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PROTECTION OF GENETIC DATA IN HEALTH SERVICES BASED ON GENOMICS TECHNOLOGY IN INDONESIA

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Abstract

Indonesia is developing precision medicine by integrating genomic capacity into health services. Currently, there is no comprehensive regulation governing these services, resulting in legal uncertainty regarding the regulation of personal data protection (genetic data) based on Indonesian statutory provisions. The purpose of this research is to immediately form implementing regulations to regulate in detail Personal Data Protection in genomics-based health services in Indonesia. The research method used is normative juridical (Legal Research) which is descriptive analytical in nature using a statutory approach and using secondary data types. The results of this study explain that broadly speaking, genetic data generated from genomics-based technology is one of the data that should be protected by the State with provisions, rights and obligations and sanctions that should be obeyed by all interested parties. The establishment of an independent Data Controller is needed in an effort to implement personal data protection. The conclusion obtained by the author is that the PDP Law has not been implemented clearly and completely so that it requires derivative regulations that ensure the implementation of the protection of personal data of the community.

Keywords: Genomics, Personal Data Protection, Health

INTRODUCTION

Human beings have inherent rights that are obtained not from the gift of others or the state. One of them is the right to health services obtained since humans are still in the womb. This right is part of human rights known as human rights (Marif et al., 2021). The concept of the welfare state as a modern state concept gives greater power to the government to promote and achieve respect for human rights. The government no longer simply guarantees that a person's rights are not harmed or violated, but must strive to uphold those rights. Similarly, with the right to health, governments have an obligation to fulfil and respect that right (Perwira, 2014).

Along with the development of technology that occurs at this time, the human mindset is also developing. Technology develops in many aspects, including the health aspect (Azzuri & Prasetyo, 2021). Precision medicine and genomics are the latest revolutionary healthcare technologies that have brought about profound changes in the treatment of diseases. In precision medicine, treatment is based on the patient's individual characteristics, including genetics, environment, and lifestyle, so

therapy can be tailored to achieve optimal results. One of the key technologies underpinning precision medicine is genomics, which involves analyzing a patient's genome to understand how genetic differences affect response to treatment. This allows doctors to prescribe more effective treatment and minimize side effects. Currently, genomic treatment has been carried out sporadically in Indonesia (Ariani et al., 2017).

The Biomedical and Genome Science Initiative (BGSi) is Indonesia's first nationally integrated biomedical initiative established to bring Indonesia into the era of precision medicine by integrating genomic capacity into healthcare. Launched by the Ministry of Health of the Republic of Indonesia on August 14, 2022 (Indonesia, 2017). This program is designed to develop more accurate treatments for the community through the use of technology in collecting genetic information (genome) from humans called whole genome sequencing (WGS).

Indonesia does not yet have a comprehensive legal framework on genomics, apart from the Decree of the Minister of Health of the Republic of Indonesia Number Hk.01.07/Menkes/1141/2022 concerning the Implementation of the Biomedical Genome-Based Science Initiative for Precision Medicines and the Development of Genomics-Based Health Services for Certain Diseases. The regulation stipulates that BGSi carries out registry activities for patients with certain diseases, regulates specimen storage (biobanking), organizes the management of human Whole Genome Sequencing (hWGS) examinations in Indonesia, and organizes the development of precision medicine (Indonesia, 2017).. The regulation also regulates biobanking operations, which are essential for storing biological samples used in genomic research.

Legal issues that arise are regarding the protection of personal data in genomic-based health services. Personal data protection is mandated by Article 28G paragraph (1) of the Constitution of the Republic of Indonesia Year 1945 which states that: "everyone has the right to protection of himself, family, honor, dignity, and property under his control, and has the right to a sense of security and protection from threats of fear to do or not do something that is a human right".

Based on the background as described above, the problem that needs to get an answer in this study is that there is legal uncertainty regarding personal data protection arrangements in this case genetic data based on the provisions of Indonesian legislation.

In this study, the author uses several theoretical foundations to answer the problem, namely: Legal Protection Theory, according to Satjipto Rahardjo defines legal protection as an effort to protect one's interests by allocating a human right power to him to act in the framework of these interests (Rahardjo, 2003).

It can be concluded that protection in general means protecting something from something harmful or more negative, which can be in the form of benefits, objects, or property. In addition, protection also means one's protection against someone who is weaker. Thus, legal protection means that the government seeks to create legal certainty to protect citizens so that their rights are not violated and violators are punished according to applicable regulations.

RESEARCH METHODS

The type of research used is normative juridical (*Legal Research*) which is descriptive analytical using a statutory approach (statute approach*)* that prioritizes legal materials in the form of laws and regulations as basic reference material in conducting research (Schotel, 2013). The data used in normative research is a type of secondary data, consisting of 3 (three) sources of legal materials:

Source of Primary Legal Material, which is legal material consisting of hierarchical laws and regulations and court decisions. In this study, it consists of:

1. Law Number 27 of 2022 concerning Personal Data Protection (PDP Law)
2. Law Number 17 of 2023 concerning Health (Law 17/2023)
3. Law Number 19 of 2016 concerning Electronic Information and Transactions (ITE Law)
4. Sources of Secondary Legal Materials, namely legal materials consisting of textbooks, legal journals, expert opinions, research results, and others legal materials outside of primary legal materials, related to the issue being studied, namely about personal data protection related to genomic-based health services in Indonesia.

Tertiary Law sources, namely data that includes dictionaries, encyclopedias, the internet and mass media related to writing topics that can be used as information for this study.

RESULTS AND DISCUSSION

Genomics-Based Health Services in Indonesia according to Law Number 17 of 2023 concerning Health

Genomics is the branch of biology that studies the genome of an organism or virus. Genomics can be said to be a branch of genetics when viewed historically, although in genomics many methods derived from other branches of biology are used, such as bioinformatics and molecular biologyer (Konczal, 2013).

Whole genome sequencing (WGS) is a technology of mapping the entire DNA sequence of an organism, WGS presents many benefits as well as challenges in its application. The most influential application of WGS lies in its ability to revolutionize personalized medicine. By decoding a person's genetic blueprint, WGS allows healthcare providers to offer more accurate care to individuals as well as communities. For example, it can identify genetic variants associated with specific diseases, enabling early intervention and targeted therapies (Nadon et al., 2017). In addition, genomic research has helped in identifying the genetic causes of various diseases including hereditary diseases such as thalassemia and phenylketonuria that support early diagnosis, counseling and development of better therapies.

The Indonesian Ministry of Health in collaboration with East Ventures supports the strengthening of innovation in the Indonesian health sector by launching *the Biomedical & Genome Science Initiative* (BGSi). This program is designed to develop more accurate treatments for the community through the use of technology in collecting genetic information (genome) from humans and pathogens such as viruses and bacteria or can also be called *whole genome sequencing* (Yuana et al., 2017). Previously, the WGS method itself has been used and plays an important role in preventing COVID-19 in Indonesia, by helping to track the spread of the disease and inform intervention strategies that allow researchers around the world to start developing vaccines.

The WGS method will be used for research and development of treatments in six major disease categories, namely: cancer, infectious diseases, brain and neurodegenerative diseases, metabolic diseases, genetic disorders, and aging. In its implementation, BGSi was carried out in seven vertical hospitals, namely Cipto Mangunkusumo Central General Hospital, National Brain Center Hospital (PON Hospital), Sulianto Saroso Hospital, Friendship Center General Hospital, Dharmais Cancer Hospital, Sardjito Hospital, and Prof. IGNG Ngoerah Hospital.

In addition to providing preventive care and appropriate treatment solutions, clinicians can plan therapies that are more tailored to a patient's genetic profile, allowing for more effective treatment and reducing side effects and can also help lower overall health care costs due to early detection and targeted treatment.

These benefits not only impact an individual's health, but can also have a huge social and economic impact. However, it is important to ensure that research and use of genomic technology in Indonesia is carried out with strict ethical and legal standards in the collection, use, and storage of genomic data. In addition, there needs to be an adequate legal and regulatory framework to protect the privacy and rights of individuals in the context of genomics and public education and awareness about genomics is also important so that the benefits can be widely felt.

In Law number 17 of 2023 (Law 17/2023) concerning Health, there are regulations on the use of health technology, including biomedical technology which includes genomic technology.

Article 338 (1) in order to support Health Services, the Central Government and Local Governments encourage the use of Health Technology, including biomedical technology. (2) The use of biomedical technology as referred to in paragraph (1) includes genomic, transcriptomics, proteomics, and metabolomics technologies related to organisms, tissues, cells, biomolecules, and other biomedical technologies (Kesuma, 2023).

Meanwhile, the storage and management arrangements are contained in article 339 as follows:

Article 339 (1) Storage and management of materials in the form of clinical specimens and biological materials, information loads, and data for the long term shall be carried out by biobanks and I or biorepositories. (2) Biobanks and/or biorepositories as referred to in paragraph (1) are organized by Health Service Facilities, educational institutions, and/or Health research and development institutions, whether owned by the Central Government, Regional Governments, or the private sector.

The passage of the new Law 17/2023 on Health aims to address gaps or vagueness in the existing legal framework, provide better clarity and direction, and meet the unique considerations required by genomics.

Article 338 of Law 17/2023 paragraphs 1 and 2 explicitly recognizes genomics as part of biomedical technology that is important to support health services in Indonesia. The law outlines the various stages at which genomics can play a role, from initial specimen collection to long-term specimen storage and even further afield to the management and utilization of specimens and related genomic data. The process aims to advance scientific knowledge and develop health technologies and health services, including precision medicine.

Article 339 of Law 17/2023 paragraphs 1 and 2 explicitly outline provisions relating to the establishment and operation of biobanks or biorepositories, which are essential for genomic studies as they are responsible for storing and managing biological samples safely in Indonesia. Health Facilities, Educational institutions,

Research institutes, both public and private sectors, can establish these biobanks or biorepositories, with approval from the government and under regulatory supervision. This requirement is a very important protective measure to address international access or exploitation issues.

Meanwhile, Article 339 paragraphs 4 and 5 of Law 17/2023 states as follows:

(4*) The collection, long-term storage, and management and utilization of materials in the form of clinical specimens and biological materials, information content, and related data in the context of utilizing biomedical technology must obtain approval from the patient and / or donor.*

(5) The obligation to obtain approval from the patient and/or donor in the management and utilization of materials in the form of clinical specimens and biological materials, information content, and related data as referred to in paragraph (4) is excluded if:

1. *Material in the form of clinical specimens and biological materials, information content, and data that cannot be traced or in the form of aggregate data;*
2. *Material in the form of clinical specimens and biological materials, information content, and data for legal purposes; and/or material in the form of clinical specimens and biological materials, information content, and data for public interest in accordance with the provisions of laws and regulations*

Genetic data captured through genomic technology is a clinical tool that supports clinical genetics, oncology, obstetrics, neurology, pediatrics, and others. When health facilities and other organizations pursuant to article 339 of Law 17/2023 obtain, collect, store, use, and disclose more genetic information, there is a greater likelihood of invasion of privacy, confidentiality, and security.

Some of the scenarios in which such breaches may occur are: (1) genetic data disclosed to or accessed by health care providers without authorization or lawful need to view it; (2) the scope of genetic data obtained and disclosed beyond that required for legitimate health care purposes; and (3) genetic data used for purposes unrelated to disclosure of health and other issues (Clayton et al., 2019).

Therefore, *informed consent* is very important as regulated in Permenkes RI Number 585 / MEN. KES / PER / X / 1989 informed consent is consent given by the patient or his family on the basis of an explanation of the medical action to be carried out on the patient. In the case of genomics-based health services, *informed consent/consent of the data subject* should also include confidentiality, access, management (including *sharing*) and storage.

In response to another issue arising in the *Human Genome Project*, namely genetic discrimination in insurance, especially health insurance. Where insurance companies can deny coverage to individuals who are genetically at risk of a particular disease whose disease is excluded from underwriting by the insurance. Law 17/2023 Article 342 states that everyone is prohibited from discriminating against the results of a person's genetic examination and analysis (1), and may be subject to administrative sanctions in the form of administrative fines up to license revocation (2).

Separately, Law No. 17 of 2023 concerning Health has not clearly regulated genomic-based health services. Technically, one of the requirements for health facilities or institutions such as what is allowed to take and store specimens, as well as medical personnel and health workers who can take and send specimens only those who have the expertise and authority obtained from licenses and / or

certifications from certain institutions. It is also unclear what the form of the *cross-border data transfer agreement* in Law 17/2023 related to the PDP Law requires ensuring that the country where the Personal Data Controller and/or Personal Data Processor receiving the transfer of Personal Data has a level of Personal Data Protection that is equal to or higher than that provided for in this Act.

Legal protection of genetic data in genomics-based health services based on Law Number 27 of 2022 concerning Personal Data Protection

Regulation of Whole Genomic *Sequences* (WGS) varies across countries and is subject to ongoing scientific, technological, and ethical considerations. Some key aspects of WGS-related regulation are related to Ethics and Privacy concerns in terms of the protection of individual privacy and the ethical use of genetic information. Many countries have regulations that require informed consent from individuals before their genomes are sequenced. In addition, there are strict rules regarding storage, sharing, and access to genomic data including genetic data to prevent misuse or unauthorized access.

The data security aspect requires regulations that can require entities performing WGS to implement strong security measures to protect the data they generate and store. Individuals should also be fully informed about the potential risks and benefits of genome sequencing, how their data will be used, and who will have access to it. If genomic data is to be shared with other researchers or organizations, it must be done in accordance with regulations and with the consent of the individuals involved. The data sharing agreement should also specify how the data will be used and protected.

According to Chander & Land, 2014; Djafar & Santoso, (2019), reminded the many surveillance practices and interception of communications carried out arbitrarily and unlawfully, including arbitrary collection of personal data, which is a form of violation of privacy rights. Effective measures should be taken by the state to ensure that information regarding a person's private life does not reach the hands of persons not permitted by law to receive, process and use it Chander & Land, 2014; Djafar & Santoso, (2019).

Personal data is basically a person's privacy, which is included as a basic right protected under the Constitution of the Republic of Indonesia Year 1945, as explained by Article 28G paragraph (1): Everyone has *the right to the protection of himself, family, honor, dignity, and property under his control, and the right to a sense of security and protection from threats of fear to do or not do something that is a human right*. This is in line with the role of the state in this case the government in an effort to protect the rights of its people related to personal data protection.

The role of law in ensuring the protection of personal data for users of information and communication technology, through laws and regulations is contained in Article 26 paragraph (1) of Law Number 11 of 2008 concerning Electronic Information and Transactions as amended by Law Number 19 of 2016 (ITE Law), regulated as follows:

"*Unless otherwise stipulated by laws and regulations, the use of any information through electronic media that concerns a person's personal data must be carried out with the consent of the Person concerned*"

Based on the explanation of Article 26 paragraph (1) of the ITE Law above, personal data protection is one part of *privacy rights*, which contains the following definitions:

1. Personal rights are the right to enjoy a private life and be free from all kinds of interference;
2. Personal rights are the right to be able to communicate with others without spying; and
3. Privacy rights are the right to monitor access to information about a person's private life and data

Law Number 11 of 2008 concerning Electronic Information and Transactions (ITE Law) generally regulates the use of electronic data and information. This ITE Law contains provisions related to privacy and data protection including sanctions for privacy violations.

Government Regulation in Lieu of Law Number 2 of 2017 concerning amendments to Law number 11 of 2008 concerning ITE regulates personal data protection and requires the processing of personal data to meet a number of principles including the principle of consent and the principle *of* reasonable *necessity*.

In addition, personal data protection is specifically regulated through Law Number 27 of 2022 concerning Personal Data Protection (PDP Law), in order to guarantee the constitutional rights of personal data subjects. This law states that personal data is data about natural persons who are identified or can be identified separately or combined with other information, either directly or indirectly through electronic or non-electronic systems.

Referring to Article 4 of the PDP Law, there are at least two types of personal data. First, specific data, then general data. Specific personal data include (Calzada, 2022) :

1. health data and information;
2. data biometrik;
3. data, genetics;
4. criminal record;
5. child data;
6. personal financial data; and/or
7. Other data in accordance with the provisions of laws and regulations.

Meanwhile, personal data of a general nature in the form of:

1. full name;
2. jenis kelamin;
3. Citizenship;
4. religion;
5. marital status; and/or
6. Personal data combined to identify an individual.

Therefore, based on article 4 of the PDP Law, genetic data produced from genomic-based technology is one of the data that should be protected by the State with provisions, rights and obligations and sanctions that should be complied with by all interested parties.

If its application follows this principle, then the processing of personal data will be carried out after fulfilling legal reasons, such as the consent of the data owner; ascertaining the processing requirements related to the contract concluded with the data owner; comply with the law with its obligations; protect the vital interests of the

data owner; carry out tasks in the public interest assigned to the data controller; or the exercise of *legitimate interest*) by the data controller or third party.

The main requirement of personal data protection not only prioritizes the application of such principles but also respects the rights of the data subject and the obligations of the data controller. The data owner has rights, among others:

1. Obtain information about the clarity of identity, the basis of legal interest, the purpose of requesting and using personal data, and the accountability of the party requesting Personal Data (Article 5)
2. Complete, update and/or correct errors and/or inaccuracies in personal data about him in accordance with the purpose of personal data disclosure, (article 6)
3. Obtain access and obtain a copy of Personal Data about him in accordance with the provisions of laws and regulations. (Article 7)
4. End processing, delete and/or destroy Personal Data about him in accordance with the provisions of laws and regulations. (Articles 8, 42, 43, 44.45)
5. Withdraw the consent to the processing of Personal Data about him that has been given to the Personal Data Controller (articles 9, 40)
6. Object to decision-making actions based solely on automated processing, including profiling, that have legal consequences or have a significant impact on Personal Data Subjects (regulated in Government Regulations) article 10 paragraph 1
7. Suspend or restrict the processing of Personal Data in accordance with the purpose of processing the Personal Data. (Articles 11, 41)
8. Sue and receive compensation for violations of processing personal data about him in accordance with statutory provisions. (Article 12 paragraph 1)
9. Obtain and/or use Personal Data about him from the Personal Data Controller in a form that is appropriate to the structure and/or format commonly used or readable by electronic systems. (Article 13 paragraph 1)
10. Use and transmit personal data about himself to the personal data controller about him to other personal data controllers as long as the systems used can communicate with each other securely in accordance with the principles of personal data protection under the law (stipulated in Government Regulations). Article 13 paragraph 2
11. The exercise of the rights of the Personal Data Subject is submitted through a registered request submitted electronically or nonelectronically to the Personal Data Controller (Article 14)

Meanwhile, the obligation of the Personal Data Controller must provide organizational and technical measures to demonstrate that the data processing has been carried out in accordance with applicable legal principles. The specific explanation of its obligations includes: providing an audit of the latest data; comprehensive provisions and procedures related to personal data protection; Privacy *by design &; by default;* Data Protection Officer; clear procedures for data subjects; data *protection assessment;* human resource capacity building; strong data security technicalities; procedures regarding Personal Data Protection breaches and failures; as well as evaluation procedures for steps that have been implemented.

Data including personal data moving across borders poses significant and complex jurisdictional issues, including possible conflicts of laws between one country and another. Data protection law should put individuals at the centre: this means ensuring that individuals' personal data is protected, regardless of whether

their data is processed within or outside the region in which they are located. This protection can be achieved in a variety of ways, including by establishing that the law:

1. Applies to controllers and processors established in that country, even if the processing takes place outside the jurisdiction of the country.
2. Applies to the processing of personal data by controllers and processors established outside the jurisdiction of the country in which the individual is located (Mattoo & Meltzer, 2018).

Article 340 paragraph 1 of Law 17/2023 states that data can be transferred outside Indonesia with the requirements listed in paragraph 2 as follows: :

1. The transfer and use of materials in the form of clinical specimens and biological materials, information content, and/or data outside the territory of Indonesia is carried out by taking into account the principles of maintaining the wealth of biological resources and genetics of Indonesia.
2. Transfer and use of materials in the form of clinical specimens and biological materials, information content, and/or data outside the territory of Indonesia as referred to in paragraph (1) can only be carried out if:
3. how to achieve the purpose and purpose of the examination cannot be carried out in Indonesia;
4. examinations can be carried out in Indonesia but to achieve the main objectives of research, it is necessary to conduct examinations outside the territory of Indonesia; and/or.

For the benefit of quality control in order to update the accuracy of diagnostic and therapeutic standard capabilities.

In this regard, article 56 of the PDP Law states that:

1. The Personal Data Controller may transfer Personal Data to the Personal Data Controller and/or Personal Data Processor outside the jurisdiction of the Republic of Indonesia in accordance with the provisions stipulated in this Law.
2. In carrying out the transfer of Personal Data as referred to in paragraph (l), the Personal Data Controller must ascertain the country where the Personal Data Controller and/or Personal Data Processor is located. receiving transfers of Personal Data has a level of Personal Data Protection equivalent to or higher than that stipulated in this Law.
3. In the event that the provisions referred to in paragraph (2) are not fulfilled, the Personal Data Controller shall ensure that there is adequate and binding Personal Data Protection.
4. In the event that the conditions referred to in paragraph (2) and paragraph (3) are not fulfilled, the Personal Data Controller shall obtain the Personal Data Subject's dispute.
5. Further provisions regarding the transfer of Personal Data are regulated in Government Regulations

The data controller is the party responsible for the implementation of personal data protection indicating compliance with the principles of personal data processing. The law should therefore regulate the data controller's liability. This liability refers to liability supported by legal sanctions and codes of ethics. Personal data shall be processed in a fair manner, based on the consent of the data subject and the best interests of the data subject (Krzysztofek, 2018).

Law No. 27 of 2022 concerning Personal Data Protection has also not been comprehensively able to provide protection for personal data (genetic data). This can be seen in the absence of an independent Data Controller who serves as the executor of the formulation, determination of policies and efforts to protect personal data, conduct supervision, become an administrative law enforcer against court violators socialization of arrangements for personal data protection activities, monitoring its implementation, handling administrative disputes, mediating, and adjudication of non-litigation related to problems Personal Data Protection. Even until now there has been no competency certification based on laws and regulations for the position.

CONCLUSION

From the above research, the author concludes that a comprehensive and harmonious regulatory framework is the first step towards genomic-based health services. Many aspects need to be considered in making regulations for genomic development. Among them are related to service, consent, protection of personal data and ethical use of data as well as about the management, sharing, storage, right of access and processing of data.

With several interrelated regulations and becoming a legal umbrella for genomics-based health services, there should be no differences in interpretation in their implementation, causing legal uncertainty. Therefore, it is necessary to immediately formulate specific derivative regulations to regulate genetic data protection so that all existing laws and regulations can be implemented effectively and efficiently and function to provide protection to the community.

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