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WEBLINK FOR CODE OF ETHICS FOR RESEARCH

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CODE OF ETHICS FOR RESEARCH

Approved at institutional committee meeting at 2011 (Letter dated 24-02-2012, Ref.PMS/PO/Acad/0156/2011, issued by Principal)

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CODE OF ETHICS FOR RESEARCH AND PUBLICATION

Research is an inevitable component of any academic institution. The purpose of the document is to provide guidance to students and faculty members of PMS College of dental science and research to maintain ethical standards in research and publication. The Code of Ethics is prepared on well-established international and national guidelines to protect the interest of participants involved in biomedical research. In India the guidelines are formulated by the Indian Council of Medical Research (ICMR) and latest version can be found at https://www.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf

Researchers in the institution should adhere to the Code of ethics as part of their professional responsibility and commitment to an ethical pursuit of knowledge. It is applicable to all faculty, students and visiting researchers of the institute. We have constituted Institutional review board (IRB) which is an administrative body established to promote research among the Students & Faculty and to protect the rights and welfare of human research subjects recruited to participate in research activities. It comprises of 2 committees, Institutional Scientific Review Committee (SRC) and Institutional Ethics Committee (IEC) which started functioning since to take adequate measures to discourage, prevent, expose, and correct unethical conduct of research in the institution. In 2014 IEC was registered under CDSCO (**Central Drugs Standard Control Organisation**) which permit the conduct of clinical trials. In 2020 a separate department of research and publication was started for coordinating the research activities of the students as well as faculty. The department also functions to provide necessary guidance for publishing in good quality journals. To fulfil

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these objectives a steering committee comprising of all heads of departments and individual working committee for research and publication has been constituted.

All research proposals from the institution should be submitted to the research department in the specified format and a soft copy mailed to researchdirector@pmscollege.ac.in. Student proposals should be forwarded by Head of the department. Written agreement or MoU from the authorized person of the involved departments or institutions should be submitted if any other departments within the institution and/or outside the institution are involved. Investigators are invited to present their proposed research work at a scheduled SRC meeting. Investigators are advised to make brief presentation of their project which will be followed by questions and clarifications. SRC scrutinize the scientific merit of each research proposal and give appropriate suggestions to improvise the same in a prescribed reviewers form. Researcher has to resubmit the proposal to SRC after making necessary corrections. Then it will be forwarded to IEC which overview the ethical aspects of all the research work carried out in the institution. Registration in clinical trial registry is mandatory for conducting any clinical trials. Research can be started only after getting approval from IEC and CTRI (Clinical trial registry of India).

Role of IEC (Institutional Ethic Committee)

a] IEC will review and approve all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and well-being of all actual and potential research participants.

b] The goals of research, however important, will never be permitted to override the health and well-being of the research subjects.

c] The IEC will take care that all the **cardinal principles of research ethics viz. Autonomy, Beneficence, Non - maleficence and Justice** are taken care of in

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planning, conduct and reporting of the proposed research. For this purpose, it will look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensations wherever required.

d] It will review the proposals before start of the study as well as monitor the research throughout the study until and after completion of the study through appropriate well documented procedures, for example annual reports, final reports and site visits.

e] The committee will also examine compliance with all regulatory requirements, applicable guidelines and laws.

f] The mandate of the IECs will be to review all research projects involving human subjects to be conducted at the Institute, irrespective of the funding agency.

Composition of IEC

IEC has a multidisciplinary and multisectorial composition. Independence and competence are the two hallmarks of IEC of PMS College of Dental Science & Research. There are 10 numbers in ethical committee and a minimum of five persons is required to compose a quorum.

The Chairperson of the Committee: should preferably be from outside PMS College of Dental Science & research and not head of the same Institution to maintain the independence of the Committee.

The Member Secretary: - should coordinate the Committee activities and should belong to the same Institution

Other members: -Eight numbers should be a mix of medical / non-medical, scientific and non-scientific persons including lay public to reflect the differed viewpoints.

The ethical committee can have as its members, individuals from other institutions or communities. There should be adequate representation of age, gender, community,

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etc. in the Committee to safeguard the interests and welfare of all sections of the community / society. Members should be aware of local, social and cultural norms, as this is the most important social control mechanism. If required, subject experts could be invited to offer their views, for example for drug trials a pharmacologist, preferably a clinical pharmacologist, should be included. Similarly, based on the requirement of research area, for example HIV, genetic disorders etc. specific patient groups may also be represented in the Committee.

The membership of IEC will include Epidemiologist(s), Sociologist(s), Lawyer(s), Theologian, Statistician(s), Clinician(s), Basic scientists, Pharmacist(s)/Clinical Pharmacologist(s) etc. They should be appointed by the Head of the Institute based on their competencies and integrity and could be drawn from any public or private Institute from anywhere in the country.

Membership requirements:

a. The duration of appointment is initially for a period of two years.

b. At the end of two years, the committee should be reconstituted, and 30% of the members will be replaced by a defined procedure.

c. A member can be replaced in the event of death or long-term non availability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.

d. A member can tender resignation from the committee with proper reasons to do so.

e. All members should maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form.

f. Conflict of interest should be declared by members of the IEC

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The Chairperson will conduct all meetings of the IEC. If for reasons beyond control, the Chairperson is not available, the Deputy Chairperson or an alternate Chairperson will be elected from the members by the members present, who will conduct the meeting. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. All decisions should be taken in meetings and not by circulation of project proposals. Member Secretary will prepare the minutes of the meetings and get it approved by the Chairman before communicating to the researchers with the approval of the appropriate authority.

Application Procedures: Required number of copies of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators / Collaborators should be submitted to the institutional ethics committee.

The date of meeting will be intimated to the researcher, to be present, if necessary to offer clarifications. The decision will be communicated in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period as specified in the communication or before the next meeting. Prescribed fee if any, should be remitted along with the application.

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Documents required:

For a thorough and complete review, all research proposals should be submitted with the following documents:

1. Name of the applicant with designation
2. Name of the Institute/ Hospital / Field area where research will be conducted.
3. Approval of the Head of the Department / Institution
4. Protocol of the proposed research
5. Ethical issues in the study and plans to address these issues.
6. Proposal should be submitted with all relevant enclosures like proforma, case report forms, questionnaires, follow - up cards, etc.
7. Informed consent process, including patient information sheet and informed consent form in local language(s).
8. For any drug / device trial, all relevant pre - clinical animal data and clinical trial data from other centres within the country / countries, if available.
9. Curriculum vitae of all the investigators with relevant publications in last five years.
10. Any regulatory clearances required.
11. Source of funding and financial requirements for the project.
12. Other financial issues including those related to insurance
13. An agreement to report only Serious Adverse Events (SAE) to IEC
14. Statement of conflicts of interest, if any
15. Agreement to comply with the relevant national and applicable international guidelines.
16. A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants; a description of the arrangements for indemnity, if applicable (in study-related injuries); a description of the arrangements for insurance coverage for research participants, if

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applicable; all significant previous decisions (e.g.,those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided.

17. Plans for publication of results — positive or negative while maintaining the privacy and confidentiality of the study participants.

18. Any other information relevant to the study.

Review procedures:

a. The meeting of the IEC should be scheduled at six months intervals. Additional meetings may be held as and when the proposals are received for review.

b. The proposals will be sent to members at least 2 weeks in advance

C. Decisions will be taken by consensus after discussions, and voting will be done whenever needed.

e. Researchers will be invited to offer clarifications if need be.

e. independent consultants/Experts will be invited to offer their opinion on specific research proposals if needed.

f. The decisions will be minuted and Chairperson's approval taken in writing

Element of review

a. Scientific design and conduct of the study.

b. Approval of appropriate scientific review committees

c. Examination of predictable risks/harms

d. Examination of potential benefits

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e. Procedure for selection of subjects in methodology including inclusion/ exclusion, withdrawal criteria and other issues like advertisement details.

g. Management of research related injuries, adverse events

h. Compensation provisions.

h. Justification for placebo in control arm if any

i. Availability of products after the study, if applicable.

j. Patient information sheet and informed consent form in local language.

k. Protection of privacy and confidentiality.

L.Involvement of the community, wherever necessary

m. Plans for data analysis and reporting

n. Adherence to all regulatory requirements and applicable guidelines

o. Competence of investigators, research and supporting staff

p. Facilities and infrastructure of study sites

q. Criteria for withdrawal of patients, suspending or terminating the study

Expedited review

All revised proposals, unless specifically required to go to the main committee, will be examined in a meeting of identified members convened by the Chairman to expedite decision making. Expedited review may also be taken up in cases of nationally relevant proposals requiring urgent review. The nature of the applications, amendments, and other considerations that will be eligible for expedited review should be specified.

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Decision-making

a) Members will discuss the various issues before arriving at a consensus decision.

b) A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises, and this should be indicated to the chairperson prior to the review of the application and recorded in the minutes. Decisions will be made only in meetings where quorum is complete.

c) Only members can make the decision. The expert consultants will only offer their opinions.

d) Decision may be to approve, reject or revise the proposals. Specific suggestions for

modifications and reasons for rejection should be given.

e) In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified.

f) Modified proposals may be reviewed by an expedited review through identified members.

g) Procedures for appeal by the researchers should be clearly defined.

Communicating the decision

a) Decision will be communicated by the Member Secretary in writing

b) Suggestions for modifications, if any, should be sent by IEC

c) Reasons for rejection should be informed to the researchers.

d) The schedule / plan of ongoing review by the IEC should be communicated to the PI.

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Follow up procedures

a) Reports should be submitted to IEC at 6 months intervals for review.
b) Final report should be submitted at the end of study.
c) All SAEs and the interventions undertaken should be intimated.
d) Protocol deviation, if any, should be informed with adequate justifications.
e) Any amendment to the protocol should be resubmitted for renewed approval.
f) Any new information related to the study should be communicated.
g) Premature termination of study should be notified with reasons along with summary of the data obtained till the date of termination.
h) Change of investigators / sites should be informed

Record keeping and Archiving

a) Curriculum Vitae (CV) of all members of IEC.
b) Copy of all study protocols with enclosed documents, progress reports, and SAEs.

   Minutes of all meetings duly signed by the Chairperson.
c) Copy of all existing relevant national and international guidelines on research ethics and laws along with amendments.
d) Copy of all correspondence with members, researchers, and other regulatory bodies.
e) Final report of the approved projects
f) All documents should be archived for prescribed period

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Updating IEC members

a) All relevant new guidelines should be brought to the attention of the members.
b) Members should be encouraged to attend national and international training programs in research ethics for maintaining quality in ethical review and be aware of the latest developments in this area.

Yearly progress of research work is assessed by IEC and necessary action will be taken to prevent any violation in ethical conduct of research. All studies that involve use of animals should follow the rules and ethics that govern such studies. No modifications in the study will be allowed after obtaining the final approval from the Institute Ethics Committee. Required modifications must be explained properly and presented by the Principal Investigator before the Institute Ethics Committee for final approval to make the necessary modifications in the study. After completion of the research work a copy of the report should be submitted to research and publication department. All research conducted in the institution will be the property of the institution. Presentations and publications made based on the research should carry the due credit for the institution and the staff involved in the conduct of the research. All records of the study must be maintained in the department for a period of 5 years.

Department of research and publication periodically conduct scientific programs by eminent researchers in related fields to stimulate research activities among students and faculty. A yearly scientific conclave is conducted for undergraduate students where innovative research ideas are presented by students under the mentorship of faculty members. Best 3 proposals are selected and students as well as mentors are awarded. Institutional funding is allotted for selected projects based on recommendation of research committee. Financial support will be provided after submission of project completion report and statement of expenditure at the end.

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of study. If study takes more than a year yearly progress report also should be submitted to research department. The data obtained from institution funded preliminary research can be utilized for applying extramural funding from various agencies. Faculty and students are encouraged to submit proposal for research funding from external funding agencies. Necessary guidance is provided to those who are interested and notifications regarding call for proposal from various funding agencies like ICMR, KSCTEC, DBT, SERB etc are intimated to students and faculty by the research department.

Students and faculty are encouraged to present their research work at international and national conferences. Financial support is also provided for selected faculty based on the merit of the paper and nature of conference as recommended by research committee.

PUBLICATION POLICY OF THE INSTITUTION

This policy is based on the norms laid by the committee on publication ethics (COPE) which addresses the following areas

1. Ethical approval and trial registration
2. Research misconduct
3. Plagiarism
4. Simultaneous submission
5. Duplicate publication
6. Ethics of authorship
7. Conflict of interest
8. Journal selection

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Guidelines for publications from the institution

Students and faculty are encouraged to publish in good quality journals preferably in journals indexed in SCOPUS, WEB OF SCIENCE OR PUBMED. They should also publish their research work in the form of books or chapters published by reputed InterNational/National publishers with ISSN/ISBN number. Under the research and publication department we have constituted a publication committee for guiding the students as well as faculty in timely publication of their results. All publications from the institution should be submitted to Department of research and publication and permission should be obtained before sending the publication. There are certain rules which should be mandatorily followed. This includes

- Authorship should be provided to those who have contributed genuinely
- Authorship order should be proportional to the contribution of each author
- Obtain consent from each author before sending the article
- Due credit to the institution should be provided in all the publications
- Faculty and students are advised to publish in high impact and indexed journals

The publication committee will scrutinize the article and will provide necessary guidance in selecting the appropriate journal, preparation of draft, analysis of data and clarify any doubts regarding the submission procedure. The institution encourages publishing in high impact and journals indexed in scopus, web of science and medline. Authors are instructed to report the Department of research and publication once the article is accepted for publication.

The institutional journal is regularly published to provide opportunity for faculty and students to showcase their research and clinical work.

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MISCONDUCT IN ACADEMIC RESEARCH

Misconduct in academic research include fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting results of research and deliberate, dangerous or negligent deviations from accepted practice in carrying out research. It includes failure to follow an agreed protocol if this failure results in unreasonable risk or harm to persons, the environment, and when it facilitates misconduct in research by collusion in, or concealment of, such actions by others. Violations of good academic practice can be minor or major. Minor Violations are because of inexperience or lack of knowledge of the principles of academic integrity and are often characterised by the absence of dishonest intent on the part of the person committing the violation. Major violations are breaches of academic integrity that are more serious in nature or that affect a more significant aspect or portion of the academic work compared with minor violations. Any complaint regarding malpractice and plagiarism among researchers of the institution will be enquired by the research committee and necessary actions will be taken without prejudice. The research committee will decide whether the allegation is serious enough to warrant an investigation by the Ethics Committee. If required, the Ethics Committee may carry out a preliminary investigation to ascertain whether there is sufficient substance to the allegation as to warrant a more thorough investigation; a formal inquiry which may include the consultation or involvement of external experts when needed. If disciplinary actions are recommended, the Ethics Committee will communicate to the research committee what action, if any, should be taken as a result of the investigation.

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