The Importance of Centralized Ethics Committee for Universities

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Abstract: The research ethics committee plays a crucial role in ensuring that all processes within the research stages are carried out according to procedures and do not violate ethical standards. Additionally, it ensures that human rights, security, safety, and well-being as subjects are well protected when involved in a research process. However, the current reality shows that University A does not yet have an institutional research ethics committee composed of medical and non-medical professionals at the university level. A centralized ethics committee at the university level is highly needed to be more easily developed and monitored institutionally. Moreover, it has the potential to receive more optimal resource allocation, ensure more comprehensive quality control of the ethical review process and procedure implementation, provide broader access for all units to obtain services, and enable more accountable and institutionalized income-generating management. This study aims to conduct an initial needs assessment to develop a centralized ethics committee institution at the university level. This type of research is qualitative, using purposive sampling, and the data are analyzed qualitatively and descriptively. The results show that of the 17 universities surveyed, 11 universities (65%) have ethics commissions at the faculty level, 5 universities (29%) at the university level, and 1 university (6%) is positioned under the Directorate of Research. All of the ethics commissions have similar rates and procedures. The study indicates that, for the development of the research ethics committee institution, there is at least a need for competent and trained ethics committee members, official appointment letters for the ethics committee members, a decree for the establishment of the institution, a secretariat office, service procedures, service information system, service rates, and administrative staffs.

Keywords: institutional, ethics committee, centralized.

INTRODUCTION

The Ethics Committee (EC) is an independent review committee working at the institutional, regional, national, or supranational level. The name of EC varies depending on the country; it may be referred to as the Ethics Committee or Institutional Review Board (IRB), commonly used in the United States. The EC comprises medical or non-medical scientists or professionals responsible for ensuring that human subjects' rights, safety, and well-being are protected when participating in a clinical trial (Ruslami, 2013).

The National Health Research and Development Ethics Committee, abbreviated as KEPPKN, is a committee that assists the Minister in fostering and enforcing research and health development ethics. The role of the Health Research Ethics Committee is to ensure the implementation of theoretical and moral concepts and their application in every research (Cahyanto, Erindra; Sudarmadji, Usman; Tri, Wulandari; Pratiwi, Nurrohima; Diana, 2022). Research differs from other activities, such as audits or journalism, as research generates scientific evidence and relevant knowledge and is conducted systematically (Menteri Kesehatan Republik Indonesia, 2020).

Health Research and Development Ethics refers to the fundamental principles that must be applied in implementing health research and development, both ethically and legally, on a universal scale. Health Research and Development Ethics have three core principles: respect for human dignity (respect for persons), the principle of beneficence (doing good) and non-maleficence (not harm), and the principle of justice (Kemenkes RI, 2021). The principle of respect for persons fundamentally aims to respect the autonomy of individuals to make their own decisions (self-determination) and protect dependent or vulnerable groups from abuse or harm (Kurniawan, 1992). Beneficence & non-maleficence involve the principle of doing good and maximizing benefits while minimizing risks. For example, if risks exist, they should be within reasonable limits. Therefore, the research design must be scientific, and researchers must have the capacity to carry out the study properly, followed by the principle of *do no harm* (non-maleficence) (Suryanto, 2005). The principle of justice emphasizes that everyone is entitled to what they deserve regarding distributive justice and equitable distribution. There should be no unfair treatment of vulnerable groups. Moreover, steps should be taken to prevent exploitation, particularly in low-income countries or regions. Justice requires that research be sensitive to vulnerable subjects' health conditions and needs (Handayani, 2018).

The Ethics Committee is essential in research because research can pose risks or harm to research subjects, whether physical, psychological, or social (Setiabudy, 2015). The Ethics Committee ensures that research is conducted safely and ethically so that any potential risks or harm can be minimized (Lestari et al., 2021). The role of the Health Research Ethics Committee (KEPK) includes protecting and supporting human autonomy, both as prospective and current research subjects; safeguarding the well-being of research subjects; and balancing moral considerations when evaluating research protocols, including respecting autonomy, protection, and enhancing well-being (Kesehatan, 2017). The functions of the Health Research Ethics Committee

(KEPK) include providing ethical approval after assessing research protocols acknowledged by the institution's leadership (Pedoman komite etik penelitian kesehatan RSD mangusada, 2019); KEPK has the right to propose sanctions to the institution's leadership and to withdraw or cancel ethical approval if violations are discovered during the research. In principle, KEPK prioritizes fostering a climate of openness and mutual trust (mutual trust) to support research development. On the other hand, KEPK is also responsible for ensuring high-quality health research by evaluating and deciding on the ethical appropriateness of the research. The scope of ethical assessment by KEPK includes health research conducted by faculty, healthcare professionals, researchers and students (Indarwati et al., 2018).

Ethical Clearance (EC) is an instrument used to measure the ethical acceptability of a research process. Specifically, in the research world, ethical clearance serves as a tool to evaluate the ethical acceptability of the research process and the feasibility of its publication. The Indonesian Institute of Sciences (LIPI), as the supervising body for researchers in Indonesia, has established a code of ethics for researchers in conducting research and scientific publication activities, as outlined in LIPI Head Regulation No. 06/E/2013 (LIPI, 2013). All research involving human subjects must not violate universally accepted ethical standards and must consider the social and cultural aspects of the community being studied (Peraturan Menteri Kesehatan No. 755/MENKES/PER/IV/2011, 2011). The primary goal of ethical clearance is to protect research subjects/respondents from physical (threat), psychological (distress, regret), social (stigma, ostracization), and legal consequences (lawsuits) as a result of participating in research. Some funding agencies and international publishers/journals require ethical clearance approval before granting funding or publishing research results (Suryanto, 2005).

The fundamental principles of research ethics include respect for individuals (respect for persons), which refers to respecting autonomy and the freedom to make independent choices. Protecting research subjects (protection of persons) involves safeguarding individuals/research subjects with limitations or vulnerabilities from exploitation and harm; beneficence is the ethical obligation to maximize benefits and minimize damage. All research should benefit society. The research design must be straightforward, and the researcher must be responsible and competent; justice (distributive justice) involves balancing the burdens and benefits of participating in research (Gunawan et al., 2020). Each research participant should be treated according to their background and condition. Differences in treatment between individuals/groups can be justified if morally accountable and accepted by society (Heryana, 2005).

In essence, research involving humans aims to discover new knowledge that benefits humanity. Ethically, research can be justified when it is conducted with respect for, protection of, and fairness to research subjects following societal norms (Iswari, 2015). Scientifically invalid research risks being unbeneficial to humans and, therefore, can be deemed unethical. For this reason, ethical clearance is crucial in research as it proves that the research meets ethical standards and that research subjects will be protected from potential risks or harm that may arise during the research (Lestari et al., 2021). This research is conducted as an initial needs assessment to develop a centralized ethics committee institution at the university level. By having a centralized Ethics Committee, some benefits can be reached such as institutional development becomes more accessible, the easiness of monitoring and evaluating the institution, better attention and resource allocation, quality control of processes, oversight, and assurance that research ethics review procedures are appropriately conducted, broader access for all units to manage EC, and the potential for more accountable and transparent income generation for the institution.

METHOD

This research implements descriptive qualitative as the method of study with the main goal of exploring the needs, strengths, weaknesses, opportunities, and threats in the establishment of an Ethics Committee institution centralized at the university level. The data collection process for this research involves the use of Focus Group Discussions (FGD), interview, and benchmarking with several other universities. The FGD and interviews were conducted to identify the needs, strengths, weaknesses, opportunities, and threats. The qualitative data will be analyzed to provide a recommendation on whether the centralized Ethics Committee institution at the university level is truly necessary and feasible to implement. The sampling technique in this research uses purposive sampling, targeting expert teams from the Center for Journal and Publication Development at University A, members of the Health Research Ethics Committee from the Faculty of Medicine, representatives of journal managers at University A, and several individuals involved in policy-making. The research started by interviewing the participants to review the existing conditions of the Ethics Committee at University A. This step is done as a preliminary step in developing this research. After doing the interview, the researcher created an FGD with the research respondents to know the needs, strengths, weaknesses, opportunities, and threats in the establishment of a centralized Ethics Committee institution at the university. The result of interview and FGD will then be analyzed by the researchers descriptively to provide comprehensive and in-depth results.

RESULTS

Description of Ethics Procedures and Conditions at University A

The level of ethical review at University A consists of four categories: exempted, expedited, full board, and rejected. The ethical review will be explained further below. Exempted review applies to research that:

1. Presents no or minimal risk/danger as a result of the research, or where the information collected is publicly available.
2. Involves the collection or study of existing data such as documents, records, pathological specimens, diagnostic specimens, or stored biological materials that are usually publicly accessible.
3. If information is recorded by the researcher:
    a. To qualify for this exemption, identifying information must be removed from the research materials before the research begins.
    b. If codes are used to identify subjects, the research is not exempted.
4. Research that has already received ethical approval from an accredited ethics committee does not require additional approval from other ethics committees.
    a. Exception: For multi-center studies involving several countries, ethical approval must be sought in each country, considering local socio-cultural aspects.
    b. Exception: Research involving multiple sites or hospitals still requires permission to conduct research.
5. Exempted reviews are not applicable to research where:
    a. The identification and disclosure of subject data could lead to serious consequences for the subjects.
    b. Surveys contain invasive or sensitive questions that may cause discomfort or increase risk.
    c. Subjects are public officials or candidates for public office.
    d. Legislation mandates that personal information confidentiality is maintained during and after the research.
    e. Research involves the use of test animals, including all vertebrates and certain invertebrates that can experience pain.

Expedited review is conducted for research where the risk to subjects is minimal or where no identifiable minimal risks/dangers to the research subjects or society are found. The risk to

subjects is reasonable in relation to the expected benefits and the importance of the knowledge gained. Subject selection is fair and non-coercive. There are several considerations when drafting the protocol, such as: informed consent is obtained from each potential subject or their legally authorized representative; informed consent is well-documented; the research plan includes adequate provisions for monitoring and collecting appropriate data to ensure subject safety; adequate measures are taken to protect subject privacy and maintain data confidentiality; in public health emergencies, such as investigations of disease outbreaks or disaster relief operations, the review is processed more quickly; the research protocol and proposal are reviewed by two reviewers.

There are some examples of research eligible for expedited review, such as: i.) Collection of hair and nails without causing injury; ii.) Collection of excreta and external secretions; iii.) Collection of prepuce, placenta, and umbilical cord; iv.) Data collection from subjects over the age of 18 using non-invasive procedures routinely used in clinical practice; v.) Light exercise by healthy subjects; vi.) Research on individual behavior, group behavior, or individual characteristics such as perception studies, cognition, game theory, or test development, which do not manipulate behavior and do not cause stress to the subjects.

Full board review is conducted for research involving: research protocols that indicate potential risks; clinical trials; sensitive ethical and religious issues; and vulnerable groups, such as fetuses, infants, children, the elderly, individuals with mental disorders, pregnant women, military personnel/police officers, prisoners, etc. The Ethics Committee invites researchers for clarification (either online or offline). A full board meeting consists of the following participants: the researcher (who may be accompanied by a supervisor) and five reviewers (including a lay person). The decisions from the review process include: Approved (the protocol is ethically acceptable and approved by the Ethics Committee); Revision required (the protocol requires additional information or amendments for re-review by the Ethics Committee); Rejected (the revised protocol is ethically unacceptable and cannot be approved by the Ethics Committee. The researcher may submit a new protocol that addresses the ethical issues raised by the Committee).

Overview of EC Fees at the Health Research Ethics Committee of University A

The results of the FGD conducted by researchers at University A show that of the 35 participants present, 26 participants (74%) stated that the ideal position of the research ethics committee is under the Directorate of Research, while 9 other participants (26%) stated that it would be better if it were under the faculty, as shown in Figure 1 below.

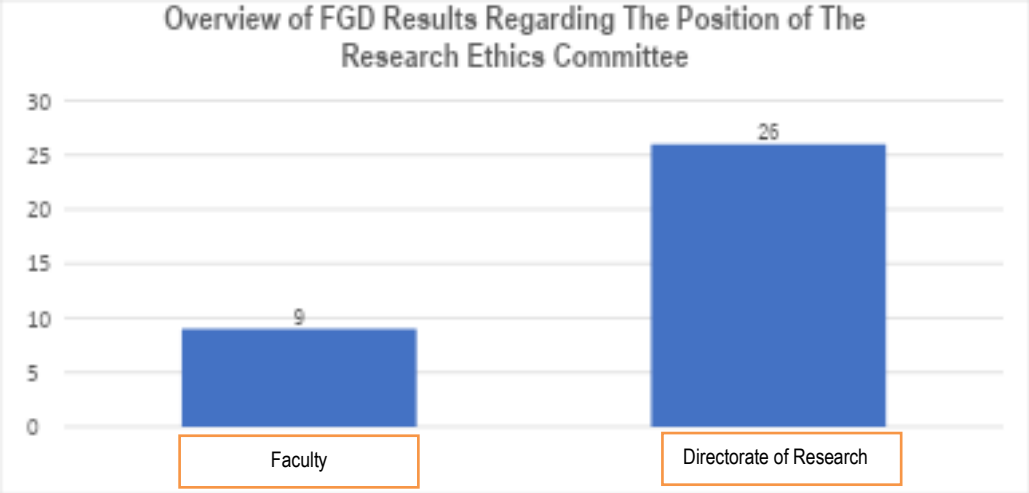

Figure 1. FGD participants' preferences for the position of the Research Ethics Committee

At University A, the fees associated with submitting research protocols to the Health Research Ethics Committee vary. However, the allocation of these fees presents certain challenges. The current honorarium for reviewers is around Rp 15,000 per review, which is seen as insufficient and inconsistently applied. Payments are typically made once a year, usually around the time of the Eid al Fitr holiday. Additionally, the fee structure is based on the number of titles reviewed, but there is no special payment scheme specifically for reviewers.

There are also difficulties in splitting the Rp 200,000 fee among multiple reviewers, especially given that the system lacks consistency in compensating reviewers for their work. This creates financial strain, as the number of submitted protocols is increasing, but the resources to fairly compensate the reviewers remain limited. As such, finding a more sustainable and standardized fee structure is necessary to support the growing workload and ensure timely reviews.

The EC fees at the Health Research Ethics Committee of University A are divided into two categories: internal and external. The internal fees are further classified into three subcategories, including students, faculty members, and researchers, each with varying costs. For internal students, the fees differ based on their academic level. Undergraduate (S1) students are charged IDR 100,000, master's (S2) students Rp 150,000, and doctoral (S3) students IDR 250,000. These fees apply to both observational and interventional research, with each category reflecting the complexity and nature of the research being conducted. Meanwhile, the fees for observational research for faculty members and researchers with S1, S2, S3, Sp-1, and Sp-2 qualifications are set at IDR 300,000. For interventional research, the fee for faculty members and researchers with

the same qualifications is IDR 350,000. These rates apply uniformly to both faculty and internal researchers, reflecting the specific demands of observational and interventional studies.

The external category includes fees for external students, faculty members, and researchers. For external students, the fees are IDR 150,000 for S1 students, IDR 200,000 for S2 or Sp-1 students, and IDR 300,000 for S3 or Sp-2 students. For observational research, the fee is IDR 350,000 for external researchers and faculty members, covering those with S1, S2, S3, Sp-1, and Sp-2 qualifications. Meanwhile, the fee for interventional research is IDR 400,000 for external researchers and faculty members, including those with S1, S2, S3, Sp-1, and Sp-2 qualifications.

The EC fees at the Health Research Ethics Committee of University A also differ for research institutions, organizations, and NGOs. For observational research, the fees are set at IDR 500,000 for researchers with S1 qualifications, IDR 1,000,000 for those with S2 or Sp-1 qualifications, and IDR 1,500,000 for researchers with S3 or Sp-2 qualifications. For interventional research, the fees are IDR 1,000,000 for S1-level researchers, IDR 1,500,000 for S2 or Sp-1 researchers, and IDR 2,000,000 for those with S3 or Sp-2 qualifications. These varying rates reflect the complexity and scale of the research being conducted by different levels of researchers.

From the results of observations and document reviews carried out, it can be seen that the 17 universities studied, it was found that 11 universities (65%) have their ethics committees based at the faculty level. These universities include University A, University B, University C, University E, University F, University G, University H, University J, University L, University N, and University Q. Meanwhile, 5 universities (29%) have their ethics committees at the university level, such as University I, University K, University M, University O, and University P. One university (6%), University D, places its ethics committee under the Directorate of Research, with similar rates and procedures across these institutions.

DISCUSSION

Several public and private universities (17 universities) in Indonesia have established Ethical Clearance (EC) websites, including University A, University B, University C, University D, University E, University F, University G, University H, University I, University J, University K, University L, University M, University N, University O, University P, and University Q. These institutions provide ethical review services for research through their EC platforms.

Generally, the documents required to be attached for online Ethical Clearance (EC) submissions through university research ethics websites include a letter of ethical review request

from the researcher's institution or a cover letter, proof of payment file, research proposal, the researcher's CV, a statement letter, research instruments or questionnaires, and informed consent. For example, universities such as University A, University F, University I, and University G, among others, follow these requirements.

The review process at University A follows a blind review system, meaning reviewers do not know whose protocol they are reviewing. However, most of the protocols tend to be from students. The strength of many protocols submitted at University A lies in their generally good quality, adhering to systematic and scientific writing formats. This is largely because students submit their protocols to the Ethics Committee (EC) after passing their proposal exams, completing revisions, and receiving approval from their examiners and supervisors. However, this Health Research Ethics Committee faces several challenges. One of these is the transition in systems, where the standards are still seen as inconsistent. Another issue is the high cost of ethics training, both basic and advanced, making it difficult to increase the number of qualified reviewers. Accreditation for the ethics committee is also voluntary, which adds complexity. Additionally, honorarium distribution remains an issue, with difficulties in splitting the IDR 200,000 fee among multiple reviewers. While reviewers are compensated around IDR 15,000 per review, this payment system has not been consistently applied. Furthermore, reviewers are only paid once a year, typically around the Eid al Fitr holiday, with payments calculated per title reviewed, but without a clear fee structure for reviewer payments.

Human resource challenges also arise, as there is a significant number of submissions from undergraduate students in fields like Public Health, Pharmacy, and Nutrition, but the number of reviewers has not increased accordingly. This has created a need for more reviewers. Some senior reviewers, who have many responsibilities, are assigned fewer reviews, which in turn increases the workload for others. Additionally, some reviewers take an extended amount of time to complete their reviews, resulting in task reassignment to meet the 14-day review deadline stipulated by the SOP.

Regarding system challenges, the Ministry of Health’s system is not compatible with IT system in University A, which poses potential security risks. A dedicated system is needed to resolve these issues. The Ethics Committee has the authority to review protocols, but monitoring has only been conducted at level 3, focusing on protocols that meet three specific criteria: sensitive issues related to culture, race, or religion; high hazard levels; or research involving vulnerable groups, such as children with HIV, even if only two children are involved in the study. Additionally,

monitoring remains inconsistent, as not all research projects are being monitored. Another significant gap is the lack of a reporting system for Severe Adverse Events (SAE), meaning serious incidents occurring during research are not reported, though such a system is necessary and has yet to be implemented.

The Ethics Committee plays a crucial role in all research, especially when studies may pose risks or harm to research subjects, whether physically, psychologically, or socially (Setiabudy, 2015). The Ethics Committee's primary function is to ensure that research is conducted safely and ethically, minimizing any potential risks or harm that could arise (Lestari et al., 2021). The committee's responsibilities include protecting and supporting the autonomy of individuals, both as potential and actual research subjects, safeguarding their well-being, and balancing various moral considerations when reviewing research protocols, such as respecting autonomy and protection and enhancing their welfare (Kesehatan, 2017).

Additionally, the Research Ethics Committee functions by providing ethical approval after evaluating research protocols acknowledged by the institution's leadership (Pedoman komite etik penelitian kesehatan RSD mangusada, 2019). The committee is also authorized to propose sanctions to the institution's leadership and has the right to revoke or withdraw previously granted ethical approvals if violations are found during the research process. Fundamentally, the committee emphasizes fostering an environment of openness and mutual trust to facilitate guidance, while also being responsible for ensuring high-quality health research through ethical assessment and decision-making regarding the suitability of a study (Indarwati et al., 2018).

CONCLUSIONS

From the 17 universities studied, it was found that 11 universities (65%) have their ethics committees based at the faculty level. These universities include University A, University B, University C, University E, University F, University G, University H, University J, University L, University N, and University Q. Meanwhile, 5 universities (29%) have their ethics committees at the university level, such as University I, University K, University M, University O, and University P. One university (6%), University D, places its ethics committee under the Directorate of Research, with similar rates and procedures across these institutions.

Some of the weaknesses in the management of the Health Research Ethics Committee, include the need for a standardized IT system, compliance with accreditation requirements, transparent and accountable financial management systems with clear tariffs and unit costs,

adequate human resources, particularly staff and the number of reviewers, and the establishment of monitoring and evaluation procedures, including a reporting system for Severe Adverse Events (SAE). To address these issues, there is a need to place at least 2-3 staff members from the educational staff sector, establish comprehensive procedures, including for monitoring, evaluation, and SAE reporting, train and increase the number of multidisciplinary reviewers (a minimum of 20-25 reviewers for 1 unit), develop appropriate the IT system for the Research Ethics Committee, and create a transparent and accountable financial management system with tariffs and unit costs. Additionally, establishing a dedicated budget and secretariat for the ethics committee under the Directorate of Research is crucial to building a centralized Ethics Committee at the university level.

Conflict of Interest

The authors declare that they have no conflict of interest.

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