

Addressing Ethics in Clinical , Public health and Animal Research: An Overview

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The objective of ethics in research on humans is to ensure dignity, rights, safety, and wellbeing of the subjects or participants of the research project. The institutional ethics committee (IEC or EC), registered with Central Drugs Standard Control Organization (CDSCO), New Delhi, approves clinical trials. The IEC registered with Department of Health Research (DHR), Government of India, New Delhi, approves other academic researches that are non-interventional in nature.

It is important that the Principal Investigators (PIs), i.e. faculty must get their research proposal approved from their respective IECs and attach the letter of approval from the IEC along with their research proposal. If the IEC meetings are delayed or for any other reasons if the faculty are not able to get the letter of approval for their research proposal from their IEC, they must mention it in the application form / inform the university. However, PI/faculty must submit it compulsorily without fail before the issue of letter of approval/fund release from RGUHS. If the IEC registration with DHR, Government of India, is still pending/not done, then as a onetime exception the faculty must get the research proposal approved by the IEC registered with CDSCO and attach the letter of approval. The letter of approval shall be on the letterhead of the IEC and the approval shall be without any preconditions and for the duration of the research project.

In case of research on animals, the letter of approval of the research project shall be from the institutional animal ethics committee (IAEC), registered with CPCSEA, New Delhi. The letter of approval for the research project shall be given on the letterhead of the IAEC and shall be without any preconditions and for the duration of the research project.

The PPT slides set provided by me with notes gives an overview of ethics in clinical, public health and animal research. Besides the faculty are encouraged to refer the following.

References:

1. Government of India. GCP Guidelines for clinical trials in Ayush, March, 2013. <http://indianmedicine.nic.in/writereaddata/linkimages/5110899178-Final%20Book%2028-03-13.pdf>
2. Indian Council of Medical Research. National Ethical guidelines for biomedical & health research involving human participants, 2017. www.icmr.nic.in/ethical_guidelines.pdf
3. Central Drugs Standard Control Organization [CDSCO] :New Drugs and Clinical Trial Rules, 2019 www.cdsc.nic.in
4. Clinical Development Services Agency (CDSA): www.cdsaindia.in
5. Clinical Trials – A beginners guide, Alice Kuruvilla and AD Paul, 1st Edition, 2013 , Paras Medical Publisher, Hyderabad [Rs. 200/-]
6. CPCSEA website - <http://cpcsea.nic.in>
