VYDEHI INSTITUTE OF DENTAL SCIENCES & RESEARCH CENTRE
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INSTITUTIONAL CODE OF ETHICS FOR RESEARCH

I. Purpose:

The Vydehi Institute of Dental Sciences- Institutional Research Committee (VIDS-IRC) represents the research interests and activities of Vydehi Dental College and Research Centre (VIDS &RC). It aims to cultivate, design, and execute high-quality multidisciplinary research in VIDS & RC.

The policy includes initiation, facilitation, integration, and support of research projects conducted by undergraduate, postgraduate students and faculty of VIDS & RC. VIDS-IRC provides a mechanism for these research groups to interact within VIDS & RC, with external collaborating individuals and organisations. VIDS-IRC is the responsible body for managing this interaction.

The VIDS-IRC offers timely and complete critical appraisal and technical guidance to the submitted research proposals. The review of the submitted research proposals is an in-house exercise, where an attempt is made to assess its feasibility, to improve relevance to the regional context, technical quality and ethical aspects of proposed research. The VIDS-IRC encourages Good Research Practice and Good Authorship Practices at VIDS & RC.

The objective of **VIDS-IEC** is to ensure the quality and consistency in review of all academic, biomedical and health research proposals involving human participants conducted at VIDS & RC, Bangalore and overseeing the conduct of such research following the **'National Ethical Guidelines for Biomedical and Health Research 2017' specified by ICMR and 'New Drugs and Clinical Trial Rules 2019'.**

II. Scope

These Policies are applicable to students, faculties and researchers involved in all biomedical, social and behavioral science research for health conducted at VIDS & RC, Bangalore involving human participants, their biological material and data.

The VIDS-IRC and Principal of the institute as Head of the Committee, scrutinizes the research proposals from students and faculty and gives approval after which the proposal will

be forwarded for Ethical clearance to Vydehi Institute of Dental Sciences –Institutional Ethics Committee (**VIDS-IEC**).

All biomedical research involving human subjects conducted at VIDS & RC, Bangalore require prior approval of Vydehi Institute of Dental Sciences –Institutional Ethics Committee (**VIDS-IEC**).

These include**:**

1. Thesis protocols (SYNOPSIS) of post graduate (MDS) students of Rajiv Gandhi University of Health Sciences (RGUHS), Bangalore.
2. ICMR projects proposals or any other research protocols submitted by BDS/MDS students and Faculties
3. Retrospective studies
4. Investigator initiated studies (from faculty)
5. Presentations made in conferences/ CDE by faculty/UG/PG which involve the Patient data of VIDS & RC.
6. All the publications from the faculty/UG/PG which involve the Patient data of VIDS & RC.
7. All clinical Data (treatment/survey/questionnaire based studies) generated during tenure of faculty- is the intellectual Property of VIDS & RC and requires Ethical clearance.

It is the moral duty of the head of the department /faculty involved to ensure that established protocols are followed. Failing this disciplinary action will be taken by the head of the institution.

III. Roles and Responsibilities

VIDS-IEC is guided in its reflection, advice, operation and decision by the ethical principles expressed in 'National Ethical Guidelines for Biomedical and Health Research 2017' specified by ICMR, directives of 'New Drugs and Clinical Trial Rules 2019', the Indian Good Clinical Practice (GCP) Guidelines 2001 by the Central Drugs Standard Control Organization (CDSCO), Drugs and cosmetic Act 2013, and Declaration of Helsinki 1964.

a. VIDS-IEC will ensure the protection of the rights, safety and well-being of human subjects involved in a research and will provide public assurance of that protection, by among other things, reviewing and providing opinion on the study protocol, suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the research participants.
b. VIDS-IEC will 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.
c. VIDS-IEC will assist in the development and education of the research community in VIDS & RC (including researchers, clinicians, students and others), responsive to local healthcare requirements.
d. VIDS-IEC will ensure and safeguard the dignity, rights, safety and well-being of all research participants. VIDS-IEC will ensure ethical conduct of research by the investigator team.
e. When a study is to be carried out in the vulnerable populations like paediatrics, geriatrics, pregnant women, mentally unstable patients etc., the consent of the trial subject and the subject's Legally Acceptable Representative (LAR) is mandatorily taken and the VIDS-IEC will determine that the proposed protocol and/or other document (s) adequately address the relevant ethical concerns and meet applicable regulatory requirements for such trials.
f. Where the protocol indicates that the prior consent of the study participants or the subject's Legally Accepted Representative is not possible, the VIDS-IEC will determine that the proposed protocol and/or other document (s) adequately address the relevant ethical concerns and meet applicable regulatory requirements for such studies (i.e., in emergency conditions).
g. VIDS-IEC will review both the amount and method of payment to subjects to defray expenses and/or compensation for any loss of income of the participant, and to ensure that this does not amount to coercion, undue influence, misrepresentation or fraud, on the study subjects. Payments to a subject will be on a prorated basis, and not wholly contingent on completion of the study by the subject.

h. VIDS-IEC will ensure that information regarding payment to subjects, including the methods, amounts, and schedule of payment to study subjects and compensation in case of study related injury or illness, is set forth in the written Informed Consent Form and any other written information to be provided to subjects.

i. VIDS-IEC shall analyze all Serious Adverse Events (SAE) occurring in clinical studies conducted at VIDS & RC.

j. VIDS-IEC will maintain the lists of audits and the inspections it has hosted.

k. VIDS-IEC will maintain absolute confidentiality of all documents relating to protocols received and the proceedings of the meetings.

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

m. VIDS-IEC will ensure that universal ethical values and international scientific standards are followed in terms of local community values and customs.

n. VIDS-IEC will review and approve the manner in which the results of the research are to be reported and published of any of the studies.

o. VIDS-IEC will ensure the Principal Investigator (PI) has adequate provisions made for monitoring, auditing and inspection for the conduct of his/ her responsibilities.

p. VIDS-IEC will consider approving the study only after obtaining the administrating approvals from Head of the Institution.

q. VIDS-IEC will participate in continuing education activities in research ethics and get updated on relevant guidelines and regulations.

r. VIDS-IEC may see that conduct of same/similar research by different investigators from same institution is harmonized.

s. Detailed standard operating Procedures of VIDS-IEC (As approved by DHR) for reference for the faculty and students is available in Dental Library, VIDS & RC as a Booklet .