

## The Urgency of Institutional Development of the Research Ethics Committee

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**Abstract:** The centralized Research Ethics Committee at the university level has several virtues; it becomes easier to develop institutionally, easier to monitor and evaluate, and has the potential to get better resource allocation, better process quality control, wider access to services, and income generation for the institution. This research aims to develop institutional design through organizational structure, division of study fields, and service operational procedures. The type of research used is qualitative, and the sampling technique used is purposive sampling. Data was collected through workshops, Focus Group Discussions (FGD), and benchmarking to other universities, and data was analyzed using content analysis. The development of institutions and organizational structures at the university level in this research is arranged in 3 main components, namely: the University Research Ethics Committee Team (consisting of the Chairman, Vice Chair (who acts as secretary) and the Coordinator of the Study Field), the research protocol ethics review team and the technical support team of the Ethics Committee (such as: IT, finance and administrative teams). Meanwhile, the scope developed is divided into four scopes of research ethics study: health, education, science and technology, and social humanities. The scope is divided into 29 research study areas. In addition to determining the scope and field, the type of document review and procedure must also be specified. This research is divided into three types: exempted, expedited, and full board, which have been prepared with SOPs.

**Keywords:** ethics committee, institutional, research, university

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### INTRODUCTION

In the era of scientific and technological advancement, research activities are one of the main foundations in academic development and social problem-solving in society. Universities as centres of knowledge have a strategic role in encouraging the birth of innovative research, both by lecturers and students. In its implementation, research must go through systematic stages, from the preparation of proposals to scientific publications. It must meet methodological standards and ethical feasibility, especially if it involves humans, experimental animals, biological tissues, or hazardous substances. The main challenge in research lies in balancing the expected benefits with the risks that may arise. Therefore, Ethical clearance is very important in a research because it proves that the research has met the ethical standards of research and that the research subject will be protected from potential risks or dangers that may arise from the implementation of the research (Lestari et al., 2021; Overall, 2025; Stahl et al., 2025).

A research is said to meet ethical standards if it has fulfilled the three main principles of ethics: the principle of respecting human dignity, the principle of doing good and not harming, and the principle of justice. Principle respect for persons aims to respect the autonomy of individuals in making conscious and voluntary decisions and protect dependent or vulnerable groups from abuse. The principle of beneficence and non-maleficence is an important foundation in research involving human subjects. However, it demands that the research meet scientific requirements, provide maximum benefits, and minimize risks. If the risk arises from the research, it must be reasonable and proportionate to the benefits obtained. This principle emphasizes the importance of safeguarding the subject's well-being and opposing all forms of abuse. Meanwhile, the principle of justice demands equal and dignified treatment of everyone as an autonomous person. The main focus is distributive

justice, which is the fair and balanced division between the burdens and benefits the subject receives as part of their participation in the research (Ministry of Health, 2021).

Without an adequate ethical mechanism, research risks containing ethical violations such as conflict of interest, falsification of data, violation of participants' rights, and plagiarism. These violations damage the credibility of research results and cause negative consequences for various parties, including researchers, institutions, and the community (Drolet et al., 2023). Therefore, to ensure that research is carried out responsibly and ethically, a Research Ethics Committee (Research Ethics Committee/REC) was formed as an independent institution tasked with assessing the ethical feasibility of research in various disciplines. This ethics committee has the role of reviewing and providing ethical approval to protect research subjects, respect the subject's autonomy rights, and minimize potential risks or harms per research ethics principles and guidelines, Good Clinical Practice (Löfström et al., 2024; Stahl et al., 2025; Wardhono & Lestari, 2022). To ensure that the role and function of the Research Ethics Committee can be carried out optimally, a clear and systematic organizational structure is needed. The organizational structure of the Research Ethics Committee consists of chairmen, secretaries, and members from various scientific backgrounds, such as scientists, lawyers, philosophers, and the public. This diversity is important to ensure that ethical assessments are made objectively and comprehensively (Mehta et al., 2023).

In supporting the smooth implementation of the duties and functions of each element in the structure of the Research Ethics Committee (REC/KEP), it is necessary to have clear and standardized operational procedures. This procedure serves as a reference in ensuring consistency, transparency, and accountability in ethical assessments. The scope of the operational procedure covers various important aspects, namely: provisions regarding ethics committee membership, ethics committee governance, involvement of independent consultants, application submission mechanism, completeness of documents that must be included in the review process, proposal review procedures, decision-making stages, communication of decision results to researchers, follow-up and monitoring of research implementation, as well as documentation and archiving systems (Ministry of Health, 2021).

In addition to containing procedural aspects and the substance of the ethical review, the Standard Operating Procedure (SOP) also ensures time efficiency in reviewing proposals. Time constraints in the ethics review process are crucial because they provide certainty for researchers and maintain the accountability of ethical institutions. Without a clear time limit, the review process can take too long and potentially hinder the implementation of the research. Therefore, according to the WHO, each review stage must have a measurable time allocation, such as one day for initial screening, ten days for a quick review, and adjustment to the meeting schedule for regular review (WHO, 2012). In addition, based on the guidelines from the Council for International Organisation of Medical Sciences (CIOMS) states that a good SOP must contain a time frame in each process to ensure the efficiency, effectiveness, and credibility of ethical institutions. Thus, time restrictions in SOPs can strengthen the commitment to the ethical principles of responsive and responsible research (CIOMS, 2016).

In addition, the Standard Operating Procedures (SOP) can also be stipulated regarding the standard for the completeness of documents that the researcher must attach as a condition for the ethical review process. The completeness of this document is very important because it is the basis for the Research Ethics Committee in assessing the ethical, scientific, and administrative feasibility of research. The documents submitted are generally in the form of research protocols that explain the background, objectives, research methodology, informed consent form, research instruments, risk and benefit analysis of planned research. The review process on these elements aims to protect the research subject, ensure that participation is voluntary and based on sufficient information, and that the risks that may occur are proportional to the expected benefits (Ministry of Health, 2021; Morgans & Allen, 2005).

In implementing the research ethics review, the financing aspect plays an important role in ensuring the review process's smoothness, efficiency, and quality. The Research Ethics Committee

requires adequate financial support to finance daily operations, member training, honorarium for reviewers, and developing administrative systems and supporting technology. Therefore, institutions need to implement workload-based planning and budgeting (Workload-based budgeting), which aims to adjust to the volume and complexity of incoming ethics applications (Page & Nyeboer, 2017).

The many important roles and functions of the Research Ethics Committee are the background for UNNES to develop the institution of the Research Ethics Committee under Institute for Research and Community Service (LPPM). On the other hand, several potential benefits can be obtained when UNNES as one of the educational institutions has a centralized Research Ethics Committee, including: institutionally this committee/commission will be easier to develop, institutions are easier to monitor and evaluate, the potential to get better resource allocation, process quality control is better maintained and ensures that the implementation of research ethics review procedures can be carried out adequately, wider access for all units in obtaining ethical clearance, this will certainly have an impact on income generation for more accountable and transparent institutions. The current problem is that UNNES does not have an adequate centralized Research Ethics Committee. This encourages the research team to conduct follow-up research in this 2nd stage, namely research to compile the institution through organizational structure of the research ethics committee, determine the scope and field of research ethics review, and prepare the required research ethics service procedures. Therefore, this research aims to develop institutional design through organizational structure, division of study fields, and service operational procedures.

## **METHODS**

This research was conducted at Universitas Negeri Semarang (UNNES), Semarang City, Central Java. The type of research used is qualitative, and the sampling technique used is purposive sampling involving a team of experts from the UNNES Journal and Publication Development Centre, members of the Ethics Committee, ethics experts, and several parties related to planning, finance, and institutions. Data was collected through workshops, Focus Group Discussions (FGD), and benchmarking to other universities as input in preparing institutions, fields of study, and work procedures for comprehensive ethics review services. All qualitative data are then analyzed using analytical content to produce institutional design, organizational structure, division of study areas, and service operational procedures.

This activity has received ethical approval through a certificate of ethical feasibility from the Health Research Ethics Commission of the Faculty of Medicine, Universitas Negeri Semarang, with No. 890/KEPK/FK/KLE/2025. This activity is carried out in 4 stages, namely identifying resources and preconditions, arranging institutions through organizational structure of the research ethics committee, determining the scope and field of research ethics review, and developing research ethics service procedures.

## **RESULT AND DISCUSSION**

The results of the initial identification indicate that Universitas Negeri Semarang already has a Health Research Ethics Commission Team under the Faculty of Medicine, where the service system is still limited, with a focus on health and medical research. Meanwhile, the need for other disciplines, namely outside the fields of health and medicine involving human respondents, is increasingly needed, more and more research protocol ethics review services both in the research process and for publication purposes, therefore the development of research protocol ethics review services is considered feasible to be developed at the university level with a wider range of services.

The institutional development and organizational structure prepared at the university level consists of 3 main components, namely: the University Research Ethics Committee Team (consisting of the Chairman, Vice Chair (who acts as secretary) and the Coordinator of the Field of Study), the research protocol ethics review team and the technical support team of the Ethics Committee (such as: IT, finance and administrative teams). In addition to the development of institutions and organizational structures, the results of interviews, FGDs and benchmarking carried out can be seen

that the advantage of the research ethics committee that is located at the Institute for Research and Community Service (LPPM) at the university level is that it can cover various scientific disciplines, because at the university level there are experts from multiple disciplines and study programs at the university. At the initial stage, four scopes of research ethics study were determined: health, education, science and technology, and social humanities. The scope is divided into 29 fields of research study, namely: Legal Science, Development Economics, Health Sciences, Public Health, Civil Law, Environmental Sector, Mathematics Education, Engineering Sector, Chemical Engineering Sector, Civil Engineering Sector, Electrical Engineering Sector, Mechanical Engineering Sector, Nutrition Sector, Medical Sector, Veterinary Medicine, Psychology Sector, Education Sector, Basic Education Sector, Early Childhood Education, Language and Arts Field, Disaster Field, Geography Education, Social Sciences, Gender Field, Social Education Field, Pure Biology, Biology Education Field, Research with Experimental Animals, and Sports Field.

In addition to determining the scope and field, the type of document review and procedure must also be specified. The three main types of document review developed are exempted, expedited, and full board, as presented in Figure 1. The design of the review time plan set out in this procedure is a maximum of 7 working days for the category Exempted, a maximum of 14 days for Expedited, and a maximum of 28 working days for Full Board.

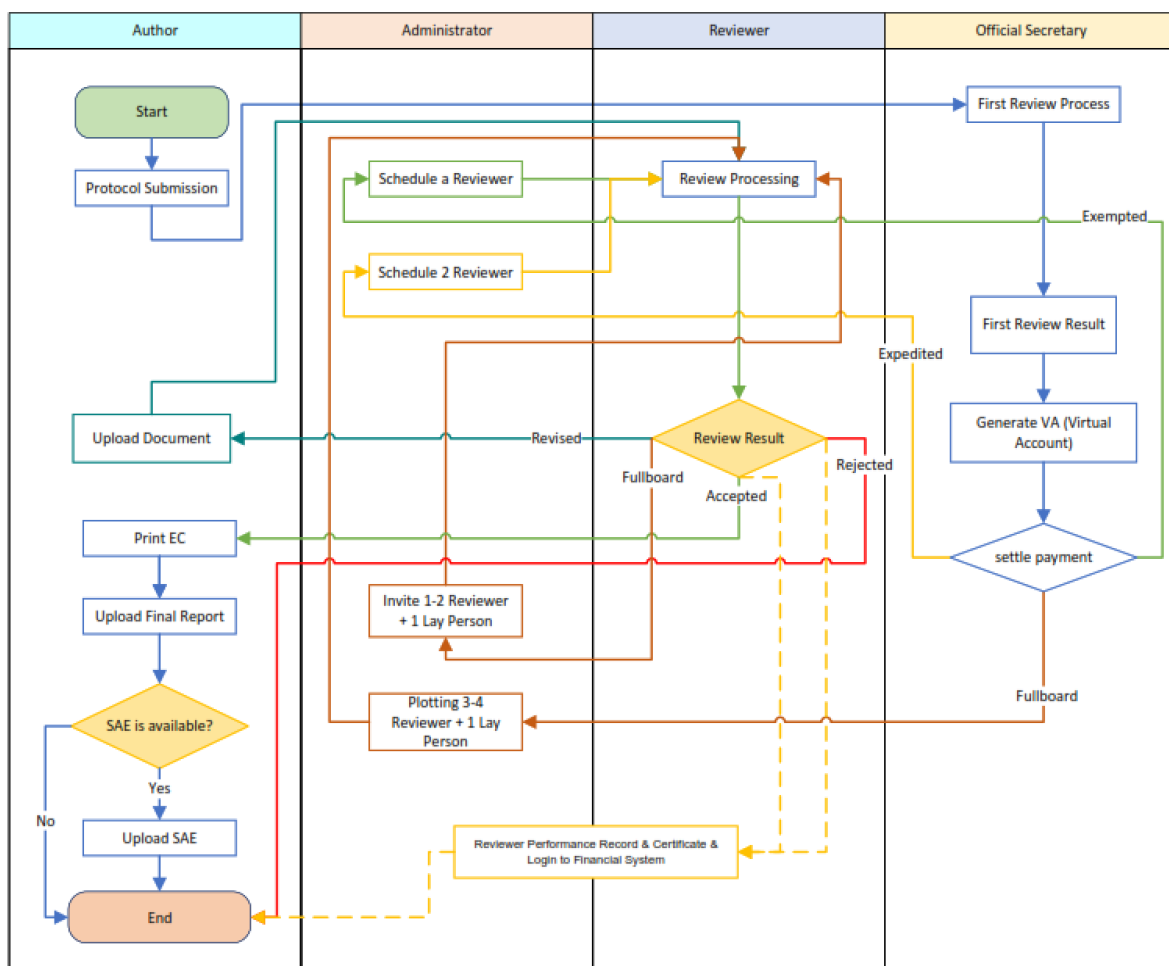


Figure 1. Procedure for reviewing research ethics documents

The Research Ethics Committee (KEP/*Komite Etik Penelitian*) is an important element in a responsible research management system. The Research Ethics Committee (KEP) has a major role to ensure that every research involving human and animal subjects is conducted in a way that does not cause harmful impacts and protects research subjects' rights, safety, and welfare (Ardhi, 2024; Schuett

et al., 2024; World Medical Association, 2025). In various universities, the Research Ethics Committee (KEP) acts as an initial filter to assess the ethical feasibility of research conducted before the research is implemented. However, the real condition in several institutions is that the KEP service system has not been built optimally, as one of which has not been carried out centrally and integrated. This can have an impact on the limitations of the services provided. For comparison, several universities in Indonesia have established centralized Research Ethics Committees with a standardized and online-based service system, such as Universitas Gadjah Mada (UGM) and Universitas Indonesia (UI). At UGM, the centralized KEP is managed by the Directorate of Research, which serves researchers from various circles, including lecturers, students, and education personnel equipped with an adequate system, clear SOPs, and cross-disciplinary researchers (UGM, 2025). This condition further emphasizes the need for a centralized, integrated, and standardized KEP system to support the ethics committee's performance quality.

In supporting the formation of a professional Research Ethics Committee (KEP) that can function optimally, it is necessary to establish a systematic organizational structure that reflects the principles of good governance. The organizational structure of the KEP ideally includes chairs, secretaries, and members consisting of various disciplines, including professionals and community representatives (Layman) or legal experts who are integrated with each other and carry out their respective functions (Ministry of Health, 2021). The committee chair is responsible for ensuring the continuity and independence of the committee's performance, encouraging the active participation of committee members, identifying potential conflicts of interest, and handling complaints directed to researchers and committee members. The Secretary plays a role in scheduling meetings, managing documentation, coordinating the protocol review process efficiently, monitoring compliance with Standard Operating Procedures (SOPs), and conducting member training. Meanwhile, members of the scientific community have the responsibility to assess the scientific feasibility and methodological validity of the proposed research protocol. Meanwhile, non-scientific members have a role as representatives of the general public and ensure the protection of the rights and welfare of research subjects (Mehta et al., 2023). This structure is designed so that the committee can work independently and transparently. The importance of a standardized organizational structure can also be seen from the practice in various universities in Indonesia, such as: the Health Research Ethics Commission at the Faculty of Medicine and Health, Universitas Muhammadiyah Jakarta (KEPK FKK UMJ/*Komisi Etik Penelitian Kesehatan Fakultas Kedokteran dan Kesehatan Universitas Muhammadiyah Jakarta*) which has implemented a clear and systematic organizational structure and the Health Research Ethics Committee at the Faculty of Medicine and Health Sciences, Universitas Muhammadiyah Makassar (KEPK FKIK/*Komite Etik Penelitian Kesehatan Fakultas Kedokteran dan Ilmu Kesehatan Unismuh Makassar*) which has even received recognition through SIDCER-FERCAP accreditation, which evaluates the structure, composition of members, regulations and ethical policies applied (UMJ, 2025; Unismuh, 2022). This shows that the right institutional structure not only supports the committee's operations but is also an indicator of professionalism and credibility globally.

After the organizational structure of the Research Ethics Committee (KEP) is formed systematically, the institutional function is highly dependent on the effectiveness of its implementing elements, one of which is the reviewer or ethical reviewer. Reviewers have an important role in ensuring the ethical feasibility of research, especially involving human subjects. The reviewer has the responsibility to examine the research protocol objectively to ensure that the entire research process is carried out in accordance with ethical principles. This review process is usually carried out by two to three reviewers whose results determine whether the research will be approved, needs further clarification, or is rejected. In addition to being a reviewer, the reviewer also plays a role as a guardian of the independence of the KEP. Therefore, the involvement of external reviewers with diverse scientific backgrounds is needed to ensure the objectivity of the assessment (Handayani, 2018; Ministry of Health, 2021). This practice has been effectively applied in a number of institutions, such as the Research Ethics Committee of the Faculty of Medicine, Universitas Sebelas Maret (KEP FK UNS/*Komite Etik Penelitian Kesehatan Fakultas Kedokteran Universitas Sebelas Maret*), which, in the

implementation of ethics review, involves internal and external reviewers. The ethics review process at the institution was efficient, with an average duration of nine days. This reflects that the reviewer's role not only ensures the integrity of the review process but also contributes to the effectiveness of time and improvement of the quality of the research design (Ardhi, 2024).

In addition to the reviewer's role, the existence of clear, standard, and structured Standard Operating Procedures (SOPs) is an important element in the work system of the Research Ethics Committee (KEP). SOPs function as a guide in implementing ethical processes, where standardized SOPs, KEP can carry out its duties consistently. SOPs can also help all parties involved to understand their respective workflows, deadlines, and responsibilities (Rahmawati et al., 2024). Several Ethics Committees in universities have developed structured and comprehensive SOPs to support ethical review. For example, the Research Ethics Committee of the Faculty of Medicine, Universitas Hasanuddin (KEP FKUH), THE SOP developed is not only related to the ethics review process but also related to the formation of KEP, member training, the selection of independent consultants, audit mechanisms, and the implementation of inspections as a form of quality control (FKUH, 2024). Meanwhile, at the Yakpermas Banyumas Polytechnic, SOPs have been systematically prepared, starting with the submission of protocols by researchers, the research selection process, ethical clearance, and the research publication process (Yakpermas, 2019). The existence of this detailed and standard SOP not only facilitates coordination between KEP's internal affairs but also provides procedural certainty for researchers, as well as strengthens the transparency and accountability of ethics committees in ethical decision-making.

Although ethics review procedures have been systematically designed through the implementation of SOPs, the success of their implementation is highly dependent on efficient time management. Therefore, time restrictions in the ethics review process are an important part of the governance of the Research Ethics Committee (KEP) to ensure responsive service and provide certainty to researchers. Ethical reviews that last too long not only hinder the implementation of research but also reduce the researcher's confidence in the credibility of KEP. This is in accordance with the Guidelines Council for International Organisation of Medical Sciences (CIOMS), which emphasizes the importance of setting clear deadlines at each review stage to ensure the ethics institution's efficiency, effectiveness, and credibility (CIOMS, 2016). The principle of time limitation in the ethics review process is not only a normative reference in international guidelines. Still, it is also implemented by a number of universities in Indonesia as part of efforts to improve ethical services. For example, the Research Ethics Committee of Universitas Ahmad Dahlan (KEP UAD) sets a measurable ethics review time, which is a maximum of 3 working days for the category Exempted, a maximum of 14 days for Expedited, and a maximum of 28 working days for Full Board (UAD, 2025). Meanwhile, in the implementation at KEP FEB Universitas Indonesia, the time for ethical review is set between 1-2 weeks, Exempted, 2-6 weeks for Expedited, and 3-7 weeks for Full Board (UI, 2025). Thus, time constraints in the ethics review process are an administrative necessity and part of professional and responsive ethical service governance. Practice in various colleges shows that establishing time limits and consistent implementation can improve work efficiency, speed up the service process, and strengthen trust in the ethical system the committee implements.

In the ethics review process, the Research Ethics Committee not only assesses the general feasibility of a research but also examines in depth all documents that aim to ensure that all aspects of the research meet the standards. The main components examined are the research protocol which contains objectives, design, methods, data analysis, participant consent forms that explain the rights, risks, benefits and freedoms to cancel participation in the research, research instruments, risk analysis and mitigation efforts against potential dangers that may arise, and supporting documents such as permits. The implementation of this comprehensive document review can be found in various universities. At Universitas Brawijaya (UB), researchers must meet the requirements of documents such as: research protocol, complete proposal, researcher CV, informed consent, questionnaires, permission letter from the institution where the research is conducted, letter of introduction to the institution, and worksheets (UB, 2025). Meanwhile, at the Banjarmasin Polytechnic, the requirements

must be met: identity card, active email, mobile number, proposal endorsement sheet, ethics review cover letter, researcher's CV, research protocol, self-assessment, informed consent, research questionnaires, and stamped statements (Banjarmasin Polytechnic, 2025). The requirements of this document are quite detailed to ensure that the research to be conducted has been designed with all ethical aspects in mind, protecting the rights and safety of research subjects, and ensuring the integrity of the research implementation. The different types of documents requested by each ethics committee show that although the ethical principles are universal, their application can be adjusted to the needs and policies of each committee.

In the process of reviewing research ethics, the financing aspect is one of the factors that determines the smoothness, efficiency, and quality of the review process. The Research Ethics Committee (KEP) needs sufficient funds to support various activities such as daily operational costs, member capacity training, the provision of honorariums for reviewers, and the development of administrative systems and supporting technology (Page & Nyeboer, 2017). The application of fees in ethics review services has been regulated in various policies, one of which is the Regulation of the Minister of Finance of the Republic of Indonesia Number 39 of 2024 concerning Input Fee Standards for the 2025 Fiscal Year, which lists the amount of ethics review honorarium of IDR 150,000 per proposal (Ministry of Finance, 2024). At the university level, a similar policy is implemented to support the operations of the Research Ethics Committee. The fees that must be paid vary between institutions and are usually adjusted to the status of the researcher (for example: undergraduate, postgraduate, and doctoral students), lecturers, external researchers and others), the level of education of the researcher, the type of research and the source of research funds are also considered. For example, at Universitas Padjadjaran (Unpad), the ethical submission fee for undergraduate Unpad students is IDR 100,000, while for undergraduate students from outside Unpad, the fee is IDR 300,000. Research by Unpad lecturers with a cooperation system revealed that the tariff charged is IDR 3,000,000, while lecturers from outside Unpad are charged a tariff of IDR 4,000,000 (Unpad, 2025). Another example at Universitas 'Aisyiyah Yogyakarta (Unisa), the tariff that must be paid for Unisa's internal undergraduate students is IDR 170,000, while for Unisa's external undergraduate students, the tariff is IDR 225,000. The tariff for Unisa's postgraduate students is IDR 220,000, while for Unisa's external postgraduate students, the rate is IDR 300,000 (Unisa, 2025). The difference in tariff variation between these institutions reflects the differences in policies and capacities of each committee. In addition, the difference in rates between students, internal lecturers, and researchers from outside the institution is based on proportionality and contribution to the institution. In-house students and lecturers typically receive institutional subsidies, while external researchers are charged higher rates for utilizing unsubsidized services from the institution.

## CONCLUSION

The development of institutions and organizational structures at the university level in this research is arranged in 3 main components, namely: the University Research Ethics Committee Team (consisting of the Chairman, Vice Chair (who acts as secretary) and the Coordinator of the Study Field), the research protocol ethics review team and the technical support team of the Ethics Committee (such as: IT, finance and administrative teams). Meanwhile, the scope developed is divided into four scopes of research ethics study: health, education, science and technology, and social humanities. The scope is divided into 29 fields of research study, namely: Legal Science, Development Economics, Health Sciences, Public Health, Civil Law, Environmental Sector, Mathematics Education, Engineering Sector, Chemical Engineering Sector, Civil Engineering Sector, Electrical Engineering Sector, Mechanical Engineering Sector, Nutrition Sector, Medical Sector, Veterinary Medicine, Psychology Sector, Education Sector, Basic Education Sector, Early Childhood Education, Language and Arts Field, Disaster Field, Geography Education, Social Sciences, Gender Field, Social Education Field, Pure Biology, Biology Education Field, Research with Experimental Animals, and Sports Field. In addition to the scope and determination of the field, the type of document review and procedure must be determined. In this research, three types of research ethics protocols are discussed, namely,

exempted, expedited, and full board, for which the SOPs have been prepared. The suggestion given as a follow-up to this research is to develop a Research Protocol Ethics Review Service Information System according to the specified fields so that this service can be accessed by the wider community and is more user-friendly.

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