Institutional Ethics Committee

Government Dental College & Hospital, Mumbai

St George's Hospital Campus, Mumbai 400001

STANDARD OPERATING PROCEDURES [SOP'S]

Version 01

April 2011

STANDARD OPERATING PROCEDURES

INSTITUTIONAL ETHICS COMMITTEE (IEC)

Version : **01**

Date : **April 2011**

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Distribution : **Members of IEC &**
Investigators of projects submitted to IEC

CONTENTS

Introduction

German Medical Practitioners, during World War II, conducted experiments on human participants without their consent and exposing them to grave risk of death and permanent impairment. Concern about protecting the rights and safety of human subjects participating in medical research came to focus and 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. Based on the preliminary efforts of the council for international organizations of Medical science (CIOMS) 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 February 1980, the Indian Council of Medical Research (ICMR) 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.

Government Dental College & Hospital established in 1938 as Sir CEM Dental College located in JJ Hospital compound, shifted to the new premises in St. George's Hospital compound in the year 1962, is a premier dental institution of India under the Government of Maharashtra. The ethical committee for the approval of various research projects, drug trials is already in function at this institution to safeguard the interests of the patients involved in the study.

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.

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 then compatible with the latest Schedule Y

The Institutional Ethics Committee (for research on Human subjects) of Government Dental College & Hospital, Mumbai earlier functioned according to the requirements laid down in Schedule Y (20 January 2005) and was 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 (2006).

Amendment to this is carried out presently according to ICMR guidelines 2017.

Authority:

Government Dental College & Hospital, Mumbai is a very prestigious, institution, previously functioning as Sir CEM Dental College in the JJ Hospital campus from the year 1938 to 1962. This is a state run Government Dental College & Hospital and is governed by the rules of state Government of Maharashtra. As per ICMR Guidelines, Government Dental College & Hospital, Mumbai has Formed Ethics Committee under Guidance of Dean who is the Head of the Institution.

Standard Operating Procedures

1. Name

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

2. Goals of IEC

2.1 Primary Goal

The primary goal of IEC is to ensure that rights and welfare of Human subjects are adequately protected in research involving human subjects at Government Dental College & Hospital

2.2 Secondary Goal

Secondary goal of IEC is to inform and assist the researchers of the Government Dental College & Hospital on ethical and procedural issues related to use of human subjects in research and to facilitate compliance with the relevant regulations of Indian regulatory authorities.

2. Role of IEC

3.1 Are of Supervision

IEC will review and approve the research involving human subjects at Government Dental College and Hospital, Mumbai.

3.2 Responsibilities of IEC

a) The basic responsibilities of an Institutional Ethics Committee (IEC) is to ensure a competent review of all ethical aspects of research proposals received by it in an objective manner.
b) The committee's primary objective would be the protection of safety, rights well-being and confidentiality of the research subjects.
c) The committee will ensure ethical conduct of research by the investigator team.
d) The committee will be responsible for declaration of conflicts of interest to the Chairperson, if any, at each meeting and ensuring these are recorded in the minutes.
e) The committee will review all research proposals submitted to it within specified time limits.
f) The committee will ensure that privacy of the individual.
g) The committee will keep all information submitted to them confidential especially the propriety information.
h) The committee will ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.
i) The committee will maintain concise but clear documentations of its views on the research proposals.
j) The committee will review all types of In-vivo and In Vitro studies.
k) The committee will screen the proposals for their completeness and depending on the risk involved categorize them into three types, namely, exemption from review, expedited review, and full committee review.
l) The committee will review the progress of each research project at appropriate and specified intervals (not less than once a year), except in case of post graduate dissertation, approved by the MUHS and regularly monitored by the concerned PG teacher, as such studies are likely to be of short duration and granting of provisional approval may lead to delay in dissertation submission. However, any adverse event will definitely be scrutinized by the IEC.
m) The committee will review the qualification of all investigators participating in the proposed research study.
n) The committee will recommend appropriate compensation for research related injury, wherever required.
o) The committee will participate in continuing education activities in research ethics and get updated on relevant guidelines and regulations.
p) The committee will make sure that a MoU is signed in case of studies involving collaboration with other institutions.
q) The committee may accept proposals of research studies from other institutes under proper ethical guidelines provided it's been approved by the ethical committee of that institute which would consider the local needs and requirements of the populations being researched and safeguard the dignity, rights, safety and well-being of the participants.
r) The committee will ensure that Clinical trial agreement between the sponsors, investigator and the head of the institution(s) (if applicable) is duly signed.

s) The ethical committee may recommend the proposals to the research and development committee for intramural or extramural funding but by themselves will not approve any payments applicable for the study.

4. 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. A list of committee members, their qualifications and their affiliations (hospitals colleges etc.) described in point 13 of this document will be maintained in the committee's records.

Terms of reference for EC members

The head of the institution will appoint all EC members, including the Chairperson.

The letter issued by the head of the institution should include, at the minimum, the following:

- Role and responsibility of the member in the committee
- Duration of appointment

Generally, the term of EC membership will be 5 years.A defined percentage of EC members could be changed on a regular basis.

Members to be appointed on the EC should be willing to fulfil the EC requirements as given below:

EC member must:

a. provide a recent signed CV and training certificates on human research protection and good clinical practice (GCP) guidelines, if applicable;
b. either be trained in human research protection and/or GCP at the time of induction into the EC, or must undergo training and submit training certificates within 6 months of appointment (or as per institutional policy);
c. be willing to undergo training or update their skills/knowledge during their tenure as an EC member;
d. be aware of relevant guidelines and regulations;
e. read, understand, accept and follow the COI policy of the EC and declare it, if applicable, at the appropriate time;
f. sign a confidentiality and conflict of interest agreement/s;
g. be willing to place her/his full name, profession and affiliation to the EC in the public domain; and
h. be committed and understanding to the need for research and for imparting protection to research participants in research.

4.1 Composition of the Committee

a. 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 organisation/theologian. of non-governmental

   iv. A lay person from the community.

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

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

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

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

4.2 Chairperson

a. The Chairperson will be selected and appointed by 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.

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

f. 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

4.3 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 publicize his/her full name, profession and affiliation.

c. A member will sign a confidentiality agreement described in Appendix 4 of this document before every meeting.

d. A member will have been trained in ethical issues or shall be willing to undergo training in ethical issues.

4.4 Member Secretary

a. The committee members will elect a Member Secretary from among themselves.

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.

4.5 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 point 4.8 of this document.

4.6 Resignation of Members

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

4.7 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.

4.8 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.

4.9 Quorum for the IEC is specified as follows:

a. A minimum of five members should be present in the meeting room.
b. The quorum should include both medical, non medical or technical or/and non-technical members.
c. Hence it is mandatory for that the Chairperson, Secretory Member, Clinician, Social Scientist and Legal expert to attend all the meetings.
d. Minimum one non-affiliated member should be part of the quorum.
e. Preferably the lay person will be part of the quorum.
f. The quorum for reviewing regulatory clinical trials should be in accordance with current CDSCO requirements.
g. No decision is valid without fulfilment of the quorum.

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), involving human volunteers or patients to be conducted at Government Dental College & Hospital, Mumbai shall have IEC permission before commencing a study.

b. Each project along with a duly completed IEC application form shall be submitted in 9 copies. The IEC application form will be available at the office of the IEC between 9.30a.m. to 5.00 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, insurance of the participants, availability of Drugs Controller General of India [DCG(1)] 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 IEC application form, a copy of the permission letter issued by the DCG(I) to the pharmaceutical company/investigator. If the DCG(I) permission is awaited, a letter of provisional approval from IEC will be issued and final IEC approval will be given after a copy of DCG(I) permission is submitted to the IEC. A study cannot begin until the final letter of permission is issued by the IEC.

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 processing fees of Rs. 10,000/- will be charged for all sponsored national projects and Rs. 15,000/- for all sponsored international projects. The fees shall be collected at the time of at the time of submission of the project. A fees of Rs. 3,000/- will be charged for each amendment.

f. The project proposal shall be submitted in soft and hard copies. Each set shall contain the documents on A 4 size paper arranged in a file in the order mentioned below:

i. IEC 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 centers (if multicentre study).

x. Insurance policy
xi. DCG(1) clearance for Phase I, II, III studies)
xii. Investigator's agreement with sponsor
xiii. Investigator's undertaking to DCG(1) [for Phase 1, 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 Appendix 1 and the checklist for documents to be submitted is as described in Appendix 2.

5.2 Procedures

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

b. The project proposals will be accepted in office of the IEC on or before the 20t 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 § 5.3.

d. A meeting, 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

The committee will then classify it in the following types and decide to consider under review.

5.3.1 TYPES OF REVIEW

1. Exemption from review

Proposals with less than minimal risk where there are no linked identifiers, for example;

• research conducted on data available in the public domain for systematic reviews or meta-analysis;

• observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person;

• quality control and quality assurance audits in the institution;

• comparison of instructional techniques, curricula, or classroom management methods;

• consumer acceptance studies related to taste and food quality; and

• public health programmes by Govt agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers).

2. Expedited review

Proposals that pose no more than minimal risk may undergo expedited review, for example;

• research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples;

• research involving clinical documentation materials that are non-identifiable (data, documents, records);

• modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s);

• revised proposals previously approved through expedited review, full review or continuing review of approved proposals;

• minor deviations from originally approved research causing no risk or minimal risk;

• progress/annual reports where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee; and

• for multicentre research where a designated main EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee common review.

• research during emergencies and disasters

3. Full committee review

All research proposals presenting more than minimal risk that are not covered under exempt or expedited review should be subjected to full committee review, some examples are;

• research involving vulnerable populations, even if the risk is minimal;

• research with minor increase over minimal risk

• studies involving deception of participants

• research proposals that have received exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee;

• amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, etc.) involving an altered risk;

• major deviations and violations in the protocol;

• any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit–risk assessment;

• research during emergencies and disasters either through an expedited review/ scheduled or unscheduled full committee meetings. Member Secretary may decide this depending on the urgency and need;

• prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.

5.4 Meetings

5.4.1 Agenda

The IEC will have an agenda for each meeting. The agenda will include listing and identifying all research project applications awaiting approval by IEC. At least 7 days in advance of the scheduled meeting date, the agenda will be made available for review by members of IEC

5.4.2 Procedure

a. The committee will hold a regular meeting once every twenty (20) weeks. When there are no research proposals to review, the meeting may be held less frequently, but not less than once every thirty (30) weeks.
b. Regular meetings may not be held in the months of May and November 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), the quorum of the IEC will be 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, and 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 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 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. Thus, the decision will be communicated to the investigator within 40 days of submission of the proposal, except for proposals submitted in the months of April and October.

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 in within, 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 for 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 (eg. 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

b. The committee may also ask for a status report from the investigpeor at carlier 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.

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

b. 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 those 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.

c. 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 are reviewed and approved by the committee. The approval for extension for study will be given for a period of one year.

8. 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 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

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. Address:

Institutional Ethics Committee,

Office of the Dean, Government Dental College & Hospital, St. George's Hospital compound, Mumbai 400001

Tel. 022-22620668

Mobile: 9820758702

e-mail: deangdch_mumbai@yahoo.com

12. Amendments to the Standard Operating Procedures

a. Amendments to the Standard Operating Procedures of the Institutional Ethics Committee, Government Dental College & Hospital, -+Mumbai shall be proposed in writing/

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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.

13. List of committee members with their affiliations and qualifications

The present composition of the Institutional Ethics Committee is listed in the table below:

DESIGNATION IN COMMITTEE	NAME OF MEMBER	QUALIFICATION & AFFILIATION
CHAIRMAN	DR. VIVEK PAKHMODE	MDS.(Oral Pathology) Joint Director DMER, Mumbai
MEMBER SECRETARY	DR. ARTI GANGURDE	MDS. Associate Professor (Prosthodontics)
CLINICIAN	DR. RAJESH GAIKWAD	MDS. Associate Professor (Periodontology)
BASIC MEDICAL SCIENTIST	DR. DINESH DHODI	MD. Associate Professor Dept. of Pharmacology
LEGAL EXPERT	DR. SANJAY JADHAV	B.Com, LLB, LLM, PhD Asst. Professor (Department of Law Mumbai University)
SOCIAL SCIENTIST	MR. DATTATRAY VIBHUTE	B.Com, M.S.W. Social Service Superintendent, St. George's Hospital, Mumbai
LAY PERSON	MR. SWAPNIL DESAI	B.Com Senior Assistant NEET

14. Appendices

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

1. All prospective and retrospective studies involving human volunteers or patients to be conducted at Government Dental College & Hospital, Mumbai should have IEC permission before commencing such a study.
2. Each project along with a duly completed IEC application form should be submitted in both Hard and Soft copy. The IEC application form will be available on the website. 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 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 IEC. If the DCG(I) permission is awaited, a letter of provisional approval will be issued by the IEC and the final IEC approval will be given after a copy of DCG(1) permission is submitted to the IEC. No study should be initiated until the final letter of permission is issued by the IEC.
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. For all projects sponsored by pharmaceuticals, a user fee of Rs. 10,000/- will be charged from 1 April 2011. Government sponsored projects, ICMR projects will be charged Rs.1000/- as per their rules and projects, which are not sponsored i.e. Undergraduate ICMR projects, research projects and dissertation for postgraduate students will not be charged. The fees shall be collected at the time of submission of the project by cheque in the name of Institutional Ethics Committee, Government Dental College & Hospital, Mumbai.
6. Soft and hard copy of the project proposal should to be submitted. The set shall contain the documents mentioned below on A 4 size paper arranged in a plastic file in the order mentioned below:

    1. Copy of research protocol
    2. Copy of Case Record Form (CRF)
    3. Copy of Patient Informed Consent Form (ICF)-Three Languages
    4. Copy if Patient Information Sheet (PIS)-Three Languages
    5. Letter from sponsor to Principal Investigator (PT)
    6. Consent letter from PI
    7. Bin-data of PI
    8. Consent letter and fio-data of Co-Investigator for Research Projects of Alternative Medicines (Ayurved/Homoepathy/Unani)
    9. Letter from Head of the Institute for Outside Proposals

10. DCGI/FDA permission for conducting trials involving drugs which are not marketed.
11. Permission from other Regulatory Bodies for specialized research
12. Adverse Drug Reaction Monitoring Form
13. Statement of Compensation in case of Serious Adverse Event (SAE/SAR)
14. Insurance Coverage (Indemnity) of trial subjects
15. Acknowledgement/Endorsement by Head of the Department
16. Relevant References/Study Material
17. Processing Fees - National Rs. 10,000/-International Rs 15,000/-
18. Other (Specify)

7. After initiation of the study, the 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 IEC expects to be informed annually about the status of the study.

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

(b) For studies which will continue for more than a year, an extension of approval for the study from the IEC needs to be taken by the principal investigator (as 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 IEC reviews the annual project report.

Appendix 2: Cheek List of Documents

Sr. No.	Documents	Yes	No
1.	Copy of research protocol		
2.	Copy of Case Record Form (CRF)		
3.	Copy of Patient Informed Consent Form (ICF)- Three Languages		
4.	Copy if Patient Information Sheet (PIS) - Three Languages		
5.	Letter from sponsor to Principal Investigator (PI)		
6.	Consent letter from Pl		
7.	Bio-data of Pl		
8.	Consent letter and Bio-data of Co-Investigator for Research Projects of Alternative Medicines (Ayurved/ Homoepathy/Unani)		
9.	Letter from Head of the Institute for Outside Proposals		
10.	DCGI/FDA permission for conducting trials involving drugs which are not marketed.		
11.	Permission from other Regulatory Bodies for specialized research		
12.	Adverse Drug Reaction Monitoring Form		
13.	Statement of Compensation in case of Serious Adverse Event (SAE/SAR)		
14.	Insurance Coverage (Indemnity) of trial subjects		
15.	Acknowledgement Endorsement by Head of the Department		
16.	Relevant References/Study Material		
17.	Processing Fees National Rs.10,000/- International Rs.15,000/-		
18.	Other (Specify)		

14.3 Appendix 3: ANNEXURE 'B'

REPORT OF ETHICS COMMITTEE

Department	
Candidate admitted year	
Course and Subject	
College Name & Address	Government Dental College and Hospital, St. George's Hospital compound, Mumbai, 400001

Reference No: Date:

To,

Dept----------,
Government Dental College and Hospital,
St. George's Hospital Compound,

Behind GPO, Near CST,
Mumbai- 400001

Sub: Research Proposal entitled:

"----------

----------"

Ref: Letter no……(Letter/Proposal of Student)

Dear Student,

The above-mentioned research proposal of dissertation topic was discussed in the Ethics Committee meeting held on ---------- at our college.

It is declared that-

1. The said title of synopsis is not repeated

   You are registered under ……(Guide)who is university recognized U.G/P.G. teacher vide universityletter no. ---------- for guidance and supervision during the course of studies.
2. Ethics committee has unanimously approved your title and synopsis of dissertation.
3. The title is recommended for study by the student from date

(Signature and Name)
Chairperson,

Ethical Committee

Government Dental College and Hospital, Mumbai

14.4 Appendix 4: Confidentiality Agreement

(To be printed on the letterhead of the Ethics Committee for Research on Human Subjects)

CONFIDENTIALITY AGREEMENT

The undersigned accept that the confidential information contained in the proposals _____ submitted by the Investigators of Government Dental College & Hospital, Mumbai for review in the IEC meeting dated _____ shall be maintained in confidence with the same degree of care, the IEC holds its own confidential information and shall not be disclosed to any third party. However, we understand that IEC records may be subjected to review by the relevant regulatory authorities.

Name of IEC member	**Signature**
Dr. Vivek Pakhmode	
Dr. Arti Gangurde	
Dr. Rajesh Gaikwad	
Dr. Dinesh Dhodi	
Dr. Sanjay Jadhav	
Mr. Swapnil Desai	

The Standard Operating Procedures of the Ethics Committee for Research on Human Subjects, Version 01, November 2005 are verified and confirmed by the following IEC members

Name of IEC member	**Signature**
Dr. Vivek Pakhmode	
Dr. Arti Gangurde	
Dr. Rajesh Gaikwad	
Dr. Dinesh Dhodi	
Dr. Sanjay Jadhav	
Mr. Swapnil Desai	

Standard Operating Procedure for Serious Adverse Event (SAE)

1. Any adverse event or adverse drug reaction (AE/ ADR) can be expected and unexpected they should be recorded and reported.
2. The medical management of the adverse event is the responsibility of the investigator, and the protocol for adverse event management with allocation of responsibilities must be pre-defined in the protocol and submitted to the Ethics Committee.
3. There must be a financial plan (including, if necessary, insurance) to manage adverse events and compensation for trial related injury.
4. An expedited review will be done by the ethics when AE or unexpected ADR are reported committee.
5. Unexpected AE/ADRs and all SAE (serious adverse event) should be reported to the sponsor by the investigator within 24 hours and to the ethics committee that accorded approval to the study protocol within seven days.
6. In the event of death the EC should also be informed within 24 hours.
7. Any unexpected SAE as defined in the Indian GCP (Good Clinical Practice) Guidelines occurring during a clinical trial should be communicated promptly within 14 calendar days by the Sponsor to the Licensing Authority and to the Investigator(s) of other trial sites participating in the study.
8. All other serious unexpected reactions (ADRs) that are not fatal or life threatening must be reported as soon as possible but not later than 14 calendar days.
9. All the SAE Reports will be discuss in an expedited review by the Members ile a Pharmacologist and 2 Clinicians.
10. The Member will review and check that proper procedure is followed or net to safeguard the well-being and rights of the subject. They would also determine whether proper treatment was given or not.

SOP for Vulnerable population

General Description:

The IEC of Government Dental College and Hospital, Mumbai takes special consideration in protecting the welfare of vulnerable subjects such as children, foetuses/neonates, pregnant women, prisoners and individuals with consent capacity impairment. The IEC carefully considers group characteristics, such as economic, social, physical, and environmental conditions, to ensure that the research incorporates additional safeguards measures for vulnerable subjects. The IEC may require additional safeguard measures to protect potentially vulnerable population. For instance, the IEC may require that the investigator submit each signed informed consent form to the IEC, that someone from the IEC oversee the consent process, or that a waiting period be established between initial contact and enrolment to allow time for family discussion

and query resolution. IEC expects to follow the principles laid down in the ICMR-Ethical Guidelines for Biomedical Research on Human Participant.

Purpose:

The purpose of this SOP is to describe how the IEC will ensure that the rights and interests of vulnerable population are safeguarded. The IEC will ensure that individuals or communities included for research are selected in such a way that the burdens and benefits of the research are equally distributed.

Scope:

This SOP applies to the process by which the IEC will protect the rights and interests of vulnerable population. Additional protection will be ensured depending upon the risk of harm and the likelihood of benefit.

Responsibility:

It is the responsibility of the IEC members to identify study proposals including vulnerable population and ensure that these are considered for full board. The IEC will ensure that measures for safeguarding rights and interests of vulnerable participants are mentioned in the study proposal, Participant /Assent Information Sheet/ and informed consent/assent form. They have the responsibility to ensure that the vulnerable population is not exploited and they will guide the investigators to design protocols and describe the process of informed consent in such a manner that this will be done.

Flow chart:

No	Activity	Responsibility	
1	Receive the submitted documents	IEC Secretariat	
2	Determine protocols including vulnerable population	IEC members and Chairperson	
3	Review of protocol by appropriate reviewers and assess whether their inclusion is justified	IEC members and Chairperson	
4	Ensure measures for protecting rights and interests of vulnerable population are described in the face sheet	IEC members and Chairperson	
5	Review the Participant /Assent Information Sheet/ and Informed Consent/Assent form	IEC members and Chairperson	

Detailed instructions:

Determine protocols including vulnerable population: Project proposals presented before the Ethics Committee Meeting which includes vulnerable population: It will be the responsibility of the IEC to see whether the inclusion of vulnerable populations in the study is justifiable or the population is just being exploited to generate clinical data. In such cases, appropriate reviewers will assess the risk and ensure measures for protecting their rights. Review of risk assessment will be documented in IEC minutes.

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

Research on genetics should not lead to racial inequalities. Persons who are economically or socially disadvantaged should not be used to benefit those who are better off than them. Rights and welfare of mentally challenged and mentally differently abled persons who are incapable of giving informed consent or those with behavioural disorders must be protected. Appropriate proxy consent from the legal guardian should be taken after the person is well informed about the study, need for participation, risks and benefits involved and the privacy and confidentiality procedures. The entire consent process should be properly documented.

Adequate justification is required for the involvement of participants such as

- Prisoners, students, subordinates, and employees, service personnel etc. who have reduced autonomy as research participants, since the consent provided may be under duress or various other compelling reasons.
- Persons, who are terminally ill, have incurable disease and mental illness.
- Pregnant and lactating women
- Children (<18 years)
- Tribal and marginalized communities
- Refugee, migrants, homeless, persons or populations in conflict zones, riots areas or disaster situations;
- Suffering from stigmatizing or rare diseases etc.

Consideration issues and protection of specific vulnerable groups:

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

Children will not be involved in research that could be carried out equally well with adults. The purpose of the research is to obtain knowledge relevant to health needs of children. For clinical evaluation of a new drug the study in children should always be carried out after the phase III clinical trials in adults. It can be studied earlier only if the drug has a therapeutic value in a primary disease of the children.

A parent or legal guardian of each child should have given proxy consent.

The assent of the child should be obtained to the extent of the child's capabilities such as in the case of mature minors from the age of seven years up to the age of 18 years.

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

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

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

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

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

Pregnant or nursing women: Pregnant or nursing women should in no circumstances be the participant of any research unless the research carries no more than minimal risk to the foetus or nursing infant and the object of the research is to obtain new knowledge about the foetus, pregnancy and lactation. As a general rule, pregnant or nursing women should not be participants of any clinical trial except such trials as are designed to protect or advance the health of pregnant or nursing women or foetuses or nursing infants, and for which women who are not pregnant or nursing would not be suitable participants.

The justification of participation of these women in clinical trials would be that they should not be deprived arbitrarily of the opportunity to benefit from investigations, drugs, vaccines or other agents that promise therapeutic or preventive benefits.

Women should not be encouraged to discontinue nursing for the sake of participation in research and in case she decides to do so, harm of cessation of breast-feeding to the nursing child should be properly assessed except in those studies where breast feeding is harmful to the infant. Compensation in terms of supplying supplementary food such as milk formula should be considered in such instances.

Research related to termination of pregnancy: Pregnant women who desire to undergo Medical Termination of Pregnancy (MTP) could be made participants for such research as per The Medical Termination of Pregnancy Act, GOI, 1971.

Research related to pre-natal diagnostic techniques: In pregnant women such research should be limited to detect the foetal abnormalities or genetic disorders as per the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, GOI, 1994 and not for sex determination of the foetus.

An **audio-video recording of the informed consent** process in case of vulnerable subjects in clinical trials of New Chemical Entity or New Molecular Entity including procedure of providing information to the subject and his understanding on such consent, shall be maintained by the investigator for record. The Ethics committee may direct the Principal Investigator for consent to take participants permission for studies involving vulnerable population.

Provided that in case of clinical trial of anti-HIV and anti-leprosy drugs, only audio recording of the informed consent process of individual subject including the procedure of providing information to the subject and his understanding on such consent shall be maintained by the investigator for record.

Glossary:

Vulnerability: The Council for International Organizations of Medical Sciences (CIOMS) defines vulnerability as "Substantial incapacity to protect one's own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchical group."

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

Conflict of interest:

If any member of the committee is either principal investigator, co- investigator or in any other way related with the study/trial being reviewed by the committee then he should bring it to the notice of the committee. The concerned member will not vote during the review of the study/trial/project.

Foundation IEC Committee:

Sr. No.	Name of Members	Qualification	Address
1.	Dr. Bappai (Primary)	B.Sc(Hon), BD S.M Phil	Assistant Director, PR and Govt. Affairs Saifee Hospital, Charni road Tel: 022-67570208 Fax: 022-67570214
2.	Dr. S.B.Patel (Primary)	M.D. (Pharmacology) D.C.H	Professor & Head Department of Pharmacology, Grant Medical College, Mumbai. Tel: 9821286701

3.	Dr. Mrs. Wadikhaye (Scientific)	MD(General Medicine)	Professor General Medicine St. George's Hospital, Mumbai Tel: 9822956466
4.	Dr. H.R.Umarji (Primary)	MDS	Professor & Head Department of Oral Medicine and Radiology Government Dental College & Hospital Mumbai Email: hemantrumarji@gmail.com Tel: 9820758702
5.	Dr.Prajwalit Kende (Scientific)	MDS(Oral Surgery)	HOD. Department of Oral and Maxillofacial Surgery Government Dental College & Hospital Mumbai Email: prajwalitkende1979@gmail.com Tel: 9324715824
6.	Dr. Avinash Kale (Legal)	BDS, L.L.M (Lawyer)	Dental Surgeon, Department of Conservative Dentistry Government Dental College & Hospital Mumbai Tel: 9967408099
7.	Mr. Dattatray Vibhute (Non-Scientific)	B.Com, M.S.W.	Social Service Superintendent, St. George's Hospital, Mumbai Tel: 9987064669 Email: dattavibhute@yahoo.co.in
8.	Mr. Hemant Pawar (Non-Scientific)	B Sc	Administrative Officer Government Dental College & Hospital, Mumbai Email: hmntpawar387@gmail.com Tel: 8097515370

Names of Supporting Staff

1. Mrs. Neena Gillon: Student Section(PG)

2. Mr. Shinde Stenographer (Office of the Dean)