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**SIDCER**  
Globalizing Ethics for Health Research



# Development and Implementation of an Online Proposal Submission Portal for Institutional Ethics Committee Review: Insights and Stakeholder Feedback from a Medical Institute in North India.

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# Introduction

- Proper submission and a timely ethical review of research proposals are critical for supporting and promoting research.
- Traditional paper-based systems for submitting proposals can be cumbersome, time-consuming, and prone to errors.
- To address these challenges, SGPGIMS, a tertiary care medical institute in North India, developed an [online portal for the submission of research proposals for review](#) by the Institutional Ethics Committee (IEC).
- This study describes the development process and evaluates its effectiveness and impact in terms of feedback from stakeholders.



# Aims

- To manage and review the projects for ethical approval online through the Bioethics cell, SGPGIMS.
- Developed an online web-based application for the Submission of all research projects for Ethical clearance by the IEC



# Methods

## Development phase

- An online portal was developed to streamline proposal submission.
- Core elements were identified based on the offline physical forms and ensured compliance with the ICMR 2017 guidelines.
- Compatibility across devices and browsers was ensured.
- The submission process involved one-time registration by the PI.
- The features included a user dashboard with details of all proposal submitted by the PI, including documents for informed consent, conflict of interest, etc.

**VIII. Archival of records by Bioethics cell for more than 3years (5years for clinical trials) after termination/completion of study:**

Yes  No

**Summary of Study/Project Proposal/Case Report Form (Introduction, objectives, inclusion and exclusion criteria)**

[Empty text input field]

And

[File upload field: Choose... No file selected.]

Update

\* Supported files formats - PDF  
\* Maximum file size - 2 MB

Mention here 'Short summary of study'

ADD TEXT  
Upload file-Detailed Project Proposal (Introduction, Objectives, Methodology, Inclusion and Exclusion criteria, sample size calculation etc.) and 'Case Report Form'

Would be better if we can have an option to upload 'Case Report Form' separately

## 2. Undertaking and Conflict of Interest Declaration by the PI

Generate Letter

Upload Undertaking and Conflict of Interest Declaration by the PI:

No file selected.

Update

\* Supported files formats - PDF

\* Maximum file size - 2 MB

## 3. Committee Approval

Generate Letter

Upload Approval File:

No file selected.

Update

\* Supported files formats - PDF

\* Maximum file size - 2 MB

## 4. Consent of Head of the PI's Department

Generate Letter

Upload Consent of Head of the PI's Department:

No file selected.

Update

\* Supported files formats - PDF

\* Maximum file size - 2 MB

5. Any other (for uploading documents other than already uploaded, can vary with proposals

# Methods

## Implementation phase

- The implementation process involved **pilot testing** to identify and resolve potential issues, initial training and support and an effort for iterative enhancements to refine the portal's performance and usability.
- **Step by step guide** was circulated on the Institute webmail for the process of registration and project submission.
- **Stakeholder feedback** was collected as part of the submission process to understand ease of use, efficiency, overall satisfaction, and specific suggestions for improvement.



# Methods

## Feedback from stakeholders

- Stakeholder feedback is collected as part of the submission process to understand
  - Ease of use
  - Efficiency
  - Overall satisfaction
  - Specific suggestions for improvement



<https://www.sgpgiethics.in/>



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Institutional Ethics  
Committee

**BIOETHICS CELL SGPGI, Lucknow**

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Principal Investigators Name \*

Department \*

Designation \*

Mobile No. \*

Email \*

Password \*

Confirm Password \*

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SGPGI Lucknow

Administrator

Dashboard

Projects

New Projects Under Review Projects Approved Projects Rejected Projects Re-Submitted Projects

Search...

S. No.	IEC Code	Project Name	PI Name	Submission Type	Submission Date	Approval Date	Notice	Action
1	NA	Cytomegalovirus reactivation in Acute Respiratory Distress Syndrome Patients	Atul Garg	Project MD	21/04/2020			<input type="button" value="Actions"/>
2	NA	Effect of cigarette smoking on platelet function in platelet collected by apheresis.	Rahul Katharia	Project Intramural	03/03/2020		demo meeting	<input type="button" value="Actions"/>
3	NA	Effect of Papaya leaf extract on increment of platelet count in neonates with sepsis: a randomised controlled trial	Girish Gupta	Project DM	03/03/2020		demo meeting	<input type="button" value="Actions"/>
4	NA	EVALUATION OF EOSINOPHILIC INFLAMMATION IN PATIENTS OF CHRONIC OBSTRUCTIVE	Mansi Gupta	Project Intramural	03/03/2020		demo meeting	<input type="button" value="Actions"/>



## MAIN NAVIGATION

[Dashboard](#)[My Projects](#)

## ACCOUNT

[My Profile](#)[Change Password](#)[Log Out](#)

## Home

[Home](#)WELCOME *VINITA AGRAWAL*

Welcome to the online portal for initial project submission and continuing review documents for approval by the Institutional Ethics Committee, SGPGIMS, Lucknow. We hope that this portal will facilitate project submission and expedite project approval.

**Note:**

1. Kindly follow instructions and fill all details for final submission of the project proposal.
2. After final submission, complete the checklist.
3. Six copies of the submitted project and of the checklist have to be sent to the Bioethics cell along with duplicate copy of document receipt form.
4. You can upload only PDF file maximum 2MB in size.

**Important Document Download**

- [General Instructions](#)
- [Instructions Online Portal](#)
- [Glossary](#)
- [Checklist and document receipt form](#)
- [Dates for Full board IEC Meeting-2019](#)
- [SOPs, IEC SGPGI](#)
- [2017\\_ICMR\\_National Ethical Guidelines for BioMedical Research Involving Children](#)
- [2017\\_ICMR\\_National Ethical Guidelines for BioMedical and Health Research involving Human Participants](#)



MAIN NAVIGATION

Dashboard

My Projects

ACCOUNT

My Profile

Change Password

Log Out

### My Project Association of SCN9A gene polymorphism with fibromyalgia

My Project

A. Identification

B. Project Details

B.III (Specimen Collections)

B.IV (For Interventional Studies Only)

C. Generate & Upload Letters

D. Final Submit

**Project ID**

To be filled by Bioethics Cell

**Date of submission of completed form**

NA

**Project Title\***

Association of SCN9A gene polymorphism with fibromyalgia

**Drug / Device trail (forma sponsored)**  Yes  No

**Co - PI**

+ Add Co - PI

Name	Department	Designation	Action
Dr Shubh Singh	Endocrinology	Gynaecologist	<a href="#">✕ Remove</a>

**Collaborator**

+ Add Collaborator



# Security and safety

- All the data related to projects is stored and maintained on a secured server located in India
- Regular backups are maintained to facilitate disaster recovery



# Results

- Online portal for submitting research proposals for IEC, SGPGIMS review-made functional for users in July 2019.
- From July 2019 to July 2024 (5years)
  - 361 faculty members registered as principal investigators
  - Submitted 1790 research projects.
  - Feedback reports from users were analyzed.



# Results: Feedback

- The users found the portal intuitive, convenient, and easy to navigate.
- Submission accuracy improved, with fewer errors and omissions.
- The portal reduced paper requirements and enabled online reviews, which was especially helpful during the COVID-19 pandemic.
- The IEC members and administrative staff also indicated high acceptance and satisfaction with the online portal.



## Ethics committee meeting by video-conferencing during Covid-19

Published online on May 27, 2020. DOI: 10.20529/IJME.2020.062.

**Key words:** Ethics Committee; Covid-19; Institutional Review Board, emergency response ethical review

The Covid-19 pandemic has created a situation demanding rapid ethical review of research on various aspects of the pandemic, while maintaining social distancing norms. Research during an outbreak is important for understanding the disease and its management and allows scientists to study the disease *in situ*.

In response to the 2013-16 Ebola virus outbreak, the World Health Organization (WHO) had issued a 'Guidance for managing ethical issues in infectious disease outbreaks' (1). The ethical guidelines for biomedical and health research, issued by the Indian Council of Medical Research (ICMR), mention that the ethics committee (EC) can undertake an expedited review or hold unscheduled meetings during humanitarian emergencies (2,3).

In 2018, a workshop organised by the WHO Global Health Ethics Team and the African coalition for epidemic research, emphasised "ethics preparedness" during outbreaks. It recommended that ECs should develop a formal standard operating procedure for emergency response ethical review (4).

Studies during infectious disease outbreaks can involve collection of data and/or clinical specimens which is useful in understanding the pathophysiology of disease and for diagnostics, management and surveillance. The drug/device interventions in outbreaks provide information about the

conducting EC review meetings during the Covid-19 pandemic through telemedicine video conferencing using an online meeting platform.

## Review process

The Institutional EC (IEC) at the Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, India, has been constituted as per international and national guidelines. It is registered and FERCAP (Forum for Ethical Review Committees in Asia and the Western Pacific) accredited. Research proposals are 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 a checklist, to confirm all necessary documentation, namely, study protocol, informed consent forms (ICFs), undertaking, record forms etc. The Member Secretary performed a pre-review of proposals and forwarded them to the Chairperson, IEC. Where required, clarifications on the proposal were sought from the Principal Investigator via email. On receiving a response, a full Board video conference meeting of the IEC 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. Members downloaded the "Zoom Cloud Meetings" application and joined the virtual meeting through their devices. The Telemedicine department staff coordinated the meeting and recorded the proceedings.

The primary reviewers summarised and presented the proposal to the IEC, highlighting the ethical and other issues

Agrawal V, Nath C, Mishra SK. Ethics committee meeting by video-conferencing during Covid-19. Indian J Med Ethics. 2020



# Results: Feedback

## Challenges

- Resistance to change from a traditional paper-based system.
- Technical glitches that required day-to-day support
- Errors due to large file sizes and the inability to upload different file formats.

## Action taken

- Training and additional instructions partially mitigated these, but this requires continuous support.

# Conclusion

- Developing and implementing an online portal for IEC proposal submissions has enhanced the ethical review process.
- Stakeholder feedback has been overwhelmingly positive.
- This effort underscores the potential of digital solutions in research and the importance of stakeholder engagement and feedback.
- Future enhancements should focus on:
  - Support for a wider range of documents
  - Integrating advanced technology such as real-time tracking
  - Complete automation and comprehensive analytics



# Acknowledgement

For the support, successful development and implementation of the online portal.

- Present and past IEC members
- Administrative staff of the Bioethics Cell
- All investigators



**Thank you**