The Understanding of Research Ethics Reviewers on Ethical Clearance Review Process: A Case Study

Arie Wardhono[1] and Yuni Lestari[2]

[1] Department of Civil Engineering, Faculty of Engineering, Universitas Negeri Surabaya, Surabaya, Indonesia
[2] Department of Public Administration, Faculty of Vocational, Universitas Negeri Surabaya, Surabaya, Indonesia
ariewardhono@unesa.ac.id

Abstract. In recent years, the requirement for ethical clearance of research has increased as a result of high demands for scientific publication in high-quality journals. However, these journals also require an ethical clearance to ensure that all research continues according to ethics principles and procedures. Therefore, knowledge of the review process of the research protocol, as well as an understanding of ethical research standards and guidelines, is very important for ethical research reviewers. This study aims to determine the level of understanding of research ethics reviewers on ethics protocol review process, and ethics research standards. This research is a quantitative descriptive study with two variables, which are the understanding of ethics research standards and the ethics review process. The subjects were university research ethics reviewers who already have a minimum of Basic Research at the Research Ethics Committee in Universitas Negeri Surabaya. The data was collected through survey questionnaires distributed via Google Forms. The result showed that although most of the reviewers demonstrated a good understanding of ethical standards and the ethical clearance process, the knowledge of most reviewers needs to be improved due to a lack of understanding of ethics principles, standards, and ethical clearance decision types. In addition, the EDL reviewers show a better understanding of ethical research standards and the ethical clearance process. This is due to the lack of opportunity for GCP reviewers to review research protocols that are still being provided to EDL reviewers.

Keywords: Research ethics reviewers, ethics standard, ethical clearance review process, understanding level.

1   Introduction

Along with the increasing demand for good quality publication in reputable science journals, the application for ethical clearance is also increasing, especially in research related to humans and other living things. This is attributed to the reputable journal's requirement for ethical clearance to ensure that all research continues according to ethical principles and procedures, as well as good clinical practice to keep the negative consequence to the research subject as small as possible. Therefore, to achieve this, knowledge of ethics standards is very important, not only for the researchers but also

for ethics research protocol reviewers who have the responsibility to provide an assessment of the appropriateness of an ethics research protocol.

The awareness of ethical issues and procedures is the responsibility of students, researchers, and scholars themselves in adhering to a research ethic. In addition, a good understanding of ethical procedures must also be possessed by an ethical reviewer to be able to make effective and appropriate decision-making in deciding an ethical eligibility [1]. In addition, an ethics reviewer has great responsibility for the process of reviewing a research protocol. A low understanding of ethics standards and review process knowledge significantly affects the decisions to be taken [2].

World Health Organization (WHO) has issued the standards and operational guidance for ethics review of health-related research with human participants [3]. This guidance elaborates the standards for the research ethics review system, especially for the responsibility for establishing the research ethics review system. Further, the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO) released the international ethical guidelines for health-related research involving humans. This guideline explains the requirements for the review of the research protocol [4]. In addition, one of the chapters in Ethics Standards and Guidelines of National Health Research and Development also explains the ethics standard and ethics review process or procedure to assess the eligibility of a research protocol [5].

Thus, this research tries to identify the understanding of Research Ethics Committee reviewers on the ethical clearance process which consists of the understanding of ethics research standards, as well as the ethics protocol review process to issue an ethical clearance decision.

2   Methods

This research is quantitative descriptive research with a sample of 29 respondents from Universitas Negeri Surabaya, Indonesia, with ages ranging from 21-60 years. All respondents are Research Ethics Committee reviewers of the Universitas Negeri Surabaya who already have a minimum of Basic Research Ethics (Etik Dasar Lanjut in Indonesia, EDL) certificate, with some of the reviewers also having advanced ethics certificate, i.e., Good Clinical Practice (GCP) certificate.

The instrument was developed to identify the understanding of Research Ethics Committee reviewers on the ethical clearance standard and process. It was categorized into two variables, i.e., the understanding of ethics research standards and the ethics protocol review process. The data was collected through survey questionnaires distributed via Google Forms.

3   Results and Discussion

The ethical research results are discussed in three sections. The first section deals with the demographic of respondents. The second section talks about the understanding of ethics research standards. The last section consists of the understanding of the ethics protocol review process.

3.1   Demographic of respondents

The profile of the respondents is 10 (34,5%) male and 19 (65,5%) female reviewers from Universitas Negeri Surabaya with the age distribution of 21-30 years old, 31-40 years old, 41-50 years old, and 51-60 years old are 1 (3,4%), 5 (17,2%), 12 (41,4%), and 11 (37,9%) respondents, respectively.
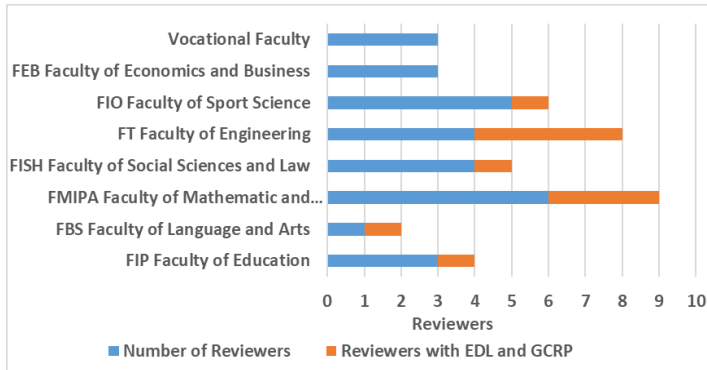

Fig. 1. Demographics of reviewers with certificate

Further, the educational background of reviewers is equally divided between master (48,3%) and doctoral (51,7%) educational background. In terms of an ethical clearance certificate, there are merely 11 reviewers (11,39%) holding EDL and Good Clinical (GCP) certificates, compared to reviewers who have had EDL certificates (18 reviewers or 62,1%) as shown in Figure 1.

3.2   The understanding of ethics research standards

The understanding of ethics research reviewers towards ethics research standards is divided into three discussions, i.e., the understanding of ethical research standards, ethics research process, and ethics principle, standard, and guidance (WHO CIOMS) as shown in Figure 2, Figure 3, and Figure 4, respectively. The ethics research reviewers are categorized into two groups which are EDL-certified reviewers and GCP-certified reviewers.

According to Figure 2, most of the reviewers had a moderate to high understanding of ethical research standards. Despite the GCP certificate being an advanced certificate from EDL, GCP-certified reviewers demonstrate a lower understanding of ethical research standards than EDL-certified reviewers. There were only 18% of GCP-certified reviewers had a high understanding of ethical research standards compared to 50% of EDL-certified reviewers. GCP-certified reviewers who have a sufficient understanding of ethical research standards account for only 27% of reviewers. In general, EDL-certified reviewers demonstrated a better understanding (94%) of ethical research standards than GCP-certified reviewers with only 73% of reviewers.
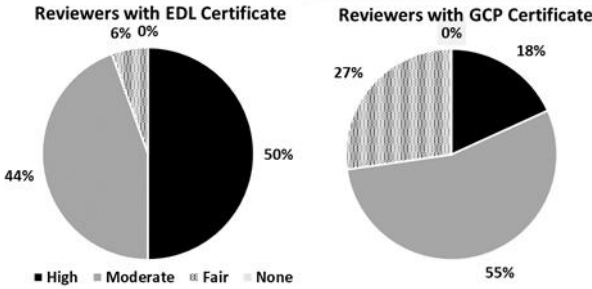
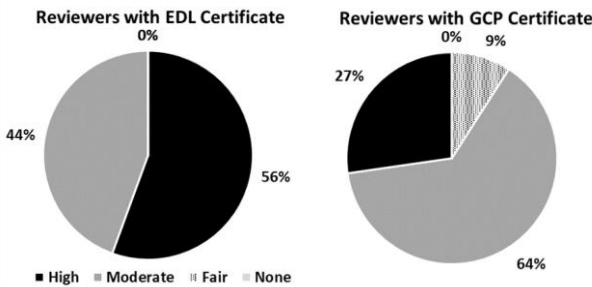**Fig. 2.** Understanding of Ethics research standards.

Fig. 3. Understanding of ethics review protocol flow.

In terms of understanding on flow process of the ethics review protocol, a similar finding was also found in Figure 3. EDL-certified reviewers demonstrated a better understanding (56%) of the ethics review protocol flow process than GCP-certified reviewers with merely 27% of reviewers. Compared to EDL-certified reviewers, most of the GCP-certified reviewers merely exhibited moderate understanding (64%) and there was still around 9% of reviewers who showed a lack of ethical review protocol flow knowledge. In general, EDL-certified reviewers had a better understanding of the ethics review protocol process with no reviewers having a below-average level of understanding.

Figure 4 illustrates that most of the reviewers, both EDL and GCP-certified reviewers, have a low understanding of ethics principles, standards, and guidance according to WHO CIOMS. Further, half of the reviewers indicated doubts about the level of understanding of ethics principles by 50% and 64% of EDL and GCP-certified reviewers, respectively. In addition, around 17% (of EDL) and 27% of (GCP-certified reviewers do not understand standard ethics. There are merely 33% of EDL-certified reviewers who understand ethics principles, standards, and guidance from WHO CIOMS. However, this is better than the understanding level of GCP-certified reviewers which is only 9% of the reviewers.
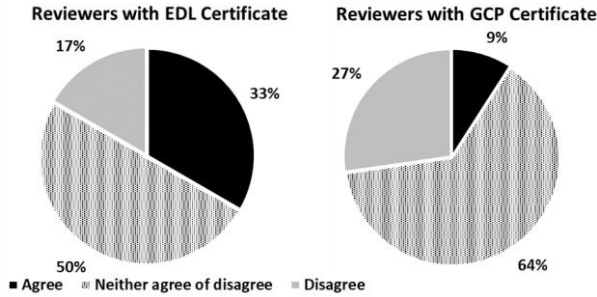
Reviewers with EDL Certificate

17%

33%

50%

Reviewers with GCP Certificate

9%

27%

64%

■ Agree ▨ Neither agree of disagree ▧ Disagree

Fig. 4. Understanding of ethics principle, standard, and guidance (WHO CIOMS).

These results corroborated the results in the previous discussion regarding the understanding of ethical research standards and the ethics protocol review process, which show that EDL-certified reviewers have a better understanding of ethical research standards. This might be because there are not many opportunities for GCP-certified reviewers to review research protocols which are still given to EDL-certified reviewers. After all, most of the research protocols are still focused on non-clinical corridors.

3.3   The understanding of the ethical clearance process

The understanding of the ethical clearance process of EDL and GCP-certified reviewers is discussed in three discussions which are the understanding of ethical clearance decision, non-presentation requirement decision, presentation requirement decision, ethical clearance process in reviewer decision as shown in Figure 5, Figure 6, Figure 7, and Figure 8, respectively.
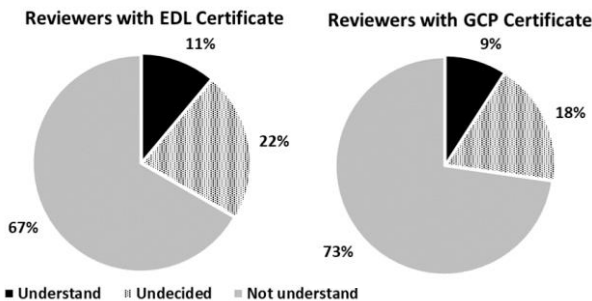
Reviewers with EDL Certificate

11%

22%

67%

Reviewers with GCP Certificate

9%

18%

73%

■ Understand ▨ Undecided ▧ Not understand

Fig. 5. Understanding of Ethical Clearance Decision.

Fig. 2 shows the understanding of all reviewers both with EDL and GCP certificates towards ethical clearance decisions. According to the Ethics Standards and Guidelines of National Health Research and Development from the Ministry of Health [5], there are four ethical clearance decisions, i.e., exempted, expedited, full board, and continuing. Each ethical clearance decision has a different procedure and is regulated by rules that all reviewers must comply with. According to Figure 2, there are only 11%

and 9% of EDL and GCP-certified reviewers familiar with the ethical clearance decision.

Most of the reviewers, both EDL and GCP-certified reviewers, are still confused between exempted and expedited decisions. Exempted is a decision that assesses a study as having no risk to the research subject so that an exemption is given from an ethical protocol review process. An expedited is a decision that assesses a research ethics protocol that has minimum risk and requires a protocol proposer to revise the research protocol [5]. This is shown in Figure 2, which illustrates the knowledge level of the research ethics reviewers regarding the ethical clearance decision, where around 89% of EDL-certified reviewers and 91% of GCP-certified reviewers expressed doubt or did not understand the ethical clearance decision type.
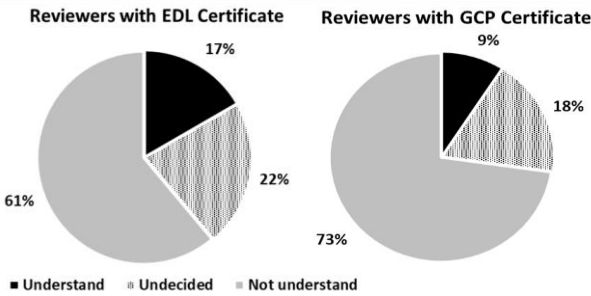

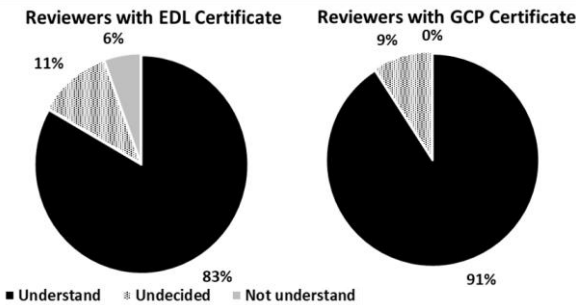**Fig. 6.** Understanding of expedited decision.

Fig. 7. Understanding of full board decision.

Figure 6 and Figure 7 show the understanding level of ethics research between expedited and full board decisions in ethical clearance. The fundamental difference between these two decisions is in the presentation process where the full board decision requires the proposer to make a presentation to the ethics reviewers' team to obtain clarification from the proposer regarding the matters that require to be confirmed. Meanwhile, the expedited decision does not oblige the proposer to make a presentation. It is enough for the proposer to revise the research protocol according to the suggestions and input from the reviewers and send back the revised protocol.

Figure 6 depicts the EDL and GCP-certified reviewers' doubts about exempted and expedited decisions. Most of the reviewers, both EDL and GCP-certified reviewers, indicated a lack of understanding of the expedited decision concept. This is different from the understanding of the full board decision in Figure 7. The doubts about the expedited decision are caused more by the similarity of the exempted and expedited decisions which depend on the justification of the ethics research reviewers regarding the level of risk involved, and the obligation to review the research protocol in expedited decision. On the contrary, no revisions are required in the exempted decision.
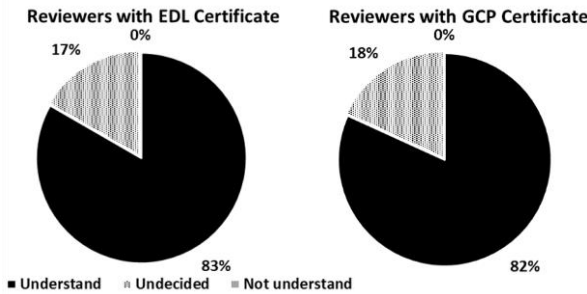

Fig. 8. Understanding of Ethical Clearance process in reviewer decision.

Figure 8 gives the understanding of EDL and GCP-certified reviewers towards the ethical clearance process from the reviewer decision perspective. Despite the previous discussion showing reviewers' lack of understanding of ethical clearance decisions, most of the reviewers demonstrate a good understanding of the ethical clearance process in determining reviewer decisions. This shows that most of the reviewers understand the procedure and ethical clearance flow process according to the Ethics Standards and Guidelines of National Health Research and Development [5]. EDL-certified reviewers merely exhibit a slightly higher level of understanding toward the ethical clearance process in reviewer decisions than GCP-certified reviewers with a level of understanding of 83% and 82%, respectively. According to previous researchers [6-7], a better understanding of the review process will improve performance and reduce dissatisfaction with ethical review results.

3.4   The understanding of research ethics reviewer on ethical clearance process, standard

Table 1 depicts the comparison results between EDL and GCP-certified reviewers, as well as overall reviewers in terms of the understanding of ethical research standards and the ethical clearance process in reviewer decisions.

Table 1. Comparison results between EDL and GCP certified reviewers, overall ethics reviewers

Variable	EDL	GCP	Overall
The understanding of ethical research standards			
Ethics research standard	96%	73%	86%
Ethics review protocol flow	100%	91%	90%
Ethics principles, standards, and guidance	33%	9%	24%
The understanding of the ethical clearance process in reviewer decision			
Ethical clearance decision type	11%	9%	10%
Ethical clearance process in reviewer decision	83%	82%	83%

According to Table 1, EDL-certified reviewers demonstrate a better understanding of ethical research standards compared to GCP-certified reviewers. A similar finding was also found in the understanding of ethical clearance during research protocol decision-making. The EDL-certified reviewers show a slightly better understanding than GCP-certified reviewers. This might be attributed to the lack of opportunity for GCP-certified reviewers to review research protocols that are still being provided to EDL-certified reviewers. This is because most of the research protocols submitted still focus on non-clinical corridors, especially in education and social science.

In general, it can be seen in Table 1 that the level of knowledge and understanding of most of the ethics reviewers is still very low, especially on ethics principles, standards, and guidance, even though the ethics reviewers have a good understanding of ethics standards and ethics review protocol flow processes. This finding is also supported by the results obtained on the reviewer's understanding of ethical clearance decisions that can be issued. This lack of knowledge may be due to the reviewer's lack of understanding of the types of decisions that require revision or presentation. Nonetheless, all reviewers understood well the process flow of reviewing a research protocol until the issuance of a proper ethical clearance certificate.

4   Conclusion

This research is concerned with the research ethics reviewer's understanding of the ethical clearance review process and standards. Based on the findings, it can be concluded that although most of the reviewers demonstrated a good understanding of ethical standards and the ethical clearance process, the competence and knowledge of most reviewers need to be improved due to a lack of understanding of ethics. principles, standards, and guidelines, as well as types of ethical clearance decisions.

In addition, despite GCP being the advanced level to the EDL ethics certificate, the EDL-certified reviewers show a better understanding of ethics research standards and guidance, as well as the ethical clearance process in reviewer decisions. This is due to the lack of opportunity for GCP-certified reviewers to review research protocols that are still being provided to EDL-certified reviewers.

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Authors' Contributions

AW and YL conceived the original idea. All authors discussed and agreed with the focus and ideas of this paper.

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