3.3.1. The institution ensures implementation of its stated Code of Ethics for research. The implementation of the stated Code of Ethics for research

PRIYADARSHINI
DENTAL COLLEGE AND HOSPITAL

INSTITUTIONAL ETHICAL COMMITTEE
(IEC-PDCH)

STANDARD OPERATING PROCEDURES -2022

Version – 2

Prepared by

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THIRUVALLUR TK & DIST. TAMIL NADU.

INDEX

PRINCIPAL
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THIRUVALLUR TK & DIST. TAMIL NADU.

MEMBERSHIP REQUIREMENTS OF THE ETHICS COMMITTEE

STANDARD OPERATING PROCEDURES

Version No: 1
Date of Implementation: 02-02-2022
Valid Till: 01-02-2025
Doc. No.: IEC-PDCH/SOP 01

Institutional Ethical Committee-Priyadarshini Dental College and Hospital (IEC-PDCH) will be a multidisciplinary and multisectoral body in composition and independent. The number of members of the Review Board may range from 7 to 15. One of the criteria for member selection is adequate representation of age and gender. A next criterion is 50% of the members are affiliated and 50% are non-affiliated. In each meeting, a minimum of five members will be present to meet the quorum requirements. There should be a balance between medical and non-medical members/technical and non-technical members.

In each meeting minimum of five members should be present in the meeting room. In a meeting there should be medical, non-medical or technical or/and non-technical members and at least one non-affiliated member should be a part. Minimum one non-affiliated member should be part of the quorum. The attendance of the lay person is preferable in each quorum. The quorum for reviewing regulatory clinical trials should be in accordance with current CDSCO requirements. No decision is valid without fulfilment of the quorum.

To maintain the independence, the principal is not be part of the ethical committee but he is the highest authority to change the committee member in case of any dispute. The Chairperson and Member Secretary can have dual roles like clinician, legal expert, basic scientist, social scientist. There is a panel of subject experts who will be consulted for their subject expertise. They will attend the meeting if necessary, to give an expert opinion on a specific proposal.

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THIRUVALLUR TK & DIST. TAMIL NADU.

Ethical committee can raise scientific queries besides ethical ones as both good science and ethics are important to ensure quality of research and participant protection.

Composition of Ethical Committee Members' Roles and Responsibilities:

S. No.	Members of EC	Roles and Responsibilities
1	**Chairperson** • Non-affiliated • A well-respected person from any background • Prior experience of having served/serving in an EC	▪ Conduct EC meetings and be accountable for independent and efficient functioning of the committee. ▪ Ensure active participation of all members (particularly non-affiliated, non-medical/ non-technical) in all discussions and deliberations. ▪ Ratify minutes of the previous meetings. ▪ In case of anticipated absence of Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson. ▪ The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting. ▪ Seek COI declaration from members and ensure quorum and fair decision making. Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data,etc.
2	**Member Secretary/ Alternate Member Secretary** (optional) • Affiliated • Should be a staff member of the institution. • Should have knowledge and experience in clinical research and ethics. • Should be able to devote adequate time to this activity which should be protected	▪ Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review ▪ Schedule EC meetings, prepare the agenda and minutes ▪ Organize EC documentation, communication and archiving ▪ Ensure training of EC secretariat and EC members ▪ Ensure SOPs are updated as and when required ▪ Ensure adherence of EC functioning to the SOPs ▪ Prepare for and respond to audits and inspections ▪ Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review. ▪ Assess the need for expedited review/ exemption from review or full review.

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PANDUR - 631 203.
THIRUVALLUR TK & DIST. TAMIL NADU.

	by the institution.	▪ Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives.
3	**Basic Medical Scientist(s)** • Affiliated/ non-affiliated. • Non-medical or medical person with qualifications in basic medical sciences. • In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist.	▪ Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report. ▪ For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.
4	**Clinician** • Affiliated/ non-affiliated • Should be individual/s with recognized medical qualification, expertise and training.	▪ Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics. ▪ Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report). ▪ Review medical care, facility and appropriateness of the principal investigator, provision for medical car, management and compensation. ▪ Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
5	**Legal expert** • Affiliated/ non-affiliated. • Should have a basic degree in Law from a recognized university, with experience.	▪ 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, such as, stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines etc. ▪ Interpret and inform EC members about new regulations, if there is.
	Social scientist/ philosopher/ ethicist/theologian	▪ Ethical review of the proposal, ICD along with the translations.

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PANDUR - 631 203.
THIRUVALLUR TK & DIST. TAMIL NADU.

	• Affiliated/ non-affiliated • Should be an individual with social/behavioural science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health-related activities.	▪ Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any. ▪ Serve as a patient/participant/ societal /community representative and bring in ethical and societal concerns.
	Lay person(s) • Non-affiliated • Literate person from the public or community. • Has not pursued a medical science/ health related career in the last 5 years • May be a representative of the community from which the participants are to be drawn • Is aware of the local language, cultural and moral values of the community.	▪ Ethical review of the proposal, ICD along with translation(s). ▪ Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks. ▪ Serve as a patient/participant/ community representative and bring in ethical and societal concerns. ▪ Assess on societal aspects if any.

The chairperson of the IEC shall be from outside the Institution to maintain the independence of the Committee.

The Member Secretary belongs to PDCH and will conduct the business of the Committee.

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PANDUR - 631 203.
THIRUVALLUR TK & DIST. TAMIL NADU.

Other members will be a mix from dental/ medical /non-medical, legal, scientific and non-scientific persons and may also include members of public to reflect the different point of view.

There will be representation of age and gender in the Committee to safeguard the interest and welfare of all sections of the society.

Member will be aware of local, social and cultural norms, as this is an important social control mechanism.

IEC may invite subject experts to take their views, whenever it is needed.

IEC members will be appointed by the Principal of Priyadarshini Dental College and Hospital based on their competencies and integrity and will be drawn from any public or private institute from the country.

The IEC-PDCH comprised of:

1) Chairperson
2) Four persons from basic medical science area (One pharmacologist compulsorily) of PDCH and Indira Medical College and Hospital
3) One clinician from Indira Medical College and Hospital
4) One legal expert
5) One representative from non-governmental voluntary agency
6) One lay person from the community
7) Member Secretary – Nominated from senior faculty member of PDCH
8) Scientific members.

All members will serve for a period of 3 years. At the end of the tenure, the committee will be reconstituted and 50% of the members will be replaced by a defined procedure. New members will be Included in the IEC in such a way that there will be a mix of recently included members and members with some years of experience.

During the term, the Head of the Institution in consultation with the Chairperson can disqualify any member if, the contribution is not adequate and/or there is long period of absence / non availability or in case of death of a member.

PRIYADARSHINI DENTAL COLLEGE & HOSPITAL,
PANDUR - 631 203.
THIRUVALLUR TK & DIST. TAMIL NADU.

A member can tender resignation of his office of membership from the IEC to the Head of the institute through the Chairperson after serving one month advance notice. Each member is required to sign the declaration and confidentiality agreement regarding IEC activities.

Conflict of interest should be declared by members of the IEC-PDCH prior to review meeting.

PRINCIPAL
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PANDUR - 631 203.
THIRUVALLUR TK & DIST. TAMIL NADU

TERMS OF REFERENCE OF THE COMMITTEE

Version No: 1
Date of Implementation: 02-02-2022
Valid Till: 01-02-2025
Doc. No.: IEC-PDCH/SOP 02

The Institutional Ethical Committee- Priyadarshini Dental College and Hospital (IEC-PDCH) will review all types of research proposals involving human participants, human tissues, and case record-based studies with a view to safeguard the dignity, rights, safety and well-being of all actual and potential research participants before approving the research proposals. The goals of research, however important, should never be permitted to override the health and well-being of the research subjects.

The IEC-PDCH will ascertain whether all the cardinal principles of research ethics are autonomy, beneficence, non – maleficence, respect for free and informed consent, respect for human dignity, respect for vulnerable persons, respect for privacy, confidentiality and justice are taken care of in planning, conducting and reporting of the proposed research. For this purpose, IEC-PDCH will look into the aspects of protocol review, selection of participants, voluntary participation of potential participants, informed consent process, risk benefit ratio, distribution of burden and benefit, maintenance of privacy and confidentiality and provisions for appropriate compensations.

IEC-PDCH will review the proposals before the commencement of the study as well as review periodically until the completion of the study through appropriate well documented procedures. Such a review may be based on the

PRINCIPAL
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PANDUR - 631 203.
THIRUVALLUR TK & DIST. TAMIL NADU.

periodic study progress reports furnished by the investigators and/or monitoring and internal audit reports furnished by the Sponsor and/or by visiting the study sites. The mandate of the IEC shall be to review all research projects to be conducted at the Institution involving human beings directly or indirectly, irrespective of the funding agency.

IEC-PDCH will provide advice to the researchers on all aspects of the welfare and safety of the research participants after ensuring the scientific soundness of the proposed research through appropriate Scientific Review Committee/ Research Committee. In case an ethics committee revokes its approval accorded to a trial protocol, it will record the reasons for doing so and at once communicate such a decision to the Investigator.

IEC Secretariat co-ordinate the activities of writing, reviewing, distributing and amending SOP's, maintain file on all current SOPs and past SOPs, ensure that all the IEC members and involved staff have access to the SOPs and working according to current version of SOPs. Chairperson / Member Secretary will appoint the coordinating staff to assist IEC functions. Member Secretary shall vote in IEC decisions but coordinating staff of IEC can't vote in any decision, while making procedure of the IEC.

Chairperson of IEC will appoint the SOP team to formulate the SOPs - consisting of Member Secretary, one / more members of IEC and coordinating staff. Chairperson will approve the SOPs with sign and date. Coordinating staff of IEC will maintain file on all current SOPs and the list of SOPs, maintain an up-to-date distribution list for each SOP distributed, maintain the SOPs with a receipt of all users, maintain file of all past SOPs of IEC, assist in the

PRINCIPAL
PRIYADARSHINI DENTAL COLLEGE & HOSPITAL,
PANDUR - 631 203.
THIRUVALLUR TK & DIST. TAMIL NADU

formulation of SOPs and assist Member Secretary. IEC members will sign and date the acknowledgement form when they would receive approved SOP, assist in all decision-making procedure of IEC and assist secretariat for any help in management.

IEC-PDCH may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities, patient groups or special interest groups. They will be required to give their specialized views but should not take part in the decision making process which will be made by the members of the IEC-PDCH.

Application procedures:

All proposals should be submitted on any working day 1 week in advance of scheduled meeting in the prescribed application form.

All relevant documents should be enclosed with application form.

Eight copies of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators / Collaborators / Research Scholars shall be submitted to the Chairperson IEC-PDCH, through member secretary. In his absence, vice-chairperson shall be taking care of chairperson duty.

Receipt of the application will be acknowledged by the IEC office.

Every application will be allotted an IEC registration number to be used for all future correspondence and reference.

The date of IEC meeting will be intimated to the Principal Investigator to attend the meeting and to make a brief presentation of the proposal and to clarify the points raised by the members.

PRINCIPAL
PRIYADARSHINI DENTAL COLLEGE & HOSPITAL,
PANDUR - 631 203.
THIRUVALLUR TK & DIST. TAMIL NADU.

The decision of the committee on the proposal will be communicated in writing or in email.

If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting.

Placing the proposal before the Ethics Committee Meeting:

After the incorporation of the comments in the protocol done by the Principal Investigator and the protocol is made presentable for the meeting with respect to technical and scientific aspects, the Principal Investigators are asked to submit the protocol files for the circulation to the members at least one week before the meeting.

The Protocol will be sent to the Members as per the agenda of the meeting.

The English and Tamil versions (If any other language as per the protocol) of the Participant Information Sheet and Informed consent documents will also be sent to all the Members.

Principal investigator (PI) will be invited to present the protocol and all IEC members will deliberate and provide inputs/suggestions if any.

Review procedures:

The meeting of the IEC-PDCH will be held on 3-4 times a year at periodic intervals. Additional review meetings can also be held with short notice as and when required. Meetings will be planned in accordance with the need of the work load. The proposals should be sent to the IEC-PDCH at least 1 week in advance of schedule meeting.

The IEC's member-secretary or secretariat shall 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 review (explanation is given below).

Decisions will be taken by consensus after discussion, and whenever needed voting will be done. Decision of chairperson will be final. Researchers will be invited to offer clarifications if need be. The Principal investigator / Research Scholar will then present the proposal in person in the meeting. When the PI is not available due to unavoidable reasons the Co PI will present the proposal. Independent consultants/experts will be invited to offer their opinion on specific research proposals if needed. The decisions will be recorded under minutes of the meeting and Chairperson's approval taken in writing.

Exemption from review:

Proposals which present less than minimal risk fall under this category as may be seen in following situations:

(a) Research on educational practices such as instructional strategies or effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(b) Systematic reviews and meta-analysis.

Exceptions:

a) When research on use of educational tests, survey or interview procedures, or observation of public behaviour can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or psychosocial harm.

b) When interviews involve direct approach or access to private papers.

c) In-vitro experiments not involving human tissues.

PRINCIPAL
PRIYADARSHINI DENTAL COLLEGE & HOSPITAL,
PANDUR - 631 203.
THIRUVALLUR TK & DIST. TAMIL NADU

Expedited Review: The proposals presenting no more than minimal risk to research participants may be subjected to expedited review. The Member-Secretary and the Chairperson of the IEC or designated member of the Committee or Subcommittee of the IEC may do expedited review only if the protocols involve:

1. If any minor deviations are to be done in the originally approved research, during the approved period of study.
2. Revised proposal previously approved through full review by the IEC or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis.
3. Research activities that involve only procedures listed in one or more of the following categories: a. In vitro / lab-based research projects.
4. Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes.
5. When in emergency situations like serious outbreaks or disasters a full review of the research is not possible, prior written permission of IEC may be taken before use of the test intervention. Such research can only be approved for pilot study or preliminary work to study the safety and efficacy of the intervention and the same participants should not be included in the clinical trial that may be initiated later based on the findings of the pilot study. A disaster is the sudden occurrence of a calamitous event at any time resulting in substantial material damage, affecting persons, society, community or state(s). It may be periodic, caused by both nature and humans and creates an imbalance between the capacity and resources of the society and the needs of the survivors or the

PRINCIPAL
PRIYADARSHINI DENTAL COLLEGE & HOSPITAL,
PANDUR - 631 203.
THIRUVALLUR TK & DIST. TAMIL NADU

people whose lives are threatened, over a given period of time. It may also be unethical sometimes not to do research in such circumstances.

6. Expedited review may also be taken up in cases of nationally relevant proposals requiring urgent review.

Full Review

All researches presenting with more than minimal risk, proposals/ protocols which do not qualify for exempted or expedited review and projects that involve vulnerable population and special groups shall be subjected to full review by all the members.

While reviewing the proposals, the following situations may be carefully assessed against the existing facilities at the research site for risk/benefit analysis:

- Collection of blood samples by finger prick, heel prick, ear prick, or veni puncture:

a. From healthy adults and non-pregnant women who weigh normal for their age and not more than 500 ml blood is drawn in an 8-week period and frequency of collection is not more than 2 times per week;

b. From other adults and children, where the age, weight, and health of the participants is not normal, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected has been considered and not more than 50 ml or 3 ml per kg, whichever is lesser is drawn in an 8-week period and not more than 2 times per week.

- Prospective collection of biological specimens for research purposes by non-invasive means. For instance:

PRINCIPAL
PRIYADARSHINI DENTAL COLLEGE & HOSPITAL,
PANDUR - 631 203.
THIRUVALLUR TK & DIST. TAMIL NADU

1. Skin appendages like hair and nail clippings in a non-disfiguring manner
2. Dental procedures - deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction of permanent teeth; supra and sub-gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth
3. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum or by applying a dilute citric solution to the tongue
4. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings

• Collections of data from non-invasive procedures are routinely employed in clinical practice. Where medical devices are employed, they must be cleared/ approved for marketing, for instance:

1. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy
2. Magnetic resonance imaging; Use of CBCT, IOPA, OPG.

• Research involving clinical materials (data, documents, records, or specimens) will be collected solely for non-research (clinical) purposes.

• Collection of data from voice, video, digital, or image recordings made for research purposes. 7.3. Elements of review of proposals All clinical trials, bioequivalence, bioavailability, biomedical and health research and academic

research study proposals are to be submitted to the Member Secretary of the IEC, PDCH in the prescribed Application format along with checklist and detailed study protocol at least one week in advance (especially for all clinical trials). The investigator shall submit their research study proposals for ethical review as per the checklist in the prescribed format.

List of documents to be submitted include:

1. Scientific design and conduct of the study.
2. Approval by appropriate scientific review committees / Research committee. 3. Examination of predictable risks/harms
4. Examination of potential benefits.
5. Procedure for selection of subjects including inclusion / exclusion, withdrawal criteria and other issues like advertisement details.
6. Management of research related injuries, adverse events.
7. Compensation provisions.
8. Justification for placebo in control arm, if any
9. Availability of products, benefits to subjects after the study is completed if applicable.
10. Patient information sheet, informed consent form in English and in local languages.
11. Protection of privacy and confidentiality.
12. Involvement of the community, wherever necessary
13. Plans for data analysis and reporting.
14. Adherence to all regulatory requirements and applicable guidelines.
15. Competence of investigators, research and supporting staff.
16. Facilities and infrastructure of study sites.
17. Criteria for withdrawal of patients, suspending or premature termination of the study.

PRINCIPAL
PRIYADARSHINI DENTAL COLLEGE & HOSPITAL,
PANDUR - 631 203.
THIRUVALLUR TK & DIST. TAMIL NADU.

18. Funding of the project.

Decision-making:

1. Members will discuss the various issues before arriving at a consensus decision. When consensus is not arrived at, the decision will be made by voting procedure.
2. 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.
3. Decision will be made only in meetings where quorum is complete.
4. Only member can make the decision. The expert consultants will only offer their opinions.
5. Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for modifications and reasons for rejection will be given.
6. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application revised will be specified.
7. Modified proposals will be reviewed by an expedited review through identified members. Procedures for appeal by the researchers will be clearly defined.

Communicating Decision of the meeting

Communicating decision of the meeting on the proposals will be communicated by the Member Secretary in writing / email to the PI / Research Scholar within 10 working days after the meeting at which the decision was taken in the specified format. A certificate of approval will be sent to the applicant within 3

weeks. All the approvals will be valid for one year or for the duration of the project whichever is less. Investigator has to get his or her project re-approved after one year if necessary.

The communication of the decision will include:

a. Name and address of IEC.

b. The date, place and time of decision.

c. The name and designation of the applicant.

d. Title of the research proposal reviewed.

e. The clear identification of registration no. and date.

f. Along with protocol, other documents reviewed

g. List of EC members who attended the meeting

h. A clear statement of decision reached.

i. Any advice by the IEC to the applicant including the schedule / plan of on-going review by the IEC-PDCH.

j. In case of conditional decision, any requirement by IEC, including suggestions for revision, and the procedure for having the application re-reviewed.

k. In case of rejection of the proposal, reason(s) for the rejection will be clearly stated by the member secretary with signature and date.

Conveying decision regarding Study Protocol:

The IEC members will discuss and clarify the comments and suggestions. The Member secretary shall record the discussions and minute it. The decision on the protocol as:

i) Approved

ii) Approved with suggestions/Conditional

iii) Minor modification/Amendments

PRINCIPAL
PRIYADARSHINI DENTAL COLLEGE & HOSPITAL,
PANDUR - 631 203.
THIRUVALLUR TK & DIST. TAMIL NADU

iv) Major Modification for full board review

v) Disapproved

Member(s) of the committee who is/are listed as investigator(s) on a research proposal and having conflict of interest shall declare conflict of interest and will not vote on the proposal and will opt out from all deliberations on the proposal by leaving the meeting room. An investigator or study team member invited for the meeting will not vote or participate in the decision making procedures of the committee. An independent consultant invited for the meeting to provide opinion will not vote or participate in the decision making procedures of the committee. If the IEC decision is 'Approved', without implies the approval of the study as it is presented with no modifications and the study can be initiated. If the IEC Decision is approved with suggestions/Conditional, it implies that the study can be initiated only after PI responses is reviewed and approved by member secretary of IEC. If the IEC decision is minor modification, it implies that the Approval is given after receiving supportive documents/Clarifications and Examination by member secretary or expedited review of the case may be. If the IEC decision is major modification for full board, it implies the PI should resubmit with the major modification for reconsideration of proposal by full board review. If the IEC decision disapproves, the committee should give reasons for the same and the Principal Investigator should submit justification for the reasons. If the study is approved, the IEC will determine the frequency of continuing review from each investigator. Usually, approval is given for one year. The Secretariat will list participating members in the meeting and summarize the guidance, advice and decision reached by the IEC members. Final communication of the Ethics Committee decision taken on the protocol will be communicated to the Principal Investigator.

PRINCIPAL
PRIYADARSHINI DENTAL COLLEGE & HOSPITAL,
PANDUR - 631 203.
THIRUVALLUR TK & DIST. TAMIL NADU

Approval Letter:

The Secretariat will prepare an approval letter to be sent to the Principal Investigator when the protocol is approved at an Ethics Committee meeting. The letter will be dated and will contain: ID no. / Proposal title, Date and Name of the PI. The Chairperson or the Member Secretary will sign the approval letter and the Secretariat will send it to the Principal Investigator.

Following up procedures for approved proposals by PI / Sponsor:

1. IEC will review the progress of all the studies for which a positive decision has been reached from the time of decision till the termination of the research.
2. Progress of all the research proposals will be followed at a regular interval of thrice a year. But in special situations, IEC will conduct the follow up review at shorter intervals basing on the need, nature and events of research project.
3. Periodic status report of study should be submitted at prescribed intervals for review, along with information and documents based on the safety concerns and this prescribed interval should be specified in the Letter of Communication of Decision to the PI from the IEC.
4. Final report should be submitted at the end of study.
5. Following instances and events will require the follow-up review/ Renewed Approval:

    a. Any protocol amendment likely to affect rights, safety or well-being of research subject of conduct of study.

PRINCIPAL
PRIYADARSHINI DENTAL COLLEGE & HOSPITAL,
PANDUR - 631 203.
THIRUVALLUR TK & DIST. TAMIL NADU

b. Serious or unexpected adverse reaction related to study or product, action taken by Investigator, Sponsor and Regulatory Authority should be informed within 24 hours.

c. Any event or information that may affect the benefit/risk ratio of the study.

6. Protocol deviation, if any, should be informed with adequate justifications.

7. Any new information related to the study should be communicated.

8. Premature termination of study shall be notified with reasons along with summary of the data obtained so far within 3 weeks.

9. Change of investigators/sites must be informed to the office of IEC.

10. Monitoring: Oversight mechanism will be in place to monitor the approved studies. Actual site visits can be made especially in the event of reporting of adverse events or violations of human rights and appropriate action will be taken when required and communicated to the applicant indicating modification/suspension/termination /continuation of the project

11. Applicant must inform the time of completion of study and must send the result summary to IEC. IEC must receive a copy of final summary of study completed from the applicant.

Responsibilities of Sponsor/Investigator

(1) The Investigator(s) shall be responsible for the conduct of the trial according to the protocol and the GCP Guidelines and also for compliance as per the undertaking given in Appendix VII of schedule Y. Standard operating procedures are required to be documented by the investigators for the tasks performed by them. During and following a subject's participation in a trial, the

PRINCIPAL
PRIYADARSHINI DENTAL COLLEGE & HOSPITAL,
PANDUR - 631 203.
THIRUVALLUR TK & DIST. TAMIL NADU

investigator should ensure that adequate medical care is provided to the participant for any adverse events. Investigator(s) shall report all serious and unexpected adverse events to the Licensing Authority defined under clause (B) of rule 21 (Schedule Y and Gazette notification 30th January 2013), the sponsor or his representative, whosoever had obtained permission form the licensing authority for conduct of the clinical trial, and the ethics committee that accorded approval to the study protocol, within twenty four hours of their occurrence. The report of the serious adverse event of death, after due analysis shall be forwarded by the investigator to Chairperson of the ethics committee and Chairperson of the Expert Committee constituted by the Licensing authority under Appendix XII with a copy of the report to the Licensing Authority and the head of the institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event of death. The report of the serious adverse event other than death, after due analysis shall be forwarded to the Licensing Authority, Chairman of the Ethics Committee and the Head of the Institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event.

(2) The investigator shall provide information to the clinical trial subject through informed consent process as provided in Appendix V of Schedule Y about the essential elements of the clinical trial and the subject's right to claim compensation in case of trial related injury or death. He shall also inform the subject or His/ Her nominee(s) of their rights to contact the sponsor or his representative whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial for the purpose of making claims in the case of trial related injury or death.

Updating IEC-PDCH members:

1. All relevant new guidelines should be brought to the attention of the members.

2. The EC members should be encouraged to keep abreast of all national and international developments in ethics through orientation courses on related topics by its own members or regular training organized by constituted body/ (i.e.), so that they become aware of their role and responsibilities. For drug trial review it is preferable to train the IEC members in Good Clinical Practice. Any change in the regulatory requirements should be brought to their attention and they should be aware of local, social and cultural norms, as this is the most important social control mechanism. This is needed for maintaining quality in ethical review.

Administration and Management

A full-time secretariat and space for keeping records is required for a well-functioning IEC. The members could be given a reasonable compensation for the time spared for reviewing the proposals. Reasonable fees can be charged to cover the expenses related to review and administrative processes for any third party (protocols submitted by researchers not employed by PDCH) submission as described in section XI Point No 6. There should be provision for allocating reasonable amount of funds for smooth functioning of the IEC.

CONDITIONS OF APPOINTMENT AND THE QUORUM REQUIRED

Version No: 1
Date of Implementation: 02-02-2022
Valid Till: 01-02-2025
Doc. No.: IEC-PDCH/SOP 03

CONDITIONS OF APPOINTMENT

Institutional Ethical Committee of Priyadarshini Dental College and Hospital has following conditions of appointment for ethical committee members.

Every ethical committee member

1. must provide a recent signed CV and training certificates on human research protection and good clinical practice (GCP) guidelines, if applicable;
2. 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);
3. be willing to undergo training or update their skills/knowledge during their tenure as an EC member;
4. be aware of relevant guidelines and regulations;
5. read, understand, accept and follow the COI policy of the EC and declare it, if applicable, at the appropriate time;
6. sign a confidentiality and conflict of interest agreement/s;
7. be willing to place her/his full name, profession and affiliation to the EC in the public domain; and
8. be committed and understanding to the need for research and for imparting protection to research participants in research.

The Principal of Priyadarshini Dental College and Hospital will appoint all IEC members including the Chairperson with the above conditions of appointment.

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Quorum Requirement

Institutional Ethical Committee of Priyadarshini Dental College and Hospital will meet three to four times a year or as and when required with the following Quorum requirements for ethical committee.

1. A minimum of five members present in the meeting room.
   -Basic medical scientists (preferably one pharmacologist).
   -Clinicians
   -Legal expert
   -Social scientist / representative of non-governmental voluntary agency /philosopher / ethicist / theologian or a similar person
   -Lay person from the community.
2. Minimum one non-affiliated member should be part of the quorum.
3. The quorum for reviewing regulatory clinical trials should be in accordance with current CDSCO requirements.
4. No decision is valid without fulfilment of the quorum.

Minimum of 50% of committee strength + 1 member and not less than 5 members will be required to compose a quorum for the meeting of which at least
one member will be from outside the institution, and one member will be a non-scientific member & one from apposite gender. All decisions will be taken in meetings and not by circulation of project proposals.

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PROCEDURE FOR RESIGNATION, REPLACEMENT OR REMOVAL OF MEMBERS

Version No: 1
Date of implementation: 02-02-2022
Valid till: 01-02-2025
Doc. No.: IEC-PDCH/SOP 04

Resignation Procedure

If any member wishes to discontinue from the EC, he/she would be required to inform the Chairperson, in writing.

Members may voluntarily resign from the committee at a month's notice citing appropriate reasons.

In-case of internal members, their membership would be considered withdrawn, if they resign from the Institute.

Procedure for Replacement or Removal of Members

During the tenure, Chairperson shall have the authority to terminate/ disqualify any of the members in the event that the member has not complied with the conditions of appointment, is absent without prior information for three consecutive meetings or on an occurrence of any event that casts a serious doubt on the integrity or ethics of the member.

In all such situations/ circumstances, the Head of Institute shall be informed of such termination to the member prior or within 15 calendar days of termination.

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Documentation of the termination shall be recorded in the minutes of the next duly constituted EC meeting and the EC membership roster and circulars shall be revised.

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THE STANDARD OPERATING PROCEDURETO BE FOLLOWED BY THE COMMITTEE IN GENERAL

Version No: 1

Date of Implementation: 02-02-2022

Valid Till: 01-02-2025

Doc. No.: IEC-PDCH/SOP 05

Institutional Ethical Committee-Priyadarshini Dental College and Hospital (IEC-PDCH) will be a multidisciplinary and multisectoral body in composition and independent. The number of members of the Review Board may range from 7 to 15.

The chairperson of the IEC shall be from outside the Institution to maintain the independence of the Committee.

The Member Secretary belongs to PDCH and will conduct the business of the Committee.

Other members will be a mix from dental/ medical /non-medical, legal, scientific and non-scientific persons and may also include members of public to reflect the different point of view. There will be representation of age and gender in the Committee to safeguard the interest and welfare of all sections of the society.

Member will be aware of local, social and cultural norms, as this is an important social control mechanism. IEC may invite subject experts to take their views, whenever it is needed.

IEC members will be appointed by the Principal of Priyadarshini Dental College and Hospital based on their competencies and integrity and will be drawn from any public or private institute from the country.

The IEC-PDCH comprised of:

1) Chairperson

2) Four persons from basic medical science area (One pharmacologist compulsorily) of PDCH and Indira Medical College and Hospital

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3) One clinician from Indira Medical College and Hospital

4) One legal expert

5) One representative from non-governmental voluntary agency

6) One lay person from the community

7) Member Secretary – Nominated from senior faculty member of PDCH

8) Scientific members.

All members will serve for a period of 3 years. At the end of the tenure, the committee will be reconstituted and 50% of the members will be replaced by a defined procedure. New members will be Included in the IEC in such a way that there will be a mix of recently included members and members with some years of experience.

During the term, the Head of the Institution in consultation with the Chairperson can disqualify any member if, the contribution is not adequate and/or there is long period of absence / non availability or in case of death of a member.

A member can tender resignation of his office of membership from the IEC to the Head of the institute through the Chairperson after serving one month advance notice.

Each member is required to sign the declaration and confidentiality agreement regarding IEC activities.

Conflict of interest should be declared by members of the IEC-PDCH prior to review meeting.

The Institutional Ethical Committee- Priyadarshini Dental College and Hospital (IEC-PDCH) will review all types of research proposals involving human participants, human tissues, and case record-based studies with a view to safeguard the dignity, rights, safety and well-being of all actual and potential research participants before approving the research proposals. The goals of research, however important, should never be permitted to override the health and well-being of the research subjects.

The IEC-PDCH will ascertain whether all the cardinal principles of research ethics are autonomy, beneficence, non – maleficence, respect for free and informed consent, respect for human dignity, respect for vulnerable persons, respect for privacy, confidentiality and justice

are taken care of in planning, conducting and reporting of the proposed research. For this purpose, IEC-PDCH will look into the aspects of protocol review, selection of participants, voluntary participation of potential participants, informed consent process, risk benefit ratio, distribution of burden and benefit, maintenance of privacy and confidentiality and provisions for appropriate compensations.

IEC-PDCH will review the proposals before the commencement of the study as well as review periodically until the completion of the study through appropriate well documented procedures. Such a review may be based on the periodic study progress reports furnished by the investigators and/or monitoring and internal audit reports furnished by the Sponsor and/or by visiting the study sites. The mandate of the IEC shall be to review all research projects to be conducted at the Institution involving human beings directly or indirectly, irrespective of the funding agency. IEC-PDCH will provide advice to the researchers on all aspects of the welfare and safety of the research participants after ensuring the scientific soundness of the proposed research through appropriate Scientific Review Committee/ Research Committee. In case an ethics committee revokes its approval accorded to a trial protocol, it will record the reasons for doing so and at once communicate such a decision to the Investigator.

IEC Secretariat co-ordinate the activities of writing, reviewing, distributing and amending SOP's, maintain file on all current SOPs and past SOPs, ensure that all the IEC members and involved staff have access to the SOPs and working according to current version of SOPs. Chairperson / Member Secretary will appoint the coordinating staff to assist IEC functions. Member Secretary shall vote in IEC decisions but coordinating staff of IEC can't vote in any decision, while making procedure of the IEC.

Chairperson of IEC will appoint the SOP team to formulate the SOPs - consisting of Member Secretary, one / more members of IEC and coordinating staff. Chairperson will approve the SOPs with sign and date. Coordinating staff of IEC will maintain file on all current SOPs and the list of SOPs, maintain an up-to-date distribution list for each SOP distributed, maintain the SOPs with a receipt of all users, maintain file of all past SOPs of IEC, assist in the formulation of SOPs and assist Member Secretary. IEC members will sign and date the

acknowledgement form when they would receive approved SOP, assist in all decision-making procedure of IEC and assist secretariat for any help in management.

IEC-PDCH may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities, patient groups or special interest groups. They will be required to give their specialized views but should not take part in the decision making process which will be made by the members of the IEC-PDCH.

Application procedures:

All proposals should be submitted on any working day 1 week in advance of scheduled meeting in the prescribed application form. All relevant documents should be enclosed with application form.

Eight copies of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators / Collaborators / Research Scholars shall be submitted to the Chairperson IEC-PDCH, through member secretary. In his absence, vice-chairperson shall be taking care of chairperson duty.

Receipt of the application will be acknowledged by the IEC office.

Every application will be allotted an IEC registration number to be used for all future correspondence and reference.

The date of IEC meeting will be intimated to the Principal Investigator to attend the meeting and to make a brief presentation of the proposal and to clarify the points raised by the members.

The decision of the committee on the proposal will be communicated in writing or in email.

If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting.

Placing the proposal before the Ethics Committee Meeting:

After the incorporation of the comments in the protocol done by the Principal Investigator and the protocol is made presentable for the meeting with respect to technical and scientific

aspects, the Principal Investigators are asked to submit the protocol files for the circulation to the members at least one week before the meeting.

The Protocol will be sent to the Members as per the agenda of the meeting.

The English and Tamil versions (If any other language as per the protocol) of the Participant Information Sheet and Informed consent documents will also be sent to all the Members.

Principal investigator (PI) will be invited to present the protocol and all IEC members will deliberate and provide inputs/suggestions if any.

Review procedures:

The meeting of the IEC-PDCH will be held on 3-4 times a year at periodic intervals. Additional review meetings can also be held with short notice as and when required. Meetings will be planned in accordance with the need of the work load. The proposals should be sent to the IEC-PDCH at least 1 week in advance of schedule meeting.

The IEC's member-secretary or secretariat shall 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 review (explanation is given below).

Decisions will be taken by consensus after discussion, and whenever needed voting will be done. Decision of chairperson will be final. Researchers will be invited to offer clarifications if need be. The Principal investigator / Research Scholar will then present the proposal in person in the meeting. When the PI is not available due to unavoidable reasons the Co PI will present the proposal.

Independent consultants/experts will be invited to offer their opinion on specific research proposals if needed. The decisions will be recorded under minutes of the meeting and Chairperson's approval taken in writing.

Exemption from review:

Proposals which present less than minimal risk fall under this category as may be seen in following situations:

(a) Research on educational practices such as instructional strategies or effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(b) Systematic reviews and meta-analysis.

Exceptions:

a) When research on use of educational tests, survey or interview procedures, or observation of public behaviour can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or psychosocial harm.

b) When interviews involve direct approach or access to private papers.

c) In-vitro experiments not involving human tissues.

Expedited Review: The proposals presenting no more than minimal risk to research participants may be subjected to expedited review.

The Member- Secretary and the Chairperson of the IEC or designated member of the Committee or Subcommittee of the IEC may do expedited review only if the protocols involve:

1. If any minor deviations are to be done in the originally approved research, during the approved period of study.
2. Revised proposal previously approved through full review by the IEC or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis.
3. Research activities that involve only procedures listed in one or more of the following categories: a. In vitro / lab-based research projects.
4. Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes.
5. When in emergency situations like serious outbreaks or disasters a full review of the research is not possible, prior written permission of IEC may be taken before use of the test intervention. Such research can only be approved for pilot study or preliminary work to study the safety and efficacy of the intervention and the same participants should not be included in the clinical trial that may be initiated later based on the findings of the pilot study. A disaster is the sudden occurrence of a calamitous

event at any time resulting in substantial material damage, affecting persons, society, community or state(s). It may be periodic, caused by both nature and humans and creates an imbalance between the capacity and resources of the society and the needs of the survivors or the people whose lives are threatened, over a given period of time. It may also be unethical sometimes not to do research in such circumstances.

6. Expedited review may also be taken up in cases of nationally relevant proposals requiring urgent review.

Full Review

All researches presenting with more than minimal risk, proposals/ protocols which do not qualify for exempted or expedited review and projects that involve vulnerable population and special groups shall be subjected to full review by all the members.

While reviewing the proposals, the following situations may be carefully assessed against the existing facilities at the research site for risk/benefit analysis:

- Collection of blood samples by finger prick, heel prick, ear prick, or veni puncture:

a. From healthy adults and non-pregnant women who weigh normal for their age and not more than 500 ml blood is drawn in an 8-week period and frequency of collection is not more than 2 times per week;

b. From other adults and children, where the age, weight, and health of the participants is not normal, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected has been considered and not more than 50 ml or 3 ml per kg, whichever is lesser is drawn in an 8-week period and not more than 2 times per week.

- Prospective collection of biological specimens for research purposes by non-invasive means.

For instance:

1. Skin appendages like hair and nail clippings in a non-disfiguring manner

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THIRUVALLUR TK & DIST. TAMIL NADU

2. Dental procedures - deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction of permanent teeth; supra and sub-gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth

3. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum or by applying a dilute citric solution to the tongue

4. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings

• Collections of data from non-invasive procedures are routinely employed in clinical practice. Where medical devices are employed, they must be cleared/ approved for marketing, for instance:

1. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy

2. Magnetic resonance imaging; Use of CBCT, IOPA, OPG.

• Research involving clinical materials (data, documents, records, or specimens) will be collected solely for non-research (clinical) purposes.

• Collection of data from voice, video, digital, or image recordings made for research purposes. 7.3. Elements of review of proposals All clinical trials, bioequivalence, bioavailability, biomedical and health research and academic research study proposals are to be submitted to the Member Secretary of the IEC, PDCH in the prescribed Application format along with checklist and detailed study protocol at least one week in advance (especially for all clinical trials). The investigator shall submit their research study proposals for ethical review as per the checklist in the prescribed format.

List of documents to be submitted include:

1. Scientific design and conduct of the study.

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PANDUR - 631 203.
THIRUVALLUR TK & DIST. TAMIL NADU

2. Approval by appropriate scientific review committees / Research committee. 3. Examination of predictable risks/harms

4. Examination of potential benefits.

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

6. Management of research related injuries, adverse events.

7. Compensation provisions.

8. Justification for placebo in control arm, if any

9. Availability of products, benefits to subjects after the study is completed if applicable.

10. Patient information sheet, informed consent form in English and in local languages.

11. Protection of privacy and confidentiality.

12. Involvement of the community, wherever necessary

13. Plans for data analysis and reporting.

14. Adherence to all regulatory requirements and applicable guidelines.

15. Competence of investigators, research and supporting staff.

16. Facilities and infrastructure of study sites.

17. Criteria for withdrawal of patients, suspending or premature termination of the study.

18. Funding of the project.

Decision-making:

1. Members will discuss the various issues before arriving at a consensus decision. When consensus is not arrived at, the decision will be made by voting procedure.

2. 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.

3. Decision will be made only in meetings where quorum is complete.

4. Only member can make the decision. The expert consultants will only offer their opinions.

5. Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for modifications and reasons for rejection will be given.
6. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application revised will be specified.
7. Modified proposals will be reviewed by an expedited review through identified members. Procedures for appeal by the researchers will be clearly defined.

Communicating Decision of the meeting

Communicating decision of the meeting on the proposals will be communicated by the Member Secretary in writing / email to the PI / Research Scholar within 10 working days after the meeting at which the decision was taken in the specified format. A certificate of approval will be sent to the applicant within 3 weeks. All the approvals will be valid for one year or for the duration of the project whichever is less. Investigator has to get his or her project re-approved after one year if necessary.

The communication of the decision will include:

a. Name and address of IEC.
b. The date, place and time of decision.
c. The name and designation of the applicant.
d. Title of the research proposal reviewed.
e. The clear identification of registration no. and date.
f. Along with protocol, other documents reviewed
g. List of EC members who attended the meeting
h. A clear statement of decision reached.
i. Any advice by the IEC to the applicant including the schedule / plan of on-going review by the IEC-PDCH.
j. In case of conditional decision, any requirement by IEC, including suggestions for revision, and the procedure for having the application re-reviewed.
k. In case of rejection of the proposal, reason(s) for the rejection will be clearly stated by the member secretary with signature and date.

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Conveying decision regarding Study Protocol:

The IEC members will discuss and clarify the comments and suggestions. The Member secretary shall record the discussions and minute it. The decision on the protocol as:

i) Approved

ii) Approved with suggestions/Conditional

iii) Minor modification/Amendments

iv) Major Modification for full board review

v) Disapproved

Member(s) of the committee who is/are listed as investigator(s) on a research proposal and having conflict of interest shall declare conflict of interest and will not vote on the proposal and will opt out from all deliberations on the proposal by leaving the meeting room. An investigator or study team member invited for the meeting will not vote or participate in the decision making procedures of the committee. An independent consultant invited for the meeting to provide opinion will not vote or participate in the decision making procedures of the committee. If the IEC decision is 'Approved', without implies the approval of the study as it is presented with no modifications and the study can be initiated. If the IEC Decision is approved with suggestions/Conditional, it implies that the study can be initiated only after PI responses is reviewed and approved by member secretary of IEC. If the IEC decision is minor modification, it implies that the Approval is given after receiving supportive documents/Clarifications and Examination by member secretary or expedited review of the case may be. If the IEC decision is major modification for full board, it implies the PI should resubmit with the major modification for reconsideration of proposal by full board review. If the IEC decision disapproves, the committee should give reasons for the same and the Principal Investigator should submit justification for the reasons.

If the study is approved, the IEC will determine the frequency of continuing review from each investigator. Usually, approval is given for one year. The Secretariat will list participating members in the meeting and summarize the guidance, advice and decision reached by the IEC members. Final communication of the Ethics Committee decision taken on the protocol will be communicated to the Principal Investigator.

Approval Letter:

The Secretariat will prepare an approval letter to be sent to the Principal Investigator when the protocol is approved at an Ethics Committee meeting. The letter will be dated and will contain: ID no. / Proposal title, Date and Name of the PI. The Chairperson or the Member Secretary will sign the approval letter and the Secretariat will send it to the Principal Investigator.

Following up procedures for approved proposals by PI / Sponsor:

6. IEC will review the progress of all the studies for which a positive decision has been reached from the time of decision till the termination of the research.
7. Progress of all the research proposals will be followed at a regular interval of thrice a year. But in special situations, IEC will conduct the follow up review at shorter intervals basing on the need, nature and events of research project.
8. Periodic status report of study should be submitted at prescribed intervals for review, along with information and documents based on the safety concerns and this prescribed interval should be specified in the Letter of Communication of Decision to the PI from the IEC.
9. Final report should be submitted at the end of study.
10. Following instances and events will require the follow-up review/ Renewed Approval:
    a. Any protocol amendment likely to affect rights, safety or well-being of research subject of conduct of study.
    b. Serious or unexpected adverse reaction related to study or product, action taken by Investigator, Sponsor and Regulatory Authority should be informed within 24 hours.
    c. Any event or information that may affect the benefit/risk ratio of the study.

6. Protocol deviation, if any, should be informed with adequate justifications.
7. Any new information related to the study should be communicated.
8. Premature termination of study shall be notified with reasons along with summary of the data obtained so far within 3 weeks.
9. Change of investigators/sites must be informed to the office of IEC.

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10. Monitoring: Oversight mechanism will be in place to monitor the approved studies. Actual site visits can be made especially in the event of reporting of adverse events or violations of human rights and appropriate action will be taken when required and communicated to the applicant indicating modification/suspension/termination /continuation of the project

11. Applicant must inform the time of completion of study and must send the result summary to IEC. IEC must receive a copy of final summary of study completed from the applicant.

Responsibilities of Sponsor/Investigator

(1) The Investigator(s) shall be responsible for the conduct of the trial according to the protocol and the GCP Guidelines and also for compliance as per the undertaking given in Appendix VII of schedule Y. Standard operating procedures are required to be documented by the investigators for the tasks performed by them.

During and following a subject's participation in a trial, the investigator should ensure that adequate medical care is provided to the participant for any adverse events. Investigator(s) shall report all serious and unexpected adverse events to the Licensing Authority defined under clause (B) of rule 21 (Schedule Y and Gazette notification 30th January 2013), the sponsor or his representative, whosoever had obtained permission form the licensing authority for conduct of the clinical trial, and the ethics committee that accorded approval to the study protocol, within twenty four hours of their occurrence. The report of the serious adverse event of death, after due analysis shall be forwarded by the investigator to Chairperson of the ethics committee and Chairperson of the Expert Committee constituted by the Licensing authority under Appendix XII with a copy of the report to the Licensing Authority and the head of the institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event of death. The report of the serious adverse event other than death, after due analysis shall be forwarded to the Licensing Authority, Chairman of the Ethics Committee and the Head of the Institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event.

(2) The investigator shall provide information to the clinical trial subject through informed consent process as provided in Appendix V of Schedule Y about the essential elements of the clinical trial and the subject's right to claim compensation in case of trial related injury or death. He shall also inform the subject or His/ Her nominee(s) of their rights to contact the sponsor or his representative whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial for the purpose of making claims in the case of trial related injury or death.

Updating IEC-PDCH members:

1. All relevant new guidelines should be brought to the attention of the members.
2. The EC members should be encouraged to keep abreast of all national and international developments in ethics through orientation courses on related topics by its own members or regular training organized by constituted body/ (i.e.), so that they become aware of their role and responsibilities. For drug trial review it is preferable to train the IEC members in Good Clinical Practice. Any change in the regulatory requirements should be brought to their attention and they should be aware of local, social and cultural norms, as this is the most important social control mechanism. This is needed for maintaining quality in ethical review.

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A full-time secretariat and space for keeping records is required for a well-functioning IEC. The members could be given a reasonable compensation for the time spared for reviewing the proposals. Reasonable fees can be charged to cover the expenses related to review and administrative processes for any third party (protocols submitted by researchers not employed by PDCH) submission as described in section XI Point No 6. There should be provision for allocating reasonable amount of funds for smooth functioning of the IEC.

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9. must provide a recent signed CV and training certificates on human research protection and good clinical practice (GCP) guidelines, if applicable;
10. 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);
11. be willing to undergo training or update their skills/knowledge during their tenure as an EC member;
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13. read, understand, accept and follow the COI policy of the EC and declare it, if applicable, at the appropriate time;
14. sign a confidentiality and conflict of interest agreement/s;
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16. be committed and understanding to the need for research and for imparting protection to research participants in research.

The Principal of Priyadarshini Dental College and Hospital will appoint all IEC members including the Chairperson with the above conditions of appointment.

Quorum Requirement

Institutional Ethical Committee of Priyadarshini Dental College and Hospital will meet three to four times a year or as and when required with the following Quorum requirements for ethical committee. A minimum of five members present in the meeting room.

-Basic medical scientists (preferably one pharmacologist).
-Clinicians
-Legal expert
-Social scientist / representative of non-governmental voluntary agency /philosopher / ethicist / theologian or a similar person
-Lay person from the community.

5. Minimum one non-affiliated member should be part of the quorum.

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6. The quorum for reviewing regulatory clinical trials should be in accordance with current CDSCO requirements.
7. No decision is valid without fulfilment of the quorum.

Minimum of 50% of committee strength + 1 member and not less than 5 members will be required to compose a quorum for the meeting of which at least one member will be from outside the institution, and one member will be a non-scientific member & one from apposite gender. All decisions will be taken in meetings and not by circulation of project proposals.

Resignation Procedure

If any member wishes to discontinue from the EC, he/she would be required to inform the Chairperson, in writing.

Members may voluntarily resign from the committee at a month's notice citing appropriate reasons.

In-case of internal members, their membership would be considered withdrawn, if they resign from the Institute.

Procedure for Replacement or Removal of Members

During the tenure, Chairperson shall have the authority to terminate/ disqualify any of the members in the event that the member has not complied with the conditions of appointment, is absent without prior information for three consecutive meetings or on an occurrence of any event that casts a serious doubt on the integrity or ethics of the member.

In all such situations/ circumstances, the Head of Institute shall be informed of such termination to the member prior or within 15 calendar days of termination.

Documentation of the termination shall be recorded in the minutes of the next duly constituted EC meeting and the EC membership roster and circulars shall be revised.

Vulnerable persons are those individuals who are relatively or absolutely in capable of protecting their own interests and providing valid informed consent.

Include economically and socially disadvantaged; children (up to 18 years);women in special situations; tribal and marginalized communities; refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster situations; afflicted with mental illness and cognitively impaired individuals, differently abled–mentally and physically disabled; terminally ill or are in search of new interventions having exhausted all therapies; suffering from stigmatizing or rare diseases; or have diminished autonomy due to dependency or being under a hierarchical system and unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent.

IECs should carefully determine the benefits and risks of the study and examine the justification provided and risk minimization strategies. Additional safety measures should be strictly reviewed and approved by the IECs. IEC must ensure that the informed consent process should be well documented and recording of assent in case of research studies involving children aged 7 to 18 years and re consent, when applicable. Informed consent from vulnerable populations may be obtained from LAR (Legally authorized representative) in presence of impartial witness after through explanation of risks and benefits.

The Member Secretary of the Ethics committee (EC) collects the information on Drugs and Cosmetics rules, notifications and supplementary amendments from time to time and informs the committee members.

Formal training in good clinical practice along with certification will be submitted at regular intervals by EC members.

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EC members will be trained in human research protection, EC functions and SOPs, and will be conversant with ethical guidelines and relevant regulations of the country.

All trainings will be documented.

Any change in the relevant guidelines or regulatory requirements will be brought to the attention of all EC members.

EC members will be aware of local, social and cultural norms and emerging ethical issues.

Conflict of interest(s), if any, will be declared by IEC members.

As a rule, any member who is directly associated with a research proposal must avoid themselves from discussions and decisions related to that particular protocol. An example of a conflict of interest would be when an IEC Member is also the Principal Investigator / research team Member of the study of which the proposal is being considered by the IEC.

All Members must maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form at the time of joining of IEC.

The Members should not discuss matters related to IEC-PDCH deliberations with anyone. All personal copies of documents and emails related to the proposal should be destroyed immediately.

The Standard Operating Procedure to Be Followed By the Committee for Vulnerable Population

Version No: 1
Date of implementation: 02-02-2022
Valid till: 01-02-2025
Doc. No.: IEC-PDCH/SOP 06

Vulnerable persons are those individuals who are relatively or absolutely in capable of protecting their own interests and providing valid informed consent.

Include economically and socially disadvantaged; children (up to 18 years);women in special situations; tribal and marginalized communities; refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster situations; afflicted with mental illness and cognitively impaired individuals, differently abled–mentally and physically disabled; terminally ill or are in search of new interventions having exhausted all therapies; suffering from stigmatizing or rare diseases; or have diminished autonomy due to dependency or being under a hierarchical system and unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent.

IECs should carefully determine the benefits and risks of the study and examine the justification provided and risk minimization strategies. Additional safety measures should be strictly reviewed and approved by the IECs. IEC must ensure that the informed consent process should be well documented and recording of assent in case of research studies involving children aged 7 to 18 years and re consent, when applicable. Informed consent from vulnerable populations may be obtained from LAR (Legally authorized representative) in presence of impartial witness after through explanation of risks and benefits.

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TRAINING FOR NEW AND EXISTING COMMITTEE MEMBERS

Version No: 1
Date of Implementation: 02-02-2022
Valid Till: 01-02-2025
Doc. No.: IEC-PDCH/SOP 07

The Member Secretary of the Ethics committee (EC) collects the information on Drugs and Cosmetics rules, notifications and supplementary amendments from time to time and informs the committee members.

Formal training in good clinical practice along with certification will be submitted at regular intervals by EC members.

EC members will be trained in human research protection, EC functions and SOPs, and will be conversant with ethical guidelines and relevant regulations of the country.

All trainings will be documented.

Any change in the relevant guidelines or regulatory requirements will be brought to the attention of all EC members.

EC members will be aware of local, social and cultural norms and emerging ethical issues.

TO MONITOR OR PREVENT THE CONFLICT OF INTEREST

Version No: 1
Date of Implementation: 02-02-2022
Valid Till: 01-02-2025
Doc. No.: IEC-PDCH/SOP 08

Conflict of interest(s), if any, will be declared by IEC members.

As a rule, any member who is directly associated with a research proposal must avoid themselves from discussions and decisions related to that particular protocol. An example of a conflict of interest would be when an IEC Member is also the Principal Investigator / research team Member of the study of which the proposal is being considered by the IEC.

All Members must maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form at the time of joining of IEC.

The Members should not discuss matters related to IEC-PDCH deliberations with anyone. All personal copies of documents and emails related to the proposal should be destroyed immediately.

	Name	Designation	Signature	Date
Prepared by	Dr.B.Karthika	Member – Alt Member Secretary		2/2/2022
Reviewed by	Dr.M.R.C.Rajeswari	Member Secretary		2/2/22
Approved by	Dr. Radhika T Sashikumar	Chair Person		2.2.22

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2. Indian Council of Medical Research. National Ethical Guidelines for Biomedical and Health Research Involving Human Participants. New Delhi; 2017.
3. Good Clinical Practices for Clinical Research in India, CDSCO, http://cdsco.nic.in
4. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), INTEGRATED ADDENDUM TO ICH E6 (R1): GUIDELINE FOR GOOD CLINICAL PRACTICE E6 (R2) [updated 2016 Nov9; cited 2019 June5].
5. New Drugs and Clinical Trials Rules 2019: Changes in responsibilities of the ethics committee http://www.picronline.org Accessed on Saturday, December 28, 2020, IP: 14.139.127.194)
6. WHO Operating Guidelines for Ethical Review Board that Review Biomedical Research (2000).
7. Declaration of Helsinki and the prevailing amendments from time to time (https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/)
8. Amendments from CDSCO office https://cdsco.gov.in/opencms/opencms/en/ClinicalTrial/clinical-trials/
9. National Accreditation board for Hospitals and Health Care Providers https://www.nabh.co

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PRIYADARSHINI DENTAL COLLEGE AND HOSPITAL
RESEARCH POLICY

VERSION: 03

Doc No: PDCH/RC/01/2022 **Date of Issue: 07/01/2022**

Prepared by

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PRIYADARSHINI DENTAL COLLEGE & HOSPITAL RESEARCH POLICY		
Doc No: PDCH/ RC/01/2022	**Version: 03**	**Date of Issue: 07.01.2022**

Preamble:

Research is a systematic process of gaining in-depth knowledge and understanding pertaining to a particular field of study to develop or contribute to generalizable knowledge. Research and innovation are considered as the vital part of science and technology which not only contributes to the growth of the particular educational organization, instead, plays a major role in the development and advancement of the nation. Hence, PDCH has considered research as one of its most important expedition.

Scope:

The scope of the research policy is to indicate a harmonious research culture among students and faculties of PDCH to encourage and promote research and its importance. This leads to various multidisciplinary/interdisciplinary basic, clinical and preventive studies that could be immensely helpful for improving the quality and quantity of research in the field of dentistry.

Aim and objectives

1. Conceptualisation of research strategy.
2. To promote research by providing a conducive environment for research activities.
3. To build a strong research infrastructure to facilitate smooth functioning of research.
4. To create research interest and awareness among the students and faculties.
5. To encourage researchers by providing them research fund and incentives to promote their endeavours in research.
6. To formulate the ethical framework (Institutional Ethical Committee) with the integral set of protocols, rules and regulations to maintain and adhere to the high standard of ethics and morality.
7. To collaborate with other governmental and non-governmental institutions/ organisations/ agencies/ industries for promoting interdisciplinary research.

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8. To organise on a regular basis, workshops/ CDE/ seminars/ guest lectures/ conferences to enhance the research culture in the college.

9. To encourage students and faculty members to submit various research proposals to the government and non-government funding agencies.

10. To execute MoUs with various research and development organisations and industries.

11. To share and expand our knowledge either in the form of presentation in various scientific forums or publication in journals of high standard, indexed in leading databases such as pub med, Scopus , web of science etc, (should abide to publication policy).

12. To formulate guidelines for granting study leave, sabbatical leave, reduction in workload etc, for students and faculty members to participate in research related activities

13. To guide the researchers to apply for IPR (Intellectual Property Rights), for protection of creation and intellectual rights through patents, copyrights and trademarks. (should abide by IPR policy).

14. To constitute research committee to supervise and guide the research activities of PDCH.

Research Committee

Research committee of PDCH is an advisory body that meets once in three months to monitor the research activities of PDCH. The composition of Research Committee consists of

1. Chairperson
2. Co-chairperson
3. Members
4. External experts

This committee ensures to maintain the standards of research and related activities of PDCH.

Ethics in research

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Doc No: PDCH/ RC/01/2022	**Version: 03**	**Date of Issue: 07.01.2022**

The basic responsibility of all the researchers is to maintain ethical standards in research. All the research proposals shall be presented to Institutional Ethical Committee (IEC) for critical analysis and review, to avoid the violation of the standard protocols of research and its ethics. They shall strictly evaluate about the welfare and safety of their subjects as well. No research will be conducted without prior approval from IEC. The researchers are constantly monitored and advised to maintain records of the research for inspection and future references.

Research support and promotion

All the students and faculty members (researchers) are encouraged to conduct quality research to create a vibrant research atmosphere in the campus.

Based on the budget allowance allocated,

1. The institution shall support the researchers with seed grants after approval by the PDCH-Research Committee based on their standard and quality of research.
2. The institution shall also provide travel grants and financial support to attend various national/international conferences/ scientific forums in order to update/ share the knowledge.
3. The institution shall provide incentives and awards in appreciation to their research work based on their standards after scrutinized by PDCH- Research Committee.
4. The institution shall provide additional financial support added to their grants or funds received, if their research work is exceptionally outstanding.

Any research undertaken with a member of PDCH or by utilising the research facility or study samples of the college, they should acknowledge PDCH in all their publications and presentations. All researchers are expected to comply to disclose their conflict of interest in their publication (Publication policy).

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Research misconduct

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In order to ensure and maintain the integrity of research, any research misconduct or violation of research guidelines will be viewed seriously and shall be investigated in line with disciplinary regulations. Any ethical issues or other departmental issues shall be referred to the decision of the institutional Academic Integrity Panel which is governed by a separate policy (Academic Integrity Policy).

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PUBLICATION POLICY

VERSION: 03

Doc No: PDCH/PC/03/2023 **Date of Issue:13.02.2023**

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PRIYADARSHINI DENTAL COLLEGE AND HOSPITAL PUBLICATION POLICY		
Doc No: PDCH/PC/03/2023	**Version: 03**	**Date of Issue:13.02.2023**

Preamble

Publication is defined as an act of publicizing a content in either a printed or digital format. Publications are the primary way to share and exchange the knowledge. Despite the various technological advances, there is always a lacunae, owing to a complete contemplation of knowledge in a particular topic of interest. To curb this lacunae, by means of facts, findings and evidences, publications are the most authentic means. Publications are standard literature evidences that share the details to its accuracy. Priyadarshini Dental College and Hospital proposes this publication to guide the faculty members and students to publish in accordance to UGC CARE (University Grants Commission - Consortium of Academic and Research Ethics), ICMJE (International Committee of Medical Journal Editors) and COPE (Committee on Publication Ethics).

Definitions

Authorship

An author is defined as a person who is the source of some form of intellectual or creative work, providing contribution towards concept, design, data acquisition and analysis, manuscript preparation, manuscript review and revision.

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Lead author: Lead author is the first author and is the one individual who carries out research as well as the manuscript preparation work. The lead author contributes to all the three components, scholarship, authorship and approval.

Co-author: Co-author is the person who collaborates with the lead author to make profound contribution towards manuscript. They primarily contribute towards authorship and approval of the manuscript.

Funding: Research funding is defined as a grant obtained for carrying out a research work through competitive /scientific process.

Potential financial interests: Support in form of commercial stocks / shares / patents by the organization that is possibly the primary organization being benefitted / directly affected by the results / reach of the publication.

Non-financial competing interests:

Refers to any association to declare any unpaid roles that may have an impact on the publication that is possibly the primary organization being benefitted / directly affected by the results / reach of the publication.

a. Unpaid membership in governmental / non-governmental organizations

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b. Unpaid membership in any affiliated lobbying organizations.

c. Any unpaid advisory position in the organization that is possibly the primary organization being benefitted / directly affected by the results / reach of the publication.

Plagiarism is an act of copying another individuals' words / works / ideas and publishing it as their own.

Duplicate publication is an instance where the author reuses a major part of his / her own data / work which is previously published without any proper acknowledgement / references.

Falsification is a process where the author manipulates the research protocol/ material / data such that the actual work is not represented accurately.

Objectives

PDCH publication policy will monitor all forms of print or digital publications like scientific articles, books, book chapters, conference papers, and other types of publications like brochures, news letters, magazines and articles for vernacular magazines.

It is mandatory that all publications from PDCH should be scrutinized and approved by the publication committee.

The objectives of PDCH publication committee are:

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a. To bring up PDCH as one of the renowned institutions in terms of research
b. Foresees ethics for all forms of publications in PDCH.
c. To promote and facilitate research / publication works in PDCH.
d. To enhance scientific collaborations pertaining to publications / research in PDCH.
e. To create rules for research/publication
f. To create awareness and identify research misconduct and correct the same.
g. To initiate action against research/publication misconduct
h. To monitor and enhance the quality of research / publication
i. To resolve interdepartmental and intradepartmental authorship disputes.

Selection of journal

Selection of journal is an important step in publishing a research work. PDCH recommends publishing of articles in journals indexed in reputed indexing authorities namely, Scopus, PubMed/Medline and Web of Science. Apart from this PDCH also accepts and recommends publications in journals listed in UGC CARE. CARE (consortium of academic and research ethics) is proposed by UGC (University grants commission) has created a reference list, which are recognized by the statutory authorities in India. PDCH guides the authors in not to publish in predatory and cloned journals.

Authorship guidelines

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Doc No: PDCH/PC/03/2023	**Version: 03**	**Date of Issue:13.02.2023**

ICMJE has proposed certain criteria to attain authorship in a research publication. PDCH also follows the same guideline to recommend authorship. The authors should have a

1. Contribution towards concept, design, data acquisition and analysis. Drafting and reviewing of manuscript.
2. Contribution towards manuscript drafting and reviewing
3. Authority of final approval
4. Accountability

Any credited author of a publication should have substantial contribution in the above four mentioned categories. The author with maximum contribution should be made the 1st author. In case of scientific collaboration equal authorship will be provided to the partnering institution, provided, significant contribution.

Acknowledgements

PDCH recommends contributor who do not meet the above mentioned criteria will only be acknowledged and will not be given authorship in the article. Contributions like editing of manuscript, acquisition of funding/grants, technical corrections, statistics will not be considered for authorship.

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Artificial intelligence tools using Large language models (LLMs) such as Chat GPT, BERT, Azure etc used in writing an article shall not be given an authorship, since the LLM tools can't hold for accountability of the research. However, usage of LLM should be mandatorily included in the methodology or acknowledgements section of the manuscript, with the details on their usage.

Conflict of interests

They are defined as financial and non-financial contributions towards a research that could preferably undermine the objective of the publication, authenticity and values of the publication, despite of the objectivity and integrity in the data.

All the authors in the manuscript must approve or declare the status of their competing interests. It is their duty to disclose the conflicts with additional financial information.

Plagiarism, duplicate publication and falsification

PDCH has constituted an Academic Integrity Panel (AIP). It monitors all the research and publication for its authenticity and scrutinizes research misconduct in forms of plagiarism, duplication and falsification according to ICMR/COPE guidelines. So any manuscript intended to be published shall go through the PDCH AIP.

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The levels of plagiarism as proposed by UGC is followed by PDCH academic integrity panel and are

Level 0:- similarities up to10%.

Level 1:- similarities above 10% and up to 40%.

Level 2:- similarities above 40% and up to 60%.

Level 3:- similarities above 60%.

Penalties implicated in PDCH, in case of plagiarism in academic and research publications

I. Level 0: Similarities up to 10% -

Minor similarities, no penalty.

II. Level 1: Similarities above 10% to 40%

i. Shall be asked to withdraw manuscript.

III. Level 2: Similarities above 40% to 60%

i. Shall be asked to withdraw the manuscript.

ii. Shall be denied a right to one annual increment / one year withholding of promotion.

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IV. Level 3: Similarities above 60%

i. Shall be asked to withdraw manuscript.

ii. Shall be denied a right to two successive annual increments.

Penalties in case of plagiarism in research misconduct

If proven for a research misconduct, the candidate shall be asked to withdraw the publication/ presentation work. Additionally, the candidate shall be denied one annual increment / one year withholding of promotion.

Methods to curb research misconduct

- All reported works will be submitted to a plagiarism checking software and provide a report generated with the draft to the consideration by the research committee.
- Submission of declaration to be done in the specific academic integrity undertaking format prescribed by AIP along with the report.
- To ensure the researchers to provide proper acknowledgment and permission of author wherever necessary.
- To provide soft copies to be submitted in institutional digital repository.

Confidentiality

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PDCH recommends the researcher despite of knowing the identity of the study subject / details, obliges to protect it from public. It upholds the matter of privacy inclusive of study samples, protocol, data and results in order to maintain the ethics and integrity.

Prior publication

The following should be scrutinized and avoided

- The content previously published as a paper in any type of journal
- The content previously published as a short article/ long abstract/ proceedings/ paper/ poster/ part of a book chapter
- Archival reports / doctoral dissertation that are available in any non-institutional / institutional digital repository.

Image integrity

- The image should be minimally processed
- The image should be of high quality
- The image should be 300 dpi in case of color / 600 dpi in case of black and white/ 1200 dpi in case of line art.

Standardization of research

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Doc No: PDCH/PC/03/2023	**Version: 03**	**Date of Issue:13.02.2023**

PDCH recommends faculty members to conduct research as per the to the following guidelines

- Declaration of Helsinki for all animal / human experiments
- Institutional ethical committee approval for all animal / human experiments
- ARRIVE guidelines for animal experiments.
- CONSORT / STROBE / STARD guidelines for human experiments
- PRISMA guidelines for systematic review and meta-analysis.

Non – scientific publication:

Non- scientific publication is an act of publicizing content in a oral, written or digital format in a non-scientific/academic forum. Any non - scientific publication by the faculty members and students of PDCH should not violate the policies of local government or management. It should be approved in prior by the head of the institution or management.

Publication promotion

- Each faculty member of PDCH should publish at least one article per year on a minimal basis in an indexed journal and journal listed in UGC CARE.
- Conduction of training programs on research/publication ethics for the faculty members and students of PDCH.

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- Mandatory IEC approval for any research and its publication from PDCH.
- Mandatory registration and ID creation of all the faculty members of PDCH in Scopus, Orcid, Web of Science and Vidwan directories.
- Incentive of Rs.5000/- will be rewarded to the 1st author for publishing in a reputed journal (PubMed /Scopus /web of science) indexed journals that can be shared among themselves.
- Awards for the students and faculty members of PDCH, who publish in the journals having high impact factor/cite score.
- Considering the quality (H index and number of citations) and quantity of publication to decide on promotion and increment.
- Recommendations from PDCH Academic Integrity Panel on the authenticity of the research will also be considered for promotion and increment.
- Additional incentive for the authors obtaining patent and grants.

To conclude, PDCH gives a profound importance in encouragement of research and publication in recommended journal. Thus, PDCH aims in establishing itself to be a renowned institution for research/ publication in national/international standards.

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