**Title:** **Ethics Committee Meeting by Video-conferencing: Indian Experience for COVID-19 Research**

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**Authors: Vinita Agrawal\*ꝉ, Chandishwar Nathỻ, Saroj Kanta Mishra§**¥

Departments of \*Pathology and §Endocrine Surgery, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, India

ꝉMember Secretary, ỻChairman, Institutional Ethics Committee, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, India

¥Faculty In charge, School of Telemedicine and Bioinformatics, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, India

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**Corresponding Author:**

Dr. Vinita Agrawal M.D, PDCC

Member Secretary, IEC

Professor, Department of Pathology,  
Sanjay Gandhi Postgraduate Institute of Medical Sciences,  
Lucknow-226014, India.

Phone: +91 522-2494253, 9415403550  
FAX: +91 522 2668017 or 2668078  
Email: [vinita@sgpgi.ac.in](mailto:vinita@sgpgi.ac.in); [vinita.agrawal15@gmail.com](mailto:vinita.agrawal15@gmail.com)

**E-mail addresses of Authors:**

Dr Chandishwar Nath- [cnathcdri@rediffmail.com](mailto:cnathcdri@rediffmail.com); Phone No. 9839448292

Dr SK Mishra- [skmishra@sgpgi.ac.in](mailto:skmishra@sgpgi.ac.in); Phone No. 8004904643

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**Abstract**

Coronavirus disease (COVID-19) has created a situation demanding rapid ethical review of research on various aspects of the pandemic, while maintaining the social distancing norms. Thus, Ethics Committees have a vital role in the efficient and timely critical review of research proposals for proper participant protection. We share our experience of video conferencing with support from Telemedicine network as a viable tool in such situations. There is an urgent need of formulating International and National standard operating procedures for functioning of Ethics Committees in such emergencies.

**Key words**: Ethics Committee; COVID-19; Institutional Review Board

**Main Article**

The coronavirus disease (COVID-19) pandemic is a global health crisis with cases rising daily all over the world. Promotion of research during an outbreak is important for understanding the disease and its management. Infectious disease outbreaks allow the scientists to study a disease in situ.

In response to the 2013-2016 Ebola virus disease (EVD) outbreak, the World Health Organization (WHO) issued a ‘Guidance for Managing Ethical Issues in Infectious Disease Outbreaks’. It covered social distancing, research and clinical care in outbreak settings.1 The National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, by the ICMR (Indian Council of Medical Research), state that the Ethics Committee (EC) can undertake an expedited review or hold unscheduled meetings during Humanitarian Emergencies and Disaster conditions.2,3

A two-day workshop in March 2018 by the WHO Global Health Ethics Team and the African coalition for Epidemic Research, Response and Training, with representatives of National Ethics Committees, emphasized that for facilitating ethics review during outbreaks, "ethics preparedness" is important. The participants recommended that ECs should develop a formal national standard operating procedure for emergency response ethical review.4

Studies during infectious disease outbreaks can involve collection and analysis of clinical data that is useful in understanding the pathophysiology of disease and improving diagnosis and management. These can also include collection of samples, which provide an opportunity to analyze the causative organism useful for diagnostics, management and surveillance. The experimental interventions in outbreaks with use of drugs/devices in human subjects provides information about development of vaccines and therapeutics.5

ECs have a vital role in the efficient review of COVID-19 studies during an outbreak. Research proposals involving more than minimal risk to human participants require critical review by the full board of the EC/Institutional Review Board (IRB). However, it is also vital to follow social distancing to reduce risk of cross-contamination caused by close contact. In the present situation, it is crucial and a challenge to give timely decisions on such research proposals. While Telemedicine is an important means of delivering care, information of its use in conduct of these meetings in emergencies has been limited. Zhang and colleagues reported the experience of ethical review of studies on COVID-19 by emergency video conference at one hospital in China and summarized the common issues.6 We present our experience of conducting EC review meetings in this COVID-19 pandemic, through Telemedicine video conferencing using an online meeting platform.

*Review process*

The Institutional EC, at Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, India is constituted as per International and National guidelines with 15 members. It is registered and FERCAP (Forum for Ethical Review Committees in Asia and the Western Pacific) accredited. Research proposals were submitted online on a dedicated submission portal developed by the Institute.

Research proposals on COVID-19 involving human participants, were screened by the Bioethics Cell office staff as per checklist, to confirm all necessary documentation, namely, study protocol, informed consent forms (ICFs), undertaking, record forms etc. Member Secretary performed a pre-review of proposals and forwarded to the Chairman, Institutional EC. If required, clarifications on the proposal were sought from the Principal Investigator on email. On receiving a response, a Full Board Video conference Meeting of the Institutional EC (Institutional Review Board) was scheduled through a licensed ‘Zoom cloud meeting platform’.

Primary review (for scientific, ethical and ICF-related issues), of the research proposals was done by two members. The members were requested to download the ‘Zoom Cloud Meetings’ application. On the day of the meeting, members were communicated the meeting id and password to join the virtual meeting through their devices. Staff from the Telemedicine department coordinated the meeting by providing a licensed platform, access to screen with display of members, muting and un-muting the speakers and recording the proceedings.

The primary reviewers summarized and presented the proposal to the IEC, highlighting the ethical and other issues in the study with comments on the informed consent forms provided for review. The discussion was then opened for rest of the members who raised hands for additional questions and to present their viewpoint. There was a lively discussion, followed by a consensus decision. The committee emphasized and welcomed the role and decisions of regulatory authorities in giving priority approvals for clinical/investigator-initiated trials. Fig. 1 presents the process and the timeline of full board review of projects on COVID-19.

*Conclusions*

The current coronavirus disease (COVID-19) pandemic has reminded us of the potential of Telemedicine to address a crisis. Making timely decisions for COVID-19 research proposals is a challenge for Ethics Committees. Video conferencing for EC meetings is a feasible option for early decision making by the ECs for research proposals especially related to the pandemic. In the absence of any formal strategy, it is important to make guidelines to assist with co-ordination and conduct of crucial EC meetings during an emergency.

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**Legend to figure**

**Figure 1.** Flow diagram showing the review process and the timeline for ethics review of covid-19 research proposals by the Institutional Review Board (IRB) by Video-conferencing.

