**Supplemental Table 1:** Comparison between the ICMR-COVID-19 EC guidelines and the ICMR 2017 guidelines

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| S. No. | Ethics themes and sub-themes | COVID-19 guidelines | ICMR 2017 guidelines | Analytical remarks |
| 1 | Benefit-risk assessment | Categorization of risk (Section 2.1) | Addressed in section 2.2 | The categories of ‘less than minimal risk’ and ‘minimal risk’ seem redundant as the risk levels associated with routine activities have changed in the current COVID-19 scenario. For example, routine activities, such as a physical examination or history taking, involve less than minimal risk under normal circumstances. However, in the current scenario, with the imposed physical distancing and isolation, these activities involve increased levels of risk. |
| 2 | Privacy and confidentiality | Stresses on the importance of maintaining privacy and confidentiality because of the stigma associated with COVID-19 infection. (Section 2.2) | Section 2.3.4 addresses the aspect about the possibility of stigma associated with certain diseases and the need to maintain privacy and confidentiality. | Somewhat tweaked; The 2019 guidelines focus entirely on COVID-19. |
| 3 | Distributive justice | Equitable distribution of burdens and benefits so as to avoid creating inequalities (Section 2.3) | Addressed in section 2.4 | Needs specific elaboration for different types of research as participant selection will vary in the current scenario. This has been further explained in paragraph 3 of the lacunae section. |
| 4 | Payment for participation/ inducement | No payment beyond routine clinical care and reimbursement of reasonable amount to cover incidental expenses (Sec 2.4) | Addressed in section 2.5 | Subtitle is contradictory to the explanation. Section talks on participant paying for routine care. |
| 5 | Compensation for research-related harm | Entitlement to free healthcare and referrals in case of direct physical, psychological, legal, social, or economic harms and compensation in case of serious adverse events (SAEs); timeline of SAE reporting (Sec 2.5) | Similar to section 2.6; assistance (financial and otherwise) in case of direct physical, psychological, legal, social, or economic harms | Direct physical and mental harm require healthcare and referral. Other research related harm will require different mode of redressal |
| 6 | Conflict of interest (COI) | Declaration and management of conflicts of interests (Sec 2.6) | Addressed in section 2.8 | Management of COI needs more elaboration. |
| 7 | Community engagement | Community engagement through involvement of community representative at all levels of research, build awareness but avoid excess of information, prevent spread of fake news. (Sec 2.7) | Similar, with few additions | Role of EC in ensuring community engagement is not clear |
| 8 | Post research access and benefit sharing | Communication of results and sharing of benefits with communities/participants (Sec 2.8) | Addressed in section 2.11 | No additional information |
| 9 | Storage of biological material/ datasets | Safeguards for storage of infectious samples and clarity on custodianship of samples (2.9) | Addressed in section 11.2 | Anonymous and irreversible anonymization may not be feasible in a highly infectious disease scenario where contact tracing and identification of hotspots are done. |
| 10 | Collaboration in research | Addresses issues of possible inequity of expertise, access between partnering institutions /funding relationships, and rapid data sharing; necessity for memorandum of understanding and material transfer agreement; approval by the Health Ministry’s Screening Committee for foreign collaborations (2.10) | Addressed in section 3.8 | No additional information |
| 11 | Public health and socio-behavioral research | Issues like inequitable participant selection, use of alternate modalities of data collection, confidentiality and privacy, risk to dignity and increased vulnerability, validity of data, all of which are unique to COVID-19 have been mentioned (2.11) | Not addressed | This section would have benefited with a more structured and elaborate presentation |
| 12 | Role of agencies/ sponsors & governance of research | Need for appropriate safety, funds, care, compensation, and training at individual, societal and/or community levels for patients, health care workers and others engaged in COVID-19 research; need for public education; expeditious review process by central authority; and conditions for approval of monitored emergency use of unregistered and experimental interventions (MEURI) (Sec 2.12) | Addressed in chapter 12 with few additional points | The applicability of the guideline to central regulatory authority for expeditious review of research for new drugs is unclear |
| 13 | Biosafety in laboratories and hospitals | Biosafety levels in research, the need for additional safeguards in handling specimens, precautions to be followed in dealing with patients, the importance of regular active screening of the hospital staff, and the possible role of telemedicine in the current scenario (Sec 2.13) | Not addressed | Entirely new section, if presented in a structured format would have added value to the guidelines. |
| 14 | Categories of research | Three categories of research: New COVID-19 related research, Ongoing non-COVID research, New non-COVID research, prioritization of review, needful amendments in ongoing research (3.1.1) | Not addressed | Appropriate |
| 15 | Registration of EC | ECs should be registered with both the Department of Health Research (DHR) and the Central Drugs Standard Control Organisation (CDSCO) (3.2.2) | Registration with appropriate relevant authority addressed in section 4.15.2 | Appropriate. EC reviewing clinical trials should be registered with the Central licensing authority (CLA). |
| 17 | Registration of trial | ECs should ensure that all COVID-19 related research, including clinical trials and biomedical health research are registered with the Clinical Trials Registry-India (CTRI). (3.2.3) | Addressed in section 3.7  CTRI registration for biomedical studies was voluntary | Appropriateness of registering nonclinical COVID-19 trials with CTRI is unclear |
| 18 | Review procedures | Situations warranting expedited/unscheduled full review, interim review and re-review, requirements for quorum, need for virtual or tele/web conferences, timely review and monitoring of approved research elaborated. Preliminary procedures may be allowed while review is still underway. Review can be conducted by any EC in India incase local ECs are not available. (3.2.4) | Addressed in section 12.5 | Nothing new added |
| 19 | Special situations | Role of more than one EC in an institute, independent EC, subcommittees of the EC. (3.3) | Addressed in section 4.2 | Nothing new added to even warrant the title of special situations |
| 20 | Ethics review | Adopt SOP for emergency review, virtual or tele video conferencing, e-copy of protocol submission, need for short agenda, frequent meeting for fast track review, prior review by subject experts/ consultants with no voting power, can be invited to obtain clarifications. (3.4) | Addressed in sections 12.5 and 4.9.15 | ICMR Common Forms added |
| 21 | Considerations during review | Highlights the need to consider oral consent, electronic method of documenting consent, oversight via phone, enquiry and identification of adverse events and serious adverse events, the importance of notifying the EC if the principal investigator (PI) is indisposed and has had to delegate parts of her/his duties temporarily to the co-investigator/others (3.4.8) | Addressed requirement for electronic/ oral consent | Appropriate, Possibility of change in PI if indisposed on account of the highly infectious nature of COVID-19 and action to be taken highlighted. |
| 22 | Privacy and Confidentiality | Risk of breach of privacy and confidentiality through the need to provide information to health authorities during an emergency. (3.4.9) | Addressed partly in sections 12.4 | New addition |
| 23 | Review of multicenter research | Suggested for the COVID-19 situation- common review by one main designated EC with provision of strict monitoring by local EC (3.5) | Addressed in section 4.10.2 | Applicable earlier to low or minimal risk research. Provision now for COVID-19 research |
| 24 | Continuing review & Monitoring | Evaluate ongoing progress, monitor study site, review SAE reports, protocol deviations/ violation/ Data safety monitoring board reports/ final reports (3.6) | Addressed in section 4.11 | Nothing new added |
| 25 | Decision regarding ongoing studies | Measures suggested to minimize risk to participants in ongoing studies, in view of the physical distancing and the travel restrictions imposed, such as extension of study duration, temporary halt, postponement, inactivation of non-initiated sites, phone/ video visits. (3.7) | Not addressed | Appropriate changes. Importance of reconsent in view of changed parameters of the study, highlighted. |
| 26 | Review of non-COVID research | Steps to minimize risk to participants, researchers and EC members should be suggested/ implemented to enable continuation of non COVID -19 research. (3.8) | Not addressed | Appropriate |
| 27 | Informed consent: Communication | Practical problems in reaching out to participants (4.1) | Addressed partly in sections 12.2 and 5.2 | COVID-19 is a disaster unlike any in the past where there is a threat to others life through coming into close physical proximity with affected people |
| 28 | Therapeutic misconception | Impaired decisional capacity | Addressed in sections 6.10.1 and 7.1.6 | Impaired cognition due to severe illness may result in therapeutic misconception. Impaired decisional capacity is likely to affect voluntariness |
| 29 | Surrogate consent | Impartial literate witness for illiterate participant (4.1.3) | Addressed in section 12.2.6 | Logistics of the same in quarantine/ isolation needs to be addressed |
| 30 | Broad consent with opt out option | For residual clinical samples (4.1.4) | Addressed in section 8.4.3 | Opt out option should be included in the PIS. Tiered consent could be considered |
| 31 | Electronic informed consent | Use of technology for interactive formats for informed consent & use of digital signature. Audio/ video recording (4.2) | Addressed in section 5.5 | Privacy & confidentiality issues need to be addressed. |
| 32 | Waiver of consent | Anonymized samples (4.3) | Addressed in section 5.7 | Irreversible anonymization may not be feasible in a COVID-19 pandemic |
| 33 | Vulnerability | Identifies various categories of vulnerable persons (5.1) | Addressed in chapter 6 | Repetition |
| 34 | Additional safeguards | To uphold autonomy, ensure voluntariness, protect privacy, confidentiality, provide ancillary care. (5.2) | Addressed in section 6.2 | Repetition |
| 35 | Safety of healthcare workers | Includes prioritization of research, biosafety precautions, and training (5.3) | Not addressed | Appropriate, but needs more detailed elaboration on various aspects and how it will affect COVID-19 research |
| 36 | Psychological needs and mental health | Requires empathy, respect emotional and psychosocial support to affected persons & families, in quarantine or isolation (5.4) | Not addressed | Appropriate and required, trained counsellors should be made available or else will lead to the likelihood of undue dependence on the researcher for all of the needs |