Standard Operating Procedures of Institutional Ethics Committee

ICMR – NIRRCH Ethics Committee for Human Studies

Title: Review Procedure during Emergency

SOP Code: 27/V1.1 Dated: 8th November 2024 Page Nos : 284 to 292

27.1. PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe how the EC will function and conduct ethics reviews in an emergency situation. A humanitarian emergency or disaster is an event or series of events both man-made and natural ones that represents a critical threat to the health, safety, security or well-being of a community or other large group of people, usually covering a wide land area.

While there may be a need to undertake research quickly, this should not impact scientific validity and the need to uphold ethical requirements. This SOP will provide clear, unambiguous instructions. The role of ECs in such circumstances is very important in reviewing protocols prepared for such emergency situation(s).

27.2 SCOPE

This SOP covers the procedures of reviewing the project proposals within the ethics committees (ICMR-NIRRCH Ethics Committee for Human Studies) during the emergency situations such as an outbreak of an infectious disease, social strife, dislocation of population due to draught/ earthquake/ war or war-like situations, disruption of transport systems etc.

27.3 RESPONSIBILITY

All basic ethics principles will remain same as mentioned earlier to guide research in order to protect the dignity, rights, safety and well-being of research participants while conducting Biomedical and Health Research. General Ethical Issues pertaining to benefit-risk assessment, privacy confidentiality, distributive justice, payment for participation, compensation for research-related harm including reporting of SAEs to EC, issues pertaining to conflict of interest, post research access and benefit sharing, principles of collaboration in research (with rapid sharing of data) whenever necessary will remain same as described in the earlier SOPs (SOP.02 & SOP.03). Wherever indicated, community representatives (e.g., Community advisory board) will be involved in ethical reviews.
Depending upon the emergency, different actions will be required. Member Secretary and Chairperson to make amendment based on the situation and communicate it to the members as well as research community.

The principal investigator must comply with Good Laboratory Practice (GLP)

27.4 Informed Consent

27.4.1 Informed Consent Process:

Obtaining valid informed consent in humanitarian emergencies of infectious diseases such as COVID-19 pandemic is a challenge due to practical difficulties in reaching out to a patient, who

may be in a COVID ward, isolation or quarantine facility. In addition, the decisional capacity of the hospitalized patient with moderate or critical disease condition would be very low and it may not be possible to differentiate between reliefs offered and research components.

All procedure to be followed as discussed in earlier SOP 06 **(ANNEX 1.3 from SOP 06, AF/1.3/06/V2.2)**.
The Informed Consent Document (ICD) can be prepared preferably utilizing electronic formats to obtain consent or written consent maintaining adequate social distancing and taking all safety precautions.

27.4.2 Electronic Consent:

In light of infection control measures, the alternative procedures to avoid direct interaction with the patient in isolation must be explored. Technology should be utilized to prepare interactive formats and using electronic tools such as text, graphics, audio, video, podcasts, interactive website, platforms to explain information related to a study and to electronically document informed assent/consent the same. Electronic methods (e.g. digital signature) must be reviewed and approved by the EC a priori. Process can be documented through audio or video recording (if required).

Special precautions should be taken for maintaining confidentiality of all soft copies such as electronic consent, video recordings etc. by using password protection of files and must be stored in a separate device kept in lock and key and not on the device routinely used by PI

27.4.3 Waiver of Consent:

Check ANNEX 1.3 from SOP 06, AF/1.3/06/V2.0 all similar procedure

27.5 ETHICAL REVIEW PROCEDURES

EC must prioritize research review based on urgency and take needful steps to facilitate initiation of new research and conduct ongoing research with necessary amendments as per need in the view of social distancing norms during the infectious disease outbreaks.

27.5.1 Ethics Committee (EC):

i EC to ensure a thorough scientific and ethical review of research as per national guidelines and regulations to safeguard the dignity, rights, safety and well-being of research participants.

ii EC to encourage relevant research to be registered on Clinical Trial Registry of India (CTRI) and seek approvals as per relevant guidelines and applicable regulations.

iii Member Secretary should categorize proposals into exempt/expedited/ or full review category as per National Ethical Guidelines and plan next steps for fast track review.

iv Research during emergencies can be reviewed through expedited review/unscheduled full committee meetings on a case-to-case basis depending on the urgency and need. If an expedited review is done, full ethical review can follow whenever next possible.

v Quorum for decision-making should have a minimum of five members, including medical/ non-medical or technical/non-technical members with one non-affiliated member.

vi Measures such as virtual or tele/web conferences should be attempted and face-to-face meetings can be avoided to observe social distancing norms.

vii In exceptional and emergency situations, preliminary research procedures including but not restricted to data/ biological sample collection that are likely to rapidly deteriorate or perish may be allowed while the ethics review process is still underway.

viii Available protocol templates could be reviewed to expedite the process and interim review/ re-review can be done if the emergency situation changes.

27.5.2 Ethics Review:

i Researchers should submit research proposals in the ICMR Common Forms for Ethics Review as soft or hard copies enclosing required documents as mentioned in earlier SOPs (SOP 06).

ii Submission of e-copy of research protocol and relevant documents followed by their screening by Secretariat for completeness and categorization as exempt/ expedited review/ emergency full committee review depending on the urgency and need.

iii Electronic documents may be accepted for review and timelines shortened for accelerated procedures

iv Virtual or Tele/Video conferences should be attempted to ensure social distancing as face-to face meetings may not be suitable. Use suitable virtual software platform, preferably a video conference to enable face to face discussion or teleconference if connectivity is an issue.

v Agenda of virtual meetings should be kept short, however, EC may meet more frequently for fast track review

vi The EC may invite review by subject expert if needed and can participate as a special invitee during the web-meeting who will leave the meeting before final decision making.

vii During the review process, the Ethics Committees should consider the following:

a. Assess if there is any additionally vulnerability of research participants due to emergency situation

b. Participants must be provided due psychosocial and emotional support. They must be respected, shown empathy and compassion and not subjected to any kind of stigma or discrimination.

c. Privacy and confidentiality of data collected and shared electronically needs special safeguards

d. Review how safety of researchers is ensured too:

1. If written consent is not possible (e.g., physical isolation/severe COVID-19 patients), consent could be given orally/ use electronic methods to document and record.

2. If oral consent is allowed, then recording of the oral consent and documenting it should be considered and there should be an independent witness for the procedure – whether done in person or electronically.

3. Due to inability of the participant to attend the site (for e.g., social distancing), the contact/communication can be made via phone, to enquire and identify adverse events, serious adverse events and ensure medical care and oversight with documentation.

4. In an ongoing study, if the designated principal investigator (PI) is indisposed for a period, she/he may need to delegate parts of her/his duties temporarily to others/ co-investigator and the same should be documented and reported to EC at the earliest.

viii Withholding information in Public Health emergencies may be a threat to national security, and therefore the right balance must be maintained to protect individual privacy and confidentiality, and relevant disclosure to public health authorities.

ix Suggest steps to protect participants of researchers from possible stigma or discrimination.

x EC members present during the virtual meeting should decide through consensus or cast online vote expressing their decision. Any disagreement to be recorded with reasons.

xi Meeting could be digitally recorded (audio/video) with permission of members and secretariat is responsible to note the attendance/ participation in the online meeting.

xii Once approved, the EC should be updated about the progress of the projects that have been approved in emergency mode. EC may decide the frequency of the continuing review report of such projects which can be more than once in a year.

27.6 Flow Chart

No.	**Activity**	**Responsibility**
	Submission and Initial Review	
1	Submit research proposal (electronically)	Researcher
2	Receive, record, verify completeness and allot reference number	Secretariat/ Member Secretary
3	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

4	If its expedited review send the proposal to 2 subject experts along with one legal and social science member. Also mark copy to chairperson and invite feedback within 3 days. If comments are minor (such that the vulnerability and risk assessment will not change), compile comments. Get Chairperson's approval and submit the comments to PI. If members opine that the project needs to be discussed in a full committee meeting as there are major queries, then Secretariat should plan a physical/virtual meeting depending on prevailing circumstances.	Secretariat/ Member Secretary
5	Perform Initial review of documents as described in *Table 4.3 of ICMR National Ethical Guidelines*, fill study evaluation form	Primary/ Secondary reviewer
6	Schedule virtual Meeting, Prepare Agenda, invite members (Independent Consultants/Subject Experts/ PI/ Member secretary of local EC/ in consultation with Chairperson).	Secretariat/ Member Secretary
Virtual Ethics Committee meeting		
1	Open the meeting, determine quorum (Section 4.8.4 of ICMR National Ethical Guidelines), COI declaration, Summaries Agenda	Chairperson
2	Brief presentation and/or address queries on the research proposal and leave meeting prior to decision	Researchers/ subject experts (optional)
3	Present observations on item reviewed	Primary/ secondary Reviewers
4	Discuss further on the item and reach consensus If feasible and necessary invite the PI to join the virtual meeting and clarify some of the issues raised.	EC members
5	Record Decision and rejoin member who had declared COI before moving on to subsequent item on agenda	Secretariat / Member Secretary
6	Record minutes of meeting, ratify approved decisions of exemption/expedited review before closing meeting	Member Secretary/ Chairperson

Post meeting activities		
1	Communication of decision and maintaining records.	Secretariat/ Member Secretary
2	Follow up/monitoring/ analysis of SAE/ handling of issues related to non-compliance, violation, complaints etc.	Member Secretary in consultation with Chairperson

Chairperson and Member Secretary can take a final call in case of minor discrepancies arising after the committee approves the project.

27.7 Review of Multicenter Research:

i Common review is generally carried out for research involving low or minimal risk, survey or multi-centric studies using anonymized samples or data or those that are public health research studies determined to have low or minimal risk.

ii EC is free to accept the decision of designated committee or to do an expedited or full committee review expeditiously. Local, site specific issues or concerns, informed consent translations, local study implementation and monitoring may be reviewed.

iii However, in an emergency situations, for all types of research including high risk studies or those involving vulnerable population can be taken up for fast track common review while ensuring strict monitoring and oversight by registered local ethics committees.

27.8 Continuing Review & Monitoring:

i Protocols approved during emergency should be monitored more frequently. PIs may be requested to give their reports every 6 months.

ii If virtual monitoring can be done, through scans and documents, it may be done that way, else physical monitoring in a safe environment should be conducted.

iii The EC should continually evaluate progress of ongoing proposals, monitor approved study site for compliance, review SAE reports, protocol deviations/violations/ non-compliance/ DSMB reports/ any new information/assess final reports.

iv For protocol deviations/violations the EC should examine the corrective actions. If the violations are serious the EC may halt the study.

v Compensation must be given for research-related injuries if applicable, as determined by the EC and as per regulatory requirement (if applicable).

27.9 Decisions Regarding Ongoing Studies:

i The impact of emergency situations on ongoing and existing studies, ongoing recruitment and continued involvement of participants needs to be considered.

ii Secretariat in consultation with Chairperson, must carefully evaluate need for other research studies that are ongoing/ near term/ have direct benefit(s) and if stopped, may pose risk to participants. These may be continued/ mechanisms should be suggested for their continuation.

iii Following measures can be taken in consideration such as, extension of study duration; temporary halt of study at some/all sites; Suspension/ Postponement of study or activation of sites that have not yet been initiated without compromising safety and well-being of patients; Continuation of study with limited parameters; conversion of physical visits into phone or video visits, postponement or complete cancellation of visits to ensure that only strictly necessary visits are performed at sites; ongoing study may need to take re-consent of already enrolled participants to implement urgent changes; it can be done via phone or video-calls and obtaining oral consents supplemented with email confirmation.

iv Further, travel restrictions, confinement of study participants and staff to perform visits should be taken into account.

27.10 Review of new non-emergency related Research:

i If priority for ethics review in a defined timeframe is given to emergency-related research, other subject research must not suffer. Studies evaluating treatments for chronic conditions or other communicable diseases or injuries or others may also be considered for review by EC as these may also be important.

ii EC should review and assess if a planned study may have a negative impact on participants' safety or increase risk to participants (as a result of the ongoing emergency situation such as outbreaks etc.), and make a sound decision with relevant suggestions for additional safeguards for conducting research in such emergency.

iii Depending on the situation and the quantum of projects to be reviewed by EC during an emergency, EC could take a decision on whether it will be able to review non-emergency protocols, or till what time it will not be able to review the same.

iv The review of these studies may be done through a virtual EC meeting ensuring appropriate scientific and ethical review and fulfilling the quorum requirements.

27.11 ANNEX

ANNEX1 AF/01/27/V1.1 Document History

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Document History

Author	Version	Date	Description of the Change
Dr. Beena Joshi	Version 1	4th January 2021	First approved copy
Dr. Vikrant Bhor	Version 1.1	8th November 2024	All bullets are numbered. Extensive modifications done in description