

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



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Institute Logo	SOP for Review of Biomedical and Health Research during COVID-19 Pandemic	SOP No: __/ V01 Effective Date: dd/mm/yyyy
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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 need for review by experts/ independent consultants/ patient /others, designate reviewers	Member Secretary in consultation with Chairperson
d.	Perform Initial review of documents as described in <i>Table 4.3 of ICMR National Ethical Guidelines</i> , fill study evaluation form	Primary/ secondary Reviewers
e.	Schedule virtual Meeting, Prepare Agenda, invite members (<i>Independent Consultants/Subject Experts/ PI/ Member secretary of local EC/ in consultation with Chairperson</i>).	Secretariat / Member Secretary
Virtual EC meeting		
f.	Open the meeting, determine quorum (<i>Section 4.8.4 of ICMR National Ethical Guidelines</i>), COI declaration, Summaries Agenda	Chairperson
g.	Brief presentation and/or address queries on the research proposal and leave meeting prior to decision	Researchers/ subject experts (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 to subsequent item on agenda	Secretariat / Member Secretary
k.	Record minutes of meeting, ratify approved decisions of exemption/expedited review before closing meeting	Member Secretary/ Chairperson
Post meeting activities		
l.	Communication of decision and maintaining records.	Secretariat/ Member Secretary
m.	Follow up/monitoring/ analysis of SAE/ handling of issues related to non-compliance, violation, complaints etc.	Member Secretary in 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 <i>Signature with date</i>	Reviewed by <i>Signature with date</i>	Page _ of _	Approved by <i>Signature with date</i>	Accepted by <i>Signature with date</i>
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