International Journal of Current Research in Multidisciplinary (IJCRM) *ISSN: 2456-0979*
Vol. 8, No. 9, (December'23), pp. 01-06

NAVIGATING PANDEMIC-INDUCED DELAYS IN EXEMPTED AND EXPEDITED APPROVALS BY THE INSTITUTIONAL RESEARCH ETHICS COMMITTEE: AN INSIGHT FROM THE EMERGING RESEARCH COMMITTEE

Najmiatul Fitria[1,2*], Elsa Badriyya[1,2], Almahdy A[1,2]
[1]*Ethical Research Commission, Faculty of Pharmacy, Andalas University, Padang, Indonesia*
[2]*Department of Pharmacology and Clinical Pharmacy, Faculty of Pharmacy, Andalas University, PadangIndonesia*

ABSTRACT: *Background: In the wake of the historic challenges posed by the COVID-19 pandemic, research endeavors worldwide have encountered substantial hurdles in obtaining timely approvals from Institutional Research Ethics Committees (IRECs). Problems arise when a pandemic occurs where all activities are restricted. One thing that is very crucial here is the waiting time to obtain research ethics approval. This study aims to determine the lag time of filing ethical approval and what are the related factors. Method: an observational study was conducted by accessing all the protocol databases submitted to the Institutional Research Ethics Committee IREC, starting from its establishment consecutively. Results: Of the 41 incoming protocols, only 40 could be reviewed, with the results of 37 protocols exempted (92.5%) and three protocols expedited (7.5%) with the required time as 26.05±14.53 and 24.67±5.13, respectively. There was no difference in the total days for ethical approval for both the exempted and expedited categories (p-value>0.05). Conclusion: The results provided show that lag time occurs in exempt reviews, even though this is the easiest review. There is still room for improvement in these gaps needs to be perfected, from conducting ethics socialization and training for applicants.*

KEYWORDS:*lag time, exempted, expedited, ethics approval, IREC*

INTRODUCTION

The pandemic that was followed by a lockdown situation afterward was something that had never happened suddenly in the past few years. Neither individuals nor institutions are ready to handle situations like this and must make some adjustments. The Institutional Research Ethics Committee (IREC) has also been affected and is still adjusting and dealing with challenges that arose during the pandemic (1,2). The IREC itself is a committee that reviews the methods and ethics of research projects involving human participants. They are also known as institutional review boards (IRBs) or research ethics boards (REBs). They aim to protect the safety and welfare of the research participants and ensure that the research meets the standards and regulations (3,4). Of course, this condition brings up a challenge for IREC to make a decision to approve a health research protocol (2,5–8).

Bavdekar et al. previously recorded the challenges faced by IREC, which were divided into two troupes. They relate to the working area and the Standard Operating Procedures (SOP) (1). These two things are closely related. The challenges faced by IREC during the pandemic resulted in lag time approval for submitting a research protocol (1,9,10). The challenges related to the working area including circumstances of permission and scheduling the virtual meeting. While the use of instruments and technology could affect the SOP, including WiFi or ethernet connection (1,10,11). Lag time is the delay between submitting a research proposal and its approval by the ethical review boardIt can affect the quality and timeliness of the research outcomes. There are different types of review processes, such as exempted, expedited, or full review board, depending on the level of risk and complexity of the research (12). Exempted and expedited reviews are faster than full reviews, but they still require careful evaluation of the ethical aspects of the research (13).

As an illustration, currently, there are more than ten ethics commissions in West Sumatra province registered with the central Health Research Ethics Committee. These ethics committees are based at the hospital as well as in academia. The Institutional Research Ethics Committee of the Faculty of Pharmacy, Universitas Andalas, is one of them. This ethics committee was established and has been officially operating since August 2022. Even though it has just been established, this ethics committee has qualified reviewers and experts in various research fields, especially those related to humans and other living individuals. Regulations regarding ethics commissions in Indonesia are contained in PMK No.7 year of 2016 (14,15) All ethical review activities are guided by the research ethics guidelines issued by the Council for International

Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO) (16).

During the pandemic, a risk-free research protocol takes 21 days to obtain ethical approval from the time it was first submitted. Especially since the outbreak in early 2020, many things have been made easier. Management of ethical protocols can also be done online. Nevertheless, the current challenge is still. There is a lag time in obtaining ethical approval. This situation affects the starting point and duration of research implementation. Therefore, this study is aimed at observing the lag time of the research protocol submission and looking at the factors that influence it.

METHOD

Materials

An observational study was carried out by accessing the protocol database submitted to IREC starting from its establishment. The data will be tabulated to see the course of the ethical protocol. Progress of ethical approval starts from the submission process by the applicant, the review process by the reviewer, and the process of signing the ethical review approval letter by the IREC chairman and the head of the institution. The flow process is provided in Figure 1.

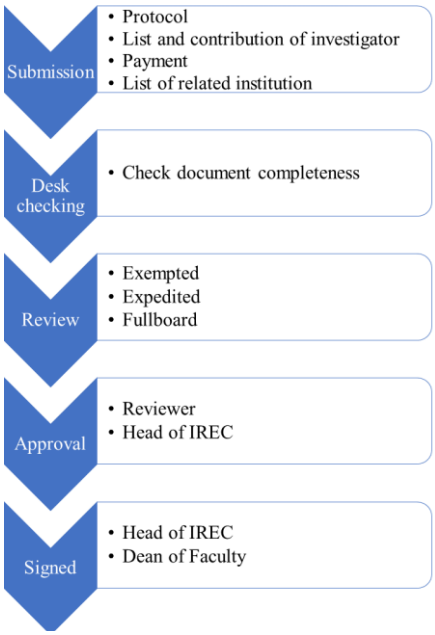

Figure 1. Flow diagram of ethical approval steps

Data analyse

Trend data for each month of one year is presented in graphical form. All the ethical approval process steps will be presented descriptively by giving the average value (min-max) and standard deviation. To determine the difference between variables on the number of days for ethical approval, it was analyzed using a paired t-test.

RESULTS

The total research protocols that were submitted from the start of establishment until July 2023 were 41 protocols with an average of 3.42 documents per month. However, not every month there is a new protocol proposal. The number of protocols submitted during the research period can be seen in Figure 2.

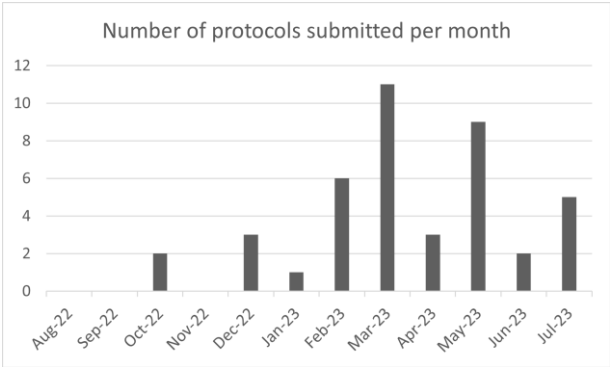

Figure 2. The number of protocols submitted per month from August 2022 to July 2023

All applications for August have not yet been completed, so they are limited to the end of July 2023. Meanwhile, the length of the application process until the issuance of research approval by IREC can be seen in Table 1.

Table 1. The days required for ethical approval

Approval decisions		N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Min	Max	*p*-value
						Lower Bound	Upper Bound			
Total (days)	Exempted	37	26.05	14.537	2.390	21.21	30.90	1	83	0.503
	Expedited	3	24.67	5.132	2.963	11.92	37.41	19	29	
	Total	40	25.95	14.020	2.217	21.47	30.43	1	83	
Lag time (days)	Exempted	37	3.62	9.160	1.506	0.57	6.68	0	53	0.872
	Expedited	3	0.00	0.000	0.000	0.00	0.00	0	0	
	Total	40	3.35	8.854	1.400	0.52	6.18	0	53	

There is a difference between the number of protocols submitted (41) and the protocols approved (40) (*p*-value >0.05). This article cannot be reviewed because when IREC requested a protocol revision, the applicant did not provide the requested fix, so the protocol could not be reviewed and became lost to follow.

From Table 1, it can be seen that the ethical review decisions were mostly “exempted” (37 protocols), even though there were also many cases of lag in the “exempted” group. On the other hand, in the "expedited" decision, there is no lag time at all. There is no difference between the number of days needed to review the protocol based on the ethical review decision, either in total days or in delayed cases.

Meanwhile, the details of the days required for each process show that the ethical approval process does not take long during the review process. There is a time lag waiting for the approval signature from the IREC chairman and the faculty dean. The length of days per process can be seen in Table 2.

Table 2. The mean value of days (mean±SD) per process that was passed by the research protocol

Category	**Desk checking**	**Review**	**Signed**	**Total**
Exempted	3.73±1.48	4.76±4.27	9.54±6.31	26.05±14.53
Expedited	3.00±0.00	2.00±1.73	12.67±0.57	24.67±5.13
p-value	0.634	0.278	0.402	0.872

Meanwhile, when viewed from the details of the days required for each process, it turns out that the ethical approval process does not completely take a long time during the review process. There is a time lag waiting for the approval signature from the IREC chairman and the Faculty Dean. The length of days per process can be seen in Table 2. Both in the exempted and expedited categories, the number of days needed to wait for the signing of documents is quite long, around 9.54 ± 6.31 and 12.67 ± 0.57, respectively, for exempted and expedited.

DISCUSSION

Since the pandemic occurred, many things have happened, especially regarding offline meeting policies. Before the pandemic, ethical review decisions were only carried out once a month through a full board meeting. When a pandemic occurred, all meeting activities were restricted so that new regulations were made where only certain very complex cases would be forwarded to the reviewers at the full board meeting.

There has never been a full board meeting for IREC at the Faculty of Pharmacy Universitas Andalas since the outbreak occurred. Even so, cases of exempted protocols require a long time for ethical review if compared to expedited protocols. This was caused by the unresponsive reviewer when the admin from IREC requested an ethical The admin can only detect it when the 21-day review limit has ended. As a result, the IREC admin had to withdraw the protocol from the unresponsive reviewer and transfer it to another reviewer. If this incident occurs only once during an ethical review application, perhaps the time required will not be long, but if this incident of unresponsive reviewers occurs repeatedly, of course, it will be detrimental to the applicant. The occurrence of this lag time can be avoided if the protocol application is aware of the waiting time. Applicants can contact the admin by telephone or e-mail. Proactivity from the application is also very necessary in managing this ethical review.

The ethical review period for the exempted category does not require a long time because it does not involve human subjects or require informed consent (12). However, each agency has its own regulations for this exempted review category (17–19). One example is at the University of Pittsburgh, USA. Different classes of minimal-risk research are exempt from the Federal Policy for the Protection of Human Research Subjects. This does not mean that they are exempt from IRB review (20). The IREC of the Faculty of Pharmacy Universitas Andalas has a slightly different regulation than the Institutional Review Board (IRB) at the Faculty of Medicine Universitas Gajah Mada(21). The IREC of the Faculty of Pharmacy, Andalas University, still provides this exempted category protocol to ethical reviewers.

An interesting thing happened to the expedited category. Even though it is related to human subjects, the risk is very minimal. Everything can be approved in the available time in this expedited category protocol. There is no lag time at all. Most applicants/researchers understand that this expedited category protocol must have informed consent despite the very small risk (22).

The IREC of the Faculty of Pharmacy has never passed ethical approval for a full-board case. There is a difference between the number of incoming and outgoing protocols because one protocol requires a full meeting. The reviewer has submitted it back to the admin because there were irregularities at the stages of the researcher's work procedure. Besides that, the researcher does not have a Good Clinical Practice (GCP)/ Good Clinical Practice (GLP) certificate to start research on human subjects. The applicant had been summoned but could not provide the requested documents, so he did not appear again when IREC made the decision to full board review. The proposed protocol has a study design in the form of a placebo control trial, requiring the principal investigator to have a GCP certificate(15). In this case, the IREC decided to close the submission of an ethical protocol with a "lost to follow" status.

In fact, the IREC of the Faculty of Pharmacy, Universitas Andalas has gradually conducted training on submitting research ethics; they are Basic Ethics and Advanced Ethics training. Institutions cannot carry out GCP/GLP training itself due to cost constraints. Because the target of this training is students and all faculty academic members, the faculty strongly supports the funding source. Even so, applicants can get training by paying fees from their own pocket. The decision maker can still fund only basic ethics and advanced ethics training.

Apart from that, another challenge from IREC itself is that it cannot accept ethical protocol submissions from its own members. This is done to avoid conflicts of interest by avoiding the assumption of privilege when submissions are made to the agency itself. Several published articles written by IREC members have ethical approval obtained from other IRBs (23–26). However, the IREC members, except the chairperson, are still permitted to apply for ethical approval at their own institution.

Strength and limitation

This study presents the data as it is. This data can be used for self-introspection on how to make IREC more resilient in the future. This is the strength of this paper. However, because IREC is still newly established, many gaps need to be perfected, from conducting ethics socialization and training for applicants to increasing the number and quality of reviewers so that there is no longer any lag time in applying for ethical approval.

CONCLUSION

From the result provided, it can be seen that lag time occurs in exempt reviews, even though this is the easiest review. There is still room for improvement in this exempted case. It is hoped that adjusting the number of qualified reviewers in the ethical review process can improve IREC's services.

Ethical approval

The ethical approval was obtained from the Institutional Research Ethics Committee Faculty of Pharmacy Universitas Andalas No 43/UN.16.10.D/KEPK-FF/2023

Acknowledgment

All authors would like to thank the IREC of the Faculty of Pharmacy for supporting the data for the writing of this article.

Funding

No funding for this research also for writing the manuscript.

Author contribution

NF designed the study. EB and AA tabulated the data. NF and EB contribute equally to approving the final version of the manuscript.

REFERENCES:

*[1] Bavdekar S B 2020 Ethics committees: Actions during pandemic and lockdown situations. J Postgrad Med**66** 119–22*

*[2] Saxena A, Horby P, Amuasi J, Aagaard N, Köhler J, Gooshki E S, Denis E, Reis A A and Ravinetto R 2019 Ethics preparedness: facilitating ethics review during outbreaks - recommendations from an expert panel. BMC Med Ethics**20** 29*

*[3] Hart R and Belotto M 2010 The institutional review board. Semin Nucl Med**40** 385–92*

[4] Hunter D J 2003 Evidence-based management: a practical guide for health professionals vol 3

*[5] Sharp R R, Taylor H A, Brinich M A, Boyle M M, Cho M, Coors M, Danis M, Havard M, Magnus D and Wilfond B 2015 Research ethics consultation: ethical and professional practice challenges and recommendations. Acad Med**90** 615–20*

*[6] Piasecki J, Waligora M and Dranseika V 2017 What Do Ethical Guidelines for Epidemiology Say About an Ethics Review? A Qualitative Systematic Review. Sci Eng Ethics**23** 743–68*

*[7] Millum J and Menikoff J 2010 Streamlining ethical review. Ann Intern Med**153** 655–7*

*[8] Page S A and Nyeboer J 2017 Improving the process of research ethics review Res Integr Peer Rev**2** 14*

*[9] Saxena A, Horby P, Amuasi J, Aagaard N, Köhler J, Gooshki E S, Denis E, Reis A A and Ravinetto R 2019 Ethics preparedness: facilitating ethics review during outbreaks - recommendations from an expert panel. BMC Med Ethics**20** 29*

*[10] Packenham J P, Rosselli R, Fothergill A, Slutsman J, Ramsey S, Hall J E and Miller A 2021 Institutional Review Board Preparedness for Disaster Research: a Practical Approach. Curr Environ Health Rep**8** 127–37*

*[11] Appel J M and Wilets I 2023 Research Ethics during Pandemics: How IRBs Can Prepare. Ethics Hum Res**45** 26–34*

*[12] Appel J M and Wilets I 2023 Research Ethics during Pandemics: How IRBs Can Prepare. Ethics Hum Res**45** 26–34*

*[13] Page S A and Nyeboer J 2017 Improving the process of research ethics review Res Integr Peer Rev**2** 14*

[14] Ministry of Health Republic of Indonesia 2016 KomisiEtikPenelitian dan Pengembangan Kesehatan Nasional

[15] KomiteEtikPenelitian dan Pengembangan Kesehatan Nasional Kemeterian Kesehatan Republik Indonesia 2021 PedomanStandarEtikPenelitian dan Pengembangankesehatan Nasional (Jakarta: Lembaga Penerbit Badan Penelitian dan Pengembangan Kesehatan (LPB))

[16] World Health Organization (WHO) 2016 International Ethical Guidelines for Health-related Research involving Humans (Geneva, Switzerland)

*[17] Linden J A, Schneider J I, Cotter A, Drexel S, Frosch E, Martin N D, Canavan C, Holtman M, Mitchell P M and Feldman J A 2019 Variability in Institutional Board Review for a Multisite Assessment of Resident Professionalism. J Empir Res Hum Res Ethics**14** 117–25*

*[18] Kateb L, El-Jayousi S and Al-Hussaini M 2022 An Overview of King Hussein Cancer Center Institutional Review Board Over 12 Years (2009-2020), Successes and Challenges, Including Those Imposed by the COVID-19 Pandemic. J Empir Res Hum Res Ethics**17** 94–101*

*[19] Polito C C, Cribbs S K, Martin G S, O'Keeffe T, Herr D, Rice T W and Sevransky J E 2014 Navigating the institutional review board approval process in a multicenter observational critical care study. Crit Care Med**42** 1105–9*

[20] Human Research Protection Office (HRPO) 2018 Exempt review

[21] Faculty of Medicine Universitas Gajah Mada 2016 Bagan AlirPermohonan Surat KeteranganKelaikanEtik(Ethical Approval) pada KomisiEtikPenelitianKedokteran dan Kesehatan 1–2

[22] Human Research Protection Office (HRPO) 2018 Exempt, Expedited and Full Board Review

*[23] Fitria N, Wulansari S and Sari Y O 2023 Potential Interactions Analysis of Antihypertensive Drugs Used in Geriatric International Journal of Applied Pharmaceutics**15** 29–33*

*[24] Juwita D A, Qalbi Y A and Fitria N 2023 the Relationship Between the Time of Use of Antiretroviral Therapy (Art) and the Amount of Viral Load in Acquired Immunodeficiency Syndrome International Journal of Applied Pharmaceutics**15** 24–8*

[25] Fitria N, Sari Y O, Ananta F T and Husnia K 2023 Adherence Assessment on Hypertension Therapy Using The Pill Count Method in Lubuk Kilangan Health Center , Indonesia | Apr N 69–75

*[26] Fitria N, Idrus L, Putri A R and Sari Y O 2023 The usability testing of the integrated electronic healthcare services for diabetes mellitus patients during the pandemic in Indonesia. Digit Health**9** 20552076231173228*