INDIAN COUNCIL OF MEDICAL RESEARCH
Department of Health Research – Ministry of Health & Family Welfare
Government of India

Press Release

ICMR National Ethical Guidelines for Biomedical and Health Research becomes mandatory to be adhered to for all biomedical research in the country

For the first time all biomedical and health research is going to be regulated through the ethics committees

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Indian Council of Medical Research's (ICMR) National Ethical Guidelines for Biomedical Research has become mandatory and needs to be adhered to for all biomedical research in the country as per the New Drugs and Clinical Trials Rules 2019 released recently by Ministry of Health and Family Welfare, Government of India. This will be effective after 180 days from the date of publication of Gazette. These details are included under clauses 15, 16, 17, 18 under Chapter IV of the New Drugs & Clinical Trial Rules.

This is for the first time that biomedical and health research is going to be regulated through the ethics committees and the system is being set up by Ministry of Health and Family Welfare which has designated Department of Health Research, as the authority for registration of ethics committee that review such research and thereby help in safeguarding the safety, rights, welfare of research participants. The salient requirements are:

1. Any institution or organization which intends to conduct biomedical and health research shall be required to have an Ethics Committee (EC) which has been constituted, functions and maintains records in accordance to ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017. ECs shall review the research before initiation and oversee throughout the duration of the research.
2. The EC shall be required to register with the Authority and the registration would remain valid for a period of five years from the date of its issue, unless suspended or cancelled by the authority. The ICMR National Ethical Guidelines will guide the ethical requirements for all institution that are engaged in such research whether

it is medical colleges, research institutions, universities, public or private funded institutions, non-governmental organisation or others.

Dr. Balram Bhargava, Secretary, Department of Health Research and Director General, ICMR, stated "The inclusions of clauses to govern biomedical and health research in the New Drugs & Clinical trials Rules, 2019 will bring about the much needed transparency and accountability in the regulation of biomedical and health research in India. This would help to improve the quality of research outcomes while ensuring protection of research participants and responsiveness to the health needs of our people."

View the guidelines here:
https://www.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf

View the handbook on guidelines here:
http://ethics.ncdirindia.org//asset/pdf/Handbook_on_ICMR_Ethical_Guidelines.pdf

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About ICMR: *The Indian Council of Medical Research (ICMR), New Delhi, is the apex body in India for the formulation, coordination and promotion of biomedical research, is one of the oldest medical research bodies in the world. ICMR's research priorities align with the National health priorities. These efforts are undertaken with a view to reduce the total burden of disease and to promote health and well-being of the population. ICMR promotes biomedical research in the country through intramural as well as extramural research.*

ICMR Bioethics Unit *is a dedicated unit set up recently at National Centre for Disease Informatics and Research (NCDIR), Bengaluru to help and guide the country in all aspects of ethics related to biomedical and health research and is engaged in developing ethical guidelines, policies and planning initiatives to build capacity for ethical conduct of research and its review in the country. Visit http://www.ncdirindia.org/ for more details.*

Salient Features of the Guidelines

- The guidelines will help in upholding the principles of bioethics and thereby imparting protection to patients as well as volunteers who become part of research.
- For the first time, the guidelines have addressed concerns in subject areas where there is scanty guidance available such as responsible conduct of research, public health research, socio-behavioral research, conducting research during humanitarian emergencies or disasters, dealing with vulnerable populations or conducting collaborative research, biological materials, biobanking and datasets.
- Researchers as well as ethics committees (ECs) play an important role in the conduct of research and its prior review. ECs are responsible to safeguard the dignity, rights, safety and well-being of all research participants. All types of biomedical and health research must be reviewed by an EC before it is conducted and to be monitored to ensure that it is conducted well.
- In the section on informed consent and ethics review process, ECs and researchers have been guided about how to safeguard the privacy and confidentiality of the participants/samples/data while conducting biomedical and health research involving human participants.
- The revised guidelines provide detailed guidance on multicentre collaborative research as well as International collaboration and describe the requirements of ethical approval, ownership of samples and data, its analysis, publication as well as dissemination. It also describes the need to communicate the findings of the research with the providers (participants/communities).
- The guidelines also discuss in detail the need for benefit risk assessment, payment of compensation in case of injury, measures for protecting privacy and confidentiality, prevention against stigmatization or discrimination, community engagement and benefit sharing.
- The guidelines discuss the procedures for declaration and management of conflicts of interest in research that exist at the level of researchers as well as ethics committee members.
- The ethical issues related to research involving new technologies such as genetic studies, Clustered Regularly Interspaced Short Palindromic Repeats technology, research using traditional medicine, research involving stored samples or biological material and datasets have also been addressed in detail.
- The specific guidance has been provided to address the various ethical issues related to public health research, social and behavioral sciences research as there is lack of awareness about the requirements of research which pertains to public health.
- Vulnerable populations such as economically and socially disadvantaged individuals, orphans, abandoned individuals, children, women in special situations, individuals with neurological or mental disabilities, sexual minorities, individuals/communities in humanitarian emergencies and disaster, etc. are incapable of protecting their own rights and interest. The revised guidelines give specific directions and guidance to researchers while planning and conducting research on such special populations with utmost ethical standards.
- The guidelines suggest ways to make the research more responsive to the health needs of the people highlighting the importance of engagement with the community and benefit sharing.