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# Legal Protection for Medical Research Doctors Concerning Human Research Subjects

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Legal Protection; Medical Researchers; Human Research Subjects; Research Ethics; Medical Research

**ABSTRACT**
Medical research or health research involving humans as research subjects has great potential in the development of medical science and technology. However, this research also poses risks to research subjects. Therefore, legal protection for medical researchers is very important. This research aims to analyze the legal basis and regulations applicable in Indonesia to protect medical researchers and humans as research subjects. The research method used is normative juridical with a statute approach and a conceptual approach. The results of the research show that Indonesia has several laws and regulations governing health research, but the material that specifically discusses the legal protection of medical researchers is not explicitly mentioned in the regulations. In the future, it is expected that medical researchers will receive balanced attention, so as to provide peace of mind for medical researchers to work, so that the development of science in the field of health and technology is more advanced and provides many benefits for the medical world.



## Introduction

Health services are efforts to maintain and improve health status based on applicable legal regulations (Wila Chandrawila Supriadi, 2001). Health is a human right and part of the welfare that must be realized in accordance with Pancasila and the 1945 Constitution. The right to health includes the right to health services and the right to self-determination (Komalawati, 2018).

The right to health care is a social right that the state must fulfill, including health protection (Kurnia, 2007). Every citizen has the right to quality health services (Jonathan et al., 2019). Scientific research in the health sector must pay attention to human rights because the subject of research is human. Human integrity and human rights must be maintained in research involving humans as subjects (Soeparto et al., 2006).

Research involving human subjects is ethically acceptable if it uses valid scientific methods. Invalid research may pose a risk of harm or reduce benefits to subjects. Research provides extrinsic

value, such as improving quality of life and saving lives, and intrinsic value in the form of new knowledge about natural phenomena (Ministry of Health). Researchers must understand scientific and ethical approaches and respect the willingness and rights of subjects, including the protection of their life, health, privacy and dignity. Experimental animals must also be treated in a civilized manner (Ministry of Health).

The principle of respecting research subjects includes recognition of dignity, free, prior and informed consent, confidentiality, equity in risk distribution, and the right to withdraw without penalty. Human rights inherent in individuals from birth cannot be violated, as stated in Article 3 of the Human Rights Law, which states that everyone is entitled to recognition, protection, and fair legal treatment. Articles 1 and 2 of the Universal Declaration of Human Rights (UDHR) state that all people are born free, have equal rights, and are entitled to freedom without discrimination (https://www.komnasham.go.id/files/1475231326-deklarasi-universal-hak-asasi-). Article 25 of the UDHR guarantees the right to health and welfare, including food, housing, health care, and protection in difficult situations.

Health science has succeeded in improving the quality and scope of health services so that the community is increasingly able to improve its health status and promote its welfare. The development of health science is spurred and directed by health research. Health research can be carried out using computer simulation models, biochemical research or research using living materials, such as cells and tissues in the laboratory which then need to be continued on an *integrated living* system using experimental animals. In order for research results to be utilized safely and effectively for human health, research is needed by involving human volunteers as research subjects (Rachmawati, 2016).

Humans need science and technology, but after technology developed very rapidly and biotechnology was born, humans began to question the effects of its use in the medical world, on human values, both in the form of physical effects and impacts on the way of life and the environment (Komalasari, 2018). Biotechnology intersects directly with humans both as actors and recipients of the consequences of biotechnology.

Humans who are research subjects must know the benefits and possibilities that can happen to them if they are willing to voluntarily become research subjects, as mentioned in Number 18 of the *Principles For All Medical Research The Declaration of Helsinki*:, (2024)

*Every medical research study involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and communities involved in the research in comparison with foreseeable benefits to them or to other individuals or communities affected by the condition under investigation.*

Research in the health sector is an inevitable necessity. Determining the optimal therapy or surgery for a patient requires an indispensable scientific foundation as well as experience from previous therapies in the same case. Humans as research subjects suffering from a disease are very important to do because the results of long-term research on animals often do not replace the results of experiments on humans. Then the discovery of certain diseases in animal experimental models

as well as the advantages of advancing medical science well with accountable risks encourage the need for medical research involving humans as subjects directly (Sujanto, 2008).

Medical research must obtain the consent of respondents / humans as research subjects (Handayani, 2018). Policies that need to be carried out in order to ensure the safety and welfare of humans as subjects of health research are required to obtain ethical *approval* before the research is carried out and the patient is given an explanation of all aspects of the research related to the subject's decision to participate or called informed consent (Gunawan et al., 2020).

Respect for the respondent is fundamental. If the respondent is a patient then informing the sick patient about their illness, treatment options, and possible prognosis of the illness is a behavioral translation of that respect. Patients should be involved in any decision-making that concerns them, as patients likely have a unique perspective on their illness and how it affects them. In this regard, patients are free to give due consideration to their situation and decide for themselves what is best for them, and patients should be allowed to express their wishes regarding possible diagnostic tests or therapeutic approaches proposed by the doctor.

*Respect for the patient is fundamental, and informing a sick patient about their disease, their treatment options, and their likely prognosis is the behavioral translation of that respect. The patients should be involved in the making of any decisions that concern them, because they have a unique perspective of their illness and how it affects them. In this regard, patients are free to give due consideration to their situation and decide for themselves what is best for them, and they must be allowed to express their wishes regarding possible diagnostic tests or therapeutic approaches proposed by the physician* (Rigaud et al., 2023).

Health research aims to obtain information and data in developing a series of scientific activities. Health research has different characteristics, but is interrelated and in a series of scientific frameworks in the health sector. Medical research or health research can be conducted either clinical or social activities will involve humans as subjects. A human subject in the research process is likely to experience discomfort and even be at risk from the impact of the research. The willingness and dignity of the subject must be respected. This obligation is called health research ethics. Research involving human subjects is ethically acceptable if it uses good and correct scientific methods. Research ethics require ethical guidelines and norms that follow the dynamic changes in society. A *scientific attitude* needs to be upheld by a researcher based on ethical principles and research norms (Pramudito & Widjaja, 2022).

Medical research involving humans has the potential to face several risks in the event of failure or results that are beyond expectations that will be achieved, causing anxiety and concern for doctors or other health workers. There must be legal rules and guidelines that serve as a basis for doctors as researchers and human subjects/respondents/patients so that the research process, sampling and review refer to fair rules, based on equality for both parties. For doctors themselves, it will provide hope for the development of science and carry out research more purposefully and get a sense of security (Ministry of Health).

Medical research or health research must pay attention to ethical aspects as described above, and must also pay attention to legal aspects because the subject of the research is human. This

health research can lead to legal disputes, both criminal and civil. Negligence is a form of error that arises because the perpetrator does not meet the standards of behavior that have been determined by law, and the negligence occurs due to the person's own behavior. Examples of negligence can occur in cases of health services, for example, due to a lack of knowledge, lack of experience, and or lack of caution by doctors (Wahyuni, 2017).

The crime of maltreatment can occur intentionally and sometimes by mistake. Intentional maltreatment indicates deliberate intent by the perpetrator with a hostile attitude. The crime of maltreatment is an arbitrary treatment in order to torture or oppress another person. Persecution that causes pain or injury to the body or limbs of another person is against the law (Wahyuni, 2022).

The legal relationship between doctors and patients, or, in this case, humans as research subjects, can include material about the legal relationship between doctors and patients. Civil law regulates the interests of individuals with each other in the order of social life (Hidayat, 2019). This is by the limits set in civil law, which regulates legal relationships between two people (Lira, 2023). The agreement between the patient and the doctor is a result of the consultation and treatment requested by the patient from the doctor. The patient-doctor relationship can be classified as an obligation to do or not do something (Lira, 2023). The main measure in the event of default or tort is carelessness in performing professional acts (Lira, 2023).

Bioethics in medical research with human subjects is something that must be taken into consideration. Ethical justification in scientific research involves humans as subjects by considering several scientific values and social values in producing knowledge and necessary means to protect and provide and improve welfare in the health sector (Luh Titi Hanadayani, 2020). The basic principles of ethics and law in the health profession with the existence of contractual and professional relationships between researchers and subjects. Ethical issues in research include *fabrication* (the act of engineering or manipulating data) , *falsification* ( addition, subtraction or alteration of existing data) , *plagiarism* (taking someone else's work and claiming it as his own) , *exploitation* (excessive use of people or research results), *injustice* (not treating everyone fairly and correctly, and giving their rights), *duplication* (republishing or reusing data or text from published works) . Activities in the research process must be guided by integrity, honesty and fairness. Ethical and legal principles, especially in the relationship between researchers and research subjects in the health sector, must always be upheld based on the ethical principles of health research (Luh Titi Hanadayani, 2020).

Research with human subjects should not be carried out if consent has not been obtained from the subject to be studied. Consent is obtained after the subject has been given adequate information and explanation. Therefore, this consent is called consent after explanation (PSP), which in international terminology is called informed consent (Istiadjid, 2024). Information on research subjects (patients and non-patients) is an absolute requirement for obtaining *informed consent* in the consent criteria. Information must be provided as fully as possible and no particular information should be withheld by the researcher. In the Declaration of *Helsinki*, the content of information to obtain *informed consent* should include: "*the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail*." In addition, it should also be

noted that the subject's consent can be withdrawn at any time, even if the research has not ended. Withdrawal or revocation of consent does not imply any risk to the research subject.

Based on the description above, it can be seen that there are many problems related to medical research or health research involving humans as subjects both in terms of law and ethics. This research aims to analyze the legal rules governing humans as research subjects. In addition, this research also aims to analyze the legal protection for doctors who conduct research involving humans as subjects of medical research . This research is expected to contribute ideas in the field of law, especially in the field of health, related to research conducted by doctors involving humans as research subjects. This research will discuss the applicable legal rules and legal liability for humans as research subjects, as well as legal protection for doctors who conduct such research. Practically, this research is expected to contribute to the development of critical thinking related to the application of rules and laws relating to the legal responsibility of doctors and the legal protection provided to them. This research aims to broaden the horizons of medical personnel, especially doctors, medical students, legal practitioners, as well as the general public, regarding the complexity of research issues involving medical personnel, which are very beneficial in the development of therapy and health improvement.

## Research Methods

This research uses a type of legal research with a normative juridical approach, which examines legal norms in legislation relevant to the research problem. The approach used is a statutory and conceptual approach, which examines related legislation and scientific views in finding legal concepts and principles to solve legal issues, especially regarding the authority of medical personnel and legal protection in medical research on humans.

The legal materials used include primary legal materials, such as the 1945 Constitution, laws and regulations, and judges' decisions; secondary legal materials, such as literature, articles, journals, and the Universal Declaration of Human Rights (UDHR); and tertiary legal materials, such as legal dictionaries and encyclopedias. The collection of legal materials was carried out through literature study and identification of legislation related to the research problem. Analysis of legal materials is carried out by inventorying, identifying, and systematizing all legal materials to draw relevant conclusions.

## Results and Discussion

### Legal Rules Related to Humans as Research Subjects.

### Laws and Regulations Governing Human Subjects of Medical Research

Human subjects in patient-related scientific health research or clinical research will develop better ways of diagnosing and treating humans, thereby alleviating or preventing suffering. While academic or non-clinical research aims to develop the scientific aspects of a study. Research physicians may be more concerned with the scientific aspects of a study than what the patient needs to get the best out of their disease therapy. But the integrity and human rights inherent in the patient

as a human being cannot be ignored. So it is very important that doctors pay attention to the juridical and ethical aspects of humans who are the subjects of their research (Soeparto et all, 2006).

To avoid any irregularities in research with human subjects, rules are needed that serve as guidelines for researchers and facilitate supervision by relevant parties. The first international forum held produced the Nuremberg *Code* in 1947. The code was developed in August 1947 in Nürnberg (Nuremberg) Germany by a panel of American judges during a trial involving 23 Nazi doctors accused of experimenting on humans in concentration camps during World War II which stated 10 points (Ken Stewart, 2024):

1. Voluntary consent of the human subject in the experimentation is absolutely essential.
2. The study's results should yield meaningful results that benefit society, are unprocurable by other methods or means of study, and are not random or unnecessary in scope and nature.
3. Any experimentation should be designed and based on the results of animal experimentation, considering the knowledge of the natural history of the issue under study that the results will justify the completion of the experimentation.
4. The methods used in the study should be conducted to avoid any unnecessary physical or mental suffering and injury to the subject or subjects taking part in the study.
5. No experimentation should be conducted where there is a prior reason to believe that disabling injury or death will occur, except if the experimental scientists conducting the study also serve as subjects in the study.
6. The degree of risk the study subjects undertake should never exceed the risk determined by the humanitarian importance of the issue under study.
7. All proper preparations should be made, and proper facilities provided to protect the subject or subjects of the study against any possibility of injury, disability, or death.
8. All experiments should be conducted by persons qualified to do so. Through all stages of the experiment, all possible efforts should be taken to ensure the highest degree of skill and care are maintained.
9. At any point during the experiment, every human subject should be allowed to bring the experimentation to an end should the subject deem that they have reached the point where continuation of the experiment appears to the subject to no longer be possible.
10. As the experiment progresses, the scientist in charge must be in a state of mind that, should they deem that the continuation of the experiment could result in injury, disability, or death to the subject, the experiment will be terminated.

The Nuremberg Code emphasizes that the voluntary consent of human research subjects is absolute, experiments must benefit society, and must not cause injury or death. Research must avoid physical or mental suffering and be conducted by qualified persons. Research subjects can stop the experiment at any time without consequence, and scientists are obliged to stop the experiment if it risks harming the subject.

The Declaration of Helsinki I (1964) and Declaration of Helsinki II (1975) stipulate that human research must have an ethical protocol and obtain ethical approval before publication. In Indonesia, the right to health is guaranteed in the 1945 Constitution, Article 28 H and Article 34,

which requires the state to provide health services. Health research is also regulated in Law No. 39/1999 on Human Rights, which emphasizes that research subjects must give consent and are entitled to protection of physical and spiritual integrity.

Some of the laws and regulations related to medical research include:

1) Constitution of the Republic of Indonesia 1945
2) Criminal Code
3) Civil Code
4) Law Number 39 of 1999 on Human Rights
5) Law Number 11 of 2019 on the National System of Science and Technology
6) Law No. 17 of 2023 Concerning Health
7) Government Regulation Number 28 of 2024 Concerning the Implementation of Law Number 17 of 2023 Concerning Health
8) Minister of Health Regulation Number 75 of 2020 concerning the National Health Research and Development Ethics Committee
9) Decree of the Minister of Health No. 1333 of 2002 on Approval of Human Health Research

**Human as Subject of Medical Research given Human Rights**

Human rights are inherent to every individual as a creature of God, including the fulfillment of basic needs such as education, shelter, food, clothing, and health. Indonesia, which has ratified the UDHR, has laws to protect human rights, including rules related to research that ensure it does not violate the law and ethics. All of these rules must be followed, with oversight from health authorities.

The Right to Health is part of human rights, covering physical, mental, and social health, which enables productive life. Health is the basis for recognizing human dignity and one of the determinants of the quality of human resources. Recognition of human rights in the health sector is regulated in various international and national instruments. The guarantee of human rights recognition in the health sector can be seen explicitly from several instruments, namely:

1. International Instruments
   a. *Universal Declaration of Human Rights (UDHR)*/DUHAM. *The Universal Declaration of* Human *Rights* is a declaration adopted by the UN General Assembly on December 10, 1948, at the Palais de Chaillot, Paris, France, through *General Assembly Resolution* 217 A (III) *(https://www.komnasham.go.id/files/1475231326-deklarasi-universal-hak-asasi--$R48R63.pdfUDHR*). The Universal *Declaration of* Human Rights () is an international standard governing the protection of human rights. It inspired international treaties, regional human rights instruments, and state constitutions and laws. All 30 articles in the UDHR serve as a reference in protecting human rights, including the rights of medical research subjects. Important articles such as Article 1, which guarantees equal dignity and rights for everyone, Article 2, which guarantees rights and freedoms; Article 3, which recognizes the right to life and safety, Article 5, which prohibits torture, and

Article 25, which guarantees the right to health and welfare, can be used as references in medical research.

b. *The Council for International Organizations of Medical Sciences (CIOMS*) is an international nongovernmental organization of 40 international, national, and association member groups representing the biomedical sciences community (https://cioms.ch/publication). The organization was founded in 1949 by the WHO and UNESCO as a successor to the International Medical Congress which held 17 conferences between 1867 and 1913. Its main goal is to advance public health by publishing guidelines on ethics, product development, and safety in medical research, such as the 2016 International Ethical Guidelines. The CIOMS Council focuses on guiding member organizations and organizes annual conferences related to health research involving human subjects.

c. International *Covenant on Civil and Political Rights (ICCPR) (https://www.ohchr.org/en/instruments-mechanisms/instruments/international-covenant-civil-and-political-rights,)*. Article 6 Paragraph (1) states that every human being is entitled to the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his right to life. Article 7 further states that no one shall be subjected to torture or other cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected to medical or scientific experimentation without his or her freely given consent. The ICCPR is a multilateral treaty adopted by the UN General Assembly on December 16, 1966. Its purpose is to affirm the basic civil and political human rights enshrined in the UDHR.

d. International *Covenant on Economic, Social and Cultural Rights (ICESCR*) (https://treaties.un.org/doc/Publication/UNTS/Volume%20660/volume-660-I-9464-English.pdf). Adopted by General Assembly Resolution 2200 A (XXI) of December 16, 1966, and open for signature, ratification, and accession. Article 12 provides that the States Parties to the Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health; the States Parties to the Covenant undertake to make: (a) Provisions for the reduction of the rate of stillbirths and child mortality and the healthy development of children, (b) Improvement of all aspects of environmental and industrial health, (c) Prevention, treatment and control of all communicable, endemic and other occupational diseases, (d) Creation of conditions which will ensure all medical services and attention in the event of illness of any person (https://protc.id/wp-content/uploads/2021/05/KOVENAN-INTERNASIONAL-HAK-HAK-EKONOMI-SOSIAL-DAN-BUDAYA.pdf).

e. *Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (Torture Convention, or CAT)*/ Convention against Torture *(https://www.ohchr.org/en/instruments-mechanisms/instruments/convention-against-torture-and-other-cruel-inhuman-or-degrading, )*.Indonesia itself ratified this convention through Law No. 5 of 1998 on September 28, 1998 *(https://bphn.go.id/data/documents/98uu005.pdf, ).* Article 1 of the

Convention against Torture puts forward an internationally agreed definition of acts that constitute torture.

f. *The United Nations Educational, Scientific and Cultural Organization (UNESCO) adopted The Universal Declaration on Bioethics and Human Rights (UDBHR),* or the UNESCO Universal Declaration on Bioethics and Human Rights (Langlois, 2024).

2. National Instruments

a. The 1945 Constitution regulates human rights in articles 28A to 28J, including the rights to life, health, protection and welfare. These articles guarantee every individual's right to life, freedom from torture, health care, and protection from discrimination and degrading treatment. The state is responsible for providing adequate health care facilities for citizens (Article 34).
b. Human Rights Law No. 39/1999 recognizes the inherent human rights of every individual, including the right to life, freedom from torture, and the right to a healthy environment (Articles 2, 4, 9). The law also mandates the establishment of Komnas HAM to enhance the protection of human rights.
c. Health Law No. 17 of 2023 and Government Regulation No. 28 of 2024 regulate the rights of medical research subjects, including ensuring the health and safety of subjects, obtaining informed consent, providing clear information, and complying with research ethics (Articles 335 and 998).

**Legal Protection of Doctors in Medical Research with Human Subjects**

**Potential Risks Related to Humans as Subjects of Medical Research**

Science and technology in the health sector continue to develop, supported by the results of health research. This includes health research or medical research involving humans as research subjects. The development of health research and its results are very useful and indispensable for welfare in the field of health for humans themselves.

Health research that involves humans certainly contains risks and constraints in its implementation. Health research on humans as research subjects must obtain ethical *approval* from the ethics commission under the institution conducting the health research. The approach to understanding the rights of research subjects must be done through an ethical approach as well as a legal approach. Ethical norms as guidelines do not have a compelling and binding force. Meanwhile, legal norms have a compelling and binding force. Legal norms in health or medical research apply nationally and internationally (https://siplawfirm.id/subjek-penelitian-kesehatan/?lang=id). Positive law protects research subjects and takes action against violators of subject rights, regulated in legislation such as the 1945 Constitution, the Health Law, and Government Regulation No. 28 of 2024.

Research involving humans as research subjects must be carried out with due regard to the health and safety of those concerned, must obtain *informed consent* and researchers must provide information about the purpose of research and health development and the use of the results, guarantee confidentiality about identity and personal data, methods used, risks that may arise, and other things that need to be known by those concerned in the context of health research and development.

Research must consider the health and safety of subjects, obtain informed consent, and provide clear information about the purpose, risks, and use of research results. Human participation in health research has ethical, legal, and social implications, so mechanisms that protect subjects' life, health, and dignity are very important (Mappaware, 2019). Research subjects are at risk of physical, psychological, and social discomfort or harm, so anticipation of these risks must be done to minimize losses (https://komite-etik.univawalbros.ac.id/).

Human subjects in health research may be subject to risks, such as:

1. Exploitation in health research occurs when subjects are regarded as mere tools for profit without responsibility, often to the detriment of others (Qotrun, 2024). These actions can harm humans, animals, and the environment. According to KBBI, exploitation is the overuse for personal gain, such as the extortion of the labor of others. To prevent exploitation, researchers must realize that medical research reflects a moral obligation to ensure public and individual health, fair resource distribution, protect individual rights, and respect ecology. A research code of conduct effectively creates moral awareness in health research.
2. Vulnerability is the inability to protect one's interests, difficulty giving consent, or lack of ability to choose services, often occurring in young individuals or those in low positions in groups (Handayani, 2018). Vulnerability can be physical, social, economic or environmental, affecting a person's ability to cope with harm (https://bencanapedia.id/Kerentanan). In a medical context, vulnerability occurs when a subject cannot distinguish medical research from usual treatment (Qotrun, 2024). In the economic and social spheres, vulnerability can occur when subjects are disadvantaged in the distribution of goods and services or are in social groups that are considered low.
3. Displeasure and discomfort. Research subjects must be fully protected from displeasure and discomfort. Discomfort and inconvenience during research may include unwanted exposure to pornography, smoking, or suicide, as well as the possibility of experimental research procedures causing pain, bruising, or swelling.
4. Threats to their health and life. The researcher should maintain the subject's physical and emotional safety and ensure that the subject understands the purpose of the research and the risks as much as possible. If the research cannot result in anything beneficial to the health of the research subject, then it should not be conducted so as not to harm the research subject. The principle of not harming aims to prevent research subjects from being treated as a means of trial and to provide protection against abuse (Handayani, 2018).

To prevent risks to health research subjects, researchers must pay attention to several things, namely:

1. The researcher must obtain consent from the research subject after providing information and explanation (informed consent).
2. Do not force research subjects to become respondents, even to close friends
3. Respect the autonomy rights of research subjects
4. Treat research subjects with kindness and dignity
5. Seeking maximum benefit and trying to reduce harm to the research subject as much as possible.

Ethical issues in research that relate to the risk of research subjects include:

1. No informed consent/lack of information especially on the risks that may occur before, during, and after the study.
2. Coercion or intimidation of volunteers

3. Using and exploiting vulnerable populations, such as pregnant women, children, or prisoners
4. Not providing adequate treatment
5. Harm to the subject such as aggravation of illness or threat of death
6. The risks to the subject exceed the benefits, the risks faced by the subject in the study exceed the benefits for both the subject and the researcher.
7. Deception e.g. to gain sympathy or raise funds
8. Violation of the subject's rights, because it does not use research methods that have been compiled by the Ethics Committee for Health Research (KEPK) and does not heed applicable legal rules.

**Legal Responsibility of Doctors Regarding Humans as Subjects of Medical Research**

The legal responsibility of research doctors is related to the fulfillment of legal provisions in conducting research. In general, research doctors must comply with research ethics, the rule of law, ensure the research is fair and safe for subjects, and pay attention to the health and safety of subjects. The legal responsibilities of research doctors are divided into three areas: civil, criminal, and administrative.

1. Civil liability

Civil law in the legal responsibility of research doctors with humans as research subjects According to civil law, the basis of liability is divided into two types, namely fault and risk. Thus, *liability based on fault* and liability without fault are known as risk liability or *strict liability* (Triwulan & Febrian, 2010). What is meant in a medical research action liability is the element of compensation if in a medical action there is a negligence or error committed. Researchers can be held liable because of an agreement.

Agreement is a legal relationship between one subject and another subject in the field of property, where one legal subject is entitled to an achievement and likewise the other legal subject is obliged to carry out its performance in accordance with what has been agreed upon. An agreement is an agreement between two or more parties, which is made in writing and is legally binding. The form of agreement between researchers and humans as research subjects used in medical research is a written agreement. A written agreement is an agreement between two or more parties, which is made in writing and is legally binding.

In carrying out health services, patients have rights that must be given by doctors and hospitals. Patient rights are contained in Article 276 of the Health Law, namely obtaining information about their health, an explanation of the health services they receive, health services in accordance with medical needs, services according to professional standards, with quality services. Then the patient can refuse or agree to medical action, except in an emergency, can get access to information contained in medical records, is entitled to get a *second opinion* or the opinion of medical personnel or other health personnel and get other rights in accordance with the provisions of laws and regulations (Tsaabitah & Siregar, 2024).

Civil lawsuits against research doctors in medical research can be caused by losses experienced by the subject of medical research. Medical research conducted by doctors can result in two possibilities, namely as expected and not as expected. Non-conformity of expectations can be caused by two things, namely caused by *overmacht* (force majeure) and can be caused by the research doctor not conducting research in accordance with medical research standards or can be said to be due to negligence.

The legal relationship between research doctors and human research subjects from a civil point of view is in a legal engagement. A legal engagement is a bond between two or more legal

subjects to do or not do something or give something (1313 jo 1234 BW). That something is called an achievement. To fulfill an achievement is basically a legal obligation for the parties who make a legal engagement (in a reciprocal legal engagement). For the doctor, the achievement of doing something is a legal obligation to do as well as possible and maximally (medical treatment) for the benefit of the success of the research, and a legal obligation not to do wrong or wrong in the treatment of medical research, in the sense of the obligation to carry out medical research procedures / health research as well as possible. Violation of agreed achievements can lead to default as stated in Article 1371 Paragraph (1) of the Civil Code that the cause of injury or disability of a member of the body intentionally or due to lack of care gives the victim the right to, in addition to compensation for healing costs. Demand reimbursement of losses caused by the injury or disability. This means that the responsibility of the research doctor only occurs if the subject of the research sues to pay compensation on the basis of the harmful act.

*Strict* liability or absolute responsibility is a principle in civil law that states that a person must be responsible for the losses incurred, without having to prove the existence of fault (*liability without fault*). In this principle, the defendant must prove the causal relationship between his actions and the loss suffered by the plaintiff. In civil law, *strict liability* is related to Article 1365 of the Civil Code which states that liability is based on unlawful acts.

In health research, research doctors can be called in violation if there is a loss suffered by the research subject and it is not in accordance with the agreed agreement. The element of fault does not need to be imposed on the plaintiff/human research subject as a basis for requesting payment of compensation. Therefore, the burden of proof is placed on the defendant/research doctor to prove the causal relationship between the act and the damage and/or loss suffered by the plaintiff/research subject. The defendant/research doctor is the party that must prove the existence of a causal relationship between the actions of the research doctor and the losses suffered by the plaintiff/research subject.

The principle of *liability based on fault* is the principle of responsibility that requires an element of fault. The principle of *liability based on fault* is regulated in Articles 1365, 1366, and 1367. Article 1365, commonly known as the article on tort, requires the fulfillment of four main elements, namely: the existence of an act, the existence of an element of fault, the existence of a loss suffered, and the existence of a causal relationship between the fault and the loss. Research doctors conducting their research must understand these articles of the Civil Code in order to avoid mistakes in conducting their research activities on humans, because if it is proven that there are elements of violation of the law, there can be legal action from the subject of their research.

2. Criminal law liability

Responsibility in criminal law determines whether a suspect or defendant is responsible for a criminal offense. The criminal act of researchers in health research is an act of research doctors that can be threatened with criminal sanctions in accordance with the law in the health sector. Criminal acts are acts that are against the law and harm other people/society.

The criminal liability of research doctors is related to criminal offenses committed during medical research. Negligence in research that results in harm or death can be subject to criminal sanctions according to the Health Law, such as in Article 440, which mentions imprisonment of up to 5 years or a fine of up to Rp500 million if it causes death. Article 310 of the Health Law also states that disputes related to medical errors must be settled out of court first.

In the Criminal Code, Articles 359 and 361 regulate the mistakes or negligence of doctors that cause death, with a penalty of up to 5 years. Negligence in criminal law refers to negligence or inadvertence that results in adverse consequences, such as death or serious injury (Article 474

Paragraph 3 of Law 1/2023). This crime can occur if the research doctor does not follow established procedures or makes mistakes that violate the law or the research code of ethics (Widowati, 2023; (Wahyuni, 2017).

The relationship between criminal acts and fault is expressed by the relationship between the unlawfulness of the act (*strafbaar feit*). In explaining the meaning of fault, the ability to be responsible is briefly explained as the state of mind of a normal, healthy person. In a research doctor who conducts research, it may be that what he does in his research efforts is wrong or does it outside the procedures determined by the laws and regulations or the rules of the research committee, the researcher's actions qualify as an offense or criminal offense that can be prosecuted.

3. Administrative law liability

Administration in health research is the management and management of resources covering various aspects, such as planning, organizing, supervising, and evaluating activities related to health research. The legal responsibilities of administration in medical research are related to the policies and provisions that must be met to conduct quality health research. Administrative law regulates the responsibilities and sanctions for administrative parties who violate the law. Sanctions may include compensation or license revocation.

Articles 1009 to 1011 of PP 28 of 2024 concerning the rules for implementing the Health Law state that research that includes humans as subjects is regulated in administrative provisions, namely: 1) carried out in the form of clinical trials, 2) clinical trials are carried out by clinical trial organizers, 3) clinical trials must be carried out at Health Service Facilities or other facilities under the supervision of Health Service Facilities, 4) clinical trials must comply with good clinical trial methods in accordance with the provisions of laws and regulations, 5) in the implementation of clinical trials can use materials, information content, and / or data, 6) The use of materials, information content, and / or data in clinical trials is regulated in a clinical trial agreement, 7) if there are remaining materials, information content, and / or data in the implementation of clinical trials, 8) the remaining material, information content, and/or data can be used for health development purposes or other purposes determined by the Minister, 9) the use of the remaining material, information content, and/or development data is carried out in accordance with the provisions of laws and regulations, 10) clinical trial organizers are required to carry out clinical trial registration, and clinical trial registration is organized by the Minister, 11) clinical trial registration is integrated with the National Health Information System, 12) the provisions for registration of clinical trial organizers are regulated by Ministerial Regulation.

The rules for conducting health research in Articles 1009 to 1011 above are further detailed in Articles 1023 to 1033 of Government Regulation 28 Year 2024. This is followed by Articles 1034 to 1035 on administrative sanctions in the form of administrative fines to license revocation if the rules that have been set are violated by researchers and research organizers. This is the administrative legal responsibility of researchers and research organizers. Article 1036 and Article 1037 state that the Central Government and Regional Governments provide facilities and support research conducted by researchers and research organizers through ease of licensing, resource support and downstream and integrate the process of recording and reporting the research process and its results in the National Health Information System.

**Legal Protection of Research Doctors on Humans.**

As a legal subject, doctors have legal responsibility for every action they take. If his actions cause harm to the patient, the doctor cannot argue that the action is not his responsibility. Likewise,

as a research doctor in humans, doctors also have legal responsibilities such as doctors who provide health services or carry out therapy to patients.

The actions of the research doctor can be considered a criminal offense if it can be proven that the doctor had malicious intent. However, if the evil act is not based on intent, it may not be considered a criminal offense. As a result of these actions, the responsibility is individual. A research doctor can obtain legal protection if the doctor carries out his duties in accordance with professional standards and standard operating procedures as well as because of the two bases for the elimination of doctor's guilt, namely justification and excuse reasons stipulated in the Criminal Code. A research doctor must take into account safe measures for himself so that he is not easily blamed or sued by the subject of his research or his family if something happens outside of what is expected.

Researchers face various risks in conducting research on human subjects. These risk factors can stem from a number of things including:

(1) Political environment. The political environment is very decisive for research doctors to take steps in conducting research. This is because researchers have to adjust to the policies set by their government. This will sometimes put pressure on researchers and research institutions because they cannot freely carry out research efforts that may be very necessary. For example, there are no regulations on medical research in cases of diseases that occur in the community because of ethical issues, such as HIV AIDS in pregnant women, or sexually transmitted diseases in patients who are in prison, and so on.

(2) Institutional and work environment. Institutional policies, such as power imbalances received by staff and research leaders. Dedicated research teams often feel the pressure of research timelines, possibly taking risks to meet recruitment goals. Staff or researchers may fear disappointing research managers and fear losing their jobs. This power imbalance may also risk the process of conducting research being less than optimal and researchers feeling under pressure.

(3) Community support networks. Frontline researchers often have to spend a lot of time getting to know participants and their families, and reporting on complex health issues, even far beyond the focus of the research.

(4) The cultural environment of the research subject. A researcher must pay attention to the culture of the community on the research subject. The ethics and customs of the community must be maintained and respected by the researcher. The norms that apply in the community where the research takes place must also be considered.

(5) Related to the issue of researcher liability towards humans as research subjects. Medical research or health research on human subjects is protected by law both civilly, criminally and administratively. The Health Law and Government Regulation 28 Year 2024 have also been explained in the previous discussion. Research on human subjects must fulfill research ethics and not violate laws, both the Human Rights Law, the Health Law and the Guidelines for Research Ethics, the Criminal Code and the Civil Code. A researcher must understand the applicable laws and regulations.

So there are many signs that must be considered by researchers and research institutions. This raises the view that researchers really need legal protection. The legal protection obtained by doctors is preventive and repressive. Research doctors can obtain legal protection if they meet the requirements, namely having a Registration Certificate (STR), a License to Practice (SIP), conducting medical research according to standards, there is *informed consent* for each action and

all must be well documented in medical records, as explained in the discussion in Chapter II. This includes preventive legal protection.

Article 28D paragraph (1) of the 1945 Constitution states that every person has the right to obtain a fair recognition, guarantee, protection, and legal certainty as well as equal treatment before the law. Article 5, paragraph (1) of Human Rights Law No. 39 of 1999 also states that every person is recognized as a private human being who has the right to demand and obtain equal treatment and protection in accordance with his human dignity before the law.

Article 304 Paragraph (1) of the Health Law states that to support the professionalism of medical personnel and health workers, it is necessary to enforce professional discipline. Then Article 308 Paragraph (1) states that if medical personnel or health workers are suspected of committing unlawful acts in health services, they can be subject to criminal sanctions but must first request a recommendation from the assembly in charge of enforcing professional discipline.

Article 334 of the Health Law and Article 997 of Government Regulation 28 of 2024 concerning implementing regulations for the Health Law provide protection for doctors who conduct research and development in the health sector, namely in the form of monitoring and evaluation and licensing. Meanwhile, Article 1015 Paragraph (2) of PP 28 of 2024 states that the implementation of research can be carried out by the Central Government, Regional Governments, and / or the community. While Articles 337-338 of the Health Law Article 1016 of PP 28 of 2024 states that the Central Government organizes policies to ensure the sustainability and usefulness of the technology obtained from health research and the government provides ease of innovation whose provisions will be regulated by Ministerial Regulation.

Article 1036 of PP No.28 of 2024 more clearly states that the Central Government and Regional Governments provide ease of licensing, resource support, and downstreaming of health technology research, development, and assessment in accordance with the provisions of laws and regulations.

Article 310 of the Health Law states that in the event of a dispute between a medical or health worker and a patient, the settlement is first made through out-of-court efforts. This rule can also be applied to research doctors who conduct medical research with human subjects. The court process is suspended, and *restorative justice* or out-of-court mediation is carried out first.

Repressive legal protection is a form of legal protection that leads to dispute resolution. Repressive legal protection provided by the government involves applying disputes through the general court in the event of default or unlawful acts or violations of criminal and administrative law in the process of health research by research doctors on humans.

There are no explicit rules stating the legal protection for research doctors who conduct health research on humans. The clause used and applied is the general rule of law applicable to doctors or health workers in general in providing health services. Regulations that the mandate of the Health Law will issue and PP 28 of 2024 do not exist to date.

To ensure the protection of the rights of research doctors in health research and health research organizers with good governance, every research doctor and facility or institution conducting medical research or health research are obliged to implement and maintain health research quality standards as a reference in conducting research that involves. Then, compile standards and implement regulations internally:

1. Provide knowledge to humans as research subjects about their rights and obligations as well as the rights and obligations of the research doctor himself. In the implementation of health research, there may be conflicts between doctors conducting research and research subjects that cannot be resolved by ethical rules; if this happens, then the rule of law can be applied.

Therefore, the rights and obligations of each party involved must be equally understood and observed. This is because resolving problems related to rights and authorities is proportional to the obligations and responsibilities of each party that have been agreed upon. So it is very important for the parties involved to know their respective rights and obligations, and to know the rights and obligations of other parties, both for doctors and humans as research subjects. Research institutions or organizers must also understand their respective rights and obligations, both the rights and obligations of researchers, subjects and research organizers themselves.

2. Implement the SOP (*Standard Operational Procedure*) for medical research. Article 291 paragraph (1) of the Health Law states that every medical and health worker in conducting health research is obliged to comply with professional standards, service standards, and standard operating procedures. This article can also be used as a reference in health research. Standard Operating Procedures, or hereinafter abbreviated as SPO, are guidelines or references for carrying out job duties in accordance with their functions based on technical, administrative, and procedural indicators in accordance with health research work procedures to create a responsible commitment for researchers. SPOs are used to measure whether research has been conducted according to research ethical guidelines and in accordance with applicable laws to protect research subjects and researchers themselves. The implementation of SPOs is an effort to maintain the safety of subjects and avoid prosecution in the future. In addition, SPOs can be used to assess the performance of the organization or institution conducting the research for its positive response, responsibility, and accountability.
3. *Informed consent* for research subjects and families. Article 293 Paragraph (1) of the Health Law states that every health service action must obtain consent. Then Paragraph (2) states that consent will be given after the patient receives an adequate explanation. In medical or health research, *informed consent* must also be obtained to minimize risks for both subjects and researchers. *Prospective respondents give informed consent* after receiving complete and clear information and understanding the purpose, process, and risks that may occur. As stated in Article 335 Paragraph (4) of the Health Law and Article 1001 of Government Regulation 28 Year 2024 health research must obtain permission from the research subject.

## Conclusion

The rules of law relating to medical research include the 1945 Constitution of the Republic of Indonesia, the Criminal Code, the Civil Code, Law Number 39 of 1999 concerning Human Rights, Law Number 11 of 2019 concerning the National System of Science and Technology, Law Number 17 of 2023 concerning Health, Government Regulation Number 28 of 2024 concerning Regulations for the Implementation of Law Number 17 of 2023 concerning Health, Minister of Health Regulation Number 75 of 2020 concerning the National Health Research and Development Ethics Committee, Minister of Health Decree Number 1333 of 2002 concerning Approval of Human Health Research. In these laws and regulations, it has been clearly stated about humans as subjects of medical research and about human rights as subjects of medical research. That humans as subjects of medical research are guaranteed in the Law and in the rules of human rights.

The legal protection of research doctors who examine humans has not been explicitly mentioned in the legislation. However, the legal protection of research doctors can be taken implicitly from the Human Rights Law on the protection of rights in Article 28D Paragraph (1) of

the 1945 Constitution which states about recognition, guarantees, as well as protection, and fair legal certainty and equal treatment before the law for everyone and Article 5 paragraph (1) of Human Rights Law No. 39 of 1999 concerning equal protection in accordance with the dignity of humanity before the law. Health Law No.17 of 2023 and Government Regulation No.28 of 2024 on the implementing regulations of the Health Law do not clearly mention legal protection for medical researchers. Likewise, regulations on research ethics discuss the legal protection of humans as research subjects more. What can be done for the legal protection of medical research doctors is to: 1) provide knowledge to humans as research subjects about their rights and obligations as well as the rights and obligations of research doctors themselves, 2) implement SOP (*Standard Operational Procedure*) for medical research, 3) *Informed Consent.*

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