kamothe, Navi Mumbai, Maharashtra 410209	MBBS, MD (Physiology)	M
6	Dr. Jaishree Ghanekar	Member (Clinician)	Prof & HOD, Medicine, MGM Medical College, Kamothe, Navi Mumbai, Maharashtra 410209	MBBS, MD (General Medicine)	F
7	Dr D. Bhusare	Member (Clinician)	Professor and Head, Emergency Medicine, MGM Medical College, Navi Mumbai	MBBS, MS (Surgery), MCh (Pediatric Surgery)	M

			Maharashtra 410209		
8	Mrs Amruta Sachin Dhavale	Lay Person	Anganwadi Worker, Kalamboli, Raigad District, Maharashtra 410209	10th Pass	F
9	Mrs Rupali Gujar	Social Scientist	Medical Social Worker, PSM MGM Medical College, Kamothe, Navi Mumbai, Maharashtra 410209	Master of Social Sciences	F
10	Dr Sheela Hosamani	Legal Expert	MGM law College, Sector 8, Nerul, Navi Mumbai, Maharashtra 400706	LLM	F
11	Ms Usha Mohite	Lay Person	Anganwadi Worker, Kalamboli, Raigad District, Maharashtra 410209	10th Pass	F

14 Appendices

14.1 Appendix 1: Guidelines for Submission of a Proposal to the MGMMC-IEC

1. All prospective and retrospective studies involving human volunteers or patients to be conducted at MGM Medical College & MGM. Hospital should have **MGMMC-IEC** permission before commencing such a study.

2. Each project along with a duly completed **MGMMC-IEC** application form should be submitted in duplicate. The **MGMMC-IEC** application form will be available at the office of the **MGMMC-IEC** between 1.30 p.m. to 3.30 p.m.. The information to be given on the application form should be preferably typed or filled in legible handwriting. It should have the designation and signatures of Principal Investigator, all the co-investigators and the Heads of the concerned departments.

3. Studies which plan to undertake an academic trial shall submit along with the MGMMC-IEC application form, requisite documents and regulatory approval letter if applicable.

4. A clinical study planned on an "alternative system of medicine" shall require a co-investigator from that system. For ayurvedic or herbal drugs, a copy of the marketing/manufacturing licence issued by FDA to the company should be submitted.

5. Subject to approval from competent authority, MGM Medical College, Navi Mumbai, a user fee of Rs. 10,000/- may be charged for all sponsored or collaborative projects with outside Institutes. Government sponsored projects may be charged Rs.5000/- and projects (Original studies), which are not sponsored, may be charged Rs 1000/-. And Case Study/Series may be charged Rs 500/- The fees shall be collected at the time of submission of the project. The amount to be collected, as processing fee will be reviewed at the end of 1 year.

6. Two sets of the project proposal need to be submitted. Each set shall contain the documents mentioned below on A 4 size paper arranged in a plastic file in the order mentioned below:

i. MGMMC-IEC application form duly filled.
ii. Protocol and any amendments to it with version and date
iii. The informed consent document (ICD), including any amendments / addenda and its translation(s) into regional language(s). The ICD should be customised for the study according to the format given in ICMR Guidelines
iv. Case Record Form
v. Scales/Questionnaire.
vi. Principal investigators current Curriculum vitae and GCP training certificate in case of Trial .
vii. Subject recruitment procedures (e.g. advertisements/letters to doctors/posters) if applicable
viii. Investigator Brochure (for sponsored and trial projects). This should give details of the study drug, toxicology studies, phase I, II, III data wherever available, safety information etc if applicable
ix. Ethics Committee clearance of other centres (if multicentre study).
x. Insurance policy if applicable
xi. DCGI/Regulatory clearance if applicable
xii. Investigator's agreement with sponsor if applicable
xiii. Investigator's undertaking for conduct of Study as per ICMR Guidelines
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 herbal drugs wherever applicable.

7. After initiation of the study, the **MGMMC-IEC** requires submission of the following:
All adverse events occurring in the study, deviations from, or changes in the protocol to eliminate immediate hazards to the trial subjects, new information that may adversely affect the safety of the subjects or conduct of the trial.
8. The I **MGMMC-IEC** expects to be informed annually about the status of the study.
(a) For studies which are completed within the **MGMMC-IEC** approval period, a study completion report should be submitted to the **MGMMC-IEC**, by the principal investigator. If a study was not initiated, or was withdrawn or terminated, the same should be informed to the **MGMMC-IEC** giving reasons.
(b) For studies which will continue for more than a year, an extension of approval for the study from the **MGMMC-IEC** needs to be taken by the principal investigator (as **MGMMC-IEC** approval for a study is for one year only). The request for extension of approval should be accompanied with a project report mentioning the following: no. of screened patients, randomised patients, active patients, no. of patients who have completed the study, no of patients who have dropped out/ withdrawn no. of patients who had an SAE, report of an interim analysis if available. The approval will be extended after the **MGMMC-IEC** reviews the annual project report.

9. The Standard Operating procedures of the **MGMMC-IEC**, Version 1 Sept 2021, are available with the administrative manager in the office of the **MGMMC-IEC**.

14.2 Appendix 2: MGMMC-IEC Application Form

1	**Full Title of Study:**
2	**Is the study a thesis/Dissertation(MD/MS/M.Sc/MPTh):** Yes / No If No directly go to Point 5
3	**If Yes, Course:** MD/MS/M.Sc/MPTh **Batch (Year):**_____
4	**Name of the student/PG researcher:** _____ Signature_____ **Department**_____
5	**Name of the Guide/Primary Investigator:**_____ Signature_____ **Department**_____
5.1	**Name of the Co-Guide/ Co-Investigator**_____ Signature_____ **Department**_____
5.2	**Name of the Co-Guide/ Co-Investigator**_____ Signature_____ **Department**_____
5.3	**Name of the Co-Guide/ Co-Investigator**_____ Signature_____ **Department**_____
6	**Is the study sponsored Yes / No** **If yes, name of Funding Agency:** _____
7	**Is the study a clinical trial ? Yes/ No** The WHO definition for a clinical trial *'any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes'.*
8	**Is the test drug an Investigational New Drug? Yes/ No** If yes submit copy of Investigators Brochure and DCGI permission
9	**What is the nature of the study? Interventional / Non-Interventional**
10	**Objectives of the study**
11	**Why this study is required?** Please provide brief background/justification.
12	**Methodology** Number of Patients/Sample size:_____ Inclusion criteria a)_____ d)_____ b)_____ e)_____ c)_____ f)_____ Exclusion criteria a)_____ d)_____ b)_____ e)_____ c)_____ f)_____ Vulnerable group: Yes/No If yes tick mark appropriate boxes

	☐ Pregnant women ☐ Children ☐ Elderly ☐ Fetus ☐ Illiterate ☐ Handicap ☐ Seriously or terminally ill ☐ Mentally challenged ☐ Economically socially backward ☐ If any other specify: Study Groups: Study design: Prospective/Retrospective Duration of treatment: Duration of follow up: Collection of body fluids/tissue/organ required: Yes/ No Investigation specifically related to Protocols: Others:
13	**Permission from Drug Controller General of India (DCGI)** 1. ☐ Required 2. ☐ Not required 3. ☐ Received 4. ☐ Applied when:
14	**Safety measures for proposed interventions**
15	**Plans to withdraw standard therapy in research** ☐ Yes ☐ No Remarks:
16	**Plan for provision of coverage for medical risk**
17	**How you will maintain Confidentiality of subject?**
18	**Costs Involved (Appx. in Rs.)** **Investigations** _____ **Disposables** _____ **Implants** _____ **Drugs / Contrast Media** _____ **Any Other** _____ **Who will bear the costs of the requirements?**
19	**Participant Information Sheet** ***(mark √ if yes)*** ☐ Attached English version _____ ☐ Attached Hindi version _____ ☐ Attached Marathi version _____ ☐ Certified that Hindi and Marathi version is a true translation of English version (enclose copy)
20	**Participant Informed Consent Form** ***(mark √ if yes)*** ☐ Attached English version ☐ Attached Hindi version ☐ Attached Marathi version _____ ☐ Certified that Hindi & Marathi version are true translation of English version

21	☐ **Whether any work on this Protocol has started or not?** *(mark √ if yes, X if no)*
22	**Attached documents** ***(mark √ if yes)*** ☐ Covering letter, through proper channel. ☐ Copy of the detailed protocol is mandatory ☐ Undertaking that the study shall be done in accordance with ICMR and GCP guidelines (separate copy) ☐ In case of multicentric study, IEC clearance of other centres must be provided ☐ Definite undertaking as to who will bear the expenditure of injury related to the trial (separate copy) ☐ In case an insurance cover is intended, Insurance certificate must be provided as per ICMR guidelines ☐ In case of Clinical trials, proof of registration of Clinical trial with regulatory body needs to be submitted. ☐ In case of Investigational New Drug DCGI approval letter and Investigators Brochure ☐ Copy of Participant Information Sheet ☐ Copy of Participant Informed Consent Form ☐ Copy of Case Record form ☐ MOU ☐ Administrative permission / NOC

We hereby declare the information given above is true and that we do not have any financial or non-financial conflict of interest

Name & Signature of PG Researcher

Name & Signature of PI/Guide

Name & Signature of HOD

Name & Signature of Dean

Date & Place:

14.3 Appendix 3: Check List of Documents

Sr. No.	Document	Yes	No
1	**MGMMC-IEC** application form		
2	Protocol		
3	Amendments to protocol		
4	Informed consent document in English		
5	Informed consent documents in Regional languages (Total No.:)		
6	Amendments to the informed consent document		
7	Case Record Form / Questionnaire		
8	Principal investigators Current Curriculum Vitae		
9	Subject recruitment procedures: advertisement, letters to doctors, notices		
10	Investigator Brochure		
10	Ethics Committee clearance of other centers (Total No.)		
11	Insurance policy		
12	Drugs Controller General (India) [DCG(I)]/Regulatory clearance		
13	Investigator's agreement with sponsor		
14	Investigator's undertaking for conduct of Study as per Guidelines		
15	Health Ministry Screening Committee (HMSC)approval		
16	Bhabha Atomic Research Centre (BARC) approval		
17	Genetic Engineering Advisory Committee (GEAC)approval		
18	Director General of Foreign Trade (DGFT) approval		
19	FDA marketing/manufacturing license for herbal drugs.		
20	Other Documents		

14.4 Appendix 4: MGMMC-IEC Approval Format

To

Dr.

Dear Dr. _____

The Institutional Ethics Committee for academic Research (state name of the committee, as appropriate) reviewed and discussed your application to conduct the clinical trial entitled "....." on .....(date).

The following documents were reviewed:

a. Trial Protocol (including protocol amendments), dated_____ Version no (s)._____

b. Patient Information Sheet and Informed Consent Form (including updates if any) in English and/or vernacular language.

c. Investigator's Brochure, dated_____, Version no._____

d. Proposed methods for patient accrual including advertisement (s) etc. proposed to be used for the purpose.

e. Principal Investigator's current CV.

f. Insurance Policy / Compensation for participation and for serious adverse events occurring during the study participation.

g. Investigator's Agreement with the Sponsor.

h. Investigator's Undertaking (Appendix VII).

The following members of the ethics committee were present at the meeting held on (date, time, place).

_____ Chairman of the Ethics Committee

_____ Member secretary of the Ethics Committee

_____ Name of each member with designation

We approve the trial to be conducted in its presented form.

The Institutional Ethics Committee for Academic research expects to be informed about the progress of the study, 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,

Member Secretary, Ethics Committee.

14.5 Appendix 5: Checklist For Submission of Serious Adverse Event Report (SAE) Occurring in Clinical Trial

Sr. No.	Details		
1.	Country (Name of the country should be specified)		
2	SAE report of death or other than death, Please tick	Death ☐	Other Than Death ☐
3	In case of serious adverse event(SAE), please specify if there is any injury to the subject (please specify Yes/ No) in the box		
4	Protocol Title		
5	Protocol Study No./ ID/ Code		
6	Copy of Clinical Trial permission obtained from CDSCO		
7	CTRI Registration No. (Mandatory for Clinical Trial Permitted after 15/0 6/09)		
8	Sponsor(Address with contact no and Email)		
9	CRO (Address with contact no and Email)		
10	Initial / Follow-up (FU)		
11	In case of follow-up : dae & duary no of intial or recently submmitted report information		
12	**Patient Details**		
a)	Initials & other relevant identifier (hospital/OPD record number etc.)		
b)	Gender		
c)	Age and/or date of birth		
d)	Weight		
e)	Height		
13	**Suspected Drug(s)**		
a)	Generic name of the drug.		
b)	Indication(s) for which suspect drug was prescribed or tested.		
c)	Dosage form and strength		
d)	Daily dose and regimen (specify units - e.g., mg, ml, mg/kg)		
e)	Route of administration		
f)	Starting date and time of day		
g)	Stopping date and time, or duration of treatment		
14	**Other Treatment(s)**		
	Provide the same information for concomitant drugs (including nonprescription/OTC Drugs) and non drug therapies , as for the suspected drug(s).		
15	**Details of the events**		
	Full description of event (s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to adescription 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).		
16	**Outcome**		
a)	Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted .		
b)	For a fatal outcome, cause of death and a comment on its possiblerelationship to the suspected reaction; any post-mortem findings		
c)	Other information: anything relevant to facilitate assessmentof the case,such as medical history including allergy, drug or alcohol sabuse; familyhistory; findings from special investigations etc.		
17	**Details about the Investigator**		
a)	CT Site Number, if any		
b)	Name		

c)	Address		
d)	Telephone/Mobile Number & Email		
e)	Profession (speciality)		
f)	Date of reporting the event to Licensing Authority:		
g)	Date of reporting the event to Ethics Committee overseeing the site:		
h)	Signature of the Investigator		
18	**Details about the Ethics Committee**		
a)	Name & Address		
b)	Name of Chairman & Address		
c)	Telephone/Mobile Number		
d)	Email		
19	Adverse Event Term / Details of SAE		
20	Causality Assessment (Related/Unrelated) by Investigator.		
21	Causality Assessment (Related/Unrelated) by Sponsor/CRO		
22 a)	Details of compensation provided for injury or death. In case no compensation has been paid, reason for the same :		
b)	Duly filled SAE Form as per Appendix XI of Schedule Y		
c)	Laboratory investigations report /Discharge summary (if available and applicable)		

Note: information not relevant to a particular SAE should be marked with NA

Fax No. 02227431094
Telphone No: 02227433404/27437888
Email :- pharmacmgm@gmail.com

14.6 Appendix 6: Sample Format of Informed Consent Document

INFORMED CONSENT DOCUMENT DEPT. OF XXXXXXX MGM Hospital , Kamothe PAGE 1 of 4

I Project title:

To test the efficacy and tolerability of XXXXXXXX (a test drug) as compared to XXXXX (a standard drug)

II Introduction:

You are invited to participate in a research study. It is important that you read this description of the study and understand your role in it including the nature and risks of participation.

Please give your consent to participate in this clinical study only if you have completely understood the nature and course of this study and if you are aware of your rights as a participant.

III Purpose of the study:

It is well known that people who suffer from XXXXX are at high risk for XXXXX. XXXXXXX medications are commonly prescribed to such patients to prevent the occurrence of XXXXX. XXXX is a new drug, which has been found to XXXXXXXXX in initial studies. The study plans to study the efficacy and safety of this drug in patients having XXXXXX.

IV Expected duration of the study and number of subjects:

You will be one of approximately XXX people who will participate in this study. You will be in the study for about XXX days. (If multicentric study – mention that the study is also being carried out at xxx other centers).

V Study procedures to be followed:

If you agree to participate in this study you will a)be asked about previous medical problems, your current health and your medications; b)have a brief physical examination (to give details);c) need to undergo baseline investigation such as XXXXXX(to give details)

The study staff will review the results of these evaluations & test. If you are eligible to participate you will be randomly assigned (like the flip of a coin) to a study group to receive one of the two study treatments.

The study would require a total of XXX visits. At each visit XXX ml (mention1-2 tsp/tbsp as applicable) of your blood will be withdrawn after fasting for XXX hours. The blood samples that are drawn, will be used to check your blood sugar levels, kidney and liver function etc. (mention whatever is applicable).

Regardless of the group to which you have been assigned, you will return to the study centre after XXXX days / weeks / months. It is important that you bring all of your study medications, diary etc. along with you.

At each visit, a) you will be asked about your health, side effects of medications, b) your physical examination will be carried out c) you will be given a new supply of study drug.

VI Risks and discomforts of participating:

The study testing 2 different therapies in high risk people that may prevent XXXXXX.

Based on studies in animals and other studies with people, the drug(s) used in this study may cause some side effects. The known risks and side effects associated with the drugs proposed for use here are summarized below.

Side effects of test drug – XXXXX (Give Details)

Side effects of standard drug – XXXXX (Give Details)

Other side effects that you may experience could include XXXXX (Mention allergic reactions to the medication, itching rash and pain at the injection site wherever applicable)

Finally new problems or side effects other than those that have been seen before could occur during this study. You will therefore be asked about side effects at each visit. It is important that you report any of the side effects described in this document or any other side effects to the study physician immediately at the numbers listed below.

While collecting blood from your vein, you will have to undergo the discomfort of brief pain or rarely develop bruising or even a minor infection. In case this occurs appropriate management will be provided.

Because the safety of the study drugs for an unborn foetus or newborn is unknown, if you intend to become pregnant, are pregnant or are breastfeeding you cannot participate in this study. If you are a woman who is able to have children, you will be required to undergo a urine pregnancy test. If you are no pregnant you will be asked to take precautions to prevent pregnancy until the end of the study. The doctors will discuss the contraception options with you. Pregnancy test may be repeated during the study. If you become pregnant despite these precautions you should immediately notify the study team. Pregnancy will be a reason to stop study treatment.

Any new important information that is discovered during the study and which may influence your decision to continue in the study will be provided to you or your legally acceptable representative in a timely manner. You will be told of any new risks or side effects.

VII Possible benefits of the study:

By participating in this study, you may have a possible cure or improvement in your condition. However, there is no guarantee that you will receive direct health benefit from

being in this study. Your participation in this study may provide information that may in the future help other patients suffering from XXXXX.

VIII What happens when the research trials stops?

Because this is a research trial, the test drug will not be available at the end of this trial for XXXXXX. Alternate therapy, if appropriate, will be provided once the trial is finished. Occasionally the company sponsoring the research may stop the study early – if this occurs the reason(s) will be explained to you.

IX Compensation for participation:

Participation in this study will be at no cost to you. The medication and clinic visits will be provided free of charge. No compensation will be provided for your participation. Payment for things such as lost wages is not available. (Wherever applicable give details e.g. Reasonable travel assistance will be provided for your participation etc.)

X Compensation for study related injury:

For academic studies: You will be provided medical care at this institute for any physical injury or illness that occurs as a direct result of your participation in this study. This medical care will be at no cost to you. You will not give up any of your legal rights by signing this form.

For sponsored studies – The company has insurance for covering study related expenses. The study sponsor will compensate anyone whose health suffers as a result of participation in this trial. You do not have to prove it was anyone's fault; if the health problem arose because of your participation in this trial, you will be compensated. You will not give up any of your legal rights by signing this form.

XI Right to withdraw from the study:

Participation in this study is entirely voluntary. You may choose not to take part or you may leave the study at any time. Your decision will not affect your further treatment at this institute. If you decide to leave the study, you may have to undergo some tests and/or procedures, which will be done to protect your safety.

XII Confidentiality:

All study records will be kept confidential at all times. Your identity will not be revealed except as required by law. The results of your treatment (details: laboratory tests, photographs, x-rays etc.) may be published for scientific reasons. Your identity will not be revealed in these publications.

XIII Contact for further information:

Thank you for taking the time to read (or have read to you) the information about this study.

Before you sign this document, you should ask questions about any thing that you do not understand. The study staff will answer questions before, during & after the study.

If you have questions about this study is being run, drug side effects or a possible research related illness or injury, contact the study doctor XXXXXXXX, designation, department XXX at telephone number XXXXXX during the office hours, or at XXXXX at outside office hours.
If you have any questions about your rights as a research participant, or complaints regarding the research study, you may contact Dr Pradeep Jadhav, who is the Member Secretary of Ethics Committee for Research on Human Subjects on the following telephone number 02227437888

XIII Consent:

1. I have read or have had read to me the information given in the Informed Consent Document for this study entitled "**XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX**".
2. I have received an explanation of the nature, purpose, duration, and foreseeable effects and risks of the trial and what I will be expected to do. My questions have been answered satisfactorily.
3. I understand that my participation in the trial is voluntary and that I may refuse to participate or may withdraw from the trial at any time, without penalty or loss of benefits to which am otherwise entitled.
4. I further understand that any information that becomes available during the course of the study that may affect my willingness to take part will informed to me.
5. Institutional review board authorities may wish to examine my medical records to verify the information collected. By signing this document, I give permission for this review of my records.
6. I understand that my identity will not be revealed in any report or publication.
7. I agree to take part in the above study.

Name of Subject/	Signature/ thumb impression of subject	Date

Name of Legal Representative	Relation to subject	Signature	Date

Name of the Impartial Witness	Signature of the Impartial Witness	Date

Name of the person administering consent	Signature of the person administering consent	Date