International Journal of Research and Review
Volume 11; Issue: 2; February 2024
Website: www.ijrrjournal.com
Review Paper *E-ISSN: 2349-9788; P-ISSN: 2454-2237*

Analysis of Legal Protection and Ethical Study in Health Research with Humans as Research Subjects Reviewed from the Republic of Indonesia Law Number 17 of 2023 Concerning Health

Rachmah Ubat Harahap[1], T. Riza Zarzani N[2], Fauziah Nur[3], Iyo Iko Rasaki[4], Hasdiana Nisya Lubis [5]

[1,2,3,4,5]Master's Program in Health and Medical Law, Universitas Pembangunan Panca Budi, Medan, Indonesia

Corresponding Author: T. Riza Zarzani N, (Tengkuriza49@gmail.com), Rachmah Ubat Harahap, (rachmahaubatharahap@gmail.com)

DOI: https://doi.org/10.52403/ijrr.20240219

ABSTRACT

Legal protection is the right of every legal subject. Ethics and morality are always linked to freedom and responsibility. Ethics imposes moral obligations on humans, which differ from obligations in legal norms; these moral obligations do not have binding force for enforcement. Moral norms are autonomous, and their enforcement cannot be compelled through external efforts (such as by authorities). Explicitly, Law number 17 of 2023 Regarding Health does not regulate legal protection for humans as research subjects. The purpose of this research is to understand legal protection and ethical considerations, examining the provisions of Law number 17 of 2023 Regarding Health concerning humans as research subjects. The method used in this research is a type of normative juridical research and a statute approach research method (legislative provisions approach). The legal materials used include primary legal materials from Law number 17 of 2023 Regarding Health and secondary legal materials such as journals, books, and other media. The research findings indicate that Law number 17 of 2023 Regarding Health does not explicitly regulate legal protection for humans as research subjects. However, in all health research involving humans as research subjects, researchers must obtain consent after providing an explanation (Informed Consent). In Law number 17 of 2023 Regarding Health, reliance is placed on three general ethical principles: respecting human dignity (respect for person) aimed at *honoring* autonomy and protecting individuals whose autonomy is compromised/limited, doing good (beneficence) and not causing harm (nonmaleficence), and justice.

Keywords: *Legal Protection, Ethics, Health Research*

INTRODUCTION

The right to health is inherent to every citizen of Indonesia, and it is the duty of the State to ensure its realization. According to Article 28H of the 1945 Constitution, all individuals are entitled to live in both physical and spiritual well-being, to reside in a favorable and healthy environment, and to access health services. Additionally, Article 34, paragraph 3 of the 1945 Constitution specifies that the State is accountable for furnishing sufficient health service facilities and general service facilities.

Law No. 17 of 2023 is the law that regulates health matters. The content of this law consists of 20 chapters and 458 articles. Chapter X specifically regulates Health Technology, which is crucial to be addressed in one chapter of Law No. 17 of 2023, particularly concerning the Transformation of Health Technology, involving the

development and utilization of technology, digitization, and biotechnology in the health sector.(BADAN LEGISLASI DEWAN PERWAKILAN RAKYAT REPUBLIK INDONESIA, 2023)

Health technology is the application of scientific knowledge manifested in the form of health tools, drugs, vaccines, other health supplies, methods, or systems, including hardware and software. It is developed as an effort to address health problems through research, dissemination, and re-development for the benefit of public health. The improvement of health aspects can be observed at the promotive, preventive, curative, rehabilitative, and palliative stages the transformation in health aims to optimize the economic growth potential of Indonesia, potentially contributing to an additional 8% yearly increase in the Gross Domestic Product, in line with the expanding demographic data. Consequently, by 2030, 68% of Indonesia's population will be in the productive age group between 15-64 years old. (BADAN LEGISLASI DEWAN PERWAKILAN RAKYAT REPUBLIK INDONESIA, 2023)

It will not be achievable without the support of a good healthcare system. Several factors influence it, one of which is looking at the aspect of Health Technology. To ensure that the law can be implemented properly, derivative regulations are created, namely draft government regulations, and there are 101 Delegated Government Regulations, one of which is related to Health Technology. One example related to Health Technology is various types of health research that undoubtedly require several research instruments, including research subjects, research tools and materials, research methods, and others. Research subjects consist of living and non-living creatures.(KOMISI ETIK PENELITIAN DAN PENGEMBANGAN KESEHATAN NASIONAL KEMENTERIAN KESEHATAN REPUBLIK INDONESIA, 2017). The abundance of research that uses humans as research subjects includes the Biomedical Genome Science Initiative (BGSi). It is the first national program initiated by Minister of Health *Budi G. Sadikin*, aimed at detecting the potential for future diseases and providing precision medicine for the public. This is achieved through the utilization of technology for collecting genetic information (genomes) from humans as well as pathogens such as viruses and bacteria, known as the whole genome sequencing method. (bgsi.kemkes.go.id, 2022). And there are many other things related to this; however, it is also related to what is happening now. There are numerous issues arising in connection with information technology and biotechnology, particularly problems concerning the updating of digital information technology and biotechnology in the healthcare sector. Consequently, there are emerging issues with the advancement of time. One example is the transfer of health data to companies or foreign countries, and there are problems related to other health technologies. With the above background, the author aims to understand and examine the existence of Law No. 17 of 2023, especially in Chapter X regarding health technology.

METHODS

This study adopts a normative juridical research methodology, which involves conducting legal research through a literature review by scrutinizing literature materials or secondary data. Specifically, the normative juridical aspect of the study focuses on evaluating regulations that address legal protection and ethical considerations for individuals serving as research subjects from a normative norm perspective. This process includes a thorough examination of Law number 17 of 2023 regarding Health, analyzing existing legal regulations, and theoretically assessing principles within the field of legal studies.

The methodology is grounded in primary legal sources, involving the analysis of theories, concepts, legal principles, and regulations pertinent to the research topic. It falls under the category of normative

juridical research as it scrutinizes legal provisions concerning the legal protection and ethical considerations for individuals serving as research subjects. The study relies on secondary data, sourced from literature books, legal regulations, official documents, research reports, academic writings, articles, and documents relevant to the research.

To collect data for this research, the author uses three types of legal materials: primary legal materials, which are authoritative and include legal regulations and official documents containing legal provisions. Other types of data are secondary and tertiary legal materials. The objective of this research is to understand legal protection and ethical considerations, examining the provisions of Law number 17 of 2023 regarding Health concerning humans as research subjects.

RESULT AND DISCUSSION

The advancement of technology and various innovations in the field of health demand experts in the health sector to enhance their skills. One form of development and improvement of knowledge and skills is through health research to discover technologies that can enhance well-being in the health sector.

Veronica Komalawati explains that (Komalawati, 2018), the relationship between humans, science, and technology is never-ending. Essentially, humans greatly need knowledge and technology. However, after technology has progressed rapidly and given birth to biotechnology, humans begin to question its consequences in the medical world, considering its impact on human values, both in terms of physical consequences and conflicts with the way of life and the environment.

Health research can be conducted using software and hardware simulation models, as stated in Law No. 17 of 2023, Article 1, which mentions, "Health Technology is organized, produced, distributed, developed, and evaluated through research, development, and testing for the improvement of Health Resources and Health Efforts." In Article 2, it states, "Health Technology as referred to in paragraph (1) includes both hardware and software."

Eka Rachmawati (Rachmawati, 2016) further explains that research can also involve biochemical studies or studies using living materials, such as cells and tissues, in a laboratory. This research then needs to be continued in an Integrated Living System using experimental animals. Before the research findings can be safely and effectively utilized for human health, studies with human volunteers as research subjects are necessary.

In Article 3, paragraph (2) of Law No. 39 of 1999 on Human Rights, it is stated that "Every person has the right to recognition, guarantees, protection, and fair legal treatment, as well as legal certainty and equal treatment before the law." In relation to that, according to *Luh Titi Handayani*, (Handayani, 2018) human rights within a research subject require the role of a doctor as a researcher to ensure the optimal enforcement of these human rights. The basic principles of ethics and law in the healthcare profession involve a contractual-professional relationship between the researcher and the research subject. Ethical and legal principles, especially in the relationship between researchers and research subjects in the healthcare field, must always be upheld based on the principles of health research ethics.

The relationship arising between a doctor as a researcher and a patient as a research subject is referred to as "*Inspanning Verbintenis,"* which translates to Effort Commitment. This signifies the doctor's utmost effort for the patient's healing, conducted with care and precision. The therapeutic agreement involves efforts or endeavors (*Inspanning Verbintenis*) to the maximum extent possible by the doctor in their attempt to heal the patient meticulously and carefully, based on appropriate scientific knowledge.

Essentially, *Inspanning Verbintenis* is recognized in the agreement between the doctor and the patient, (Alam, 2018) stating

that in the implementation of treatment, the doctor and the patient must adhere to the principle of trust (Fiduciary Relationship). However, *Inspanning Verbintenis* also applies in the legal relationship between the research subject and the researcher because in health research, the research subject is a patient undergoing treatment, and the researcher is a doctor administering the treatment. The conclusion drawn from this is that the legal relationship between the researcher and the research subject cannot be separated from the legal relationship between the doctor and the patient. (Rachmawati, 2016).

All potential outcomes must be communicated to the patient, prioritizing the fundamental principles of ethics. Furthermore, as described by *Muchtan Sujanto* (Sujanto, 2008), research involving humans as subjects should be based on the fundamental principles of research ethics, namely:

1. Respecting individuals (respect for person), which requires thorough consideration of the potential risks and abuse of research, as well as the need for protection of research subjects vulnerable to research risks;
2. Beneficence, to maximize benefits and minimize harm or risks to the subjects, and to minimize research errors. Ensuring non-harm to research subjects (nonmaleficence) by reducing risks to subjects and protecting them'
3. Justice, by treating subjects fairly.

The alignment of interests between patients and healthcare professionals is one of the supporting factors for the success of development in the health sector. Therefore, legal protection for both of these interests is equally important, with a special emphasis on patient safety.

In health research, researchers must explain the most significant risks that may arise from the research, and responsibility will be entrusted to the researcher. In all health research involving humans as research subjects, researchers must obtain consent after providing an explanation (Informed Consent). If the research subject is unable to give consent, approval must be obtained from someone legally authorized to represent them. The absence of Informed Consent is only justified in specific circumstances and is an exception that must be approved in advance by the Research Ethics Committee.(see DECISION OF THE CHIEF EXECUTIVE OFFICER OF THE CENTRAL GENERAL HOSPITAL Dr. HASAN SADIKIN BANDUNG NOMOR: HK.02.03/X.4.1.3/17501/2018., 2018)

Health research activities involving humans as legal subjects must have passed the Ethical Suitability Test conducted by the National Commission on Health Research Ethics (KNEPK) or, in an institution, by the formed and named Health Research Ethics Committee (KEPK). The existence of KEPK facilitates and, at the same time, selects the eligibility of health research, including Health Research involving humans as research subjects. (Sujanto, 2008). In its implementation, researchers must prioritize the interests and rights of patients. If we look at Law No. 17 of 2023 Chapter X on Health Technology Article 335 paragraph 1: "In Health Technology as referred to in Article 334, research can be conducted in laboratories, research utilizing experimental animals, plants, and stored biological materials, or research that involves humans as subjects."

If a serious unforeseen event occurs, the researcher is obligated to report it to the Research Installation, sponsor, and Contract Research Organization (CRO), the Quality Control Committee, and the Health Research Ethics Committee (KEPK) within 24 hours, followed immediately by a detailed written report. The responsible party is the researcher and/or the insurance used in a clinical trial. Research subjects who suffer unintentional injuries as a result of their participation are entitled to receive financial assistance or other compensation equivalent to disability or temporary/permanent incapacity. In the case of death, their dependents are entitled to receive material compensation. The right to compensation

may be waived. Compensation is provided to subjects who experience significant physical injuries from procedures conducted solely to achieve research objectives. Justice requires that every biomedical research subject automatically has the right to fair compensation for any injuries. Compensation is generally not provided to research subjects who suffer anticipated adverse reactions from research therapy or other procedures conducted for the diagnosis or prevention of disease. Such reactions are no different in nature from reactions that occur in medical practice. (Pusat Mata Nasional Rumah Sakit Mata Cicendo, 2018). Research involving human subjects, especially in healthcare services such as Educational Hospitals, must obtain approval from the Health Research Ethics Committee (KEPK). The KEPK will assess whether the research is considered safe and does not harm patients. If it is not detrimental to patients, the research will proceed; however, if it poses a risk to patients, the research will not be granted ethical approval by the KEPK. Policies created by educational hospitals to protect patient research subjects are guided by the National Guidelines for Health Research Ethics (PNEPK) and standard ethical research guidelines established by the research ethics committees of each educational hospital. The National Guidelines for Health Research Ethics (PNEPK), a primary publication of the National Commission on Health Research Ethics (KNEPK) in Indonesia, need periodic review to ensure their relevance to current developments. Given the advancing times and in line with technological advancements, many new methods are applied to ensure the safety of research.

CONCLUSION

From the analysis of the discussion in this research, Law Number 17 of 2023 Regarding Health does not explicitly regulate legal protection for humans as research subjects. This matter is specifically addressed in Chapter X on Health Technology, found in Articles 188, 335 (4), (5), (6). Based on the research findings, Law Number 17 of 2023 Regarding Health is founded on three general ethical principles: respecting the dignity of individuals (respect for person), which aims to respect autonomy and protect individuals whose autonomy is disturbed or lacking, doing good (beneficence) and not causing harm (nonmaleficence), and justice. Research involving humans must be conducted while considering the health and safety of the individuals. Research and development using humans as subjects must obtain informed consent. Before seeking the consent of research subjects, researchers must provide information about the purpose of the research and health development, the use of its results, confidentiality guarantees regarding identity and personal data, methods used, potential risks, and other relevant information. This process is carried out to ensure ethical considerations in research and health development, and it requires approval from the Health Research Ethics Committee (KEPK).

Law Number 17 of 2023 Regarding Health should explicitly regulate legal protection for humans as research subjects. Given that humans are legal subjects with rights and obligations that need to be protected by legal rules, when they become research objects, their rights can be protected, and the goals of the law can be achieved. This is a good starting point and should be further developed in the form of more in-depth ethical studies, allowing researchers to conduct research with proper ethics and adherence to applicable norms.

Declaration by Authors

Acknowledgement: None

Source of Funding: None

Conflict of Interest: The authors declare no conflict of interest.

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How to cite this article: Rachmah Ubat Harahap, T.Riza Zarzani N, Fauziah Nur, Iyo Iko Rasaki, Hasdiana Nisya Lubis. Analysis of legal protection and ethical study in health research with humans as research subjects reviewed from the republic of Indonesia law number 17 of 2023 concerning health. *International Journal of Research and Review*. 2024; 11(2): 172-177. DOI: *https://doi.org/10.52403/ijrr.20240219*

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