

## ***“Frequently Asked Questions about Ethical Clearance of Research Proposals”.***

### **1. Which type of research requires Ethics Committee Approval?**

All research involving human participants, human specimens and secondary health data from any public domain needs mandatorily Ethics Committee approval.

### **2. Is Ethical Clearance for research study mandatory?**

National Ethics Committees Registry for Biomedical and Health Research (NECRBHR) was set by Ministry of Health and family Welfare, Department of Family Welfare to ensure that every research either academic or clinical trial must obtain ethical clearance from registered ethics committee working in purview of ICMR guideline 2017 and NDCT 2019 before the recruitment of first participant into the study.

### **3. What you mean by Registered Ethics Committee?**

ICMR guideline 2017 made it clear that every working ethics committee must be registered with National Ethics Committees Registry for Biomedical and Health Research (NECRBHR), Department of Health Research, Govt. of India, in case of Clinical Trial Review Ethics Committee must be registered with Central Drugs Standard Control Organization, Director General Health Services, Ministry of Health and Family Welfare, Govt. of India.

### **4. Is Institutional Ethics Committee – CHARUSAT registered with regulatory bodies?**

Yes, IEC-CHARUSAT is registered with National Ethics Committees Registry for Biomedical and Health Research (NECRBHR), Department of Health Research, Govt. of India to review academic research, it also registered with CDSCO, Therefore, IEC-CHARUSAT can review clinical trials including drug trials and it also registered with international agency Office of Health Research Protections (OHRP), Supported U.S Department of by Health and Human Services (HHS), researcher who has international collaboration can get IEC-CHARUSAT approval. Visit our website to view or download all approvals: [charusat.ac.in](http://charusat.ac.in)

### **5. Can everyone get approval from IEC-CHARUSAT?**

Yes, anyone conducting research within the radius of 50 kms can avail the approval from IEC-CHARUSAT.

Visit our website to view or download annexures to be filled for Full Review, Exempt from full review and expedite review.

Guidelines and instructions are also available.

### **6. What are pre-requisites for availing IEC-CHARUSAT approval?**

There must be either MoU between the host institute and CHARUSAT or one of research team member should be from CHARUSAT.

**7. Is there any fee to be paid to avail IEC-CHARUSAT approval?**

It is absolutely free for CHARUSAT students and faculty members. Researchers from other institutions need to pay Rs. 2000/- plus GST for any academic research and Charges for clinical trial is Rs. 50000/- plus GST as per current SOPs of IEC-CHARUSAT.

**8. How can I pay the fee for IEC-CHARUSAT?**

Member Secretary generates a bill on your institute/ organization name as applicable and issues you a bill which will have all the details including account number, IFSC code, fee, GST etc. then you may proceed for payment in any mode (NEFT/UPI/Cheque/Cash).

**9. What if a researcher doesn't avail Ethics Committee approval before recruiting the participant or for study?**

Notification from Govt. of India, Ministry of Health and Family Welfare (Department of Health Research) reiterates that no research study is considered valid unless research study is approved by registered ethics committee. (Reference: File No. U-11022/01/2020-HR, dated 20.06.2022 and File no. U-11024/2018-HR (Part-2)/8015255, dated 12.09.2019). Repute journals never publish the research work done without Ethical clearance from registered ethics committee.

**10. Can I apply online for proposals review to IEC-CHARUSAT?**

Yes, anyone can apply online for IEC-CHARUSAT approval, for more details visit our website: [charusat.ac.in](http://charusat.ac.in) or for more contact Member Secretary, IEC-CHARUSAT: email: [iec.coordinator@charusat.ac.in](mailto:iec.coordinator@charusat.ac.in), phone: 02697-265204/70/5034.

**11. Should I compulsory visit CHARUSAT?**

Yes, it is compulsory to visit CHARUSAT once on scheduled date of meeting for review.

**12. Do all the research team (PI, Co-I's) should remain present during the review meeting?**

Preferable to have whole team while discussion, but it is not mandatory. It is also fine if only Principal Investigator/Co-I remains present during the meeting.

**13. What are other benefits to institutions by signing MoU with CHARUSAT?**

Scope of MoU elaborately mentions the benefits, to mention few, helps in exchange programs for both students and faculty, develop consultancy, and strengthen research between host institute and CHARUSAT.