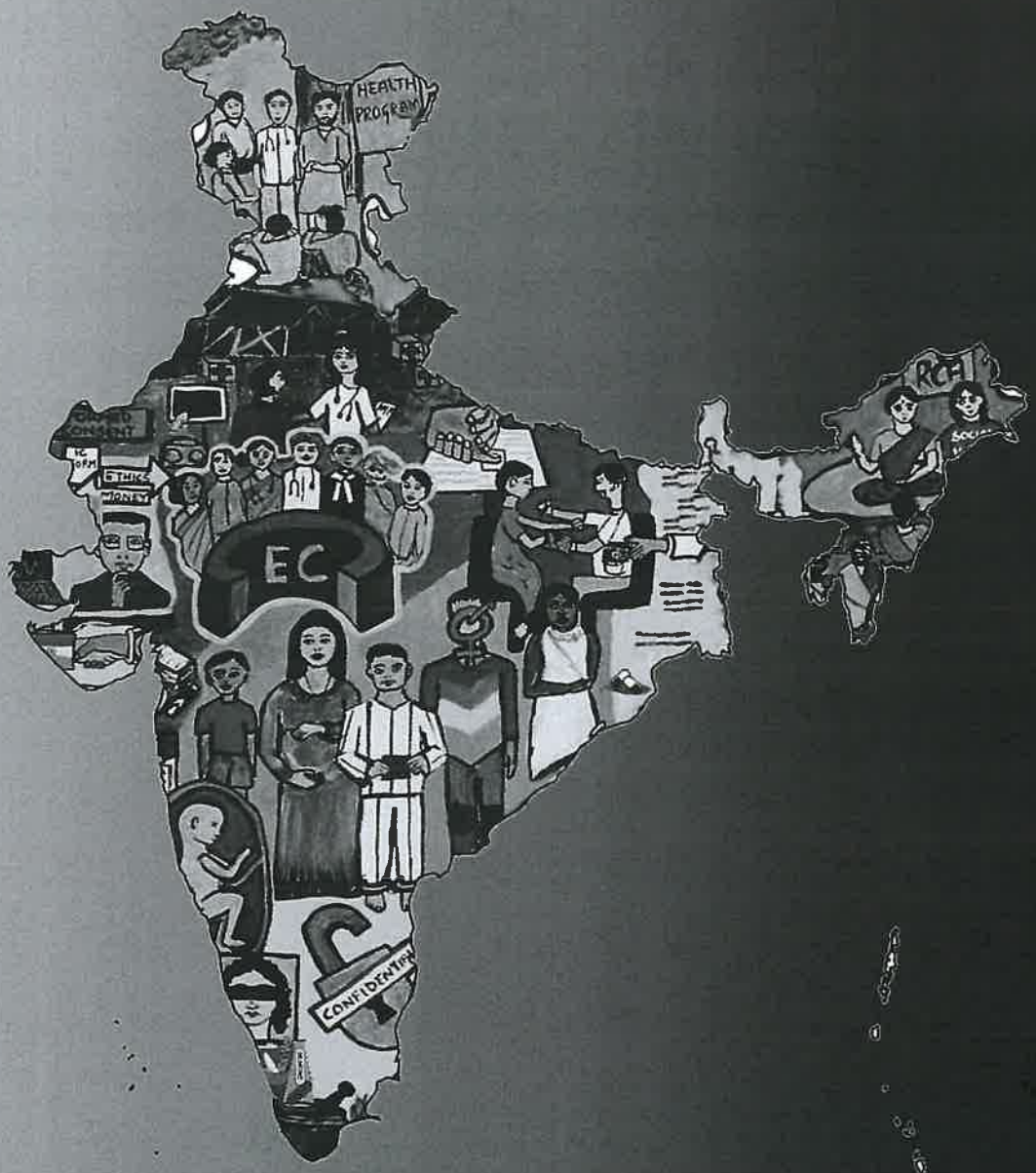
NATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL AND HEALTH RESEARCH INVOLVING HUMAN PARTICIPANTS



INDIAN COUNCIL OF MEDICAL RESEARCH

2017

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INDIAN COUNCIL OF MEDICAL RESEARCH
2017

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TABLE OF CONTENTS

DAYANANDA SAGAR COLLEGE OF DENTAL SCIENCES

Shavige Malleshwara Hills, Kumaraswamy layout, Bengaluru

INSTITUTION CODE OF ETHICS

PRINCIPAL
Dayananda Sagar College of Dental Sciences
Kumaraswamy Layout,
Bangalore - 560 078.

INSTITUTION'S CODE OF ETHICS FOR RESEARCH

Dayananda Sagar college of Dental Sciences, Bangalore has drafted a code of ethics which provide guidelines for professional and ethical conduct of research by the faculty, doctorate students, post graduate students and the undergraduate students. Code of research ethics is a set of principles of research conducts. It sets a benchmark for researchers while conductingtheir research and fulfil their duties to the research subjects, public, profession and the fellow researchers. Although ethics and laws are intricately related to each other they are not one and the same. Ethical obligations are more binding our human conscince when compared to legal stipulations. Hence, ethical obligations may and often do exceed legal duties.

The code of ethics pertains to the way in which health research has to be conducted while adhering to all the ethical principles of research. When human subjects, patients, animals are recruited for conducting research the researcher should be very careful in adhering to ethical principles. Several international and national agencies have established multiple ethical guidelines which refer to the ethical principles to be followed while recruiting subjects and also conducting and reporting of research. Majorly there are seven ethical principles which are to be strictly followed while conducting research:-

1. Social and clinical value
2. Scientific validity
3. Fair subject selection
4. Favourable risk-benefit ratio
5. Independent review
6. Informed consent
7. Respect for potential and enrolled subjects

1. Social and clinical value

   Every research is designed with an intention to answer a specific research question. The question should be relevant and when answered by conducting a research, should be beneficial to the subjects, patients, fraternity, administrators, policy makers and community at large. The question should be justifiable so that the research subjects, patients may be asked to accept some risk or inconvenience. This principle refers to the utility, beneficence to the stake holders of research. It refers to the contribution of research output in expanding the knowledge base, improving the treatment methods, helping the community at large in reducing the burden of disease so that it justifies exposing the research subjects to the given risk and burden of research.

2. Scientific validity

   A research study should follow scientific principles of planning, conducting,

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analysing, reporting and publishing. The principles of research methodology should guide the process of research scrupulously. The scientific rigors maintained in a research ultimately provides validity to research. Scientifically invalid research is outright unethical because it is a waste of recourses and subjects or patients are being exposed to unnecessary risks.

3. Fair subject selection

   The subject selected for research should not come under vulnerable groups. Vulnerability refers to physical vulnerability, psychological vulnerability, social vulnerability, financial vulnerability and many more. The research subjects who participate and accept the risks involved should also be in a position to enjoy the benefits. Soon after completing the research a debriefing session should be organised and the benefits of the research should be extended to the other group which did not receive the benefit while the research was being conducted. Orphans, specially abled, institutionalised children, mentally unsound and insane, pregnant women, aged and shelter less, asylum seekers, illegal emigrants and ethnic minorities are considered as vulnerable groups unless proved otherwise. The researchers should be careful to avoid such vulnerable groups being recruited since they are easily available, accessible to conduct research unless there is a strong reason to justify their inclusion. Institutional Review Board (IRB) should look into this issue and resolve any deficit in fairness while selecting research subjects.

4. Favourable risk-benefit ratio

   Any research exposes the research subjects or participants to some degree of inconvenience, unknown and known risks while providing some benefits. There is uncertainty with respect to the equation between risks and benefits of a research until research it is completed. Every effort should be made by the researchers to minimise the risks and maximise the benefits. The risks may be physical, psychological, economic, or social. There are certain scientific methods to assess the anticipated risks and the potential benefits of a given research. Researchers should establish that the benefits are overwhelming when compared to risks. IRB should strictly scrutinize the research proposal and ascertain that the potential benefits supersede the anticipated risks well before the approval is given.

5. Independent review

   Any research proposal should be thoroughly reviewed by a review board consisting of a panel of experts, nonexperts, lay persons as prescribed by the guidelines of a national, international, local, ethical organisations or agencies. The panel should scrutinize the scientific and ethical validity of the intended research by asking important questions;

   a. Are those who are conducting, examining, diagnosing and treating the research subjectsare free of bias?
   b. Is the methodology adopted by the researchers scientifically sound?
   c. Are the human rights of the research subjects protected at all cost?

d. Has the trial being ethically designed and risk benefit ratio favourable?

The review board monitors the study even while it is going on in order to keep a strict watch on any violations. In our institution a structured IRB is established as per the guidelines of ICMR.

6. Informed consent

It is the primary duty of the researcher to obtain a written informed voluntary consent from the research participant. The prospective participant should be given all the required information about the research in which he/she is participating, the pros and cons ofparticipating in the research, the right to withdraw from research at any phase, the role need to be played by the participant and the minimal information about the nature of the intervention in a language simple and understandable by the patient. This can be done by preparing a "Participant information letter" which is either handed over or explained to the patient. After giving thorough information, the consent is obtained from the participant so that human rights are protected. At times when the participant is legally a minor, proxy consent is obtained from the parents or the legal guardians after providing the required information through the participant information letter. Coercion, appeasement and exorbitant incentives for participating in the research are strictly prohibited. The research subject is given access to the member secretary of IRB by proving the contact details so that the participants are free to communicate any grievances at any time while the research is going on.

7. Respect for potential and enrolled subjects

The participant should be treated with respect as soon as they come forward to participate in the research till the completion of research and even after the research completed. This amounts to protecting the human rights and the rights of a research participant.

a. Respecting the privacy and maintaining the confidentiality with respect to the data and the identity of the participant during the research and after.
b. Permitting the participants to withdraw from the research at any moment without any penalty. This refers to respecting their decision at any phase of research.
c. Monitoring their welfare, adverse reactions, side effects and their health status regularly so that at times the decision is taken by the researcher to remove the participant fromthe respective arm.
d. After the research is completed a debriefing session is organised and a clear information is given to the participant about the research outcomes and the arm under which the subject was treated so that no suspense is maintained thereafter with respect to the intervention and the details of the intervention which were administered.

Prof. Dr. Hemanth M
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Policy Document

Institutional Review Board Committee

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INSTITUTIONAL REVIEW BOARD'S POLICY DOCUMENT

TERMINOLOGIES

"RESEARCH" refers to a class of activities designed to develop or contribute to generalizable knowledge; generalizable knowledge consists of theories, principles, or relationships, or the accumulation of information on which these are based, that can be corroborated by acceptable scientific methods of observation, inference, and/or experiment.

HUMAN BIOMEDICAL RESEARCH (HBR) refers to any research on human subjects that involves:

a. Intervention on, interaction with, or observation of, humans.

b. Use or manipulation of any human biological derivative (e.g. human cells, tissues and body fluids, including those which were previously acquired and stored).

c. Review, analysis and publication of previously compiled identifiable data; for the purpose of studying, diagnosing, treating and/or preventing, any ailment, injury or adverse condition of the human mind or body.

THERAPY

An activity that is undertaken with the intention of improving the health of the patient may be considered **"THERAPY"**.

DRUG

PREVENTIVE AGENT

Preventive medicine -The application of preventive measures by clinical practitioners. A specialized field of medical practice composed of distinct disciplines that utilize skills focusing on the health of defined populations in order to promote and maintain health and well-being and prevent disease, disability, and premature death. In addition to the knowledge of basic and clinical sciences and the skills common to all physicians, the distinctive aspects of preventive medicine include knowledge of and competence in biostatistics; epidemiology; administration, including planning, organization, management, financing, and evaluation of health programs; environmental health; application of social and behavioural factors in health and disease; and the application of primary, secondary, and tertiary prevention measures within clinical medicine.

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SUPPLEMENT INTERVENTION

Intervention study - An investigation involving intentional change in some aspect of the status of the subjects, e.g., introduction of a preventive or therapeutic regimen or an intervention designed to test a hypothesized relationship; usually an experiment such as a randomized controlled trial.

ANIMAL RESEARCH

Animal model - A study in a group of laboratory animals that uses conditions of animalsanalogous to conditions of humans to model processes comparable to those that occurin humans.

BASIC ETHICAL PRINCIPLES

All HBR must be conducted in accordance with these three fundamental ethical principles:

1. **Autonomy (Respect for persons)**

   This incorporates at least two basic ethical considerations:

   - ✓ *Respect for autonomy,* which requires that those who are capable of deliberation about their personal choices should be treated with respect for their capacity for self- determination.
   - ✓ *Protection of persons* with impaired or diminished autonomy (such as children or the mentally disabled), which requires that those who are dependent or vulnerable be afforded additional security against harm or abuse.

2. **Informed consent:** It should be voluntary, legal, and comprehending and should berecorded from every subject recruited in the study.

3. **Non-maleficence**

   This is the principle in which the actions or practices are right insofar as they avoid producing bad consequences. This is the foundation of all health care and describes the first obligation that every health care provider embraces — do no harm. In Latin, the term is *primum non nocere* which means first, do no harm.

4. **Beneficence**

   This refers to the ethical obligation to maximize benefits and to minimize harm. In the research context, it is unlikely that direct benefit will accrue to research subjects. Benefits should overweigh the harms.

5. **Justice**

This refers to the ethical obligation to treat each person in accordance with what is morally right and proper, and to give to each person what is due to him/her. It is based on the principle of distributive justice. For HBR, the investigator must ensure that potential benefits and risks are reasonably balanced and risks are minimized. Justice also requires that research be responsive to the health conditions or needs of vulnerable subjects. Especially attention must be given to vulnerable persons, i.e. those with higher susceptibility to harms and/or with reduced ability to protect their rights and welfare, such as pregnant women, minors, prisoners and the mentally incapacitated

6. **Privacy and Confidentiality**

The information, data revealed by a research subject or a patient in a relationship of trust should be maintained confidentially and should not be divulged to others. Examination of the research subject, oral consultation, counselling should be done with atmost privacy.

7. **Veracity**

8. **Fidelity**

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Dayananda Sagar College of Dental Sciences- Institutional Review Board (DSCDS – IRB) is a vehicle to review and approve all research proposals on biomedical, social and behavioural science research for health involving human participants, their biological material and datato safeguard the dignity, rights, safety and well-being of all research participants. Thus, IRB implements its system of ethics governance of research carried out in the institution and is a competent and independent board in its functioning.

- ✓ The institution, DSCDS is responsible for providing logistical support, such as infrastructure, staff, space, funds, adequate support and protected time for the member secretary to run the IRB functions.
- ✓ DSCDS is responsible for establishing a DSCDS-IRB to ensure an appropriate and sustainable system for quality scientific & ethical review and monitoring.
- ✓ All types of biomedical and health research (whether clinical, basic science, policy, implementation, epidemiological, behavioural, public health research, etc) will be reviewed by the DSCDS-IRB before it is conducted.
- ✓ DSCDS-IRB will perform its functions according to written policies and operating procedures, maintain written records of their activities, and comply with all relevant institutional and regulatory requirements.
- ✓ DSCDS-IRB will have in-depth understanding of the basic ethical principles governing research, and be familiar with existing national regulations, legislative requirements and institutional policies governing the conduct of Human Biomedical Research (HBR).

GUIDELINES FOR SELECTION OF MEMBERS

- ✓ DSCDS-IRB will be carefully composed such that there will be no room for any public perception that it is not independent of its institution/researchers, but its compositionwill vary depending on local circumstances.
- ✓ There will be clear institutional policies on the administration of IRB with respect to the appointment, disqualification, resignation, and replacement of the members. Office bearers, e.g. Chairperson, and other members of the IRB, will be appointed with proper terms of reference, which are mentioned in the below sections.
- ✓ Members will be selected in their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise. Their experience in the domain field and profile with availability of time to review and monitor the progress of the studies would also be necessary criteria.
- ✓ The members representing medical scientist and clinicians will have a post graduate qualification and adequate experience in their respective fields. Conflict of interest willbe avoided while making appointments, with transparency with regard to financial and non-financial interests.
- ✓ The conflict of interest if any will be disclosed and confidentiality agreement will be signed by all members.
- ✓ The members will collectively possess the expertise and understanding of the types of research commonly carried out in the institution.

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- ✓ All IRB members will be properly oriented to their roles and responsibilities and will be given appropriate initial and continued training, where required.
- ✓ To further reinforce the independence of the IRB, and to ensure that the decisions of the board are carried out in accordance with scientific thinking accepted within the community, additional external representation by specialists of favorable reputation from other institutions will be encouraged.
- ✓ The member would have demonstrated an understanding of the purposes and operations associated with institute's Human Research Protection Program, and also the policies and procedures with respect to designing, receiving approval for, andconducting human research.

Note:

The potential members of RD & SC and IEC must have the qualities, skills and experience to meet the criteria as below:

- ✓ Have a strong personal commitment to ensuring the highest standards for health care research.
- ✓ Have a strong personal commitment to the interests of research participants who take part (or are asked to) in health care research.
- ✓ Be able to read, understand and analyse complex issues from research proposals and weigh up conflicting opinions.
- ✓ Be able to take an objective stance, looking at a situation from different perspectives.
- ✓ Be a good communicator with a practical approach and confidence to voice his/her opinions.
- ✓ Be able to discuss issues with people who may not agree with the member including being able to influence others from a range of backgrounds.
- ✓ Be committed to the public service values of accountability, probity, openness and equality of opportunity.
- ✓ Be able to demonstrate an ability to contribute to the work of the RD & SC and IEC.
- ✓ Understand the requirement for confidentiality in issues faced by an RD & SC and IEC.
- ✓ Be willing to undertake training to equip to carry out his/her role.
- ✓ Need to be confident about expressing and supporting their opinions.
- ✓ Live in, or close to, the geographical area of the institution RD & SC and IEC.
- ✓ Have experience of conducting research projects.
- ✓ Flexibility, excellent communication skills and a desire to 'make a difference'.

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APPOINTMENT

- ✓ The Head of Institute shall appoint the Chair person, Member Secretary and other members of the DSCDS - RD & SC and IEC.
- ✓ For all the members as well as experts invited for meetings, files will be maintained by the secretariat.
- ✓ The files will have details of qualification, area of expertise, organization details (to which, member is affiliated), role in RD & SC and IEC, complete contact details and updated CV.
- ✓ Independent consultants are appointed by the chairperson.
- ✓ For the expert members, evidence of invitation of particular meeting will be retained and documented.

TERM OF OFFICE

- ✓ The membership of IRB will be for a period of one to two years and shall be renewed after the stated term. At the end of the term, at least one third of the IEC members will be replaced to maintain the composition. Extension of membership can be considered due to non-availability of members of similar stature, qualification and intent to contribute to ethical human testing.
- ✓ In case of the resignation/ discontinuation/ disqualification/ death/ chronic absenteeism of any member, before the completion of the tenure of the existing appointed committee, the chairperson can appoint a replacement.
- ✓ This appointment will be effective for the remaining tenure of the existing committee.

RENEWAL OF MEMBERSHIP

- ✓ The membership shall be renewed after the stated term.
- ✓ Selection of members will be done at least one month in advance.
- ✓ Designated members of the RD & SC and IEC who wish to attend meetings as observers will be informed to read, understand, accept and sign the agreement contained in the Confidentiality/Conflict of Interest form at the beginning of the RD & SC and IEC meeting and/or before scientific and ethical review tasks.

SELF-EVALUATION

- ✓ IRB will conduct self-evaluation periodically, at least annually. The evaluation will be done for the appropriateness of its composition, attendance of members, adequate resources for functioning of IRB, the review process, etc.

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- ✓ If there is any process failure, root cause analysis will be done to identify the process failure and the corrective and preventive action taken will be documented.

RESIGNATION

- ✓ If any member wishes to discontinue from the RD & SC and IEC, he/she will inform the Chairperson, in writing.
- ✓ Members may voluntarily resign from the committee at a month's notice citing appropriate reason.

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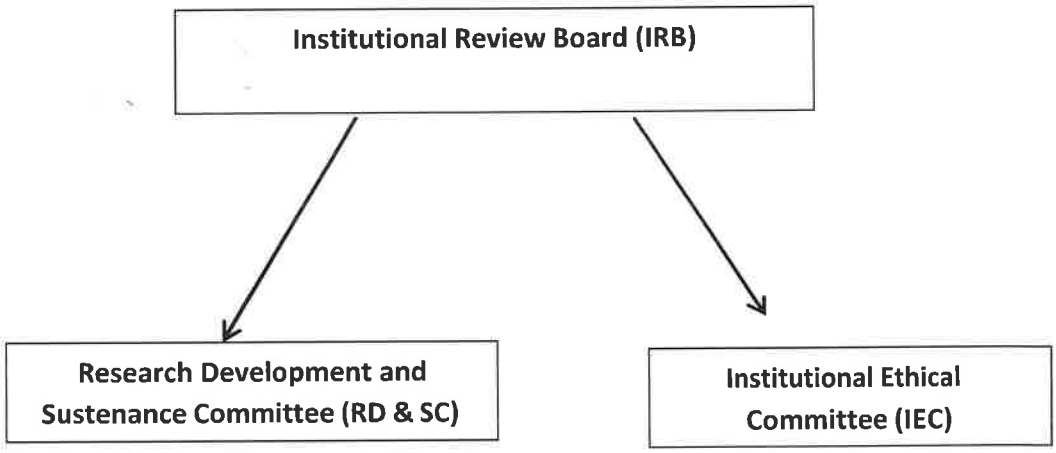
DAYANANDA SAGAR COLLEGE OF DENTAL SCIENCES-INSTITUTIONAL REVIEW BOARD

Research Development and Sustenance Committee (RD & SC) + Institutional EthicalCommittee (IEC)



Institutional review board of Dayananda Sagar Collegeof Dental Sciences will have two committees functioning under the common board and complement each other. Namely,

1. RESEARCH DEVELOPMENT AND SUSTENANCE COMMITTEE (RD & SC)

2. INSTITUTIONAL ETHICAL COMMITTEE (IEC)

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RESEARCH DEVELOPMENT AND SUSTENANCE COMMITTEE

Composition of DSCDS-RD & SC

1. Committee chairperson (Principal or any person designated by him)
2. Member secretary
3. Research methodologist
4. Biostatistician
5. Subject experts – Atleast two from each department.
    a. Internal subject expert (selected from the institution) – 2 (from each department)
    b. External subject expert – 1 (from each department)

    External subject expert would be selected by the chairperson from anyother dental college. These selections are done by the chairperson based on the academic credentials of the candidate and inputs given by the rest of the members.

The presence of member secretary, research methodologist is mandatory for everymeeting. Minimum one subject expert from each discipline of dentistry should be present in every meeting. Quorum is said to have reached when a minimum of eleven members are present in any meeting.

FUNCTIONS OF THE DSCDS - RD & SC

1. Scrutinizing the **scientific integrity** of the submitted synopses, protocols, proposals or any other scientific manuscripts.

    Scientific integrity refers to –

    a. Scientific rigors maintained while planning, designing, conducting, andreporting the research (Methodological integrity)
    b. Scientific rigors maintained with respect to data treatment, data analysis and interpretation of data (Statistical integrity)
    c. Adherence to conventions of scientific writing with respect to language, grammar, punctuations, style (Scientific writing Integrity)

GENERAL GUIDELINES & GUIDELINES FOR CONDUCTING THE MEETINGS

- RD & SC will hold face-to-face meetings periodically based on the requirement.
- The dates of these meetings will be scheduled, announced and communicated to

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all the members in advance.

- The manuscripts submitted to the committee would be sent online to all the members at least 7-10 days in advance of the meeting. They can review the manuscripts and come prepared to the meeting.
- Quorum is said to have reached, when a minimum of 11 members are present for the meeting. The presence of member secretary and research methodologist is mandatory for conducting the meeting.
- Decisions will only be made at meetings where a quorum is present.
- The Chairperson or the Member Secretary will extend a formal welcome and invite the committee to conduct the proceedings.
- The research synopses or protocols or proposalshave to be presented in front of the committee by the researchers on the day of meeting and also elaborate on specific issues when called for. If the researcher is a student, the guide should be present along with the student in order to answer, explain, discuss and clarify when the issues are raised by the committee members.
- Each member would be given an opportunity to place his/her comments, queries, opinions, suggestions and remarks regarding the presented research in front of the committee.
- After thorough scrutiny, synopses or protocols or proposals may be labeled as "outright accepted" or instructed to "re-submit after suggested modifications". A synopsis might also be labeled as "outright rejected" in case the synopsis/proposal is presented after conducting the study or if the study doesn't meet the basic requirements (lack scientific and ethical integrity).
- The resubmitted manuscripts are assessed for compliance with respect to the suggestions given earlier by the committee. Member secretary and the research methodologist should scrutinize the revised manuscripts and after ensuring 100% compliance, they may be labeled as accepted, without holding a meeting again.
- The Chairperson and Member secretary would consider the inputs from the committee members and decide whether the intended research is technically sound and can be forwarded to IEC for ethical review and approval. Such a decision would be taken after eliciting the consensus.

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INSTITUTIONAL ETHICAL COMMITTEE (IEC)COMPOSITION OF DSCDS-IEC

Committee members (7 members)

1. Committee chairperson (External person designated by Principal)
2. Member secretary
3. Advocate
4. Social scientist (An anthropologist, psychologist, theologian, a member affiliated to an NGO engaged in service to humanity or a person who has done course in Bio-ethics, philosopher or person with religious affiliation)
5. Basic medical scientist
6. Pharmacologist
7. Lay person from community

Quorum is said to have reached only when all members are present in any meeting.

NOTE:

✓ When IEC regularly reviews research involving vulnerable populations (children, pregnant women, cognitively impaired persons, or prisoners), at least one member should be knowledgeable about and experienced in working with the subjects. After reviewing the manuscripts the member secretary would involve any such member as per requirement.

FUNCTIONS OF THE DSCDS – IEC COMMITTEE

✓ The IEC will be competent and independent in itsfunctioning.

✓ Ensure proper review and approval of all ethical aspects of the research in an objective manner.

✓ Provide advice to researchers on all aspects of welfare and safety of research participants.

✓ Protect the dignity, rights and wellbeing of research participants.

✓ IEC would ensure the continued validity of ethical approval of projects until the research is completed and evaluation of adverse event reports provided by researchers.

✓ Any modification to the protocol has to be brought to the prior notice of IRB and approval should be obtained, otherwise it amounts to protocol violation which would attract certain strictures.

✓ Providing feedback and maintaining dialogue about applicable standards with their constituent researchers.

✓ Reporting any unusual or unexpected events arising from the research, to their respective institutions.

✓ IEC have the authority to withdraw the ethics approval of research projects where there are sufficient concerns over the safety and well-being of research subjects.

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- ✓ Ensures that the universal ethical values and international scientific standards are exposed in terms of local community values and customs.

GENERAL GUIDELINES & GUIDELINES FOR CONDUCTING THE MEETINGS

- ✓ IEC will hold face-to-face meetings periodically, which will be planned after the RD & SC approval of synopses/protocols/proposals.
- ✓ The dates of these meetings will be scheduled, announced and communicated to all the members in advance.
- ✓ The manuscripts which are approved by RD & SCare forwarded to the IEC. They would be sent online to all the members at least 7 days in advance of the meeting. They can review the manuscripts and come prepared to the meeting.
- ✓ Quorum is said to have reached, only when all members are present for the meeting.
- ✓ Decisions will only be made at meetings where a quorum is present.
- ✓ The Member Secretary will extend a formal welcome and invite the committee toconduct the proceedings.
- ✓ The research synopses will be handed over to all the members on the day of meeting.
- ✓ Each member would be given an opportunity to place his/her comments, queries, opinions, suggestions and remarks regarding the presented research in front of the committee.
- ✓ When queries are raised or clarifications are required by the committee members the researcher would be called for and in case the researcher is a student, the guide will also be invited to defend, discuss or justify.
- ✓ The presented synopses or protocols or proposals may be labeled as "outright accepted" or instructed to "re-submit after suggested modifications". A synopsis might also be labelled as "outright rejected" in case the synopsis/proposal doesn't meet the ethical integrity.
- ✓ The resubmitted manuscripts are assessed for compliance with respect to the suggestions given by the committee. Chairperson and member secretary should scrutinize the revised manuscripts and after ensuring 100% compliance, they may be labeled as accepted, without holding a meeting again.
- ✓ The chairperson & member secretary would consider the inputs from the committee members and decide whether the intended research is ethically sound and can be granted an ethical clearance to carry forward the research. This would be done after eliciting the consensus.
- ✓ All accepted synopses/protocols/proposals would be granted an approval letter drafted by IRB and authenticated with an appropriate registration number.

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Research proposal submission

Role of institution

1. Institution promotes conducting and publishing research by providing congenial and conducive environment to the faculty, doctoral, post graduate and undergraduate students.
2. As multiple technical, managerial, life sciences and allied health institutes are located in the same campus belonging to the same management, scope for conducting interdisciplinary, multidisciplinary and transdisciplinary research is possible and such a research is always promoted by the institution.
3. Institution believes in early immersion of students into research practice. Hence, undergraduate students are encouraged to conduct research, publish and present. ICMR, STS projects and RGUHS funded researches are being taken up by the undergraduate students, post graduate students and faculty.
4. A research culture is induced in the institution by providing regular training sessions, FDPs and CDE programs on research methodology, biostatistics, scientific writing, research protocol writing, publications and scientometrics. Institutional review board (IRB) is constituted and performing as per the guidelines set by ICMR. It has two committees namely;

    a. Research Development and Sustenance Committee (RD&SC)

    This committee scrutinizes the scientific validity of the submitted research proposals. Only those research studies which are found to be scientifically valid as per the review done by this committee would be forwarded for ethical review. This committee consists of Chairperson, Member secretary, Coordinators, Internal & External subject experts. They are selected based on their subject and research expertise that they possess. The term of RDSC members is for two years, following which new members are selected

    b. Institutional Ethical Committee (IEC)

    This committee scrutinizes the Ethical integrity of the research proposal which is forwarded by the research development and sustenance committee. This committee consists of a chairperson person, mandatorily an external member with the required competence and training in bioethics, research ethics and research methodology. In addition the committee has a member secretary, coordinators, external review members ( ) as per theguidelines of ICMR. The term of the IEC members is for two years, following which new members are selected. Only after a thorough review of the research proposal conducted by both the committees (RDSC & IEC), a research proposal is either approved, disapproved or instructed to modify and resubmit.

5. Once approval is given for conducting research by the IRB, the Principal investigators, co-investigators, Mentors and Guides may execute the research protocol. It is the sole responsibility of the Principal investigator along with the research team to ensure that the research is conducted ethically by adhering to all the ethical principles. Emphasis is being laid on the process of obtaining informed consent very scrupulously while recruiting the research subjects. The progress of the research should be periodically reported to IRB.

6. Any gross ethical violations noticed by the IRB would be handled stringently and at worst IRB may instruct the trial to be stopped. Any adverse reactions, serious morbidities, deaths and harms noticed while conducting research should be brought to the notice to IRB as immediately as possible. No research is admitted in the institution without obtaining prior written approval from the IRB.

7. IRB will meet twice yearly, which would be informed to all the faculty and students atleast one month in advance. When the research proposal doesnot involve any serious ethical implications like in case of invitro studies on biological samples, invitro material property studies, FEA studies, descriptive surveys (questionnaire studies) expedited reviews done and approval would be given bypassing the full committee, regular review. In such cases the opinion of subject expert and chairman along with three other members would be taken and approval given.

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ROLES AND RESPONSIBILITIES OF RESEARCH DEVELOPMENT AND SUSTENANCE COMMITTEE

Scrutinizing the scientific integrity of the submitted synopses, protocols, proposals or any other scientific manuscripts. Scientific integrity refers to:

a. Scientific rigors maintained while planning, designing, conducting, and reporting the research (Methodological integrity)

b. Scientific rigors maintained with respect to data treatment, data analysis and interpretation of data (Statistical integrity)

c. Adherence to conventions of scientific writing with respect to language, grammar, punctuations, style (Scientific writing Integrity)

ROLES AND RESPONSIBILITIES OF INSTITUTIONAL ETHICAL COMMITTEE

1. The IEC will be competent and independent in its functioning.
2. Ensure proper review and approval of all ethical aspects of the research in an objective manner.
3. Provide advice to researchers on all aspects of welfare and safety of research participants.
4. Protect the dignity, rights and wellbeing of research participants.
5. IEC would ensure the continued validity of ethical approval of projects until the research is completed and evaluation of adverse event reports provided by researchers.
6. Any modification to the protocol has to be brought to the prior notice of IRB and approval should be obtained, otherwise it amounts to protocol violation which would attract certain strictures.
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Guidelines for Research Publications

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RESEARCH PROPOSAL SUBMISSION AND REVIEW PROTOCOL

ROLE OF INSTITUTION

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RESEARCH MISCONDUCT AND OTHER UNACCEPTABLE PRACTICES

Research misconduct amounts to breach of trust on the part of researchers. There areusually three types of research misconduct, namely;

a. Fabrication: It is making up results which amounts to concocting and fudging
b. Falsification: It refers to manipulating research materials, equipment, instruments and processes. Any changing, omitting, suppressing the data or results without justification also amounts to falsification.
c. Plagiarism: Using and quoting other people's work without giving due credit to the original source amounts to plagiarism. There are software to check for plagiarism. When a research write up is subjected to plagiarism check and if the content is found to be plagiarized an admissible limit, the write up would not be allowed to be sent for publication. The researchers in the institution are strictly instructed to subject their write up to plagiarism to unadmissible check and submit their report to the IRB before they are permitted to upload the manuscript for publication.
d. Intellectual property rights (IPR) is an important issue related to research and innovations. Violation of IPR is a serious offense and the researchers should have a fair knowledge. In this connection regular seminars, seminars and

training sessions are being organized by the IRB for the benefit of the researchers in the institution.

PUBLICATION AND DISSEMINATION

These are some stipulated code of ethics with respect to Publications that happen when studentsand faculty are affiliated to our institution and even after by name of institution. They are:-

1. All the authors are responsible for the content of the publication. Authorship and order of meeting the authors is an important issue which the research team has to resolve before starting the research. Only those researches who have substantially contributed for the research work should be considered as authors. The corresponding author should be responsible for all communications and preferably he/she should be the first author.

2. Authors should only acknowledge the work, help, assistance and intellectual contributions of any collaborations assistants, internal or external funding or any other agencies and also individuals who extended their support to the research work in any form.

3. It is ethical responsibility of all the others to declare any conflicts of interest (financial or any other) if that exists. If a conflict of interest exists and not possible to manage and resolve author/s should gracefully stay away from the research project and should not claim authorship.

4. Authors should consider negative results as important and go ahead publishing. Negative results are as important as positive results as long as research is conducted with scientific rigors.

5. All the authors should read the final draft and provide inputs before consenting to be sent to editorial board. Once accepted for publishing by any journal editorial board, the copyright form has to be duly signed by all the authors or the corresponding author as per the guidelines of editorial board of the journal.

6. Duplicate publications by any researcher would be dealt seriously. Scientific misconduct such as fabrication, falsification and Plagiarism are considered as serious violations of code of ethics. Such violations are brought to the notice of special committee which will take necessary actions.

7. In addition to above said violations there may be some other unacceptable practices. When such practices are noticed the concerned researchers are liable to be sanctioned or punished by the special committee after the impartial enquiry of the alleged person/s.

8. Self citations when justified do not constitute ethical violations. But when self citations are done with the purpose of boosting one's reputation or metrics, the act is considered as ethical violation.

9. Gifting authorship is a ethical breach and institution discourages, prevents and

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prohibits such a practice

10. IRB of the institution will make every effort to prevent discourage and stop such acceptable practices. In this connection, periodic training would be provided to the researchers. Mentoring programs would be arranged so that the mentors ensure that the research ethics be practiced while conducting research.

DEALING WITH VIOLATIONS AND ALLEGATIONS OF RESEARCH MISCONDUCT(SCIENTIFIC MISCONDUCT)

Any ethical violations brought to the notice of IRB and institution would be dealt by special committee having methodological ethical and social experts. Investigations are held in a consistent and transparent manner enough opportunity is provided to the accused to defend before taking a final decision.

a. Enquiry is going to be fair ,comprehensive and held in a manner without compromising accuracy objectivity e and thoroughness.

b. Enquiry is carried in a manner that it reaches logical conclusion.

c. Proceedings are held in a manner that confidentiality is maintained.

d. Institution makes every effort to protect the rights of whistle blowers. Their career professional growth is not allowed to be endangered for having blown the whistle. The Action is going to be taken against persons on whom allegations of misconduct is upheld . the action should be proportional to the intensity of violation.

f. Appropriate restorative action be taken if the alleged person is exonerated of allegations of misconduct

g. Any person accused or alleged of scientific misconduct is considered innocent until proven otherwise.

Prof. Dr. Hemanth M

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