MGM INSTITUTE OF HEALTH SCIENCES

(Deemed University u/s 3 of UGC Act, 1956)

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ETHICS COMMITTEE FOR RESEARCH ON HUMAN SUBJECTS

STANDARD OPERATING PROCEDURES

Version 06

Update July, 2026

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(ECRHS)

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Distribution	:	Members of ECRHS & Investigators of projects submitted to ECRHS

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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. SOPs of Ethics Committee, has been developed 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.

0n 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 and further Notification of New Drugs and Clinical Trial Rules dated 19th March, 2019. 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 Ethics Committee for Research on Human Subjects presently functions according to the requirements laid down in Schedule 'Y" (Drugs and Cosmetic Act 1940: Amendment 20th Jan 2005 Amendment 2017), WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011, 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 2017 and new Clinical Trial Rules 2019.

Standard Operating Procedures

1. Name

This committee will be known as the Ethics Committee for Research on Human Subjects (ECRHS). 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:

i. To ensure the protection of the rights, safety and well-being of human subjects involved in a research project.

ii. To provide public assurance of that protection.

iii. This SOP defines the process for writing, reviewing, distributing, and amending SOPs within the ECRHS. The SOP also defines procedure for documentation, archival, retrieval, destruction of SOP to ensure that the latest SOPs are followed.

iv. Scope : The SOP applies to all activities performed by the Institutional ECRHS .

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

3. Membership:

The committee will consist of members who collectively have the experience and expertise to review and evaluate the scientific, medical and ethical aspects of a proposed research project. In evaluating protocols and ethical issues, the ECRHS MEMBERS must be aware of the diversity of laws, culture and practices governing research and medical practices in various countries around the world and especially in India. . A list of committee members, their qualifications and their affiliations (hospitals, colleges etc.) will be maintained in the committee's records

3.1 Composition of the Committee:

The ECRHS is to be established by the Head of the Institution (HOI). It is multidisciplinary and multi-sectoral in composition. The members should be a mix of medical and non-medical, scientific and non-scientific persons including lay persons to represent the different points of view. The members having different backgrounds are included as this would promote complete and adequate review of research activities commonly conducted at MGMIHS.

The regular members of the committee will ideally 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.

a. The committee will have representation from both men and women.

b. At least two of the medical scientists or clinicians will be independent of the institution.

c. At least one of the non-scientific members will be independent of the institution.

d. Members from other areas, such as a journalist or a member from a consumer protection activity may be included in the committee.

3.2 Chairperson:

a. The Chairperson will be selected and appointed by the Head of the Institute.
b. The Chairperson will be independent of the Institution.
c. The appointed Chairperson will select and appoint members of the committee.
d. The Chairperson will be responsible for conducting all committee meetings, and will lead all discussions and deliberations pertinent to the review of research proposals and ensure participation of all members.
e. Chairperson will have the power to handle complaints such as against researcher, EC members, conflict of interest related issues and request for use of EC data etc.
f. The Chairperson will preside over all elections and administrative matters pertinent to the committee's functions.
g. Chairperson will ratify minutes of previous meeting and seek conflict of interest declaration from members before starting a meeting
h. 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 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. 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
d. A member will sign a confidentiality agreement described in § 14.7 of this document before every meeting.
e. A member will have been trained in ethical issues or shall be willing to undergo training in ethical issues.

3.4 Member Secretary:

a. The committee members will elect a Member Secretary from among themselves who should be preferably affiliated to Institute.
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. Ensure training of EC secretariat and EC members
xi. Ensure SOPs are updated as and when required
xii. Ensure adherence of EC functioning to the SOPs
xiii. Prepare for and respond to audits and inspections
xiv. Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review.
xv. Assess the need for expedited review/exemption from review or full review.
xvi. Assess the need invite independent consultant, patient or community representatives if required.
xvii. Ensure quorum during the meeting and record discussions and decisions.
xviii. Performance of other duties assigned by the Chairperson.

Basic Medical Scientist(s):

Affiliated/ non-affiliated Qualifications

Non-medical or medical person with qualifications in basic medical sciences at least one of the basic medical scientist should preferably be a pharmacologist.

They should be involved in 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.

Clinicians:

May be Affiliated/ non-affiliated members:

i. Should be individual/s with recognized medical qualification, expertise and training
ii. Should be involve with Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics
iii. Ongoing review of the protocol (SAE,protocol deviation or violation, progress and completion report)
iv. Medical Care, facility, provision for medical care, management and compensation.
v. Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.

Legal Expert:

i. Affiliated/ non-affiliated member

ii. Should have a basic degree in Law from a recognized university, with experience Desirable: Training in Medical Law.

iii. Should be involve with Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions

iv. Interpret and inform EC members about new regulations if any

A social worker/representative of a non-governmental organisation/ theologian:

i. Affiliated/ non-affiliated should be an individual with social/ behavioural science/ philosophy/ qualification and training and/or expertise and be sensitive to local cultural and moral values.

ii. Can be from an NGO involved in health-related activities.

iii. Should be involved with Ethical review of the proposal, ICD along with the translations.

iv. Assessment of impact on community involvement, socio–cultural context, religious or philosophical context, if any

v. Serve as a patient/participant/societal/community representative and bring in ethical and societal concerns.

Lay person(s)

i. Should be Non-affiliated to Institute

ii. Literate person from the public or community

iii. 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 well equated with the local language, cultural and moral values of the community

iv. Desirable: involved in social and community welfare activities

There is a provision to invite institutional /extra-institutional member as subject expert if required

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 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. conduct unbecoming of a member of the IEC
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:

1. The committee's primary responsibility will be the protection of safety, rights, well-being and confidentiality of the research subjects.
2. The committee will review all research proposals submitted to it within specified time limits.
3. The committee will keep all information submitted to them confidential especially the proprietary information.
4. The committee will maintain concise but clear documentations of its views on the research proposal.
5. The committee will review the progress of each research project at appropriate and specified intervals, but not less than once a year.
6. The committee will review the qualifications of all investigators participating in the proposed research study.

5. Functions and Operations:

5.1 Submission of the Research Proposal

a. All prospective and retrospective studies (on drugs, investigational techniques as well as devices or any other procedure, data analysis), involving human volunteers or patients to be conducted at MGM Medical College & MGM Hospital, shall have ECRHS permission before commencing such a study.
b. Each project along with a duly completed ECRHS application form shall be submitted in duplicate. The ECRHS application form will be available at the office of the ECRHS

between 9.30 a.m. to 4.00 p.m. 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. All details in the form such as type of patients phase of drug trial, duration of study, sponsoring agency, budget of the trial, availability of Drugs Controller General of India [DCGI] permission and other relevant approvals etc. shall be completed while submitting the proposal.

c. Studies which plan to use a new drug (as defined in 122-E of the Drugs and Cosmetics Act, 1945) shall submit along with the ECRHS application form, a copy of the permission letter issued by the DCGI to the pharmaceutical company/investigator. If the DCGI permission is awaited, a letter of provisional approval from ECRHS will be issued and final ECRHS approval will be given after a copy of DCGI permission is submitted to the ECRHS. A study cannot begin until the final letter of permission is issued by the ECRHS.

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. 75,000/- (non-refundable) will be charged for all Industry sponsored projects. Government sponsored projects from outside of the institute will be charged Rs.5000/-, and projects which are not sponsored and academic projects will be charged a nominal-processing fee of Rs. 500/-. The fees shall be collected at the time of submission of the project.

No additional fee will be charged for following

1. Review of Revised Industry sponsored projects.
2. Yearly monitoring the progress of industry sponsored project for the period of maximum 2 Years.

f. ECRHS may review proposals where research is conducted in institute of nearby area other than MGM Medical College & MGM Hospital by signing a MOU by both institution only.

Submission of Research Proposal

The complete project proposal shall be submitted in duplicate alongwith 12 copies as synopsis. Each set shall contain the documents on A4 size paper arranged in a file in the order mentioned below:

i. ECRHS application form duly filled.
ii. Summary of protocol (in not more than 500 words)

iii. Protocol and any amendments to it with version and date

iv. 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 14.5.

v. Case Record Form / Questionnaire.

vi. Principal investigators current Curriculum vitae.

vii. Subject recruitment procedures (e.g. advertisements/letters to doctors/posters)

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

ix. Ethics Committee clearance of other centres (if multicentre study).

x. Insurance policy

xi. DCGI clearance[for Phase I, II, III studies]

xii. Investigator's agreement with sponsor

xiii. Investigator's undertaking to DCGI [for Phase I, II, III studies]

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.

The guidelines for submission of a research proposal are as described in 14.1 and the checklist for documents to be submitted is as described in 14.3.

5.2 Procedures :

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

b. The project proposals in the format mentioned in 5.1. will be accepted in office of the Research Secretariat between 10.00 am to 04.00 pm. from Monday to Friday.

c. The projects submitted will be circulated to all committee members and the proposal shall be reviewed for elements described in 5.3.

d. A meeting, as described in 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 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 at least four times in a year as and when required, but not less than once every sixteen (16) weeks.
b. Regular meetings may not be held in the months of May and October when the college closes for vacation.
c. All members will receive notification of meeting schedules at least two (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. Quorum:

   Meetings will be held as scheduled provided there is a quorum. In accordance with Schedule Y (20th January 2005) and now during clinical trial rules 2019, the quorum of the ECRHS will be 50% of the members including at least five members with the following representations:

   i. a basic medical scientist (preferably one pharmacologist),
   ii. a clinician,
   iii. a legal expert,
   iv. a social scientist and
   v. a lay person.

i. Hierarchy:
   i. There will be one Chairperson and one Member Secretary.
   ii. The Chairman will be the head of the committee.
   iii. The Member Secretary will be the guardian of all documents and funds in the committee's possession.
   iv. All other members will be regular committee members with equal ranking.

j. 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.

k. 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 ECRHS 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 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. Request for modification giving reasons

d. Request for additional information

e. Clear disapproval giving reasons.

f. 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 working days of the meeting.

5.7 Approval:

All projects will be given approval for a period of one year from the date of the meeting on which the project was approved. The approval shall be in the format described in § 14.4

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 twelve (12) 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 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 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 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.

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 24 hrs. 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, 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/ member secretary 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. Constitution and composition of Ethics Committee
b. Standard operating procedures (SOPs) of the committee
c. Guidelines for submission established by the committee.
d. Annual reports of the committee
e. Membership list along with their appointment letters
f. Curriculum Vitae of the members
g. Agenda of meetings
h. Minutes of meetings

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

a. One copy of all materials 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
g. Records related to serious adverse events, Medical Management of trial subjects, compensation paid.

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

10. Reports to the Relevant Regulatory Authorities

The committee will make a yearly activity report for submission to the relevant regulatory authorities, which will include the following elements:

a. A quantitative evaluation of the activities of the committee in a year
b. The list of the proposals reviewed in a year
c. Status of each study proposal

11. Location and Business Address:

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

Ethics Committee for Research on Human Subjects

MGM Institute of Health Sciences

Sector -1, MGM Medical College Building

3rd Floor, Kamothe, Navi Mumbai 410 209.

12. Amendments to the Standard Operating Procedures:

a. Amendments to the Standard Operating Procedures of the Ethics Committee for Research on Human Subjects (ECRHS), 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. Amendments to valuable subjects:

Receiving the protocol with valuable population vulnerable persons are those who are relatively or absolutely incapable of protecting their own interest. More formally they may have insufficient power, intelligence, education, resources, strength or other needed attributes to protect their own interest. Individuals whose willingness to volunteer in a research study may be unduly influenced by the expectation. Whether justified or not, or benefit associated with participation, or by a retaliatory response from senior members of hierarchy in case of refusal to participate may also be considered valuable.

Protocol should be reviewed keeping in mind the following points when it concerns research that involve group that could be potentially vulnerable to coercion:

a. Measure to protect autonomy
b. Risk/benefit determination with respect to vulnerabilities
c. Bearing unequal burden in research responsibilities

Responsibility:

It is the responsibility of Secretary of IEC to maintain upto date tool for review or research pertaining to vulnerable groups based on how and evolving applicable regulations and guidelines.

IEC Chairperson and Member Secretary is responsible for ensuring that IEC members are well versed in new and evolving regulations and guidelines pertaining to vulnerable population while discussing projects related to them with special emphasis given to assessment of potential for coercion.

14. List of committee members with their affiliations and qualifications

The present composition of the Ethics Committee for Research on Human Subjects is listed in the Table below. Ethics Committee Re-registration no. **ECR/457/Inst/MH/2013/RR-25 dated 03 Oct 2025** amendment to the composition of the Ethics Committee, CDSCO. The registration is valid from 20-Mar-2025 to 19-Mar-2030,

SN	Name	Qualification with Specialization	Current Organization	Telephone Number, Fax Number E-Mail ID. & Mailing Address	Designation/ Role of member in Ethics Committee	Affiliation of member with institute that has constituted the Ethics Committee
1	Dr. Subodh P. Sirur	MBBS, DNB, LLB	Mahatma Gandhi Memorial Hospital, Mumbai Consultant – Dermatology and Venereology	8/16 Talmakiwadi, Tardeo Road, Mumbai- 400007. Email: subodh.sirur@yahoo.com Mob. No: +91-9821066407	Chairman	External

2	Dr. Prakash Narayan Khandelwal	M.D. Pharmacology	Emeritus Professor of Pharmacology MGM Medical College, MGMIHS, Navi Mumbai	MGM Medical College & Hospital Sector -1, Kamothe Navi Mumbai – 410 209. Email: drkhandelwalpn@gmail.com Mob. No: +91-982207226	Member Secretary (Clinician)	Internal
3	Dr. Deepak Langade	M.D. Pharmacology	Professor Pharmacology	School of Medicine, Dr. D.Y Patil University , Nerul, Mumbai- 400 614. E-Mail: drdgl@hotmail.com Mob. No: +91-9930550009	Medical Scientist	External
4	Dr. Ipseeta Ray	PhD Pharmacology	Professor of Pharmacology MGM Medical College, Kamothe, MGMIHS, Navi Mumbai	MGM Medical College & Hospital Sector -1, Kamothe Navi Mumbai – 410 209. rayipseeta@gmail.com Mob. No: +91-9819908498	Medical Scientist	Internal
5	Dr. Smita Mahale	PhD, FNASc, FNA (Biochemistry)	Emeritus Scientist Director (Retired) National Institute for Research in Reproductive Health (ICMR)	A-503, Devedeveshawar Telly Galli Cross Lane Andheri (E) Mumbai 400069 smitamahale@hotmail.com Mob. No: +91-9920391165	Scientific Member	External
6	Dr. Chandramani Pathak	Ph.D.	Professor & Director MGM Institute of Health Sciences, Navi Mumbai	A-801, Jindal Uptown Avenue Sai Nagar, Thana Naka, Old Panvel -410209 Email Id: cmpathak@mgmuhs.com Mob. No: +91-8140169410	Scientific Member	Internal
7	Dr. Prakash Doke	MD, DNB, PhD, FIPHA, FISCD	Professor Department of Community Medicine Bharti Vidyapeeth University Medical College, Pune	51, Adwait,Sai Krupa Society, Sridhar Nagar, Danakwadi, Pune – 43. Email Id: prakash.doke@gmail.com Mob. No: +91-9623450225	Clinician	External
8	Deepashri Naik	MBBS, M.D. (Microbiology)	Associate Professor, MGM Medical College, Navi Mumbai	Associate Professor, Department of Microbiology, MGM Medical College, Kamothe, Navi	Clinician	Internal

				Mumbai 410209 Email: deepashri82@gmail.com Mob. No: +91-9370250582		
9	Dr. Vijay Kamale	MBBS, MD (Paediatrics)	Head & Professor Department of Paediatrics MGM Medical College & Hospital, Kamothe Navi Mumbai – 410209.	A 303, Pouras Chhaya CHS, Plot no 18, Sector 24, Juinagar, Navi Mumbai -400705 Email: drvijaynkamale@yahoo.co.in Mob. No: +91-9224475712	Clinician	Internal
10	Dr. Sheela S Hosamani	LL.B, L.L.M (Bus. Law) PhD (Law)	Asst. Professor MGM Law College, Nerul	Sagar Residents Association NL-5, Building N0.29, Flat No.16, Sector -3, Phase -1, Besides Nerul Post Office, Nerul (E), Navi Mumbai – 400706. Email: hosamanisheela@gmail.com Mob. No: +91-8976511858	Legal Expert	External
11	Dr. D.P Singh	M.Sc., Ph.D.	Professor	School of Research Methodology Tata Institute of Social Scientist Email: dpsingh1212@gmail.com Mob. No: +91-981917709	Social Scientist	External
12	Ms. Shreeya Pagde	B.Sc. CS	Lay Person	A-707, Saipooja CHS, Sector – 01 Kalamboli, Navi Mumbai Email: pagdeshreeya@gmail.com Mob. No: +91-9594898971	Lay Person	External

14. Appendices

Appendix I: Guidelines for Submission of a Proposal to the ECRHS

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

ii. Each project along with a duly completed ECRHS application form should be submitted in duplicate. The ECRHS application form will be available at the office of the ECRHS between 9.30a.m. to 4.00 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.

iii. Studies which plan to use a new drug (as defined in 122-E of the Drugs and Cosmetics Act, 1945) require DCG (I) permission. For such studies, a copy of the permission letter issued by the DCG (I) to the pharmaceutical company/investigator also needs to be submitted to the ECRHS. If the DCG (I) permission is awaited, a letter of provisional approval will be issued by the ECRHS and the final ECRHS approval will be given after a copy of DCG (I) permission is submitted to the ECRHS. No study should be initiated until the final letter of permission is issued by the ECRHS.

iv. 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.

v. For all projects sponsored by pharmaceuticals/sponsored industry, a user fee of Rs. 75,000/- (non-refundable) will be charged from 1st June 2026 onwards. Government sponsored projects from outside of the institute will be charged Rs.5000/- and projects, which are not sponsored, will be charged a nominal fee of Rs. 500/-. The fees shall be collected at the time of submission of the project. Additional, annual review fee Rs. 10,000/- will be charged after the period of 24 months.

vi. 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:

a) ECRHS application form duly filled.
b) Summary of protocol (in not more than 500 words)
c) Protocol and any amendments to it with version and date
d) The informed consent document (ICD), including any amendments / addenda and its translation(s) into regional language(s). A format of the ICD is available in the office of the ECRHS. The ICD should be customised for the study using this format.
e) Case Record Form / Questionnaire.
f) Principal Investigator's curent curriculum vitae. (In case of dissertation the Guide's CV may be submitted).
g) Subject recruitment procedures (e.g. advertisements/letters to doctors/posters)
h) Investigator Brochure (for sponsored projects). This should give details of the study drug, toxicology studies, phase I, II, III data if available, safety information etc.
i) Ethics Committee clearance of other centres (if multicentre study).
j) Insurance policy / Statement regarding compensation of study related injury by sponsor
k) DCG (I) clearance[for Phase I, II, III studies]
l) Investigator's agreement with sponsor
m) Investigator's undertaking to DCG (I) [for Phase I, II, III studies]

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

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

p) Copies of Synopsis

After initiation of the study, the ECRHS 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.

1. The ECRHS expects to be informed annually about the status of the study.

(a) For studies which are completed within the ECRHS approval period, a study completion report should be submitted to the ECRHS, by the principal investigator. If a study was not initiated, or was withdrawn or terminated, the same should be informed to the ECRHS giving reasons.

(b) For studies which will continue for more than a year, an extension of approval for the study from the ECRHS needs to be taken by the principal investigator (as ECRHS 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 ECRHS reviews the annual project report. A user fee of Rs. 5000/- will be charged for extension of approval of projects sponsored by pharmaceuticals.

The Standard Operating procedures of the ECRHS, Version 3, May 2019, are available with the Administrative Manager in the office of the ECRHS.

Appendix II : ECRHS Application Form

Title of the Project_____

_____

_____

_____

_____

	Name	Designation	Dept. & Inst.
Principal Investigator			
Co-Investigator			
Co-Investigator			
Co-Investigator			

Non-sponsored study □ **Sponsored study** □

If Non-Sponsored Study

Thesis/dissertation □ ICMR student ship □ Other Academic □

Please mention approx. date of submission of thesis/dissertation (month & year)_____

If Sponsored study whether

1. Indian □ a) Government □ b) Industry □ c) Institutional □

2. International □ a) Government □ b) Private □ c) UN agencies □

3. Industry □

Address of Sponsor:

Total Budget : Rs._____

Research Fund will be deposited in: DJST □ DDF □ Research Society □ Other □

If other, please specify_____

Please give details of allocation of budget in attachment.

1.Type of Study :

Prospective □ Retrospective □

Single center □ Multicentric □ If multicentric, how many centres _____

2. Does the study involve use of : Drug / Vaccine □ Device □ Alternative Medicine □

Any other □ Not Applicable □ If other, please specify_____

i) Is the test drug / device marketed in India **Yes** □ **No** □

Is it marketed in other countries: **Yes** □ **No** □ Specify _____

If **marketed** in India, please **attach package insert**

If **not marketed** in India, please **attach Drugs Controller General (India) [DCG(I)] permission**.

ii) Is the test drug an Investigational New Drug (IND)? Yes □ **No** □

If yes, please submit Investigator's Brochure which contains data of pre-clinical studies.

If IND, please also **attach DCG(I) permission**.

iii) Does the test drug involve a change in use, dosage, route of administration? **Yes** □ **No** □

If yes, please attach copy of DCG(I) permission.

3. Clinical Study is : Phase I □ Phase II □ Phase III □ Phase IV □

4. Subject selection:

i) Number of subjects at this centre ☐ multicentric, total number of subjects ☐

ii) Vulnerable subjects Yes □ No □ ***(If yes, tick the appropriate boxes)***

pregnant women □ children □ elderly □ fetus □ illiterate □ handicapped □

seriously/terminally ill □ mentally challenged □ economically/socially backward □

any other □ If other, please specify_____

iii) Special group subjects Yes □ No □ ***(If yes, tick the appropriate boxes)***

employees □ students □ nurses/dependent staff □ any other □

If other, please specify _____

4. Does the study involve use of		
i) fetal tissue or abortus	Yes	No
ii) organs or body fluids	Yes	No
iii) recombinant/gene therapy **If yes, please submit a copy of Genetic Engineering Advisory Committee (GEAC) permission**.	Yes	No
iv) ionising radiation/radioisotopes **If yes, please submit a copy of Bhabha Atomic Research Centre (BARC) permission.**	Yes	No
v) infectious / biohazardous specimens	Yes	No
vi) Will pre-existing/stored/left over samples be used?	Yes	No
vii) Will samples be collected for banking/future research	Yes	No
viii) Will any sample collected from patient be sent abroad? **If yes, please submit a copy of Director General of Foreign Trade (DGFT) permission.**	Yes	No
ix) Is there any collaboration with any foreign lab., clinic or hospital ? **If yes, please submit a copy of Health Ministry Screening Committee (HMSC) approval.**	Yes	No

5. Will any advertising be done for recruitment of Subjects? (Posters, flyers, brochures, etc.) **If yes, kindly attach a copy for ECRHS review.**	Yes	No
6. Data Monitoring i) Is there a Data & Safety Monitoring Board/Committee (DSMB)?	Yes	No
ii) Is there a plan for interim analysis of data?	Yes	No
iii)For how long will the trial data be stored? _____years		
7. Is there compensation for participation? If Yes, Monetary □ In kind □ Specify amount / type: _____	Yes	No
8. Are there any arrangements for compensation of trial related injury? **Yes** □ **No** □ **Please submit a copy of the insurance policy if it is available.**		

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

Signature of Principal Investigator: _____

Signatures of Co- investigators: 1._____ 2._____3._____

Forwarded by Heads of Department(s) _____ _____

Stamp/Seal of the Department(s)

Appendix: III Check List of Documents

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

Appendix IV: ECRHS Approval Format

To

Dr.

Dear Dr. _____

The Institutional Ethics Committee / Independent Ethics Committee (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 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.

Appendix V: Checklist For Submission of Serious Adverse Event Report (SAE) Occurring in ClinicalTrial

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 /06/09)		
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 finding		
c)	Other information: anything relevant to facilitate Assessment of the case, such as medical history including allergy, drug		

	or alcohol abuse, 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 a pplicable)		

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

Fax No. 022- 27431094/022 -27431092
Telphone No. 022-27432471/27432994
Email :- research@mgmuhs.com

Appendix VI: Format of Informed Consent Document

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

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. (mentionwhatever 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. Prakash N Khandelwal, who is the Member Secretary of Ethics Committee for Research on Human Subjects on the following telephone number 02227432471 extension 7688.

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**

Appendix VII : Conflict of Interest Form

DECLARATION OF CONFLICT OF INTEREST BY EC MEMBERS

EC Meeting held on …… at …… am at MGMIHS, 3rd Floor, Conference Room.

I hereby declare that, I have no conflict of interest for the projects considered for discussion in IEC meeting held on ……. of following Research Projects:

Sr. No.	Title of Research Project	Principal Investigator

Name of IEC member :
Association to IEC :
Signature :

15. References :

International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996. http://www.ich.org/LOB/media/MEDIA482.pdf (last accessed 31st July 2017)

ICMR's Ethical Guidelines for Biomedical Research on Good Human Participants, ICMR 2017 http://www.icmr.nic.in/ethicalguidelines.pdf (last accessed 31st July 2017)

Schedule Y(Drugs and Cosmetic Act 1940; amendment 8th February 2013) http://www.cdsco.nic.in/html/Schedule-Y%20(Amended%20Version-2005)%20iriginal.htm

World Medical Association Declaration of Helsinki, http://www.wma.net/en/30publications/10policies/b3/(last accessed 31st July 2017)