

Indian Council of Medical Research

Guidelines on Code of Conduct for Research Scientists engaged in field of Life Sciences

Preamble

Bioethics has emerged as a new discipline over the past couple of decades and is poised to become a multidisciplinary specialty. Institutional review boards/Institutional ethics committees have evolved as conscience keepers of professionals with the view to safeguard the welfare of members of society against any possible harm from scientific advances. Bioethical discussions and debates provide perspectives on the relevance of new as well as existing processes to human values, enabling appropriate decisions by the different stakeholders.

Advances in laboratory technologies in the recent times have created new and complex ethical dilemmas in their wake. Laboratory services are an integral part of disease diagnosis, treatment, response monitoring, surveillance programmes and research. Therefore, personnel working in clinical and/or research laboratories should be aware of their ethical responsibilities. It is necessary to comply with the ethical code of conduct prescribed by national and international organisations, and address the emerging ethical, legal and social concerns in the field of biological and biomedical sciences. The basic principles enshrined in the codes and guidelines followed by different countries are:

1. **Autonomy** – Respect for persons including informed consent, privacy and confidentiality
2. **Beneficence** – Fruitful result, Do good
3. **Non-Maleficence** – Do no deliberate harm
4. **Justice** – Ensure equitable distribution of risks and benefits

Modern technology can have dual use; it can be applied not only for peaceful purposes but also for hostile ones. Modern biology and biotechnology offer novel ways of manipulating basic life processes. Purposefully or unintentionally, genetic modification of microorganisms could be used to create organisms that are more virulent, are antibiotic-resistant, or have greater stability in the environment. Advances in genetic modifications and manipulations may facilitate changes of the immune response system of the host population to modify susceptibility to a pathogen or disrupt the normal host response. Many more such new discoveries are being reported from different parts of the world as scientific advances are occurring with great speed.

The scientists engaged in such research activities should be aware of the potential risks and concerns relating to science and its wider applications and the ethical responsibilities they shoulder. They should not only be aware of but comply with the requirements of international conventions and treaties relevant to their research work.

The use in armed conflicts of biological weapons, as well as of chemical weapons, was prohibited by the Geneva Protocol in 1925. To date more than 130 States have ratified, acceded to or upon independence declared succession to the Geneva Protocol. The Biological & Toxin Weapons Convention (BTWC), which entered into force in 1976, is more comprehensive and prohibits the development, production, stockpiling, transfer or acquisition of biological agents and equipment for hostile purposes. 146 States have ratified or acceded to the BTWC. One of the recommended confidence building measure between the countries is promulgation and adoption of code of conduct for scientists. With BTWC in mind, several agencies and professional bodies across the world have drafted codes of conduct for scientists engaged in life sciences.

The Indian Council of Medical Research has a long standing interest in ethics in biomedical research. It had brought out in February 1980, a document entitled, "Policy statement on ethical considerations involved in research on human subjects". This has now been updated and published as "Ethical Guidelines for Biomedical Research on Human Subjects", 2000, and subsequently updated as "Ethical Guidelines for Biomedical Research on Human Participants" in 2006, and ICMR is assisting Department of Health Research, MOH&FW in the process of its enactment as a Bill.

The Indian National Science Academy (INSA) guidelines for Care and Use of Animals in Scientific Research (2000) and the Approved guidelines by CPCSEA on the norms and practices for regulation of Animal Experimentation are recommended to be followed by scientists using animals for scientific research.

Aim

The aim of the code of conduct for scientists is to ensure that all research activities involving microbial or other biological agents, or toxins whatever their origin or method of production, are only of types and in quantities that have justification for prophylactic, protective or other peaceful purposes.

In considering whether this aim is best achieved by something called a code of *conduct* or a code of *practice*, it is important to recognise that there are general perceptions relating to these two terms. There is a broad appreciation that a code of *conduct* is something to which individuals aspire as an objective but actual practice may fall short of that objective. On the other hand, codes of *practice* are widely utilised in the implementation of national regulations which require activities to be

carried out in accordance with a set out code of practice and that whilst such a code of practice may itself not be mandatory, the onus is on the individuals to demonstrate that they are observing the code of practice.

Code of Conduct

In order to prevent the use of scientific research for purposes of bioterrorism or bio-warfare, all persons and institutions engaged in all aspects of scientific research should abide by this code of conduct which are governed by the following principles:

- 1. Principles of non-maleficence** whereby, it is ensured that the discoveries of biomedical research scientists and knowledge generated do no harm to humans, animals, plants and environment.
 - i) by refraining to engage in any research that is intended or likely to facilitate, bio-terrorism or bio-warfare, and
 - ii) by not contributing to the development, production or acquisition of microbial or other biological agents or toxins, whatever their origin or method of production, of types and/or in quantities that have no justification for prophylactic, protective, therapeutic, or other peaceful purposes.
 - iii) by taking due precautions to protect self and others from any harmful effects and reporting immediately to concerned authorities if any untoward incident happens or likely to happen.
- 2. Principles of beneficence** whereby, it is ensured that legitimate benefits are being sought and that they out-weigh the risks and harms. The scientists work for the ethical and beneficent advancement, development and use of scientific knowledge;
- 3. Principles of risk minimization** whereby, due care and caution is to be taken to restrict the dual use information and knowledge to those who need to know. In case there are serious risks that information or knowledge, intentional or non-intentional, could be readily misused to inflict serious harm through bio-terrorism or bio-warfare, bring them to the attention of the appropriate persons/ authorities.
- 4. Principle of Confidentiality** whereby, the scientists uphold the basic principle of maintaining all such information highly confidential and reveal it to only legitimate individuals or organizations under a contract agreement as prescribed by law .

5. **Principle of Ethical review** whereby, all relevant research activities are subjected to ethics and safety. reviews and monitoring to establish their ethical acceptability and if human or animal subjects are involved, to ensure that such involvement is ethical and essential for carrying out highly important research only for the benefit of the society.
6. **Principles of transmission of ethical values** whereby (the duties and obligations embodied in this code), the ethical principles upon which it is based are transmitted faithfully to all who are, or may become, engaged in the conduct of such scientific research.
7. **Principles of voluntariness** whereby, researchers are fully apprised of the research, the impact and risk of such research, and whereby scientists retain the right to abstain from further participation in research that they consider ethically or morally objectionable.
8. **Principles of compliance** whereby, scientists abide by laws and regulations that apply to the conduct of science, duties, and obligations embodied in this code and disseminate the same to all concerned.
9. **Principles of institutional arrangements** whereby, appropriate care is taken to ensure that all procedures are required to be complied with and all institutional arrangements are made to assure bio-safety and biosecurity. Access (which should be in a transparent manner) is allowed to biological agents that could be used as biological weapons only to bonafide scientists who shall not misuse them and whose work can be monitored by their Institutions
10. **Principles of totality of responsibility** whereby, the professional and moral responsibility, for the due observance of all the principles, guidelines or prescriptions laid down generally or in respect of the research or experiment in question devolves on all those directly or indirectly connected with the research or experiment. Such research shall be duly monitored and constantly be subjected to review and remedial action at all stages of the research and experiment for its present and future use.
11. **Principles of research integrity** whereby, scientists are expected to adhere to highest professional standards in proposing, doing and reporting of research results to ensure reproducibility. The proposing and conduct of research should be done with due regard to accepted global professional codes, norms and guidelines besides adhering to the national and, wherever applicable, international rules and regulations. During the conduct of research, data should be collected, collated, analyzed and reported with honesty and integrity. During publication, unethical practices as fabrication, falsification, plagiarism etc. should be avoided and appropriate credit be given to collaborators who have contributed to the

intellectual content of research being reported as reflected in the authorship of manuscripts sent for publication. The interests of young scientists should be especially protected while according credit and they should also be provided appropriate guidance and imparted with the value system of research.

Ethical considerations in this Code of Conduct, would be binding on all laboratory scientists involved in scientific research concerning dangerous organisms and toxic weapons against any living being or environment.

Name of Institute.....

UNDERTAKING

I have carefully read the guidelines on Code of Conduct for research in the field of Life Sciences and taken note of the principles and ethical considerations in this Code of conduct. I agree to abide by them during the conduct of the scientific/research activities being undertaken by me.

Name of scientist

Signature with Date

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3.

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