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ICMR puts emphasis on ethical guidelines for biomedical research

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



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."