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Editorial

Good clinical practice in India: What a researcher should know?

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Good clinical practice (GCP) forms the cornerstone in ensuring the protection of human rights participants as well as ensuring the credibility of the clinical data generated in a research study.[1] The researcher in an Indian doctor is generally borne during the postgraduation study period as a student must undertake a postgraduate thesis to be eligible to sit in final postgraduate examination. Despite the fact that most of the medical research is conducted in medical teaching institutes, research has shown that most researchers have only average knowledge of GCP.[2]

Therefore, researchers must be well educated about GCP. Briefly, the researchers should know about the following: (i) To ensure uniformity, and consistency in GCP guidelines, the International Council for Harmonization (ICH) was formed, which released the ICH-GCP guidelines in the year 1996. The guidelines were revised in the year 2016;[1] (ii) all research conducted in India, must be done in accordance with ethical guidelines released by the Indian Council of Medical Research Guidelines (ICMR) titled "National Ethical Guidelines for Biomedical and Health Research Involving Human Participants," released in the year 2017;[3] and (iii) the New Drugs and Clinical Trial Rules (NDCT) 2019, released by the Indian Central Drugs Standard Control Organization provide rules and regulations for conduct of clinical trials involving pharmaceutical drugs including new drugs and investigational new drugs. These rules also provide for quantum of compensation that needs to be provided to the trial participant in case of any injury or death related to clinical trial.[4]

To strengthen the research component in teaching medical institutions, the National Medical Commission (NMC) has also now made it mandatory for the postgraduate students as well as the teaching medical faculty in NMC recognized institutions to successfully pass the Basic Course in Biomedical Research by ICMR, available from National Portal on Technology Advanced Learning (NPTEL) portal. The course consists of 25 chapters and five sections, namely, "conceptualizing a research study," "epidemiological considerations in designing a research study," "bio-statistical considerations in designing a research study," "planning a research study," "ethical issues in conducting a research study," and "writing a research protocol" which can be studied at self-paced learning through the online NPTEL portal, followed by an offline written examination at designated examination centers.

The study material to study these resources is freely available on the internet. Thus, any researcher or physician conducting biomedical research must ensure knowledge of the ICMR-Ethical guidelines 2017, ICH-GCP guidelines 2016, and NDCT Rules 2019 to ensure quality and ethical biomedical research in India.

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