

**ETHICAL REVIEW BOARD
(ERB)**

(Ethical Auditing)

**Standard Operating Procedures
(SOP)**

for

Researches on Humans, Plants & Environment



Hemvati Nandan Bahuguna Garhwal University,
(A Central University)

Srinagar, Garhwal, 246 174, Uttarakhand, India

Ethical Review Board (ERB)

Introduction: -

Ethics and Morals although sound similar but are different as, - **morals** refer to individual's own principles regarding right or wrong whereas, - **ethics** are the rules provided by an external source (e.g. code of conduct in workplace or principles). Thus, ethics should be implied and followed for all the species and the environment according to norms or as per the rules laid down by the different ethical committees.

All the researches, conducted in any discipline / field are always human centric and for the welfare of humans & humanity. Humans being the most vital component of any research, and thus the research ethics should be followed for humans and the environment related to them. Every research, whether experimental, theoretical or hypothetical etc., are directly or indirectly based upon humans or for the humans. Each and every species is important and have very important and specific role in its ecosystem. Thus, morals & ethics should be followed while carrying out research not only on living organisms e.g. plants, animals, humans etc. but on their environment also. At the same time the disposal of scientific biomaterials also plays a vital role, as the bio-contaminants can be hazardous and may have ethical issues, if not disposed off properly. Thus, the moral & ethical guidelines should be followed in synchronization with researches.

The group of species (humans, animals, plants, microorganisms etc.) included for research should be taken care of and should not be harmed physically or morally. In fact, their morals and values should be our highest priority as they serve for the benefit of mankind when used for research purposes. The environment in which we dwell should also be balanced ecologically and therefore bio-safety should also be given due attention.

Globally, there are populations more than billion but, out of the billions only handful of them forms the basis of research. The handful population which participates voluntarily or used for any research purposes should be given due consideration and they should be protected through ethical guidelines. Ethics should be of prime importance in case of plants, microorganisms and other such species which serve as models for genetics (GMO's), breeding, tissue culture, cell culture, biochemical, stem cell technology and hybridization experiments etc.

The ethical committee should support research of the highest ethical standards and review all the researches involving humans, animals, plants, microorganisms including the environment etc and thus an Ethical Review Board (ERB) has been constituted.

Ethical Review Board (ERB): - The **ERB** will be the highest body in the University to see and review the ethical, social and humanitarian / subjective issues related to human, plant and environmental researches in toto. It will monitor all the studies involving experiments/ participants/ surveys related researches on human, animals, plant and their environment in order to ensure the legal, moral and ethical concerns and unnecessary risks / disclosure of the information out of the study. The ERB will be responsible to review the ethical clearance granted to different projects / researchers/ investigators by different Institutional Ethical Committees (IECs) of the University.

Basic responsibilities of ERB:-

- Evaluation and review of all ethical clearance granted by IECs for researches.
- Ensure safety, rights and well-being of the potential research participants.
- Ensure scientific evaluation and ensure technical appropriateness of study.
- Ensure universal ethical values and international scientific standards in the study.
- Ensure implementation of different IECs Guidelines (SOPs) time to time.

Constitution, qualifications, specific roles & responsibilities of ERB members:-

The ERB must include members representing diverse field of knowledge relevant to the conduct / review of ethical issues on research. Member of ERB must be institutional (Affiliating) and non-institutional (Non-Affiliating) and must be having experience / immense knowledge about scientific and ethical conduct on research such as legal issues and standards for professional conduct. In addition, non-institutional members (non-scientific) usually should be community member and represents the community standards for assessing the ethics of a study.

Constitution of Ethical Review Board.

Responsibilities: -

The Head of Institute (HoI) will be responsible to initiate constitution and conduct of **Ethical Review Board (ERB)** in the University.

Appointing / nominate of Member Secretary and Chairman of ERB.

- HoI, will initially nominate / appoint a Member Secretary of ERB considering the ability and interest of member in accordance to the need of ERB..
- The Member Secretary in consultation with HoI will appoint / nominate the Chairman.

Appointing of other members of ERB: -

Member Secretary in consultation with Chairman and HoI will nominate / appoint members of ERB, in different sections according to their specific discipline. The qualification & experience of members will be ensured that they will be able and capable enough to review and evaluate the Scientific, Medical, Social, Moral and Ethical etc. aspect of study approved by different IECs.

- Member Secretary will invite the members to join ERB by sending the official request letter by a hard copy or through e-mail.
- Members will confirm their acceptance to Member Secretary by providing a written letter for membership.
- Member Secretary will call meeting of ERB in consultation with Chairman as & when required or as office of the Member Secretary consider it essential. However, the meeting of ERB will be conducted the meeting at least once in a year and maximum twice in a year.

Members, their Qualifications and responsibilities: -

1. Chairperson: - (Non-affiliated)

A well - respected / eminent person from the background of Medical / Animal / Plant Sciences having experience to see Ethical and Moral issues of research proposal.

- Conduct meetings and be accountable for independent & efficient functioning of ERB
- Ensure active participation of all members in all discussions and deliberations
- Ratify minutes of the previous meetings and also handle complaints against researchers, IEC & ERB members, conflict of interest issues and requests for use of ERB data, etc.

2. Member Secretary (Affiliated)

A person should be a staff member of the University, having knowledge and experience in the field of teaching, research & ethics,

- Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review
- Schedule ERB meetings in consultation with Chairman, prepare the agenda and minutes and organize ERB documentation, communication and archiving.

3. Category of Member(s):- There will be two type of members of ERB, - **Non-affiliated & - Affiliated.** **Affiliated** members: -

Affiliated members: - Medical Practitioner / Pharmacologist Scientist, Agriculture / Plant Scientist, Environmental / Earth Scientist, Educationist / Social Scientist, Psychologist / Philosopher, Linguist / Theologist / Psychologist, Human / Animal Scientist, Basic Sciences / Science and Technology; and

Non-affiliated members: - Chairman, Social Activist / NGOs representatives, Common Man / Lay Person, Legal Advisor / Legal Expert.

Category of Member(s):-

- Members should have a basic experience in ethical review of research projects / proposal, protocol specific other permissions, such as, community & biomedical research, animal, environment, earth science, plants, agriculture, social science, science & technology, biosafety, tissue culture, stem cell, transgenic, GMOs research, compliance with specific guidelines etc. Also may have awareness and understanding of researches, knowledge of regulatory bodies and moral & ethical approvals,
- Should be an individual having qualification / training / expertise and be sensitive to local cultural & moral values of the community and their environment. The member should be aware of the moral & ethical values and welfare activities of the community & its environment.

Appointment of Members:-

The Member Secretary in consultation with Chairman and HoI will nominate / appoint rest of the members of Review Board. The qualification / discipline(s) of the member to be nominated, should be taken in to consideration while nominating / appointing any member. Once the members are appointed they will serve and be a part of the ERB at least for three years in continuation.

Composition of Ethical Review Board (ERB)

- | | |
|---|----------------------------------|
| 1) Chairperson, an Eminent Person (01 Person). | <u>Non- Affiliating.</u> |
| 2) Medical Practitioner / Pharmacologist Scientist (01 Person) | <u>Affiliating.</u> |
| 3) Agriculture / Plant Scientist (01 Person) | <u>Affiliating.</u> |
| 4) Environmental / Earth Scientist (01 Person) | <u>Affiliating.</u> |
| 5) Educationist / Social / Behavioral Scientist (01 Person) | <u>Affiliating.</u> |
| 6) Psychologist / Philosopher (01 Person) | <u>Affiliating.</u> |
| 7) Linguist / Theologist / Psychologist (01 Person) | <u>Affiliating.</u> |
| 8) Human / Animal Scientist (01 Person) | <u>Affiliating.</u> |
| 9) Basic Sciences / Science and Technology (01 Person) | <u>Affiliating.</u> |
| 10) Social Activist / NGOs representatives (01 Person) | <u>Non- Affiliating</u> |
| 11) Common Man / Lay Person (01 Person) | <u>Non- Affiliating</u> |
| 12) Legal Advisor / Expert (01 Person, Advocate, High Court) | <u>Non- Affiliating</u> |
| 13) Member Secretaries of all Institutional Ethical Committees. | <u>Affiliating.</u> |
| 14) Advisor(s) (if required, may be nominated, as per specific field) | <u>Non &/or Affiliating.</u> |
| 15) Member Secretaries ERB (01 Person) | <u>Affiliating.</u> |

Meeting of ERB:-

At least once or maximally twice in a year, if need arises, the Member Secretary in consultation with Chairman will call the meeting. In every meeting the Member Secretary of the concerned Institutional Ethical Committee (IECs) will present the ethical clearance granted by the concerned IEC to respective project / investigator/ researcher. If required and found necessary the ethical review board may call the investigator / Researcher for further presentation / clarification on the research work.

Power of ERB:

To review the approvals submitted by IECs. It exists to protect the rights and safety of human subjects, plants, animals and other living organisms & their environment. The ERB can conduct periodic reviews of the study approved by the different institutional ethical committees and monitor the research progress and address any ethical issues. ERB has the right to carry out additional reviews and actively conduct surprise inspections of research records. The decision of the ERB will be considered final in case of any discrepancy among the IEC's, researchers and participants.

Term of appointment, Policy for removal or Resignation/ Replacement of members

Initial three years term of appointed Members, could be extended for another term of 3 years by HoI, on the recommendation of Chairman & Member Secretary of ERB.

Policy for removal of member

- A member may be relieved or terminated of his/her membership in case of conduct unbecoming for a member of the ERB.
- Inability to participate in the meetings on any grounds for more than 3 meetings.
- The membership shall be reviewed by Member Secretary & Chairman, if the member is a regular defaulter.
- If deemed necessary, the Member Secretary ERB may decide to terminate the membership and recommend to the Chairman for necessary action.
- In all such situations, Member Secretary will serve a letter of termination to the member.
- Documentation in this regard will be recorded in the meeting minutes of the next duly constituted ERB meeting and ERB membership circular will be revised.

Resignation / Replacement procedure

The members who have resigned may be replaced at the discretion of the competent or appointing authority for the same.

ERB members who decide to resign must provide his/her proposed resignation date at least 30 calendar days prior to the next scheduled meeting to Chairman & Member Secretary of ERB.

In case of resignation, Chairman & Member Secretary would appoint a new member, falling in the same category of membership.

Procedure for convening and conducting IEC meetings

Chairman & Member Secretary are responsible to conducting the meetings.

- The Member Secretary in consultation with the Chairman may convene the ERB meeting as and when required.
- All members will receive notification of meeting schedules in advance.
- A minimum one plus half number of members are required to form the quorum without which a decision would not be taken. Presence of Chairman & Member Secretary is essential.

This Ethical Review Board of HNB Garhwal University will operate according to the specific guidelines issued for specific IECs. The different SOPs of different IECs will be final while resolving the issues to be reviewed by the ERB.

Institutional Ethical Committee(s) to be Constituted as: -

1. **Institutional Ethical Committee for Biomedical Research on Human Participants (ICMR).** (questioners based and physical handling)

Dr. Rahul Kumar Singh, Department of Microbiology

All departments / disciplines deal with human Biomedical Researches.

2. **Institutional Ethical Committee for Bio-safety and Bio-contaminant Research (Dept. of Biotech, GoI).**

Dr. Vineet Maurya, Department of Microbiology

All advance researches deals with the issues related to Bio-safety, Bio-contaminant, RDT and other on Biological Materials (plants, animals and environment, specially endangered / rear plant and animals) etc....

Biotechnology, Biochemistry, Botany, Microbiology, Zoology, Pharmaceutical Science, Medical, Animal House, Poly House etc

3. **Institutional Ethical Committee for Animal Research (IAREC).**
Biotechnology, Biochemistry, Microbiology, Zoology, Pharmaceutical Science, Medical, Animal House etc

Dr. Indrashish Bhattacharya, Department of Zoology

4. **Institutional Ethical Committee for Social Sciences, Humanities, Law and Theology Research.** (questioners based not physical handling)

All departments / disciplines deal with human researches (not biomedical). Commerce, Education, Languages, Humanities, Philosophy, Psychology, Marketing, Management etc.

Prof. Rajpal Negi, Department of History

5. **Institutional Ethical Committee for Science and Technology.**
All departments / disciplines Science and Technologies deal researches related to Biological materials.

Prof. RCS Kunwar, Department of Defense & Strategic Studies

6. **Institutional Ethical Committee for Plants & Agriculture related Research**
All departments / disciplines deal with plants researches