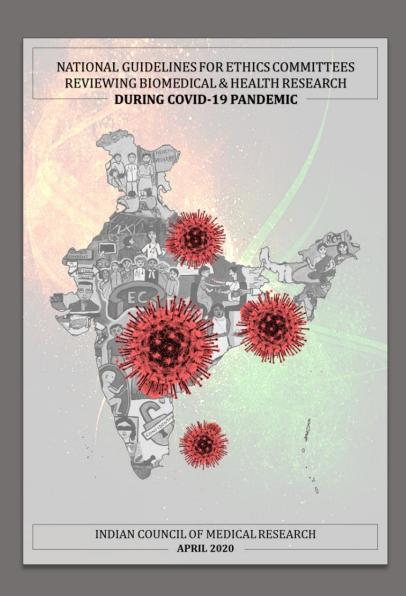
SOP TEMPLATE FOR ETHICS REVIEW OF BIOMEDICAL AND HEALTH RESEARCH DURING COVID-19 PANDEMIC —



ICMR Bioethics Unit

National Centre for disease Informatics and Research
Indian Council of Medical research
Kannamangala Post, Bengaluru- 562110
http://ethics.ncdirindia.org/
email: icmr.bioethics@gmail.com

Institute Logo	SOP for Review of Biomedical and Health Research during COVID-19	SOP No:/ V01
	Pandemic	Effective Date: dd/mm/vvvv

1. Purpose:

The purpose of this Standard Operating Procedure (SOP) is to describe how the EC will function and conduct ethics review in an emergency situation with restrictions as imposed by social distancing requirements during the COVID-19 outbreak.

2. Procedures & Responsibilities:

SN	Procedure	Responsibility				
	Submission and initial review					
a.	Submit research proposal (electronically)	Researchers				
b.	Receive, record, verify completeness and allot reference no.	Secretariat/ Member Secretary				
c.	Categorize depending on risk (Exempt/ Expedited, Full committee), identify	Member Secretary in				
	need for review by experts/independent consultants/ patient /others,	consultation with Chairperson				
	designate reviewers					
d.	Perform Initial review of documents as described in Table 4.3 of ICMR	Primary/ secondary Reviewers				
	National Ethical Guidelines, fill study evaluation form					
e.	Schedule virtual Meeting, Prepare Agenda, invite members (Independent	Secretariat / Member Secretary				
	Consultants/Subject Experts/ PI/ Member secretary of local EC/ in					
	consultation with Chairperson).					
	Virtual EC meeting					
f.	Open the meeting, determine quorum (Section 4.8.4 of ICMR National Ethical	Chairperson				
	Guidelines), COI declaration, Summaries Agenda					
g.	Brief presentation and/or address queries on the research proposal and	Researchers/ subject experts				
	leave meeting prior to decision	(optional)				
h.	Present observations on item reviewed	Primary/ secondary Reviewers				
i.	Discuss further on the item and reach consensus	EC members				
j.	Record Decision and rejoin member who had declared COI before moving on	Secretariat / Member Secretary				
	to subsequent item on agenda					
k.	Record minutes of meeting, ratify approved decisions of	Member Secretary/ Chairperson				
	exemption/expedited review before closing meeting					
	Post meeting activities					
I.	Communication of decision and maintaining records.	Secretariat/ Member Secretary				
m.	Follow up/monitoring/ analysis of SAE/ handling of issues related to non-	Member Secretary in				
	compliance, violation, complaints etc.	consultation with Chairperson				

3. Detailed Instructions:

- The Research Proposal should be submitted electronically in ICMR Common Forms for Ethics Review (http://ethics.ncdirindia.org/Common_forms_for_Ethics_Committee.aspx) with supporting documents (Informed Consent, Brief CV of PI/ Co PIs, Questionnaire/ Case report form, Approval/ Comments of scientific committee, CTRI/ CDSCO/ HMSC/ MTA/ MoU/ insurance coverage) as applicable.
- Once received, the secretariat will verify protocol for completeness (if not ask PI) and number.
- Member Secretary to categorise research into full review, expedited review or exemption from review.
- Member Secretary (in consultation with Chairperson) will identify need for review by subject experts, independent consultants, special invitees, patient representatives, others for prior review or to present views during the meeting.
- The project for full review will be included in agenda of virtual full-committee meeting to be scheduled at the earliest (48 hrs) by the Member Secretary in consultation with the Chairperson.
- The members will be briefed about the technological requirements and virtual platform used for the conduct of the meeting.
- Quorum requirements for review will be applicable as per Section 4.8.4 ICMR National Ethical Guidelines, 2017.
- Review procedures as per ICMR National Ethical Guidelines will also hold good for the virtual web ethics meeting.
- **4. Annexures:** *if any*
- 5. References: ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants

Prepared by	Reviewed by	Dago of	Approved by	Accepted by
Signature with date	Signature with date	Page _ of _	Signature with date	Signature with date