

REFORMING PROCEDURES FOR ASSESSING RESEARCH PROTOCOLS DURING COVID-19 PANDEMIC

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Abstract: Covid-19 pandemic has caused dramatic changes in daily activities. In particular, human interactions were limited, and most daily duties were directed into an online environment. This study aimed to describe the characteristics of research protocols submitted to the Research Ethics Committee (REC), Faculty of Medicine, Universitas Sebelas Maret (UNS), and evaluate the effectiveness of ethical review procedures implemented during the pandemic era. The following data were retrieved: protocol identity, researcher's institution, researcher's educational background, type of study, the date of protocol submission, and the date when the ethical clearance (EC) certificate was issued. Two hundred seventeen research protocols were submitted to the REC from 1 January 2021 until 30 June 2022. Most researchers were university students, lecturers, physicians, and service providers. Observational studies were more prevalent than interventional studies. The ethical reviews were usually completed within 2-3 weeks unless a few protocols required major revisions. Most applicants and reviewers were satisfied with the process of online review. The REC secretariat played a crucial role in keeping everyone working on schedule. In conclusion, restricting direct human interactions during the COVID-19 pandemic does not affect the ethical review process. With familiar tools, online review becomes more effective than face-to-face meetings.

Keywords: Ethical review, ethics committee, research ethics, ethics protocol, Covid-19 pandemic.

INTRODUCTION

In late 2019, Covid-19 was first detected in China and then spread globally. In Indonesia, the index case was first identified in March 2020. Following this, the pandemic waves continued to hit the country with two significant peaks in

mid-2021 and early 2022 due to the Delta and the Omicron variants, respectively. As of the time this article was written (July 2022), the COVID-19 pandemic is still ongoing, and new variants emerge due to the virus' constant mutation. The existence of highly transmissible variants

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can pose a great challenge to COVID-19 preventive measures, including vaccination (Burhan & Rachmadi, 2022).

Although the pandemic lasted more than two years and the vaccines have been massively distributed, it is unclear when it will end. A Bayesian wave model forecast predicts that the Jakarta pandemic will reach its final peak in early 2023, and hopefully, there will be zero new COVID-19 infections by mid-2023 (Chandra & Abdullah, 2022). In the meantime, people must adapt to new working environments by maintaining health protocols and preparing for flexibility to work offline or online.

The vaccination program in Indonesia was initiated in April 2021, when it was first targeted at healthcare workers, public officials, and the elderly, followed by targeting the general community (Nugraha et al., 2021). By the end of 2021, 40.37% of people in Indonesia had received a total dose of the Covid-19 vaccine (Chu et al., 2022). Starting on 12 January 2022, the Indonesian government distributed the third dose of the vaccine (booster). In July 2022, the government implemented a policy that booster vaccines are required for foreign travelers to enter Indonesian territory.

In an online press statement in Jakarta on 1 July 2022, the Coordinator of the Expert Team and Government Spokesperson for Handling COVID-19, Wiku Adisasmito, explained that the national booster vaccination coverage has only reached 24% (Liputan 6, 2022). Meanwhile, school and office activities have occurred like the pre-pandemic era, even though 28-34 provinces have less than 30% vaccination coverage.

With the threat of a pandemic amid a "new normal" working and learning situation, adjustments are needed to optimize performance and minimize the impact of the pandemic. During the Covid-19 pandemic era, Indonesia itself enforces a work-from-home (WFH) policy based on the level of "Implementation of Restrictions on Social Activities = Pemberlakuan Pembatasan Kegiatan Masyarakat (PPKM)" in a corresponding region. The PPKM policy consists of 4 levels, corresponding to the maximum capacity allowed in critical and non-essential sectors based on the daily new COVID-19 cases in that area. For example, PPKM level 1 entails that all sectors can operate at a maximum capacity of 75-100%, while level 4 indicates that the capacity must be reduced to 25-50%, all the

students learn from home, and the workers are mostly WFH because the offices are closed except critical sectors.

When this article was written (mid-July 2022), there were more than 2,000 new COVID-19 cases daily in Indonesia, showing the resurgence of the outbreak since April (Bloomberg, 2022). Thus, the implementation of PPKM may be tightened, and as a consequence, human interactions may be restricted as the number of new cases rises.

The Research Ethics Committee (REC) of the Faculty of Medicine, Universitas Sebelas Maret (UNS), was established at the end of 2017. The ethical review process was done offline at the beginning of its establishment. The applicant submits the research protocol and supporting documents to the REC office. The reviewers conduct studies through regular REC meetings every month. In the meeting, the REC team may invite applicants and their research supervisors to clarify or obtain further information, and the REC team can seek advice from independent consultants.

Starting from January 2019, the process of ethical review at the REC of the Faculty of Medicine UNS was conducted online using the SIM-EPK application (Kemkes RI, 2022). When the

COVID-19 pandemic broke out in Surakarta, the members of REC, who were mostly clinicians, were busy handling the outbreak's impact; therefore, some members did not have time to monitor the SIM-EPK application. For this reason, since January 1, 2021, the ethical review has been conducted online by utilizing tools commonly used in the daily life of the REC team, such as email, WhatsApp, and Zoom. This study aimed to describe the ethical protocols submitted to the REC of the Faculty of Medicine UNS and assess the effectiveness of online ethical reviews during the pandemic.

METHOD

This study analyzed research protocols submitted for ethical review at the REC of the Faculty of Medicine UNS from 1 January 2021 until 30 June 2022. The data collected were the protocol identity number, research title, type of research, applicant's origin, date of application for ethical review, and the issue date of approval certificate.

RESULT AND DISCUSSION

This study reviewed two hundred seventeen research protocols; i.e., 129 protocols were received in 2021, and 88

protocols were received until the first half of 2022. By the end of 2022, the REC is expected to receive more protocols than in 2021 as the research activities are starting to become active again in line with the campus re-opening.

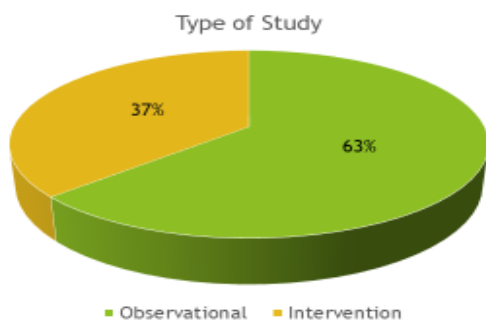


Figure 1. The characteristics of the research protocols submitted to the REC of the Faculty of Medicine UNS.

Figure 1 shows the characteristics of the research protocols submitted to the REC of the Faculty of Medicine UNS during the study period. Most (63%) protocols were observational studies, followed by intervention studies, including clinical trials. Observational studies do not need control groups, so the researcher requires fewer participants, which is more convenient than interventional studies (Sugiyono, 2018).

Based on the origin of the applicants, 215 (99%) were from educational institutions, and the majority (n=198; 91%) were from UNS (Figure 2). Based on the researcher's status, the

applicants for ethics review were dominated by students, and most of them were postgraduate students, i.e., 99 (46%) protocols. Other applicants include lecturers (n=59; 27%), bachelor students (n=43; 20%), vocational students (n=11; 5%), and service providers (n=5; 2%).

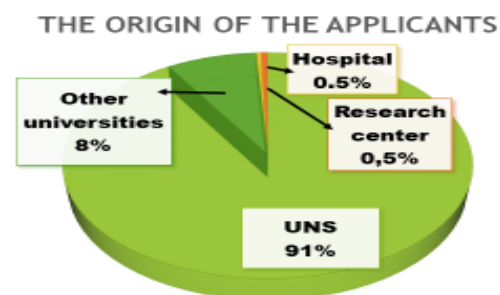


Figure 2. The origin of the applicants submitting research protocol to the REC of the Faculty of Medicine UNS.

To our knowledge, there are at least six RECs in Surakarta. Our data showed that the REC of the Faculty of Medicine UNS is well-known and highly accessible to UNS students and lecturers. Hence, it is understandable that most protocols were observational studies as the applicants' access to clinical trials is more limited than that in the hospital REC. Moreover, the service at REC of the Faculty of Medicine UNS is highly appreciated by internal academics. Our previous study indicates that 73% of respondents are satisfied or very satisfied, and 27% of respondents felt satisfied

enough. None of the respondents are dissatisfied with our service (Cahyanto et al., 2022). This high level of satisfaction could be the main contributing factor to REC preference among researchers.

Figure 3 shows the ethical review process during the study period. Initially, the applicant submits the research protocol and supplementary documents to the official REC email. Following this, the REC secretariat categorizes the protocols into three categories: i.e. exempted, expedited, or entire board.

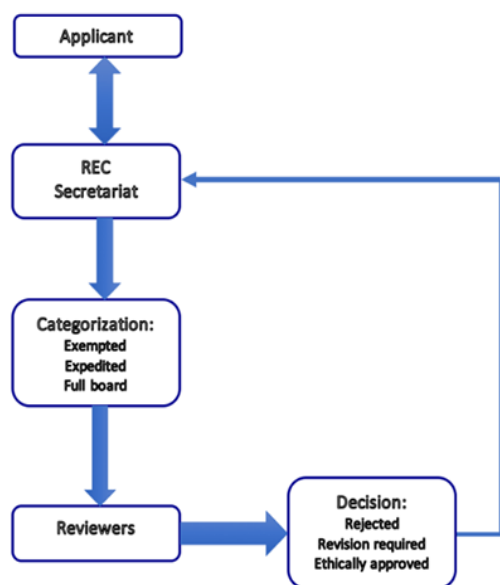


Figure 3. The workflow of ethical review at the Research Ethics Committee (REC) of the Faculty of Medicine, Universitas Sebelas Maret (UNS) in 2021-2022

Alternatively, the ethical approval certificate can be issued immediately for

protocols in the "exempted" category. Research that aims to observe community behavior, anonymous surveys from invulnerable subjects, and research about educational practices are categorized as exempted (Byerly, 2009).

Three reviewers will review protocols in the "expedited" category via the Whatsapp application, and the review should be completed within a maximum of one week. Expedited review is performed on protocols that collect blood samples or body specimens without invasive procedures and protocol amendment involving minor changes (Millum & Menikoff, 2010).

Full-board reviews are conducted via Zoom meeting within three weeks of receiving the protocol. A protocol is submitted for a full-board review if the research subjects are prone to experience risk(s) of more than minimal and research involving vulnerable persons. Thus, such protocols need to be reviewed by more reviewers (Lapid et al., 2019).

The result of the review is then sent to the applicant. If a protocol needs revision, REC will issue the ethical approval certificate after reviewers approve the revision. When the applicants visited the REC office to obtain the printouts of the ethics approval

certificate, the REC secretariat had the opportunity to ask for their comments on the REC service. Most applicants gave positive comments and felt satisfied.

The present study's average time from protocol receipt to ethical approval certificate issuance is 18 days. Compared to the previous data, the ethical review process has improved from year to year, indicated by the shorter process duration (Susilawati et al., 2021).

Figure 4 shows the duration of ethical review from the last five years. The average duration of ethical review from 2018 to the first half of 2022 is 20 days, 55 days, 34 days, 19 days, and 16 days, respectively. This study shows that the online ethical review process using familiar tools such as email, WhatsApp, and Zoom takes a shorter time than the SIM-EPK application and is similar in duration to the offline ethical review method.

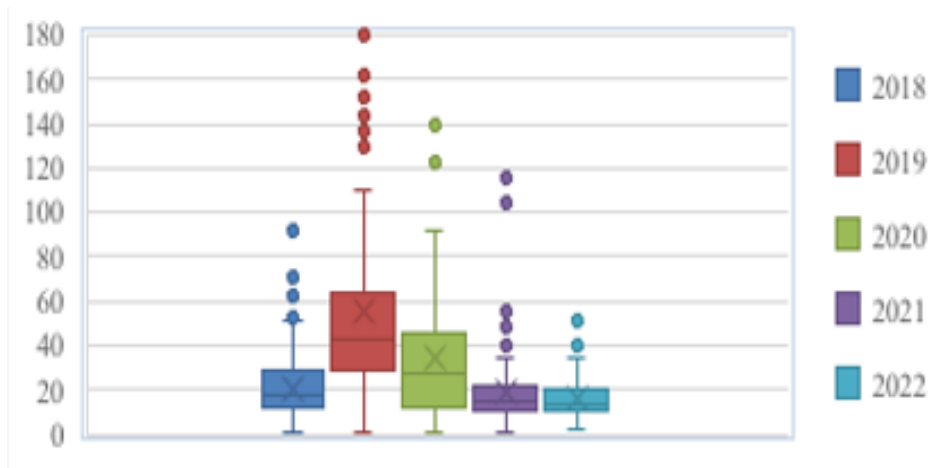


Figure 4. The duration of the ethical review (in days) at the Research Ethics Committee (REC) of the Faculty of Medicine, Universitas Sebelas Maret (UNS) from 1 January 2018 until 30 June 2022.

The online information system speeds up the ethical review process as the system facilitates reviewers to do the task anywhere and anytime, and the head of REC can monitor the progress. A study at the REC of the University of Houston reported that using information systems decreases the average review time from

52.27±33.23 days to 46.96±20 days, or a 15% decline (Liberale & Kovach, 2017). Similarly, the REC team at the Faculty of Medicine UNS was pleased with implementing familiar tools for facilitating ethics review, especially during the COVID-19 pandemic. Whatsapp, Zoom, and email are helpful

as the reviewers frequently use the applications in daily communication. In Pakistan, protocol reviews are performed via teleconference, and the meeting frequency is increased thrice weekly (Shekhani et al., 2021). The REC secretariat of the Faculty of Medicine UNS consists of two staff who are essential in accelerating the review process. This role is crucial to facilitate effective and efficient teamwork.

CONCLUSION

Ethical reviews require effective and efficient teamwork supported by a robust standard operating procedure. To speed up the process, applicants should have a good knowledge of research ethics and the role of REC. Regular socialization and training must be done to minimize the protracted ethical review process. The institution has made several efforts to optimize ethical review. Among

others, members of the REC of the Faculty of Medicine of UNS must attend ethics workshops and training on the management of research protocols. The REC also organizes ethics workshops and training in writing research protocols for internal and external researchers. The REC team is reformed every two years, and the performance of each reviewer is evaluated monthly. To improve the governance of REC, it is necessary to conduct further research, including examining problems that may arise during ethical review, both from the perspective of the applicants and the REC team.

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