D Y PATIL DENTAL SCHOOL

Dr. D Y Patil Knowledge City, Charholi Bk, Via Lohegaon, Pune 412105

Affiliated to Maharashtra University of Health Sciences, Nashik

Recognized by Dental Council of India

SELF STUDY REPORT (CYCLE 1) 2018-2023

Criteria 3: Research, Innovations and Extension

Key Indicator 3.3: Research Publications and Awards

Metric 3.3.1: The Institution ensures implementation of its stated Code of Ethics for research.

CODE OF ETHICS FOR INSTITUTIONAL RESEARCH

Institutional Ethics Committee DYPDS,Lohegaon,Pune
Standard Operating Procedure
(As Amended up-to-date)

STANDARD OPERATING PROCEDURE
INSTITUTIONAL ETHICS COMMITTEE, IECDYPDS

Date: 12th May 2023

Authors: Dr. Arti Hajarnavis & Dr. Karibasappa G N

Member Secretary & Member IEC, DYPDS

Approved & confirmed by: **Dr. Anita Anup Barde**

Chairman, IEC, DYPDS

Dr. Anand Shigli

Dean, DYPDS,Lohegaon ,Pune

Distribution: Member of IEC, DYPDS,Pune, Research Scholars, Available on the Institute website

www.dypds.com

LINGARAJ J SHIGLI ANAND

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PERMISSION LETTER

File No. EC/NEW/INST/2020/1115

सत्यमेव जयते

Government of India
Ministry of Health & Family Welfare
Department of Health Research
(National Ethics Committee Registry for Biomedical and Health Research)

2nd Floor, IRCS Building,
Red Cross Road,New Delhi – 110001
Date : 05-Oct-2023

FORM CT-03

(See rules 17 and 18)

GRANT OF REGISTRATION OF ETHICS COMMITTEE RELATING TO BIOMEDICAL HEALTH RESEARCH

Registration No. **EC/NEW/INST/2023/MH/0353**

The designated authority hereby registers and permits Institutional Ethics Committee D Y Patil Dental School IECDYPDS , D Y Patil Dental School D Y Patil Knowledge City ,Charholi (BK) , City-Pune , District-Pune - Maharashtra - 412105 Contact No.: 02067077779 Fax No.: to perform duties of ethics committee as specified in the New Drugs and Clinical Trials Rules, 2019.

2. The ethics committee shall observe the conditions of registration specified in Chapter IV of the New Drugs and Clinical Trials Rules, 2019 and the Drugs and Cosmetics Act, 1940.

ANU NAGAR
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Date: 2023.10.05 14:21:26 +05'30'

Designated Registration Authority
Stamp

Place : New Delhi

Date : 05-Oct-2023

सत्यमेव जयते

Government of India
Ministry of Health & Family Welfare
Department of Health Research
(National Ethics Committee Registry for Biomedical and Health Research)

2nd Floor, IRCS Building,
Red Cross Road,New Delhi – 110001
Date : 10-Oct-2023

To

The Chairperson
Institutional Ethics Committee D Y Patil Dental School IECDYPDS
D Y Patil Dental School D Y Patil Knowledge City ,Charholi (BK), City-Pune , District-Pune - Maharashtra - 412105

Subject: Ethics Committee Registration No. EC/NEW/INST/2023/MH/0353 issued under New Drugs and Clinical Trials Rules, 2019

Sir/Madam,

Please refer to your file No. EC/NEW/INST/2020/1115, dated 25-Sep-2020 submitted to this National Ethics Committee Registry for Biomedical and Health Research (NECRBHR, Department of Health Research) for the Registration of Ethics committee.

Please find the enclosed registration of the Ethics committee in form CT-03 vide Registration No. EC/NEW/INST/2023/MH/0353, dated 05-Oct-2023. The said registration is subjected to the conditions as mentioned below.

Yours faithfully,

BISWABANDAN SENAPATI
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Date: 2023.11.03 17:14:18 +05'30'

(B. Senapati)
Director

Conditions of Registration

The following include few of the conditions to be followed by the Ethics Committees (ECs) registered with the Designated Authority (NECRBHR, DHR).

1. The registration is valid for a period of five years from the date of its issue, unless suspended or cancelled by the Designated Authority, NECRBHR, DHR. The EC has been registered for the purpose of reviewing Biomedical and Health Research. For Clinical Trials review, registration with CDSCO is required.

2. This certificate is issued to you on the basis of declaration/submission made by you.

3. An institution or organization or any person shall conduct any Biomedical and Health Research with the approval of the Ethics Committee registered under rule 17, Chapter IV of New Drugs and Clinical Trials Rules 2019.

4. EC registration number provided by DHR should be displayed on every certificate of approval issued by the Ethics committee.

5. The Ethics Committee should be constituted in accordance with the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017 as may be specified by the Indian Council of Medical Research from time to time and shall function in accordance with said guidelines.
   a) EC composition should be as follows:
      i) ECs should be multi-disciplinary and multi-sectoral.
      ii) There should be adequate representation of age and gender.

iii) Preferably 50% of the members should be non-affiliated or from outside the institution.

iv) The number of members in an EC should preferably be between 7 and 15 and a minimum of five members should be present to meet the quorum requirements.

v) The EC should have a balance between medical[*1] and non-medical members/technical[*2] and non-technical members, depending upon the needs of the institution.

b) Composition of the said Ethics Committee is as per the Annexure-I.

c) Any change in the membership or the constitution of the registered Ethics Committee shall be intimated in writing to the Designated Authority NECRBHR, DHR.

6. The Chairperson of an Ethics Committee (EC) should be a non-affiliated person from any background with prior experience of having served/serving in an EC whereas the Member Secretary should be a staff member of the Institution and should have knowledge and experience in clinical research and ethics.

7. EC Members should be conversant with the provision of New Drugs and Clinical Trials Rules 2019, ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants and other regulatory requirements to safeguard the rights, safety and well-being of the human participants.

8. Conflict Of Interest (COI) should be declared and managed in accordance with Standard Operating Procedures (SOPs) of the EC. EC members are responsible for declaration of COI to the Chairperson, if any, at each meeting. The member who has declared COI should withdraw from the EC meeting while the research proposal is being discussed and the quorum must be rechecked and it should be recorded in the minutes of meeting.

9. In case of studies involving vulnerable population and stigmatized populations, the Ethics Committee, may associate with representatives of patient groups and subject experts who are not its members, in its deliberations but such experts shall not have voting rights, if any.

10. Ethics Committee shall indicate the reasons that weighed with it while rejecting or asking for a change or notification in the protocol in writing to the Principle Investigator.

11. The EC should continuously evaluate progress of ongoing proposals, review Serious Adverse Event (SAE) reports from all sites along with protocol deviations/violations and non-compliance, any new information pertaining to the research and assess final reports of all research activity.

12. The function, proceedings of Ethics Committee and maintenance of records shall be as per the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017. The Ethics Committee shall maintain data, record, registers and other documents related to the functioning and review of Biomedical and Health Research study, as the case may be, for a period of three years after completion of such study.

13. Where any SAE occurs to a study participant during its conduct of Biomedical and Health Research, the Ethics Committee shall analyse the relevant documents pertaining to such event and maintain reports and comply with the provisions of chapter – IV, New Drugs and Clinical Trials Rules 2019 and ICMR National Ethical Guidelines 2017.

14. The Ethics Committee shall undertake proper causality assessment of Serious Adverse Events (SAE's) with the help of subject expert's wherever required, for deciding relatedness and quantum of compensation as per condition no. (12) mentioned above.

15. Funding mechanism for the Ethics Committee to support their operations should be designed and approved to ensure that the committee and their members have no financial incentive to approve or reject particular study.

16. SOP's for funding of the Ethics Committee in order to support their operations must be maintained. The records of income & expenditure of Ethics Committee shall be maintained for review and inspection.

17. The EC should be competent and independent in its functioning. The institution is responsible for providing logistical support, such as infrastructure, staff, space, funds, adequate support, etc.. Ethics Committee records will be maintained.

18. The Ethics Committee shall allow experts/officials authorized by Department of Health Research (DHR) to enter its premises to inspect any record, data or any document related to research study

and provide adequate replies to any query raised by such experts/officials, as the case may be, in relation to the conduct of Biomedical and Health Research.

19. When Ethics Committee fails to comply with any provisions of the New Drugs & Clinical Trials Rules 2019 and ICMR National Ethical Guidelines 2017, the Designated Authority may issue show cause notice to such Ethics Committee specifying therein such non-compliances and the period within which reply shall be furnished by such Ethics Committee. After consideration of the facts and reply given by the Ethics Committee the Designated Authority, NECRBHR, DHR may take one or more actions specified under provision of Rule 18, Chapter IV of New Drugs and Clinical Trials Rules 2019.

20. To maintain independence, the Head of the Institution should not be part of the EC but should act as an appellate authority to appoint the committee, including Chairperson or to handle disputes. The appointment letter issued to all members should specify the Terms of References (TORs) and should include, at the minimum, the role and responsibility of the member in the committee, duration of appointment and conditions of appointment.

21. The Chairperson and Member Secretary could have dual roles in the EC as they could fulfil a role based on their qualifications (i.e. clinician, legal expert, etc.) in addition to taking on the role of Chairperson or Member Secretary.

22. The Institutions could have subcommittees such as SAE subcommittee or expedited review committee which should be a part of the main committee and comprise Chairperson/ Member Secretary and one to two appropriate designated members of the main EC as defined in the SOPs.

23. The EC can also have a set of alternate members who can be invited as members with decision-making powers to meet the quorum requirements and can have the same TORs as regular members and can attend meetings in the absence of regular members.

24. The Ethics Committee shall make an application for renewal of registration in Form CT-01 along with documents as specified in sub-rule (2) at least ninety days prior to the date of the expiry of its final registration: Provided that if the application for renewal of registration is received by the authority designated under sub-rule (1), ninety days prior to the date of expiry, the registration shall continue to be in force until an order is passed by the said authority on the application: Provided further that fresh set of documents shall not be required to be furnished, if there are no changes in such documents furnished at the time of grant of final registration, and if the applicant renders a certificate to that effect indicating that there is no change.

*1 Medical members are clinicians with appropriate medical qualifications.

*2 Technical members are persons with qualifications related to a particular branch in which the study is conducted, for example: - Social Science.

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IECDYPDS COMPOSITION

File No. EC/NEW/INST/2020/1115

Annexure 1

सत्यमेव जयते

Government of India
Ministry of Health & Family Welfare
Department of Health Research
(National Ethics Committee Registry for Biomedical and Health Research)

2nd Floor, IRCS Building,
Red Cross Road,New Delhi – 110001
Date : 10-Oct-2023

Composition of the Ethics Committee:

S.No.	Name of Member	Qualification	Role/Designation in EC
1	Dr. Anita Anup Barde	Other (Faculty of Medicine , Pharmacology)	Chair Person
2	Dr. Arti M Hajarnavis	BSc (MSc PHD - Biochemistry)	Member Secretary
3	Dr. Pradeep Shetty	BDS (Conservative and Endodontics)	Basic Medical Scientist
4	Dr. Kamal A Shigli	BDS (MDS- Prosthodontics)	Clinician
5	Dr. Pritesh Gawali	Other (Pedodontics and Preventive Dentistry)	Clinician
6	Dr. Sandeep Atmaramji Jethe	Other (Orthodontics)	Clinician
7	Ms. Trushna Satish Kamble	BA-Sociology (MSW-Sociology)	Social Scientist
8	Dr. Kamaljeet Kaur Siddhu	LLB (Master of Laws (LL.M.))	Legal Expert
9	Ms. Sheetal Thorat	Other (Attender)	Lay Person
10	Mr. Vinod Krishna Dolas	BA (Not Applicable)	Member
11	Mr. Onkar Bhosale	B. COM (Not Applicable)	Member
12	Dr. Karibasappa Nagappa	BDS (MDS-Public Health Dentist)	Scientific Member
13	Mr. Vinayal Bhosale	BA (Office Superindent)	Other Supporting Staff

BISWABANDAN SENAPATI
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Date: 2023.11.03 16:46:13 +05'30'

(B. Senapati)
Director

INTRODUCTION

D Y Patil Dental School. Lohegaon,Pune**,** (IECDYPDS) is an autonomous Institute under the Ministry of Health and Family Welfare established for Dental Education, Research, and Patient care especially in the Maharashtra, India. One of the mandates of the DYPDS,Lohegaon,Pune, is to conduct research in various branches of Dental Sciences involving human beings. The involvement of the human beings raises issues of ethics in Research. Institutional Ethics Committee is required to be constituted in every such institute to ensure the ethical practices by the researchers.

DYPDS, Lohegaon,Pune, complies with all the regulations as stated by CDSCO (DCGI) and also,drug and cosmetic rule 1945 of the schedule Y and other regulatory requirement of ICMR.

Today the ICH GCP guideline is followed globally for clinical research. This guideline elaborates the composition and functioning of an Institutional Ethics Committee to review clinical research proposals.

In India, Ethics Committee for Research on Human Subjects presently functions according to the requirements laid down in Schedule Y and is guided by the ICH GCP guidelines for Good Clinical Practice, ethical principles set forth in the Declaration of Helsinki and the Ethical Guidelines for Biomedical Research on Human Subjects laid down by Indian Council of Medical Research.

2. NAME OF THE ETHICS COMMITTEE

This committee will be known as **Institutional Ethics Committee, DYPDS**

3. AUTHORITY UNDER WHICH THE ETHICS COMMITTEE HAS BEEN CONSTITUTED:

The Director, DYPDS shall constitute the IEC in accordance with the SOP.

Resolution passed and amended on administrative committee meeting on 4th April 2023.

The extract of the administrative committee meeting of 1st IEC, DYPDS Held at conference hall Administrative Block, DYPDS regarding formation of ethics committee

The following member of IEC, DYPDS were present on the last meeting held on 3th& 4th May 2023

1) Dr .Anand Shigli
2) Dr.Sandeep Jethe
3) Dr.KamalShigli
4) Dr Pradeep Shetty
5) Dr. Arti Hajarnivas
6) Dr. Karibasappa G N
7) Dr .Anagha Shete
8) Dr. Pritesh Gawali
9) Dr .Anita Anup Barde
10) Dr Kamaljeet Kaur
11) Mr.Vinod Dolas
12) Mr. C S Patil

4. MEMBERSHIP REQUIREMENTS OF ETHICS COMMITTEE

4.1 The Members will be nominated by the Institute Head based on certain criteria. The usual procedure Chairperson will be appointed by Institute Head. The Chairman should necessarily be from outside Institute. Member Secretary should be from the Institute are willing to work as an Ethics Committee Member

4.2 The period of Membership will be Five (5) years, or until they cease to be members either at their own request or by a decision of the other Committee members, whichever happens first. There should be always a mix of old and new members. For this purpose after completion of the tenure 25 - 50% members may be replaced.

4.3 New members will be appointed to replace members who have resigned or whose tenures of membership have expired, according to the process described in 6.2.

4.4 Members should maintain confidentiality of all discussions during the meeting and sign a confidentiality agreement at the start of their term.

5. TERMS OF REFERENCE OF THE COMMITTEE:

5.1 Chairperson

5.1.1 The Chairperson of the committee shall be from outside the parent organization appointed by the Head of the parent organization.

5.1.2 The Chairperson will be responsible for conducting all Committee meetings, and will lead all discussion and deliberations pertinent to the review of research proposals.

5.1.3 The Chairperson will preside over all the matters pertinent to the Committee's functions.

5.1.4 In Emergent situation, the Chairman will nominate a Committee Member as Chairperson OR In case of absence of the chairperson, it is better that the members elect an acting chairperson among themselves preferably from the outside of the Institute to avoid conflict of interest.

5.1.5 The Acting Chairperson will have all the powers of the Chairperson for the respective meeting.

5.2 Member Secretary

5.2.1 The Member Secretary will be nominated by the Head of the Institute from the Members; he/she may be drawn from the parent organization.

5.2.2 In consultation with the Chairperson, the Member Secretary will be responsible for the following functions:

i) Inviting all the Committee members to come on board.

ii) Receiving all the research proposals.

iii) Forwarding all the documents to be reviewed to the Committee members

iv) Preparation and dissemination of agenda for all Committee meetings seven (7) days or less than seven (7) prior to the meeting date as per 13.6.5.

v) Inviting special attendees from relevant area including therapeutic of the scheduled meetings, if needed.

vi) Preparation and circulation of minutes within seven (7) working days from the date of the meeting.

vii) Notification of review outcome to Principal Investigated or Sponsor or CRO of research proposals within seven (7) working days from the date of the meeting.

viii) Generated and dispatch review letters of respective research proposals.

ix) Retention and safe keeping of all records and documentation as describe in 5 and 6.

x) Performance of other duties assigned by the Chairperson.

xi) Administrative matters pertinent to the Committee's functions.

xii) Signing on behalf of the Chairperson, in consultation

xiii) Doing all the communications on behalf of the Committee.

5.2.3 In case of anticipated absence of the Member Secretary, the Acting Member Secretary will be nominated by the Chairperson and / or the Member Secretary and documentation for the same will be maintained. The Acting Member Secretary will perform the duties of the Member Secretary and have all the powers of the Member Secretary for that meeting.

ROLES AND RESPONSIBILITIES OF THE EC

The basic responsibility of an EC is to ensure protection of the dignity, rights, safety and well-being of the research participants.

The EC will ensure ethical conduct of research by the investigator team.

The EC is responsible for declaration of conflicts of interest to the Chairperson, if any, at each meeting and ensuring these are recorded in the minutes.

The EC would perform its function through competent initial and continuing review of all scientific. Ethical, medical and social aspects of research proposals received by it in an objective, timely and independent manner by attending meetings, participation in discussion and deliberations

The EC will ensure that universal ethical values and international scientific standards are followed in terms of local community values and customs.

The EC would assist in the development and education of the research community in the given institute (including researchers, clinicians, students and others), responsive to local healthcare requirements.

Responsibilities of members would be clearly defined. The SOPs would be given to EC members at the time of their appointment.

The Chairman would support the Member Secretary in all their functions and would be trained in documentation and filing procedures under confidentiality agreement.

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

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

The EC would recommend appropriate compensation for research related injury, wherever required

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

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

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

Policy for Fees Related to Ethics Committee Activities:

As a policy of the appointing authority IECDYPDS does not charge any fees for processing any project proposals, review of SAE and inviting subject expert as well as for any other of its activities. However, reasonable processing fees for clinical trial may be charged in consultation with the institute authority.

A. For drug trials a sum of Rs.10, 000 /- (Ten thousand only) per project.

B. There will however be no fees for the thesis protocols of MDS/ICMR/MUHS LTS/STS and projects of BDS student of this institution.

PROPOSALS FROM OUTSIDE THE INSTITUTION

Policy on fee structure and reviewing of per protocol documents

Institutional Ethics Committee (IEC) fees structure for reviewing of per study documents is INR 50,000/-

Clinical trials or Drug trials requiring Expedited Review fee would be INR 1, 00,000/-

Institutional Ethics Committee fees structure shall be INR 25,000/- for reviewing of the following:-

A. Changes /amendment made in the submitted documents for resubmission and re-approval.

B. New patient safety information / additional information for reviewing and approval.

C. Changes or amendment made in Inclusion Exclusion criteria/ Protocol including administrative or patient safety.

D. Any other document other than the previously approved documents.

E. Payee name: D Y Patil Dental School,Pune

F. Mode of Payment : Online

6. CONDITIONS OF APPOINTMENT, TENURE AND THE QUORUM REQUIRED

6.1 Conditions of Appointment

6.1.1 A member should be willing to revealed his / her full name, profession and affiliation; all reimbursement for work and expenses, if any, within or related tothe Committee as these details will be made available to the appropriate authority upon request.

6.1.2 A member should sign a confidentiality agreement regarding meeting deliberations, applications, information on research participants and related matters; in addition, all of the Committee administrative staff should sign a similar confidentiality agreement.

6.2 Appointment of New Members

6.2.1 New members will be appointed under the following circumstances;
i) When a regular member completes his / her tenure.
ii) If a regular member resigns or drops out before the tenure is completed.
iii) If volume of proposals and frequency of review demands appointmentof new members.

6.3 A new member shall be appointed, it is advisable to induct a member in the same category to fulfill the norms the same category.

6.4 Tenure of Membership

6.4.1 The tenure of Committee Membership will be a continuous period of Five (5)years.

6.4.2 Extension of membership will be decided by Head of Institute.

6.4.3 There will be limit to the number of times that membership can be extended. To avoid COI, bring new ideas and dimensions in the review limitation the extension to 1 or 2 times.

6.5 Quorum of Committee

6.5.1 The regular member of the committee will ideally include at least 7 and maximum of 15 individuals as follows:

i) 1- Chairperson
ii) 1- Member Secretary from the Institute
iii) 1-2Basic Medical Scientist (Preferably a Pharmacologist)
iv) 1- 2 Clinicians from the Institute
v) 1-2 Legal Expert

vi) 1-2 Social Scientist / Social Worker / Ethicist

vii)1-2 Lay Person preferentially a non-professional lady from the community

6.5.2 The Committee will have representation from both men and women

6.5.3 All members will act in the manner independent of any influence of the existing relationship with any organization, institute or individual.

Member's list of Institutional Ethics Committee

SrNo	NAME	DESIGNATION	AFFILIATION	GENDER
1	Dr. Anita Anup Barde	Chairman	Professor & Head Department of General & Dental Pharmacology& Therapeutics Sinhgad Dental College& Hospital,VadgaonBudruk, Pune-41	Female
2	Dr. Arti M. Hajarnavis	Member Secretary	Prof & Head Department of Biochemistry D Y Patil Dental School Pune	Female
3	Dr. Pradeep shetty	Clinician	Prof & Head Department of Conservative & Endodontics D Y Patil Dental School Pune	Male
4	Dr. Sandeep Jethe	Clinician	Prof & Head Department of Orthodontics D Y Patil Dental School Pune	Male
5	Mr Trushna Satish Kamble	Social Scientist	Center for Advocacy and Research Pune	Female
6	Dr. Kamaljeet Kaur	Legal Expert	Director,Coroporate affairs Ajeenkya D Y Patil University Pune	Female
7	Smt SheetalTorat	Lay Person	Attendent D Y Patil Dental School Pune	Female
8	Dr.Anagha Shethe	Member	Prof & Head Department of Oral Medicine & Radiology D Y Patil Dental School Pune	Female
9	Dr.Pritesh Gawli	Scientific Member	Reader Department of Pedodontics & Preventive Dentistry D Y Patil Dental School Pune	Male
10	Mr.C S Patil	Member	Office Superintend D Y Patil Dental School Pune	Male
11	Dr .Kamal Shigli	Scientific Member	Prof & Head Department of Prosthodontics D Y Patil Dental School Pune	Female
12	Dr Karibasappa G N	Scientific Member	Prof & Head	Male

			Department of Public Health Dentistry D Y Patil Dental School Pune	
13	Mr.Vinod Dolas	Member	Medical OS D Y Patil Dental School Pune	Male
14	Mr.Vinayak Bhosale	Member	Student Section D Y Patil Dental School Pune	Male

6.6 Special Invitees

As appropriate, the Committee will decide the need for participation of qualified special invitees to have unbiased scientific and / or ethical opinion for the study protocol to be discussed. Special Invitees shall participate in the discussion and deliberations, but will not vote on a research proposal. However, the opinion of the special invitee shall be recorded.

7. PROCEDURE OF RESIGNATION, REPLACEMENT AND REMOVAL OFMEMBERS

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

7.1 If a member resigns from the Committee

7.2 If a member is incapable of performing his / her duty as a Committee member.

7.3 In case of demise of a member.

7.4 Rotation system for membership will be considered to allow for continuity,development and maintenance of expertise within the Committee and regular inputof fresh ideas and approaches.

7.5 In case of resignation,

Any member may resign before completing their terms by writing their intention to theChairperson. The members have to serve for One (1) month notice period before they can be relieved. However, the Chairperson shall review the same and decide whether to allow the member to leave the Committee with immediate effect or after serving the notice period of One (1) month.

8. ADDRESS OF THE OFFICE OF ETHICS COMMITTEE

D Y Patil Dental School

Secretariat of IEC, DYPDS,
Dean Office, Administrative Block, DYPDS, Lohegaon, Pune
D Y Patil Knowledge City
Charholi,BK,Via Lohegaon
Pune-412105
Maharashtra
Phone: 020 6707780 Fax 020 67072718
Mob No: 9890032163

9. DETAILS OF CHAIRMAN (BRIEF PROFILE)

Dr. Anita Anup Barde
A1-2204,F Residences,
Near Kaizen Society,
Sopan baug,
Balewadi,
Pune-411 045
Mob : 7798355883

10. DETAILS OF MEMBERS OF ETHICS COMMITTEE

Sr no	Name	Address	Ph No	E-mail	Qualification
1	Dr. Anita Anup Barde	A1-2204,F Residences, Near Kaizen Society, Sopan baug, Balewadi, Pune-411 045	7798355883	anita.barde72@ gmail.com	MSc,Faculty of Medicine Pharmacology
2	Dr ArtiHajarnavis	Profile Ede,Flat No 1,39/2,Erandwana,prabhat road,len 8,pune - 411004	9890032163	artihajarnavis@gmail.com	MSC medical biochemistry PHD in Biochemistry
3	Dr. Pradeep shetty	Truptideep,#25Sukhwani Oasis,Sec 11,PCNTDA,Chikhli, Chinchwad-411019	8888611011	docpradeepshetty@gmail.com	BDS,MDS,PHD
4	Dr Sandeep Jethe	C-5,Dwarka Vishaw Housing Society,Indrayani Nagar,Bhosari,Pune-411026	9822269241	sandeep.jethe@gmail.com	BDS,MDS
5	MrTrushna Satish Kamble	1,Ahilya Housing Society,Golf Club Road,Yerwada,Pune	9970963495	trushna.kamble255@gmail.com	MA,MSW Sociology
6	Dr. Kamaljeet kaur siddhu	Gourinandana", Plot No.56, S.No. 293/7A, Skyline Park, Nimbalkar Nagar, Lohegaon, Pune 411047, Maharashtra	9657712926	kamaljeetzone@gmall.com	LLB
7	Smt Sheetal Torat	37/2551,maharastra housing board,nearmoze School,pune-411006	7350867505	Sheetalthorat667@gmail.com	7th standard
8	Dr. Anagha Shethe	204/Durain, Nyati Environ, Tingre Nagar Lane 5, Vishrantwadi, 411015	8668760597	dranaghashete@yahoo.com	BDS,MDS,PHD
9	Dr.Pritesh Gawli	#56,Srno 48,Sai Nagari Society,Chanddannagar, Pune-411014	9820007575	drpriteshgawali@gmail.com	BDS ,MDS
10	Mr.C S Patil	A3,Staff Qtrs,D Y Patil Dental School,Pune	9665182413	cs.patil9767@gmail.com	Bcom
11	Dr Kamal Shigli	Gateway Towers,Tower No	8007305050	kamalshigli@yahoo.co.in	BDS MDS

		98,#904,Amanora Park,Pune-411028			
12	**Dr Karibasappa GN**	**A 3,Staff Quarters,D Y Patil Knowledge City ,Pune 412105**	**9326555659**	**karibasappa.gn@dypds.com**	**BDS MDS**
13	**Vinod Krishna Dolas**	**Bhausaaheb Sadan, Sr. No-3, Gaikwad Nagar, Dighi, Pune-411015**	**9822117837**	**vinoddolasl975@gmail.com**	**BA**
14	**Mr Vinayak Bhosale**	**Moze Nagar,Lane 2,Punnagatti Complex,Lohegaon-411047**	**9987369987**	**vinayak991@gmail.com**	**BA**

11. DETAILS OF SUPPORTING STAFF OF IEC

1, Chandrakant S. Patil

Office Superintend-IEC, DYPDS

Pune-412105

Mob No – 9665182413

cs.patil@dypic.in

2. Mr. VinayakBhosale

Student Section

IEC, DYPDS

Mob No – 9987369987

12. CLINICAL RESEARCH REVIEW

TO WHOM IT MAY CONCERN

Stated that Institutional Ethics Committee, DYPDS in short IEC,DYPDS has been formed and **registered** with National Ethics Committee Registry for Biomedical and Health Research (NECRBHR) with file no **EC/NEW/INST/2020/1115** on 05 – 10 –2023.

Till date Committee has not reviewed any clinical trial but Committee would like to review the clinical research types like pharmaceuticals, devices, herbals etc

However, till now epidemiological, prospective, retrospective studies are reviewed and followed up the process from IECDYPDS.

(Signature of the Member Secretary)

13. STANDARD OPERATING PROCEDURE TO BE FOLLOWED BY THECOMMITTEE IN GENERAL

13.1 Name, Formation & Registration

This committee will be known as IEC, DYPDS. This name will remain unchanged.

13.2 Objectives and Responsibilities

The primary objective of this committee will be**:**

13.2.1 To protect the right, safety and wellbeing of the research subject and assist in welfare and benefit of the society.

13.2.2 To review the qualifications of all investigators participating in the proposed research study.

13.2.3 To keep all information submitted to them confidential especially, the proprietary information.

13.2.4 To review all research proposals submitted to the committee within the specified time limits

13.2.5 To maintain concise but clear documentation of its use on the research proposals.

13.2.6 To review the progress of each research project at appropriate and specified intervals and also review the summary of final report of the studies approved by them.

13.3 Functions & Operations

13.3.1 Submission of the Research Proposals

1) All communications with the Committee will be in writing (Physical or electronic)

2) Before receiving the review materials, it is advisable to obtain COI (Conflict of Interest) declaration and CA (Confidentiality Agreement) from the Member Secretary, Chairperson & Members. If it is required by Sponsor/CRO/Investigator/Institution. A copy of this agreement will be filed with the official records of the Committee and another copy will be returned to the Sponsor / CRO / Investigator / Institution.

3) The Committee will require the submission in Printed (member copies + 1PI Reference copy (if required) + Guest Member copy (if any) & electronic copy (whenever possible) of study dossier as listed for every research proposal.

4) All the relevant revised documents which are resubmitted for review should be submitted in two copies (Committee reference copy + one copy) if there submission involves only those changes which are suggested by the Committee with no other modification.

5) In case of any amendment to the research proposal or any modification which is not suggested by the Committee and is not administrative, submission should be as directed in 13.3.1 (3).

6) The documents required for submission are the following:

a) Study proposal with covering letter.

b) Protocol along with compensation details and any amendments to it, Informed Consent Form (ICF), including any amendments and its translation(s) into regional language (s) with translation certificates.

c)Written information to be provided to the subjects {e.g., Patient Information Sheets (PIS), if applicable}.

d) Investigator's Brochure (IB).

e) Undertaking by Investigator.

f) Subject recruitment procedures (e.g., advertisements), if applicable.

g) Available safety information.

h) Information about payments and compensation available to the subjects.

i) Investigator's current Curriculum Vitae indicating qualification and experience.

j) Approval from competent regulatory authorities.

k) Copy of the Insurance Certificate.

l) DCG (l) clearance (whenever applicable).

m) Investigator's agreement with the Sponsor / CRO.

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

o) Food and drug Administration (FDA) marketing / manufacturing license for herbal drug wherever applicable.

13.3.2 Prescribed Application Form for Clearance of Research Project by IEC:

a. Name of the Investigator/co-investigator with designation:

b. Name of the Department where research will be conducted:

c. Protocol of the proposed research involving human samples / participants*:

d. Ethical issues in the study and plans to address these issues:

e. Copies of Proforma / Case Report Forms / Questionnaires / Follow-up Cards,etc.:

f. Details of Informed Consent Process, including patient information sheet andthe Informed Consent Form in local language /English / Hindi:

g. For any drug / device trial, all relevant publications / pre-clinical data andclinical trial data from other institutions within the country / other countries, ifavailable :

h. Curriculum Vitae of all the investigators with relevant publications during the last five years:

i. Regulatory clearances (other than IEC, DYPDS), if required:

j. Details of Funding agency/sponsors and fund allocation for the proposed work.

k. An agreement to report only Serious Adverse Events (SAE) to IEC:

l. Statement of conflicts of interest, if any:

m. A statement specifying pecuniary risks involved and the measure(s) taken to provide compensation to the research participants, the human subjects involved as participants in research (as defined in the guidelines of various nationalagencies), the researchers themselves, and such other persons who may bedirectly or indirectly at risk in the conduct of the research:

n. Plans for publication of results – positive or negative - while maintaining the privacy and confidentiality of the study participants:

o. Agreement to comply with the relevant national guidelines for research inhuman genetic, transplantation etc, as and when applicable.

p. Any other information relevant to the study:

Signature of Principal Investigator (PI)

Place:

Date:

Signature of Co-investigator(s)

Place:

Date:

*The protocols should include among other things the following:

a. Clear research objectives and rationale for undertaking the investigation inhuman subjects in the light of existing knowledge.

b. Subject recruitment procedures.

c. Inclusion and exclusion criteria for entry of subjects in the study.

d. Precise description of methodology of the proposed research, includingintended dosages of drugs, planned duration of treatment and details ofinvasive procedure, if any.

e. A description of plans to withdraw or withhold standard therapies in the courseof research.

f. The plans for statistical analysis of the study.

g. Safety of proposed intervention and any drug or vaccine to be tested, including results of relevant laboratory and animal research.

h. Storage and maintenance of all data collected during the trial.

i. Agreement to comply with national and international GCP protocols forclinical trials.

13.3.3 Procedure for Document Receipt & Handling:

1. Receiving the Study Documents

The Member Secretary will receive the study documents and other relateddocuments in hard copies at the Ethics Committee office, submitted by thePrincipal Investigator / Institution / **Sponsor / CRO.**

2. Checklist for Submitted Documents

The Member Secretary will check the following:

i) A Submission Letter addressing the Ethics Committee.

ii) Total number of copies of all documents.

13.3.4 Circulating the Documents

i) Study documents will be circulated to the members along with a Document Circulation Log to maintain the record of the same and the template of Document Circulation Log is given below.

ii) The Document Circulation Log will be filed by the person receiving thedocuments.

iii) After the documents have been circulated. Document Circulation Log willbe checked for completeness and will be archived in master log file.

IEC, DYPDS

DOCUMENT CIRCULATION LOG

Sponsor / CRO;

Protocol No.:

Member's Name	**Receiver's Name**	**Date**	**Signature**

Return of the Documents

i) On the meeting day, the members will bring their hard copies of the study documents to be reviewed.
ii) After taking the decision for the proposed study, the members return their copies at the office.
iii) All the returned copies will be discarded if not asked to be returned by theInvestigator / Institution / Sponsor / CRO, except for two copies, one Committee reference copy and one copy to may be kept with the Chairperson.
iv) Out of the two copies, one Committee reference copy will be archived at the Committee office and the Archival Log will be updated accordingly and the second copy will be kept with the Chairperson.
v) Archival will be done as described in Section 6.
vi) In case a member is not able to attend the meeting, it will be the member'sresponsibility to return the documents to the Committee.

13.3.5 Elements of Review

The submitted proposal shall be reviewed both for scientific content and ethical principles. The Committee members shall review the proposal with reference tothe following:

a. Scientific design of the study
b. Justification / Rational of the study
c. Selection criteria for subjects
d. Justification for use of placebo, if any
e. Potential benefits to the study subjects, predictable risks to the study subjects
f. Criteria for discontinuation / withdrawal of the subjects
g. Monitoring of serious adverse events
h. Compensation to the subjects for participating in the study
i. Subject recruitment procedures (e.g., advertisements), if applicable
j. Patient retention activities
k. Compensation for study related injury or death
l. Post trial benefits
m. Protection of privacy and confidentiality and plans for publication of results(positive or negative)

n. Statistical analysis

o. Informed consent document in English and regional languages

p. Competence of the Investigators, supporting staff and infrastructure facilities

q. Approval of regulatory authorities wherever applicable.

13.3.6 Safety Information

Adverse Event/ Serious Adverse Event reporting may be required for

(1) The protection of the subject

(2) Proper use of drug once it is marketed.

Adverse Event (AE): Any untoward medical occurrence in a Patient or Clinical InvestigationSubject administered the pharmaceutical product and which doesnot necessarily have acausal relationship with this treatment. An AE can therefore be any unfavorable andunintended sign (including an abnormal laboratory finding), symptom or diseasetemporarily associated with the use of the Medicinal (Investigational) Product, whetheror not related to the Medicinal (Investigational) Product. Expected adverse event may beknown to occur and is listed in the Investigational Brochure, Informed Consent, orGeneral Investigational Plan; whereas unexpected adverse event may not be listed in Investigational Brochure, Informed Consent, or General Investigational Plan, also not listed in a drug package insert.

Serious Adverse Event (SAE) or **Serious Adverse Drug Reaction (Serious ADR)** is any untoward medical occurrence that at any dose:

~ Results in death

~ Is life-threatening: If subject was at substantial risk of dying at the adverse event time,or continued use of the device or other medicinal product which might have resulted in the death of the subject.

~ Requires inpatient hospitalization or prolongation of existing hospitalization: If subjectrequires admission to the hospital or prolongation of hospitalization was a result ofadverse event.

~ Results in persistent or significant disability/ incapacity: If the adverse event resulted in a substantial disruption of a person's ability to conduct normal life functions, i.e.,significant, persistent or permanent change, impairment or damage or disruption in theperson's body function/ structure/ physical activities and/or quality of life.

~ Is a Congenital Anomaly/ Birth Defect: If exposure to a medicinal product during pregnancy may have resulted in an adverse outcome in the child.

~ Important medical event like allergic bronchospasm, blood disorders, seizures/convulsions, the development of drug dependence or drug abuse.

~ Required medical or surgical intervention (treatment) to prevent permanent impairment of a body function or damage to a body structure as a result of medicinal product usage.

Timeline for reporting of SAE as per 122 DAC of Schedule-Y

Responsibility of Investigator:

To	Within 24 hours of identifying the event	Within 14 days of Occurrence of SAE	Within 21 days	Within 30 days
Sponsor DCGI Office Ethics Committee Head of Institution Chairman of Expert committee-at CDSCO Office	Notification Notification Notification	Report of Death+ other SAE Report of Death+ other SAE Report of Death+ other SAE Report of Death Only		

Responsibility of Sponsor:

To	**Within 24 hours of identifying the event**	**Within 14 days of Occurrence of SAE**	**Within 21 days**	**Within 30 Days**
DCGI Office Ethics Committee Head of Institution Chairman of Expert committee-at CDSCO Office	Notification Notification	Report of Death+ other SAE Report of Death+ other SAE Report of Death+ other SAE Report of Death only		The sponsorshall pay the compensation in case of clinical trial related injury or death within 30 days of receiving the order from Licensing Authority DCGI

NOTE:

1. In case if the sponsor fails to provide medical management/ financial compensationto the subject, the Licensing Authority (DCGI) may after giving an opportunity to show cause why such order should not be passed and/or may suspend or cancel theclinical trial and/or restrict sponsor to conduct any further clinical trials in thecountry.

2. For SAE other than Death, trial subject will get the compensation.

3. For Death, nominee of the subject will get the compensation.

Responsibility of Ethics Committee: shall forward its report after due analysis on SAE with its opinion on the financial compensation (if any) to be paid by the sponsorto:

To	**Within 24 hours of identifying the event**	**Within 14 days of Occurrence of SAE**	**Within 21 Days**	**Within 30 days**
DCGI Office Chairman of Expert committee-at CDSCO Office	Notification	Report of Death+ other SAE Report of Death only		

Responsibility of Expert Committee (CDSCO Office) & Licensing Authority(DCGI Office):

~ The Expert Committee shall examine the report of death and gives its recommendations (including quantum of compensation) to the Licensing Authority within 30 calendar days of receiving the report from the Ethics Committee.
~ After considering the recommendations of the expert committee, the Licensing Authority shall decide the quantum of compensation and issue an order (shall be paid by Sponsor) within 3 months of receiving the report of SAE.
All SAE should be submitted as per the format of Appendix XI of Schedule Y and Ethics Committee should analyze and forward its opinion as per procedures specified in Appendix XII of Schedule Y.

13.5. Criteria for the Approval of Research

In order to approve the research proposal, the Committee shall determine that all of the following requirements are satisfied:

13.5.1 Risks to subjects, if any, are reasonable in relation to anticipated benefits. In evaluating risks and benefits, the Committee should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).
13.5.2 Selection of subject is equitable. In making this assessment, the Committee should take into account the purposes of the research and the setting, in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
13.5.3 Informed consent will be sought from each prospective subject or the Legally Authorized Representative of the subject.
13.5.4 When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
13.5.5 When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
13.5.6 In case, in which the documentation requirement is waived, the Committee may require the Investigator to provide subjects with a written statement regarding the research.

13.5.7 When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

13.5.8 The Committee shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with the Committee's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reason /s for the Committee's action and shall be reported promptly to the Investigator, appropriate institutional officials, the department or agency head.

13.6 Meetings

13.6.1 The committee will hold regular meeting, depending on the number of research proposals for review. However the committee will meet at least once every 3-4 months.

13.6.2 A maximum of 5 proposals can reviewed at each meeting if the proposals are of the different molecules and different study designs; however, if proposals require urgent review, the same can be done irrespective of number of protocol. In case, the proposals are with the similar molecule and/or similar study design they can be reviewed in the same meeting.

13.6.3 The Member Secretary will check the availability of the members for the meeting and shall invite the members for the same accordingly.

13.6.4 Primary reviewer could be assigned by the chairperson to conduct a detailed review of a research protocol and provide a report at the meeting

13.6.5 All regular members will receive notification of meeting schedules at least five (5) days in advance. In case of molecule/ combination of molecules Which has already been discussed earlier by the Committee and / or the molecule/ active ingredient that have been in case for considerable period of time, review meeting for such protocols / studies can be scheduled well within five(5) days or short notice as per availability of members. Towards the same, a list of molecules reviewed will be updated on regular basis for ready reference

13.6.6 The proposal may be sent to a subject expert for his/ her assessment and opinion of the research proposal. The subject expert may be invited for the meeting if deemed necessary by the Committee.

13.6.7 The Investigator and / or Co- Investigator may be invited to the meeting to provide clarifications on the study protocol if deemed necessary by the Committee.

13.6.8 Specific patient group representatives may also be invited for the meeting based on the requirement of the research area if deemed necessary. E.g. Subjects with HIV/AIDS or genetic disorders etc.

13.6.9 Meeting will be held only if quorum is met. A quorum will be defined as a minimum of five (5) members including one basic scientist (preferably a pharmacologist), one clinician, one legal expert; one social worker/representative of a non – governmental organization / theologian or a similar person, one lay from the community.

13.7 **Minutes**

The proceeding of the meeting will be recorded in English and in form of minutes. The Members Secretary will be responsible for coordination, recording and circulation of the meeting minutes.

13.8 **Decision Making**

13.8.1 Decision for each proposal / study shall be individual voting.
13.8.2 All members present at the meeting will vote on the research proposal
13.8.3 The decision will not be declared until the consensus is reached amongst all themembers regarding the opinion to the proposal/ study under consideration.
13.8.4 The queries comments or suggestions from the member (s) not in favour of the approval shall be forwarded to the Sponsor / CRO/ Principal Investigator and reply received from their end will be discussed with members. After all themembers (s), are satisfied with the reply, the chairperson shall take the final decision regarding further action on the protocol depending on the opinion /decision which is favored by majority of the quorum members present at the meeting.
13.8.5 Absent members will not have a right to vote However, if absent members havebeen a part of the entire discussion via any electronic media from (e .g.telecom, webcam etc.) They will be eligible to vote.
13.8.6 Member (s) of the Committee who is/ are listed as investigator (s) on a research proposal will opt out from all deliberations on the proposal and will not vote on the proposal.
13.8.7 An investigator or study team member invited for the meeting will vote orparticipate in the decision making procedures of the Committee.
13.8.8 The Committee shall reserve the right to withhold favorable opinion/approval on a research proposal when the Committee does not have reasonable assurance about the qualification of the Investigator(s), the site facilities, the Sponsor/CRO or the research protocol itself.
13.8.9 The Committee shall notify the Investigation/ Sponsor / CRO in writing of its decision to approve or disapprove the proposed research activity. If the Committee decides to disapproval a research activity, it shall include in its written notification, a statement of the reasons for its decision and give theInvestigator / Institution / Sponsor /CRO an opportunity to respond in person or in writing.

13.9 Review Outcome

The Committee will document its view as the following:
13.9.1 Approval – Unconditional or Conditional
13.9.2 Request for Modification or Information
13.9.3 Disapproval
13.9.4 Termination/ Suspension of the research proposal / ongoing study

13.10 Notification of Review Outcome

The outcome of the Committee review will be recorded and conveyed to the Investigator / CRO/Sponsor Within seven (7) Working day from the date review

13.11 Approval Period

All projects will be given approval for a period of one (1) year from the date on which the project was approved and for the projects continuing for longer than one year annual renewal will be mandatory.

13.12 Procedures for Appeal after Protocol Rejection

For research proposals rejected by the Committee, the applicant may appeal for a repeat review in writing, within Twelve (12) weeks of the receipt of the Committee's decision. While doing so, the applicant shall give justification relevant to the issues /objections raised by the Committee.

13.13 Amendments to the Approved Research Proposal and Informed Consent Documents

13.13.1 All amendments to the approved research proposal shall be submitted to the Committee immediately for its review as directed in 13.3.1 (4) and 13.3.1 (5).

13.13.2 No changes in the protocol and/ or Informed Consent Documents shall be initiated without prior written approval from the Committee, except when necessary to eliminate immediate hazards to the subjects, or when the change(s) involve only logistical or administrative aspects of the trial (e.g. change of monitor (s), telephone number (s).

13.13.3 Research studies that are Exempt Ethical approval:

Within the definition of research, the following are not considered to be **'research'**and would be exempt:

- Service evaluation
- Performance reviews
- Literary or artistic criticism
- Testing within normal education requirements
- Quality assurance/audit projects that do not involve access to or collection of private or sensitive data

Research Studies that are "Exempt Ethical Approval*

The following types of research do not require ethical approval from IEC, DYPDS (unless approval is specifically required by an external funding body or other external body) and should be submitted to IEC, DYPDS only for 'Exempt',

Stating clearly the clause under which the exemption is sought:

Clause	Research Type	Example
1	Research involving information freely available in the public domain.	Published biographies, newspaper accounts of an individual's activities and published minutes of a meeting which would not be considered 'personal data'
2	Research involving anonymised records and data sets that exist in the public domain.	Data sets available through the offices of National and State agencies where appropriate permission have already been obtained and it is not possible to identify individuals from the information provided.
3	Studies of public behavior those are purely observational.	All non-invasive and non-interactive studies where the recorded observations **do not** identify individuals (names, photographs) which could place them at risk of harm, stigma or prosecution
4	Research involving the use of non sensitive, completely anonymous studies	All anonymous educational tests, survey and interview procedures when the participants are not defined as "vulnerable" and participation will not induce undue psychological stress or anxiety.
5	Research involving the use of education tests, survey and interview procedures on human participants in the public arena.	All elected or appointed officials, candidates for public office, artists.
6	Taste and food quality evaluation &consumer acceptance studies. 'Exempt' doesn't apply to food evaluation studies where ethical issues related to local socio-religious and cultural practices of the studied population may be a concern.	Studies where the food consumed is: a) wholesome without additives or b) contains a food ingredient, agricultural, chemical or environmental contaminant, for a purpose and at a level declared safe by the relevant National/State food safety agency.

In accordance with the above criteria, Scientific Research Committee of DYPDS will have to make the final judgement as to whether a particular activity should be submitted to IECDYPDS for a formal Ethics committee approval or just an 'Exempt'

***Note that exemptions above do not apply to research involving vulnerable participant.**

For example children and young people, those with a learning disability or cognitive impairment or individuals in a dependent or unequal relationship.

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 of the IEC or designated member of the Committee or Subcommittee of the IEC do not expedited review only if the protocols involve

1. Minor deviations from originally approved research during the period of approval (usually of one year duration).

2. Revised proposals 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. Clinical studies of drugs and medical devices only when

i. Research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population or

ii. Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.

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 trial that may be initiated later based on thefindings of the pilot study.

a. Research on interventions in emergency situation when proven prophylactic, diagnostic, and therapeutic methods do not exist or have been ineffective, physicians may use new intervention as investigational drug (IND)/devices/vaccine to provideemergency medical care to their patients in life threatening conditions. Research in such instance of medical care could be allowed in patients

i.When consent of person/patient/responsible relative or custodian/team of designated doctors for such an event is not possible. However, information about theintervention should be given to the relative/legal guardian when available later;

ii. When the intervention has undergone testing for safety prior to its use in emergencysituations and sponsor has obtained prior approval of DCFI;

iii. Only if the local IEC reviews the protocol since institutional responsibility is of paramount importance in such instances.

iv. If Data Safety Monitoring Board (DSMB) is constituted to review the data;

b. Research on disaster management 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. Disasters create vulnerable persons and groups in society, particularly so in disadvantaged communities, and therefore, the following points need to be considered when reviewing such research:

i. Research planned to be conducted after a disaster should be essential culturally sensitive and specific in nature with possible application in future disaster situations.

ii. Disaster affected community participation before and during the research is essential and its representative or advocate must be identified.

iii. Extra care must be taken to protect the privacy and confidentiality of participants and communities.

iv. Protection must be ensured so that only minimal additional risk is imposed.

v. The research undertaken should provide direct or indirect benefits to the participants, the disaster affected community or future disaster affected population and a priori agreement should be reached on this, whenever possible, between the community and the researcher.

vi. All international collaborative research in the disaster affected area should be done with a local partner on equal partnership basis.

vii. Transfer of biological material, if any, should be as per Government rules taking care of intellectual property rights issues.

13.14 Expedited Review Procedures

13.14.1 The Committee may use expedited review procedure in case of minor changesin the previously approved research. The expedited review may also be used when the amendments appear to involve no more than minimal risk to the study subjects.

13.14.2 Under the expedited review procedure, the review may be carried out by the Chairperson, or by one or more experienced reviewers designated by theChairperson from amongst the members of the Committee. The reviewers may exercise all the authorities of the Committee except that the reviewers may not disapprove the research.

13.14.3 An On-going research activity may be disapproved only after review in accordance with non-expedited review procedure as mentioned. The members will be informed about the expedited review proposal in next full board meeting.

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

13.15 Review of On-going Studies

The Committee will conduct continuing review of each On-going Study at intervals appropriate to the degree of risk to the human subjects, but not less than once a year, and can also have authority to observe or have a third party observe the research activities.

13.15.1 The investigator should promptly report the following to the Committee;

i) Deviations from or changes to the protocol to avoid immediate hazards to the trial subjects.

ii) Deviations / changes that increase the risk to subjects and / or affect significantly the conduct of the trial.

iii) All serious and/ or Unexpected Adverse Events should be reported to the Committee by the Investigator within 24 hours of their occurrence as perapplicable regulatory guidelines. The report of the serious adverse event of that orsevere adverse event other than that after due analysis should be submitted withinten (10) Calendar days of occurrence.

iv) New information that may affect adversely the safety of the subjects or the conductof the trial.

13.15.2 In addition, the Investigator should submit the progress report of the study atintervals appropriate to the degree risk to the human subjects or as directed by the Committee.

13.15.3 In case of serious adverse event of death or other serious adverse events, the Committee will meet as and when required, in the view of recent amendment by CDSCO. The Committee may also invite an expert for his / her opinion on thesame. The Committee will generate the report after due analysis and submit the same to the applicable authority within timelines specified in the applicable regulatory guidelines.

13.16. Annual Progress Report.

For the study continuing for longer than the period of one year, the first report shall be submitted within thirty (30) days of completion of one year following the date of the first approval. Subsequent report shall be submitted at one year intervals following the first report. The Committee can recommend termination of ongoing clinical trials for the reasons like patient's safety, breach of any condition of approval, noncompliance on part of the Investigator, goal of the study achieved midway, complaint from thesubject etc.

13.17 Annual Renewal Process

For studies, whose duration is more than one year, an extension of approval shall begiven, after the status report and all other relevant reports mentioned are reviewed and approved by the Committee by the Annual Renewal Process. The approval forextension for study will be given for a period of one year.

13.18 Records Retention

The Committee will retain the following records;

13.18.1 Standard Operating Procedures (SOPs) in effect at the time of review and the previous SOPs.

13.18.2 Membership list at the time of review and the previous membership records.

13.18.3 Occupation/ affiliations of the members at the time of review with CVs andtraining records of the members as well as CV of guest expert members.

13.18.4 Invitation Letter, Consent Letter and CDA signed by members and guest expert members and Resignation Letters of the members who have resigned.

13.18.5 Agenda of meetings, minutes of meetings and all correspondence with the Principal Investigator.

13.18.6 Copies of all research proposals reviewed, scientific evaluation, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by the Investigators, reports of injuries to the subjects etc.

13.18.7 Applicable regulatory guidelines.

13.18.8 Registration details of the Ethics Committee.

13.19 Archival Policy

13.19.1 The Committee reference study documents and other related documents will be archived for five(5) years after the completion of the study. And after five(5)years, the respective Principal Investigator / Sponsor/ CRO will be informed about the end of archival period and the documents will be returned or discarded as instructed by the respective authority.

13.19.2 The Archival Log will be updated accordingly.

13.19.3 The documents will be archived within a secure place in a log cupboard with restricted access.

13.19.4 The documents of the completed study can be archived at a separate facility and the details for the same will be maintained in the archival log.

13.20 Reports to the Relevant Regulatory Authorities.

The Committee will make a yearly activity report for submission to the Relevant Regulatory Authorities upon request, which would include the following elements;

13.20.1 A quantitative evaluation of the activities of the Committee and list of proposals reviewed.

13.20.2 Status of each study proposal.

13.20.3 Statements of significant new findings provided to subjects.

13.21. Handling of Subject Queries

13.21.1 The subjects can call on the Committee Office number which is given in the Informed Consent Document.

13.21.2 Subject's queries shall be documented by the Member Secretary and the same shall be conveyed to the Chairperson. The reply of the Chairperson will be conveyed back to the concerned subject.

13.21.3 In case the subjects want to talk directly to the Chairperson, the Chairperson's number shall be provided from the Committee Office.

14. STANDARD OPERATING PROCEDURE FOLLOWED BY THECOMMITTEE FOR VULNERABLE POPULATION

i) The committee will give special consideration to the proposals involving vulnerable population for protecting the right and welfare of vulnerable subjects. Potentially vulnerable groups may include.

- Medical, pharmacy, dental and nursing student, subordinates hospital and laboratory personnel, employees of the pharmaceutical company.
- Members of the armed forces and persons kept in detention
- Unemployed or impoverished person
- Patients with incurable diseases
- Patients in emergency situation
- Ethnic or racial minority groups
- Homeless persons, nomads, refugees
- Pregnant women, foetus and neonates
- Decisionally in capacitated

ii) The committee will include representation in selected vulnerable population if additional expertise is needed in reviewing and approving the proposed research that involves vulnerable subjects. The committee may work with these participants, to be part of the review process. The documentation for the same will be maintained.

iii) The committee will follow the applicable regulation and guidelines in reviewing the research that involves vulnerable population as research subjects.

iv) The Committee will ensure that adequate justification for the involvement of vulnerable subject is provided in the protocol and other pertaining document wherever applicable.

v) The new study submission including vulnerable groups as potential research participants will be reviewed by the full board meeting and cannot be reviewing under expedited procedures.

vi) Subsequent review of amendment and continuing review applications involving vulnerable group as potential research participants can be reviewed by expedited review procedures.

15. POLICY REGARDING TRAINING OF NEW AND EXISTING MEMBERS

PURPOSE:

All IEC members are conversant with Guidelines for Research involving Human Subjects

RESPONSIBILITY:

A team of trainers chosen for this purpose by Member Secretary will ensure that new members get trained with in fortnight after being inducted

PROCEDURE:

All IEC members will be made conversant with ICMR Guidelines for Research involving Human Subjects 2006, Schedule Y of Drugs and Cosmetics Act and ICH-GCP guidelines

Training schedule for new members of IECDYPDS

S.No	Session Topic	Facilitator	Time period
1	Roles & responsibilities of IEC and its members	Member Secretary	1 hour
2	Discussion on regulatory guidelines on IEC	IEC member nominated by Member Secretary	2 hours
3	Interactive session	With at least two members nominated by Member Secretary	2 hours

Additionally Institutional Ethics Committee will hold retraining for all the members of IEC once in 6 months for 2-3 hours on the topics listed in the above table

16. POLICY TO MONITOR AND PREVENT THE CONFLICT OF INTEREST

i)The Committee Member with conflicting interest should not accept the protocol for review. The same should be communicated to the Member Secretary / Chairperson /Committee.

ii) In case, the member has conflict of interest for any protocol received for review, member shall immediately inform Member Secretary / Chairperson / Committee well in advance of the scheduled meeting and withdraw from the meeting or withdraw from deliberation of that particular protocol. Another suitable member shall beinvited to fulfil the quorum requirements.

iii) In Committee members need information on the study from the member with a conflicting interest, then the member may remain present in the meeting room duringpresentation of the study. The member must than leave the meeting room during the deliberative discussion and voting of protocol.

iv) The same will be recorded in the Declaration of Conflict of Interest Form (the template for the same is attached in annexure XII) and Minutes of Meeting.

17. DECLARATION OF CONFLICT OF INTEREST FORM

Investigator/Sponsor / CRO;

Protocol No.:

Protocol Title:

Sl no	**Member's Name**	**Designation**	**Conflict of Interest Declared** Yes / No	**Signature and Date**

18. COMMITMENTS:

(i) The Committee shall review and accord its approval to a clinical trial and also carry ongoing review of the trial at appropriate intervals, as specified in ScheduleY and Good Clinical practice Guidelines for Clinical Trials in India and other applicable regulatory requirements for the safeguarding the rights, safety and wellbeingof the trial subjects.

(ii) In case of any serious adverse occurring to the clinical trial subjects during theclinical trial, the Committee shall analyse and forward its opinion as per procedures specified under APPENDIX XII of Schedule Y

(iii)The Committee shall allow inspectors or officials authorized by the Central Drugs Standard Control Organisation to enter its premises to inspect any record, data orany document related to clinical trial and provide adequate replies to any query bysuch inspectors or officials, as the case may be, in relation to the conduct of clinicaltrial.

(iv)We agree to maintain adequate and accurate record after the completion ortermination of the study for not less than five years from the date of completion or termination of the trial (Both in hard and soft copies).

Institutional Ethics Committee (IEC), DYPDS

DYPDS ,Loheagon,Pune

SOP Title: Preparing Standard Operating Procedure (SOP): Writing, Reviewing, Distributing & Amending SOP for the Institutional Ethics Committee (IEC)

SOP No: IEC/SOP/000/01.0 Page: 1 To 32

Effective Date: 12/05/2023

Authors

Dr. Arti Hajarnavis
Member Secretary,
IEC,DYPDS,Pune

Dr .Karibasappa.G N
Scientific Member
IEC,DYPDS,Pune

Approved by

Dr. AnandShigli
Dean ,DYPDS,

19. IMPLEMENT, DISTRIBUTION OF SOP

19.1 The approved SOP will be implemented from the effective date and will bedistributed to the IEC members and the Investigator by the Member Secretary IEC.

19.2 For public access one printed and signed copy will be available at library at DYPDS and PDF version of the SOP will be publish in the DYPDS website (www.dypds.com)

19.3 When revised version is distributed the old version will be retrieve from all person.The old version will be no longer effective and it will be archived.

19.4 One complete original set of current SOP will be file centrally in the SOP masterfile by the Member Secretary IEC and keep the file in the Secretariat.

19.5 Photocopy made from paper version of the SOP will be consider officially only ifstamped and signed by Member Secretary. A distribution log should be maintain.

20. REVIEW & REQUEST FOR REVISION OF THE EXISTING COMMITTEE

20.1 Any member of IEC or Investigator of DYPDS who notices and inconsistency or any suggestion on how to improve a procedure should becommunicate through the Member Secretary/Chairman of the IEC.

20.2 If IEC agree with the request and appropriate team will be designated by the Director DYPDS and Chairman of IEC, DYPDS to proceed with therevision process. If Committee does not agree the Member Secretary will inform the person who made the request for the decision.

20.3 The Member Secretary will regularly prepare the amendment or addendum (if any)to the existing SOP to the approved discussion points in the IEC meetings.

20.4 The Member Secretary will review the SOP at least every two years and incorporate the amended and record the date of review in the SOP master file.

21. REFERENCES

1. WHO Operational guidelines for Ethical Review Committee that Review BiomedicalResearch (Geneva 2000) Retrieved from – www.who.int/tdr/publications/publications accessed on 10th July2018

2. International Conference on Harmonization, guidance on good clinical practice (ICHGCP) (1996) Retrieved from – http://www.ich.org/LOB/media/482.pdf access on 10th July 2018

3. ICMR Ethical Guidelines for Biomedical Research on Human participants, ICMR(2006)Retrieved from http://www.icmr.nic.in/ethical guidelines.pdf access 19th Aug 2018

4. Scheduled Y (Drugs and cosmetic Act 1940; amendment 20th January 2005)Retrieved from http://www.cdsco.nic.in/html/Schedule- Y 20 (Amended 20version-2005) accessed 19th Aug 2018

Appendix – I

1st Institutional Ethics Committee (IEC), DYPDS,Pune.

Constituted by: **Prof. (Dr.) Rahul Hegde Director**, DYPDS, Dated - 4th April 2019

Members:-

1. Dr .AnandShigli , Prof &H.O.D., Pedodontics , DYPDS – DEAN
2. Dr. Anita Barde, Professor, Pharmacology-Sianghad Dental College- Chairperson
3. Dr. Sandeep JetheProf & HOD .Orthodontics - Member
4. Dr .Kamal Shigli Prof &H.O.D., prosthodontics, DYPDS – Member
5. Dr. Pradeep Shetty.Prof & H O D, Conservative & Endodontics - Member
6. Dr. Karibasappa G N. Prof & H O D. Public Health Dentistry- Member
7. Dr. Arti Hajaranivs. Professor& H O D, Biochemistry,DYPDS, – Member Secretary
8. Mr. Trushna S Kamble .Center for Advocacy & Research – Social Scientist
9. Dr. Kamaljeet Kaur- DYPDS- Legal Expert
10. Dr. Anagha Shete Prof & . H O D. Oral Medicine & Radiology–DYPDS – Scientific Member
11. Dr. Pritesh GAwali .Reader. Pedodontics & Preventive Dentistry-Member
12. Mr. Vinayak Bhosale.-Member
13. Smt .Sheetal Torat .Attendent –DYPDS- Layperson
14. Mr.Vinod Dolas- Medical OS- Member

D Y PATIL DENTAL SCHOOL, PUNE

CODE OF ETHICS FOR RESEARCH

Introduction

Research at the D Y Patil Dental School (DYPDS) is conducted according to the principles of integrity, academic excellence, accountability, inclusiveness and professionalism. All research must follow appropriate ethical, legal and professional frameworks, obligations and standards. The Code-of Ethics for Research Practice have been composed at par with the principles laid out in other relevant policies, guidelines and codes of conduct, including those of funding bodies.

This describes the principles underpinning the ethical conduct of research and defines the process and principles for the objective and rigorous ethical review of research, which falls within its scope

This code applies to all the faculty, students and visiting researchers of the Institute, including persons holding honorary appointments and students on placements, who conduct research within or on behalf of the institute.

Purpose of the Code of Ethics:

The purpose of the code of ethics in dental research is to establish a set of codes of principles that should help the dental student, intern, faculty or a researcher to reach professional standard guided by legal and ethical principles. Research ethics is the application of ethical codes or principles in scientific investigation.

All the members of the DYPDS are individually responsible to ensure their work is conducted in accordance with the institutional values and policies that form part of the terms and conditions of employment or study. Disregard to this policy may lead to failure of assessed work, suspension of study/research projects, and/or funding from research sponsors and consent to publish.

Research is, any original investigation undertaken in order to acquire knowledge and understanding which would include the invention and generation of ideas, images, performances leading to new or substantially improved insights in health care, scholarship such as the creation, development and maintenance of the intellectual infrastructure of subjects and disciplines (e.g., research databases), the use of existing knowledge and experimentation to develop new or substantially improved materials, devices, products and processes, including design and fabrication.

Good research practices are based on fundamental principles of research integrity. They guide researchers in their work as well as in their engagement with the practical, ethical and intellectual challenges inherent in research.

These principles are:

Reliability in ensuring the quality of research; reflected in the design, the methodology, the analysis and the use of resources. .

Honesty in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair, full and unbiased way.

Respect for colleagues, research participants, society, ecosystems, cultural heritage and the environment.

Accountability for the research from idea to publication, for its management and organization, for training, supervision and mentoring, and for its wider impacts.

The **Code of Ethics** for research is described in the following contexts:

- Research Environment
- Training, Supervision and Mentoring
- Research Procedures
- Safeguards
- Data Practices and Management
- Collaborative Working

- Publication and Dissemination
- Reviewing, Evaluating and Editing

Research Environment.

- Promote awareness and ensure a prevailing culture of research integrity. .
- Demonstrate leadership in providing clear policies and procedures on good research practice and the transparent and proper handling of violations.
- Provides support with good infrastructure for the management and protection of data and research materials in all their forms (encompassing qualitative and quantitative data, protocols, processes, other research artifacts and associated Meta data) that are, necessary for reproducibility, traceability and accountability.
- Promotes research activities by acknowledging and appreciating the researchers with rewards.

Training, Supervision and Mentoring

- Ensure that researchers receive rigorous training in research design, methodology and analysis
- Develop appropriate and adequate training in ethics and research integrity and ensure that all concerned are made aware of the relevant codes and regulations.
- Researchers across the entire career path, from junior to the most senior level, should undertake training in ethics and research integrity
- Senior researchers, research leaders and supervisors should mentor their team members and offer specific guidance and training to properly develop, design and structure their research activity and to foster culture of research integrity

Research Procedures

- Researchers should write and submit the synopsis of intended work/project to the research committee, ethical committee, research grants committee (if required) and clinical trial registry of India (if applicable) respectively.
- Researchers should design, carryout, analyze and document research in a careful and well-considered manner.
- Researchers should make judicious and conscientious use of granted research funds.
- Researchers should publish results, interpretations of research in an open, honest, transparent and accurate, manner, and respect confidentiality of data or findings when legitimately required to do so.
- Researchers should report their results in a way that is compatible with the standards of the discipline and, where applicable, can be verified and reproduce

Safeguards

- Researchers should comply with codes and regulations relevant to their discipline.
- Researchers should handle research subjects, be they human, animal, cultural, biological, environmental or physical, with respect and care, and in accordance with legal and ethical provisions.
- Researchers should have due regard for the health, safety and welfare of the volunteering subjects, community, collaborators and other individuals involved in respective research projects.
- Research protocols take account of and are sensitive to, relevant differences in age, gender, culture, religion, ethnic origin and social class.
- Researchers should recognize and manage potential harms and risks relating to their research.

Data Practices and Management.

- Researchers should ensure appropriate stewardship and curation of all data and research materials, including unpublished ones, with secure preservation for a reasonable period.
- Researchers should ensure access to data will be in line with the **FAIR** Principles (Findable, Accessible, Interoperable and Re-usable) for data management. .
- Researchers should provide transparency about how to access or make use of their data and research materials to the institute.
- Researchers, research institutions and other organizations should have a reciprocal acknowledgement for data as legitimate and citable products of research.
- Researchers should ensure that any contracts or agreements relating to research outputs include equitable and fair provision for the management of their use, ownership, and or their protection under intellectual property rights

Collaborative Working

- All partners in research collaborations should take responsibility for the integrity of the research.
- All partners in research collaborations should agree at the outset on the goals of the research and on the process for communicating their research as transparently as possible.
- All partners should formally agree at the start of their collaboration on expectations and standards concerning research integrity, on the laws and regulations that will apply, on protection of the intellectual property of collaborators, and on procedures for handling conflicts and possible cases of misconduct.
- All partners in research collaborations should be informed and consulted about submissions for publication of the research results.

Publication and Dissemination

- All authors are fully responsible for the content of a publication, unless otherwise specified.
- All authors should agree on the sequence of authorship, acknowledging that authorship itself is based on a significant contribution to the design of the research, relevant data collection, analysis and interpretation of the results.
- Authors should ensure that their work is made available to colleagues in a timely, open, transparent, and accurate manner, unless otherwise agreed, and are honest in their communication to the general public and in traditional and social media.
- Authors should acknowledge important work and intellectual contributions of collaborators, assistants, funding agencies, and any other individual who have influenced the reported research in appropriate form.
- All authors should disclose any conflicts of interest and financial or other types of support for the research or for the publication of its results.
- Authors can issue corrections or retract work if necessary, however the reasons shall be clearly stated. .
- Authors and publishers should consider negative results to be as valid as positive findings for publication and dissemination.
- Researchers should adhere to the same criteria as those detailed above whether they publish in a subscription journal, an open access journal or in any other alternative publication form.

Reviewing, Evaluating and Editing

- All the researchers should take seriously their commitment to the research community by participating in refereeing, reviewing and evaluation.
- All the researchers should review and evaluate submissions for publication, funding and reward in a transparent and justifiable manner.
- Reviewers or editors with a conflict of interest should withdraw from involvement in decisions on publication, funding and reward.
- All the reviewers should maintain confidentiality unless there is prior approval for disclosure.
- All the reviewers should respect the rights of authors and applicants, and should also seek permission to make use of the ideas, data or interpretations presented.

Violations of Research Integrity

It is of crucial importance that researchers master the knowledge, methodologies and ethical practices associated with their field. Failing to follow good research practices violates professional responsibilities. It damages the research culture, degrades relationships among researchers, and undermines trust in and the credibility of research. It misuses the resources and may expose research subjects, users, society or the environment to unnecessary harm.

Research Misconduct and other Unacceptable Practices

Research misconduct is traditionally defined as fabrication, falsification, or plagiarism (the so-called FFP categorization) in proposing, performing, or reviewing research, or in reporting research results:

Fabrication is making up results and recording them as if they were real.

Falsification is manipulating research materials, equipment or processes or changing, omitting or suppressing data or results without justification.

Plagiarism is using other people's work and ideas without giving proper credit to the original source, thus violating the rights of the original author(s) to their intellectual outputs.

These three forms of violation are considered particularly serious since they distort the research record. There are further violations of good research practice that damage the integrity of the research process or of researchers. In addition to direct violations of the good research practices set out in this Code of Conduct, examples of other unacceptable practices include, but are not confined to:

- Manipulating authorship or denigrating the role of other researchers in publications.
- Re-publishing substantive parts of one's own earlier publications, including translations, without duly acknowledging or citing the original ('self-plagiarism').
- Citing selectively to enhance own findings or to please editors, reviewers or colleagues.
- With holding research results.
- Allowing funders/sponsors to jeopardize independence in the research process or reporting of results so as to introduce or promulgate bias.
- Expanding unnecessarily the bibliography of a study.
- Accusing a researcher of misconduct or other violations in a malicious way.
- Misrepresenting research achievements.
- Exaggerating the importance and practical applicability of findings.
- Delaying or inappropriately hampering the work of other researchers.
- Misusing seniority to encourage violations of research integrity
- Ignoring putative violations of research integrity by others or covering up inappropriate responses to misconduct or other violations by institutions.
- Establishing or supporting journals that undermine the quality control of research ('predatory journals')

In their most serious forms, unacceptable practices are sanctionable but at the very least every effort must be made to prevent, discourage and stop them through training, supervision and mentoring and through the development of positive and supportive research environment.

Dealing with Violations and Allegations of Misconduct

National guidelines details us to how violations of good research practices or allegations of misconduct are to be handled. However, it always is in the interest of society and the research community that-violations are handed in consistent and transparent fashion. The following principles need to be incorporated into any investigation process.

Integrity

- Investigations are fair, comprehensive and conducted expediently, without compromising accuracy, objectivity or thoroughness.
- The parties involved in the procedure declare any conflict of interest that may arise during the investigation
- Measures are taken to ensure that Investigations are carried through to a conclusion.
- Procedures are conducted confidentially in order to protect those involved in the investigation.
- Institutions protect the rights of 'whistle- blowers' during investigations and ensure that their career prospects are not endangered.
- General procedures for dealing with violations of good research practice are publicly available and accessible to ensure their transparency and uniformity

Transparency.

- Investigations are carried out with due process and in fairness to all parties.
- Persons accused of research misconduct are given full details of the allegation(s) and allowed a fair process for responding to allegations and presenting evidence.
- Action is taken against persons for whom an allegation of misconduct is upheld, which is proportionate to the severity of the violation.
- Appropriate restorative action is taken when researchers are exonerated of an allegation of misconduct.
- Anyone accused of research misconduct is presumed innocent until proven otherwise.

Informed Consent

The investigator should comply with the applicable regulatory requirements, and should adhere to GCP and other ethical principles that have their origin in the Declaration of Helsinki

The investigator, or a person designated by the investigator should fully inform the subject or, if the subject is unable to provide informed consent, the subject's legally acceptable representative, of all pertinent aspects of the trial including the written information and the approval/ favorable opinion by the IECDYPDS.

Rights of the researcher

The right to research freedom

Researchers at the DYPDS are free to choose the subject of their studies related to the thrust area and to seek support for their research from any appropriate source.

Researchers have the right to information required for their research, in so far as there is no legal or moral limitation on furnishing such information.

The right to research environment conducive for research

Institute has the responsibility to create an environment that promotes research and fosters good research. Institute will create an environment in which research can flourish, by, and among other things, visionary policy innovative programs, sound support services, appropriate incentives, effective financial management and mobilization of funding.

The right to the facilities, services and other resources of the institute

The institute has the responsibility, in so far as it is feasible, to make facilitates, equipment and services available for use in research, with a view to the creation of an environment, which is conducive to research.

Where the institute does not have sufficient resources to give effect to this right, it should endeavor to obtain resources to give effect to this right, it should endeavor to obtain resources from other sources and to allocate them to researchers.

Researchers are allowed to negotiate facilities, funds and other resource from elsewhere for research programmes in case of limited availability of resources, with due permission from Head of Institution.

Intellectual property

Researchers should be aware of all the provisions and should themselves to all the regulatory guidelines of the institute. The principles underlying are:

Promotion of free and creative work to the benefit of science and society as a whole. The conservation of traditional university practices and privileges with regard to the making available and publication of academic works.

Establishment of ethical standards and procedures with regard to intellectual Property

Promotion of creative and innovative research and cooperation by the establishment of mechanisms recognizing the rights of all the parties concerned, promoting the acquisition-of benefits from

research and guaranteeing the equitable distribution of benefits from research by establishing principles and procedures for distributing revenue from inventions and creative work (as per the funding agencies); protecting and marketing the institute's assets, including its intellectual property, to the benefit of all interested parties

CODE OF ETHICS TO CHECK MALPRACTICES AND PLAGIARISM IN RESEARCH

In Scientific Research, Plagiarism has become a serious problem. It is, therefore, necessary for D Y Patil Dental School (DYPDS) to formulate well defined code of ethics to check menace of plagiarism. Accordingly, DYPDS has framed the following guidelines using UGC notification 23rd July, 2018 regarding Promotion of Academic Integrity and Prevention of Plagiarism in Higher Educational Institutions, UGC (http://www.ugc.ac.in/pdfnews/8864815_UGC-Public-Notice-on-Draft-UGC-Regulations,- 2017.pdf and 23rd July, 2018)

"Plagiarism" means an act of academic dishonesty and a breach of ethics. It involves using someone else's work as one's own. It also includes data plagiarism and self-plagiarism;

Zero Tolerance Policy:

The core work carried out by the student, faculty, staff and researchers shall be based on original ideas and shall be covered by Zero Tolerance Policy on Plagiarism. In case, Plagiarism is established in the core work claimed, then Plagiarism Disciplinary Authority (PDA) of DYPDS shall impose maximum penalty.

The core work shall include abstract, summary, hypothesis, observations, results, conclusions and recommendations.

Levels of plagiarism

Plagiarism would be quantified into following levels in ascending order of severity for the purpose of its definition:

- Similarities up to 10% : excluded
- Level 1: Similarities above 10% to 40%
- Level 2: Similarities above 40 % to 60 %
- Level 3: Similarities above 60 %

Plagiarism Disciplinary Authority (PDA):

PDA shall be constituted by the institute and take appropriate decision after giving a hearing to the accused person.

There shall be three members in the PDA

- Dean- Chairman

- Senior Academician
- One Member nominated by Dean

Penalties OR Guidelines for Action:

Plagiarism Disciplinary Authority (PDA) of DYPDS shall impose penalty considering the severity of the Plagiarism. The committee experts will use the best possible software provided by UGC-INFLIBNET or institution for detecting the plagiarism. Penalties in the cases of plagiarism shall be imposed on students pursuing studies at the level of UG, PG, Ph.D. and faculty / staff of the DYPDS only after academic misconduct on the part of the offender has been established without doubt, when all avenues of appeal have been exhausted and individual in question has been provided with adequate opportunity to defend himself or herself in a fair or transparent manner. The degree of penalty served will commensurate with the degree of seriousness of offence and misconduct established.

Penalties for Students (PG and Ph D Student)

Plagiarism Disciplinary Authority (PDA) of DYPDS, shall impose penalty considering the severity of the Plagiarism.

Level 0: Similarities up to 10% - minor Similarities, no penalty

Level 1: Similarities above 10 % to 40 % - Such student shall not be given any marks and/or credit for the plagiarized script and shall be asked to submit a revised script within a stipulated time period not exceeding 6 months

Level 2: Similarities above 40 % to 60 % - Such student shall not be given any marks and/or credit for the plagiarized script and shall be asked to submit a revised script after a time period of one year but not exceeding eighteen months.

Level 3: Similarities above 60 % -Such student shall not be given any marks and/or credit for the plagiarized script and his/her registration for that course will be cancelled.

Note 1: Penalty on repeated plagiarism- Such student shall be punished for the plagiarism of one level higher than the previous level committed by him/her. In case where plagiarism of highest level is committed then the punishment for the same shall be operative.

Note 2: Penalty in case where the degree/credit has already been obtained –If plagiarism is proved on a date later than the date of conferring of degree or credit as the case may be then his/her degree or credit shall be put in abeyance for a period decided by the PDA.

Penalties for faculty, staff, Post Doc researchers

Level 1: Similarities above 10 % to 40% - Shall be asked to withdraw manuscript submitted for publication and shall not be allowed to publish any work for a minimum period of one year.

Level 2: Similarities above 40 % to 60 % - shall be asked to withdraw manuscript submitted for publication and shall not be allowed to publish any work for a minimum period of two years and shall be denied a right to one annual increment and shall not be allowed to be a supervisor to any UG, PG, Ph.D. student/scholar for a Period of two years.

Level 3: Similarities above 60 % - shall be asked to withdraw manuscript submitted for publication and shall not be allowed to publish any work for a minimum period of three years and shall be denied a right to two successive annual increments and shall not be allowed to be a supervisor to any UG, PG, Ph.D. student/scholar for a period of three years.

Note 1: Enhanced penalty on repeated plagiarism - shall be punished for the plagiarism of one level higher than the lower level committed by him/her. In case, where plagiarism of highest level is committed then the punishment for the same shall be operative. In case level 3 offence is repeated then the concerned person shall be dismissed.

Note 2: Penalty in case where the benefit or credit has already been obtained - If plagiarism is proved on a date later than the date of benefit or credit obtained as the case may be then his/her benefit or credit shall be put in abeyance for a period decided by PDA .

Note 3: If there is any complaint of plagiarism against the Head of Institution, a suitable action, in line with these regulations, will be taken by the Competent Authority as the title may be.

Short summary

Levels of Plagiarism and penalties / punishment

Faculty /student who submits plagiarized thesis or dissertations shall be punished considering the level of the plagiarism in his/ her work as following…

Sr. No.	**Levels of Plagiarism**	**% of Plagiarism**	**Penalties/ punishment**	
			Thesis And Dissertations	**Academic And Research Publications**
1	Level – 0	up to 10%	Minor Similarities, no penalty.	Minor Similarities, no penalty.
2	Level – 1	10% to 40%	Such student shall be asked to submit a revised script within a stipulated time period not exceeding 6 months.	Shall be asked to withdraw manuscript.

3	Level – 2	40% to 60%	Such student shall be debarred from submitting a revised script for a period of one year.	Shall be asked to withdraw Manuscript. Shall be denied a right to one Annual increment. Shall not be allowed to be a supervisor to any new Master's, Ph.D. Student/scholar for a period of two years.
4	Level – 3	above 60%	Such student's registration for that programme shall be cancelled.	Shall be asked to withdraw Manuscript. Shall be denied a right to two Successive annual increments. Shall not be allowed to be a Supervisor to any new Master's, Ph.D. Student/scholar for a period of three years.

Note: It is clear that those who are guilty of plagiarism there is some penalty / punishment. The punishment is not only for the student but also for the guide/supervisor of the thesis.

LINGARAJ J SHIGLI ANAND
Digitally signed by LINGARAJ SHIGLI ANAND
Date: 2024.06.28 17:16:24 +05'30'