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Expedient Reviews during the Covid-19 Pandemic Period: Concept to Current Practice of the Institutional Review Board in the Resource-Constrained Scenario

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Abstract

During the COVID-19 pandemic period, the IRB at the Department of Medical Research (DMR), Myanmar has accepted the online submission of research proposals, conducted reviews, communicated decisions and virtual approvals from April 2020 to date. Monitoring IRB metrics in the pandemic period is essential to improve the review process in provision of the real-time empirical evidence. Thus, this study aimed to identify how IRB adjusted with the COVID-19 pandemic for sustained ethics review by comparing the IRB metrics before (June 2019-March 2020; period 1) and during the pandemic (April-October 2020; period 2). A desk-based review of the electronic database revealed a total of 158 *vs* 108 proposals during periods 1 and 2 respectively. Among the research proposals reviewed online in period 2, the COVID-related proposals contributed around 22% (16/73) of which public health and socio-behavioural research prevailed. The IRB metrics did not vary much compared to those before this period except the high volume of expedited reviews. The minimal risk proposals for COVID-19 accounted for the average turnaround time of 6 days from submission to approval. The waiver of documentation of informed-consent or some alterations were not uncommon. Functional adjustments for the expedient reviews during the pandemic period at IRBs in resource-constrained settings require extensive evaluation for feasibility.

Keywords: Online reviews; Institutional review board; IRB metrics; COVID-19 pandemic; Informed-consent

Background

In response to the COVID-19 pandemic, unanswered research questions emerge for the development of innovative interventions that pose new pressure and challenges among researchers and the research ethics committees. As such, there is a need for an urgent review of time-sensitive COVID-19 related studies which is also applicable for some non-COVID proposals that need to meet the timeline of funding agencies and international degree courses [1,2]. Also, gathering IRB members in the hearing sessions require secure, remote, and virtual arrangements [3]. WHO Guidelines (2016) and (2020) further supported the concerns to observe ethical issues during the outbreaks of infectious diseases including COVID-19 [4,5]. Ethical challenges required to address by the Research Ethics Committees (RECs) cover different dimensions of research: biomedical, public health, and clinical entities [6,7].

During the unprecedented period, the Institutional Review Boards (IRBs) within the platform of Forum for Ethical Review Committees in the Asian and Western Pacific (FERCAP) Regions adjust for ethical oversight by expedient reviews through the online system in April 2020 [8]. Meanwhile, the Indian Council of Medical Research (ICMR) has published the National Guidelines to deal with ethical challenges for research in the global pandemic and to cope with expedient reviews [9]. Above all, Kumar and Muthuswamy (2020) [10] highlighted and discussed the strategies to foster ethical soundness of biomedical and health research in India which was also applicable to other developing country context.

On 23 March 2020, the first two confirmed cases of COVID-19 were reported in Myanmar followed by the travel restrictions, lockdowns, contact tracing and other precautionary measures as the commitment of the State and health sector response. The IRB at the Department of Medical Research (DMR), Myanmar has introduced its new Standard Operating Procedure (SOP) on rapid reviews and accepted the submission of research proposals and conducted its online reviews through the electronic mail system and intermittent zoom meetings, and communicated decisions and virtual approvals for the first time from April 2020 to date [11]. There were 13 full board

meetings and expedited reviews across six months (April to October) except in May during which there was no full board meeting. Despite urgency, quality ethics review process is a necessity as noted by the recently published study highlighting the IRB operations and its way forward to further improvement in the resource-constrained scenario [12].

The embedded ethical principles in International Ethical Guidelines for Health-related Research involving Humans from CIOMS (Guideline #20) are tangible for research in disasters and disease outbreaks [13]. Even under the difficult circumstances, obtaining the individual informed consent is the trademark of voluntary participation and the symbol of respect. This is the responsibility of researchers, sponsors, international organizations, research ethics committees, and other relevant stake holders unless the conditions for a waiver of informed consent are met [13]. Also, during the expedient reviews of both COVID and non-COVID research proposals, the IRBs need to assess the Informed Consent Forms (ICF) that could demonstrate respect for the autonomy in the decision of research participants to protect their interests explicitly in the outbreak situation [14].

Except for one study from China [15], there are no studies to date in Myanmar and elsewhere and little is known about the IRB operations during the pandemic period to arrange timely reviews of research proposals being scrutinized for technical soundness and ethical competence. Monitoring IRB metrics in the pandemic period is essential to improve the review process in the provision of empirical evidence by researchers in real-time in support of program planners. By comparing with IRB deliberations during the non-epidemic period, this study could ascertain the similarities and dissimilarities that might have implications on changes in IRB policy and procedures during Public Health Emergencies (PHE). There is also a need to canvass current ethical issues by introducing the online review system. The objectives of the study were to identify how IRB (DMR) adjusted with the COVID-19 pandemic for sustained ethics review; to compare the IRB metrics before (June 2019-March 2020) and during the pandemic period (April to October 2020) and to analyse the appropriateness of the Informed Consent Form (ICF) during the pandemic period.

Methodology

A cross-sectional descriptive study was performed in October 2020 by means of a retrospective desk-based review of the secondary data available from the electronic database of the IRB (DMR) with the permission of administrative authorities. The data extracted covered the first nine months before the pandemic period starting from June 2019 when the IRB at DMR has reorganized its structure till the end of March 2020 (period 1) and for six months during the pandemic excluding May 2020 (April to October 2020; period 2).

There were no meetings in the month of May due to temporary closure of the IRB office at the height of the epidemic in Yangon. For revealing the adjustment of the IRB operations in the time of public health emergency condition, the characteristics of research proposals reviewed through the online system and virtual meetings *vs* the conventional system were analysed. Furthermore, a minimal set of IRB metrics measured for comparison of two periods of time included the average number of proposals reviewed per month, the level of review, studies that needed more than one IRB review, type of data acquisition, inclusion of biological materials, data collection portal, the ICF waiver status and the average turnaround time (starting from the date of review to the date of approval).

These metrics were used to self-evaluate the satisfactory performance of the IRB in its review process by applying a checklist stated in the standard operating procedure before reaching the final decision of approved, major revisions, minor revisions and disapproved. A minimal set of the metrics used in this study could directly reflect the operational efficiency of the IRB and could be able to identify the performance gaps during the self-appraisal thereby facilitating the improvement in quality of review.

A Waiver of Consent refers to a waiver from obtaining consent from subjects before conducting research; An Alteration of Consent refers to a consent procedure which omits or alters some or all of the elements of consent in the consent language; A Waiver of Documentation refers to a waiver of obtaining a signature on a written or electronic informed consent form as part of the consent procedure. A Partial Waiver refers to those proposals using both primary and secondary data for which the use of secondary data was entitled for a waiver request.

The univariate analysis was performed by using SPSS version 22.0 that included frequency distributions and percentages, statistical averages (median and interquartile range) and cross-tabulations of variables of interests. The Chi-squared or Fisher's Exact Test was used as appropriate to confirm the expected differences between the online reviews *vs* conventional reviews (Table 1) and between the reviews done during period 1 *vs* Period 2 (Table 2) and $p<0.05$ was considered as significant.

Findings

The IRB at DMR received a total of 158 *vs* 108 proposals registered during the periods 1 (June 2019-March 2020) and 2 (April-October 2020) respectively and only one proposal was exempted from review process in period 1 and six out of 108 were exempted in period 2.

The adjustment of the IRB with the COVID-19 pandemic for sustained ethics review

In period 2, there were fluctuations in new cases of COVID-19 with flexible lockdown approaches and social distancing. These circumstances provoked the IRB to conduct the full board review meetings through the online platform intermittently for 37% (40/108) of proposals being determined as more than minimal risk. In contrast, all expedited reviews (n=62) were carried out through the internet-based electronic mail system. Among the proposals eligible for expedited reviews, continuing reviews and amendments contributed for 16%.

Table 1 provided the brief description on the characteristics of research proposals reviewed by type of review system. During period 2, in congruence with the new standard operating procedure, rapid reviews of the submitted proposals *via* online were done: 11 *vs* 62 for full-board and expedited reviews, respectively. Among the research proposals reviewed online, the COVID-related proposals significantly contributed around 22% (16/73) (p=0.04) of which public health and socio-behavioural research prevailed. The overall number of proposals using digital platforms for data collection (*via* online Facebook social media, mobile apps, and video conferencing through Facebook messenger) were not as high as those using other forms of data collection such as self-administered questionnaire, face-to-face interviews, telephone interviews, focus group discussions, primary collection of biological materials, secondary data collection by reviewing the existing records, registers, and documents (19 *vs* 82). Findings were statistically not significant (Table 1).

Table 2 analysed the distribution of the submitted proposals that underwent reviews during period 2 (n=42) by vulnerability of the study population. The proposals with less vulnerable populations

Table 1: Characteristics of the research proposals reviewed at the IRB (DMR) during April-October 2020 (Period 2) by type of review system.

Characteristic	Online review system		Not online system		p value
	No.	%	No.	%	
Level of review	(n=79)		(n=29)		NA
Full board	11	14	29	100	
Expedited*	62	78	0	0	
Exempt	6	8	0	0	
Category of research	(n=73)		(n=29)		
COVID related	16	22	1	3	0.036^
Not COVID related	57	78	28	97	
COVID related research	(n=16)		(n=1)		NA
Public health & Socio-behavioral aspect	13	81	0	0	
Laboratory and genetics aspect	0	0	1	100	
Two or more aspects combined	3	19	0	0	
Not COVID related research	(n=57)		(n=28)		0.514
Public health & Socio-behavioral aspect	26	46	10	36	
Laboratory and genetics aspect	14	25	7	25	
Clinical aspect	3	5	4	14	
Two or more aspects combined	14	24	7	25	
Data collection portal	(n=73)		(n=29)		0.189
Digital platform	16	21	3	10	
Non digital platform	56	75	26	90	
Combined	3	4	0	0	

*New submission, proposals that required approval for continuation & amendments were included.
^Fisher's Exact Test; NA=Not Applicable.

Table 2: Type of vulnerable populations involved in proposals reviewed at the IRB (DMR) between April-October 2020 (Period 2).

Characteristic	Online review system	Not online system	Combined
	(n=22)	(n=20)	(n=42)
COVID-19 patients	2	1	3
Neonates and children	6	2	8
Pregnant women & women in delivery	2	2	4
Adolescents	2	4	6
Patients with cancer & other chronic illness	4	3	7
Patients with acute conditions	2	5	7
Elderly	1	0	1
Drug users	1	1	2
Mobile migrants & poverty-stricken rural households	2	2	4

and of minimal risk in the proposed design and data collection were not included. The IRB has identified neonates as the vulnerable population with more than minimal risk in eight proposals reviewed through online and without online systems whereas seven proposals each composed of patients suffering from acute illness conditions and chronic illnesses including cancer followed by six proposals that included adolescents. The vulnerability, risks and benefits and the recruitment procedures accounted for ethical challenges encountered by the IRB before moving to voluntary participation in research and the attainment of the informed consent and assent as appropriate.

Comparison of IRB metrics

Table 3 compared the minimal set of IRB metrics between two periods. During the pandemic in period 2 (between April-October 2020), the IRB metrics did not vary much compared to period 1 (between June 2019 and March 2020) except the significantly higher

Table 3: The comparison of IRB metrics at the IRB (DMR) by period of review.

Characteristic	Period 1: June 2019-March 2020 (n=158)		Period 2: April-October 2020 (n=108)		p value
	No.	%	No.	%	
Average number of proposals reviewed per month (Median)	17		17		
Level of review					0.001
Full board	85	54	40	37	
Expedited	72	45	62	57	
Exempt	1	1	6	6	
Review system					NA
Online	0	0	79	73	
Not online	158	100	29	27	
> One IRB approval	(n=156)		(n=102)		0.209
Required	20	13	8	8	
Not required	136	87	94	92	
Aspects					0.293
Public health	78	50	49	48	
Lab & genetics	44	28	22	22	
Clinical	11	7	7	7	
>=Two aspects	23	15	24	23	
COVID related					NA
Yes	0	0	17	17	
No	156	100	85	83	
Biological materials involved					0.351
Yes	75	48	43	42	
No	81	52	59	58	
Type of data					0.024
Primary	108	69	83	81	
Secondary	34	22	9	9	
Both	14	9	10	10	
ICF requirement					0.009
Required	112	72	75	74	
Partial	11	7	6	6	
Waived document	1	1	8	8	
Fully waived	32	20	13	12	
Revised ICF required					0.953
Yes	82	53	54	53	
No	74	47	48	47	
Average turnaround time* (Median days)					
Online system					
Full board	-		28		
Expedited**	-		22		
Not online system					
Full board	60		41		
Expedited**	46		-		
COVID related					
Yes	-		6		
No	54		30		

*Proposals exempted, withdrawn, and disapproved were excluded; **Expedited review for new proposals only.
^Fisher's Exact Test; NA=Not applicable.

Table 4: The nature of ICF revised in period 2: April-October 2020at the IRB (DMR) by type of review system.

Characteristic	Total* (n=54)		Online review System		Not online system	
	No.	%	No.	%	No.	%
Language correction	7	13	3	43	4	57
Incentives	10	19	5	50	5	50
Feedback requirement	4	7	3	75	1	25
Procedural changes	30	56	19	63	11	37
Correction of inconsistencies	5	9	3	60	2	40
Specific benefits	6	11	2	33	4	67
Others**	11	20	7	64	4	36

*Column percentages did not add to 100; represented for single item only.
**Others include minor corrections for the title and statements mentioned.

volume of expedited reviews for minimal risk (62/108, 57% *vs* 72/158, 45%; p=0.001). Due to pandemic restrictions and the necessity to avoid face to face personal contacts, the IRB has practised the intermittent online review system during period 2. As such, the IRB did not use the online system only for 27% (29/108) of the submitted proposals.

During period 2, the submitted proposals were less likely to require more than one IRB review that included student research and international collaborative research works but not significant. Conversely, in period 2, there were more proposals focused on more than two aspects: biomedical, clinical and public health issues compared to period 1 (23% *vs* 15%). Among reviews in period 2, only 17% (17/102) of proposals were COVID related.

Above all, the research proposals of clinical and biomedical entities reviewed during period 2 were less likely to include prospective collection of biological samples thus, without any physical risk. Findings were not statistically significant. The proportion of research proposals expressing the intention to collect leftover/residual materials in period 2 contributed for 16% (7/43) which was higher than 12% (9/75) in period 1 but not significant. Nevertheless, the proposals that included primary data collection prospectively was significantly higher in period 2 compared to period 1 (81% *vs* 69%; p=0.024) for which the results should be interpreted with caution.

Concerning with an Informed Consent Form (ICF), proposals submitted during period 2 were more likely to request the waiver compared to period 1 (12% *vs* 20%). Moreover, eight proposals were entitled to waive for the documentation of informed consent in period 2. Findings were statistically highly significant at p=0.009. The proportion of requirement to revise the ICF (<60%) was almost similar between two periods. Apparently, using online reviews in period 2 could be able to shorten the turnaround time for the full board as well as expedited reviews compared to the paper-based system in period 1 as well as in the same period. The average turnaround time for the expedited review process was 6 days for COVID-related proposals in period 2, from the time of submission to approval (Table 2).

Amid pandemic restrictions, there were no major differences in the metrics for the two periods that might have the impact on the efficiency of IRB operations especially in terms of the workload (the exact similarity in the average number of IRB reviews per month). In fact, this might be the benefit of introducing the online review system at the IRB to adjust with the pandemic. Conversely, no significant difference in the requirement for approval by more than one IRB reflected fewer numbers of submitted proposals (student research and international collaborative research) during this difficult time. However, the similar rates for the requirements to revise the ICF between two periods indicated the universal requirement to conform the revisions of ICF whenever the IRB suggested for some alterations in data collection methods for instance, switching face to face data collection to remote methods due to the effect of public health emergency.

The appropriateness of the informed consent forms

Table 4 analysed the distribution of specific content of the ICF revised during the pandemic period. The waiver of documentation and alterations of ICF was not uncommon depending on the type of study design, vulnerability of the study population and the nature of data collection. Procedural changes in the ICF were the most common revised item among others (56%; 30/54) and it was also true for the proposals reviewed online (63%; 19/30). The next commonly revised item in the ICF was related to incentives (19%; 10/54).

Discussion

The efficiency of rapid online reviews and their impact

The attempt of IRB (DMR) was noted as productive and efficient during the trying time in terms of the same average number of reviews per month in period 2 inclusive of the online review system compared to period 1. The IRB policies and procedures are explicitly beneficial to review, assess, remediate, and improve IRB process quality and efficiency [16] and those values should also be applicable during the public health emergency. Conversely, the earlier study in 2008 [17] pointed out the fact that most of the time, research ethics reviews did not pay adequate attention to outcomes assessment which was undesirable in evaluating the improved efficiency.

By and large, the ethical and regulatory frameworks designed for non-acute epidemics are not necessarily fit for acute epidemic research [5,18-20]. In this context, it is critical to avoid disruptions to the routine operations in non-ideal circumstances. It is obvious that the turnaround time of COVID-related proposals with minimal risks eligible for expedited reviews by the online system provoked the shortest duration of '6 days'. The priority and speed of reviews solely depend on risk stratification as stated in the standard operating procedure of IRB [11].

Moreover, rapid circulation of submitted proposals and required documents online among the members and the assigned reviewers could facilitate the conduct of review meetings at earlier dates. Nevertheless, configuration of online review meetings by licensed

zoom cloud apps as a virtual tool already stated in an Indian study [21] requires perfect arrangements including the specifications of computer hardware, smart phones, and tablets apart from the bandwidth, high-speed internet, Wi-Fi connections and adequate investment in resource-constrained settings.

Ethical challenges encountered during the public health emergency

The findings of this study indicated the proportion of research proposals that targeted vulnerable populations was around 24% in period 2. During this period, we focused ethical considerations on the transmission risk of COVID-19 to research participants as well as to the researchers especially for interview arrangements and specimen collections apart from considering the scientific merits, potential benefits and the ICF according to the ethics review guidelines of IRB (DMR).

Besides, ethical considerations focused on discarding biological specimens by strictly following the biosafety measures. In this connection, we need to follow the shared ethical values/principles stated in the Belmont Report, CIOMS guidelines, Helsinki Declaration and ICH-GCP other than the existing SOP [13,22-24]. It is critical for IRBs to identify the nature of physical, social, psychological, and legal risks as appropriate while reviewing the proposals and suggested to mitigate those risks in the conduct of research especially during PHE [24-27].

In this study, only 19 out of 102 (19%) submitted proposals stated data collection through digital platforms. Attracted by new avenues of digital technologies offering the researchers for collecting data in real-time especially during public health emergencies, IRBs need thorough scrutiny of proposals for data sharing ethics [27-29].

Meanwhile, we should draw attention towards ethical approval through the rapid but quality ethics review process while trying to meet the urgency. Factors associated with turnaround time require monitoring for improvement and to avoid unnecessary delays. It is imperative to prepare the members of IRB concerning rapid review procedures during PHE [2,3,5].

The nature of the ICF and alterations

The ICF is an icon to promoting transparency and trust in research that also denotes informed decisions for voluntary participation free from external influences according to the Helsinki Declaration [23]. In this study due to the high volume of minimal risk proposals in period 2, there were complete waivers as well as partial waivers. The IRB to waive the ICF either totally or partly is depending upon the study population and data collection methods and is also supported by Karbwang J, et al. 2018 in their multi-country study launched by Forum for Ethics Review Committees in Asian and the Western Pacific (FERCAP) Regions [30]. Besides, a request for the waiver of the documentation of informed consent was not uncommon especially in research using the online data collection through the Facebook media which was conformed to other studies [28,29].

In this study, over half of the alterations suggested for ICF required to comprehend on procedural changes by the revised proposals. In so doing, the investigators could facilitate the research participants for an improved understanding of the purpose, benefits, and potential risks during the public health emergency thereby making reasonable judgments for their autonomous decisions [31,32].

Strengths and limitations

This is the first study reported from one of the IRBs in Myanmar concerning its metrics at the time of pandemic in a resource-constrained setting. It raises issues that are not fully addressed in the adjustment of the review system during the public health emergency period by observing bioethics principles, international guidelines, and the SOP. This study has followed the STROBE guidelines for reporting observational studies [33]. The empirical research brings out evidence which could support the improvement in IRB operating mechanism during the public health emergency also generalizable to other IRBs in the similar settings. However, due to time constraint and other restrictions, this study could not include the viewpoints of other IRBs/RECs in Myanmar to handle with their ethics reviews during this difficult time and their perceptions and opinions towards the virtual review meetings. In addition, researchers' perspectives on the online review system could not be explored.

Conclusions

The intensification of IRB reviews in resource-constrained settings is mandatory to meet the urgency of research in real-time and to safeguard the safety and welfare of human research participants as well as the researchers amid COVID-19 pandemic. It is critical to upholding the IRB metrics for the sustenance of satisfactory practices within the pandemic restrictions. Functional adjustments for the online reviews during the pandemic period at IRBs in resource-constrained settings require extensive evaluation for feasibility.

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References

1. Sisk BA, DuBois J (2020) Research Ethics during a Pandemic: A Call for Normative and Empirical Analysis. Am J Bioeth 20: 82-84.
2. Aarons D (2019) Addressing the challenge for expedient ethical review of research in disasters and disease outbreaks. Bioethics 33: 343-346.
3. Singh JA, Bandewar SV, Bukusi EA (2020) The impact of the COVID-19 pandemic response on other health research. Bull World Health Organ 98: 625-631.
4. Training in Tropical Diseases (TDR) (2016) New guidance on managing ethical issues in infectious disease outbreaks. TDR news item, World Health Organization, Geneva.
5. Health Ethics & Governance (2020) Guidance for research ethics committees for rapid review of research during public health emergencies. World Health Organization, 1-5.
6. Sigfrid L, Maskell K, Bannister PG, Ismail SA, Collinson S, et al. (2020) Addressing challenges for clinical research responses to emerging epidemics and pandemics: a scoping review. BMC Med 18: 190.
7. Ma X, Wang Y, Gao T, He Q, He Y, et al. (2020) Challenges and strategies to research ethics in conducting COVID-19 research. J Evid Based Med 13: 173-177.

8. Forum for Ethical Review Committees in Asia and the Western Pacific (2020) FERCAP statement during the COVID-19 pandemic. WHO-TDR Clinical Coordination and Training Center (CCTC), Thailand.

9. Arunachalam MA, Halwai A, Arunachalam C (2020) National guidelines for ethics committees reviewing biomedical & health research during COVID-19 Pandemic: An analysis. Indian J Med Ethics 1-6.

10. Kumar NK, Muthuswamy V (2020) Fostering ethical biomedical and health research in India during the COVID-19 pandemic. Research Ethics 16: 1-10.

11. DMR (2020) The standard operating procedure for rapid review. Institutional Review Board, Department of Medical Research.

12. Aung HM, Wai KT, Oo YTN, Thu HM, Htun ZT, et al. (2020) Strengthening quality research ethics review in a developing country. Global Bioethics Enquiry.

13. CIOMS (2016) International ethical guidelines for health-related research involving humans. Fourth Edition. Geneva. Council for International Organizations of Medical Sciences (CIOMS), Geneva, Switzerland.

14. Nijhawan LP, Janodia MD, Muddukrishna BS, Bhat KM, Bairy KL, et al. (2013) Informed consent: issues and challenges. J Adv Pharm Technol Res 4: 134-140.

15. Zhang H, Shao F, Gu J, Li L, Wang Y (2020) Ethics committee reviews of applications for research studies at 1 hospital in China during the 2019 novel coronavirus epidemic. JAMA 323: 1844-1846.

16. Adams P, Kaewkungwal J, Limphattharacharoen C, Prakobtham S, Pengsaa K, et al. (2014) Is your ethics committee efficient? Using "IRB Metrics" as a self-assessment tool for continuous improvement at the faculty of Tropical Medicine, Mahidol University, Thailand. PLoS One 9: e113356.

17. Coleman CH, Bouësseau M (2008) How do we know that research ethics committees are really working? The neglected role of outcomes assessment in research ethics review. BMC Med Ethics 9: 6.

18. Bain LE, Ngwain CG, Nwobegahay J, Sumboh JG, Nditanchou R, et al. (2018) Research Ethics Committees (RECs) and epidemic response in low and middle income countries. Pan Afr Med J 31: 209.

19. Millum J, Beecroft B, Hardcastle TC, Hirshon JM, Hyder AA, et al. (2019) Emergency care research ethics in low-income and middle-income countries. BMJ Glob Health 4: e001260.

20. Tan Z, Wu S, Han X (2020) Ethics discussion on responding to public health emergencies. Health Econ Res.

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

22. Department of Health, Education, and Welfare, National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (2014) The Belmont Report. Ethical principles and guidelines for the protection of human subjects of research. J Am Coll Dent 81: 4-13.

23. The World Medical Association (2018) WMA Declaration of Helsinki-Ethical Principles Medical research involving Human Subjects.

24. Bhatt A (2017) International Council for Harmonisation E6(R2) addendum: Challenges of implementation. Perspect Clin Res 8: 162-166.

25. Saxena A, Horby P, Amuasi J, Aagaard N, Köhler J, et al. (2019) Ethics preparedness: facilitating ethics review during outbreaks-recommendations from an expert panel. BMC Med Ethics 20: 29.

26. Alirol E, Kuesel AC, Guraiib MM, Fuente-Núñez V, Saxena A, et al. (2017) Ethics review of studies during public health emergencies - the experience of the WHO ethics review committee during the Ebola virus disease epidemic. BMC Med Ethics 18: 43.

27. Nuffield Council on Bioethics (2020) Research in global health emergencies: call for evidence analysis.

28. Braun R, Blok V, Loeber A, Wunderle U (2020) COVID-19 and the onlineification of research: kick-starting a dialogue on Responsible online Research and Innovation (RoRI). J Responsible Innov 7: 680-688.

29. Riso B, Tupasela A, Vears DF, Felzmann H, Cockbain J, et al. (2017) Ethical sharing of health data in online platforms - which values should be considered? Life Sci Soc Policy 13: 12.

30. Karbwang J, Koonrungsesomboon N, Torres CE, Jimenez EB, Kaur G, et al. (2018) What information and the extent of information research participants need in informed consent forms: a multi-country survey. BMC Med Ethics 19: 79.

31. Blackwood RA, Maio RF, Mrdjenovich AJ, VandenBosch TM, Gordon PS, et al. (2015) Analysis of the Nature of IRB Contingencies Required for Informed Consent Document Approval, Account Res 22: 237-245.

32. Klitzman RL (2013) How IRBs view and make decisions about consent forms. J Empir Res Hum Res Ethics 8: 8-19.

33. Elm EV, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, et al. (2007) The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: Guidelines for reporting observational studies. Int J Surg 12: 1495-1499.