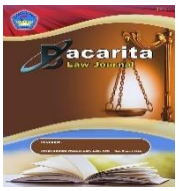
BACARITA Law Journal
Volume 5 Issue 1, August 2024: h. 61 - 74
E-ISSN: 2775-9407
: 10.30598/bacarita.v5i1.13635



Genetic Engineering Therapy of Stem Cells in Health Law

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Abstract

This research aims to reveal legal protection based on health law related to the practice of stem cell therapy as a controversial genetic engineering product in Indonesia. This research used a qualitative method with unstructured interviews that focus on normative-empirical studies, supported by statute approach, case approach and various sources of literature studies. Stem cells therapy shows the potential to cure various types of diseases using genetic engineering technology developed by researchers as a hope for future health. This research found that the role and support of the Government in protecting subjects throughout the practice of stem cells therapy can be seen in the Government's commitment through efforts to improve and set standardized health services in accordance with health law and the 1945 Constitution. The implementation of stem cell therapy in Indonesia is limited to service-based research because the Government does not yet have minimum service standards as guidelines to ensure the safety of the procedure and its success rate. The issues that have been found need to be considered as evaluation material for the Government to immediately establish minimum service standards for stem cell therapy, so that all parties such as hospitals, laboratories, and cell banks have equal standards.

Keywords: Legal Protection; Government; Genetic Engineering; Stem Cell; Health.

Submitted: 2024-06-07 *Revised: 2024-08-18* *Accepted: 2024-08-25* *Published: 2024-08-31*

How To Cite: Aqilla Nur Syaharani, Fokky Fuad Wasitaatmadja. "Genetic Engineering Therapy of Stem Cells in Health Law." *BACARITA Law Journal* 5 no. 1 (2024): 61-74.https://doi.org/10.30598/bacarita.v5i1.13635

INTRODUCTION

The world has progressed in science and technology to more recent developments in multidimensional systems that recapitulate organ complexity using stem cells. This has attracted researchers from diverse backgrounds, who are focusing the application of stem cell technology on very different fields, including developmental biology, cancer biology, disease modeling, drug discovery, and regenerative medicine. This collaborative work across disciplines has enriched the field of biotechnology, offering new perspectives and supporting the development of clinical applications globally. Continued progress in this field depends on scientists' ability to reliably model human systems using stem cell technology.[1]

Indonesia is one of the countries that has developed research in the field of biotechnology, especially in stem cell therapy and clinical applications with a focus on regulation and infrastructure to promote scientific innovation. With today's advanced technology, research has created new breakthroughs for the development of more effective, efficient, and innovative drugs for the cure of various types of diseases related to the body system.[2]

[1] Tenneille E Ludwig et al., "ISSCR Standards for the Use of Human Stem Cells in Basic Research." *Stem Cell Reports. Cell Press* 18 (2023): 1744-1752, doi:10.1016/j.stemcr.2023.08.003.

[2] Michele De Luca et al., "Advances in Stem Cell Research and Therapeutic Development." *Nature Cell Biology* 21 (2019): 801-811, doi:10.1038/s41556-019-0344-z.

Every living thing has genes as unit cells that make up the physical body and appearance of living things and carry information related to the physical body.[3] Genetic engineering is an advanced technology in this era capable of modifying genes and is referred to by many terms, such as recombinant DNA technology, artificial manipulation, or gene modification.[4] Genetic engineering works by inserting new genetic information into existing cells to modify certain characteristics of the organism.[5] Since its use in humans, genetic engineering has evolved to improve the quality of human life. A wide range of innovations have been created including preventing disease transmission, reducing the risk of inherited diseases, eliminating disabilities, and creating physically and mentally healthy humans.[6]

Gene therapy is the administration of genetic material into cells to provide beneficial therapeutic effects and cure diseases. Stem cell therapy is a drug development method that can significantly improve the effectiveness of other therapeutic modalities and reduce their side effects. Several investigational therapeutic protocols based on stem cells are now in preclinical trials with promising results.[7] Stem *cells* are defined as undifferentiated cells that have the *potential* to proliferate and grow into specific cells. Stem cells can reach damaged tissue and unite with other cells in the tissue to *renew* themselves *(self-renewing)*, then develop into specific cells with specific functions of the tissue or organ that occupies them *(transdifferentiation)*.[8] Therefore, stem cells can repair or create new healthy tissue *(regeneration)* in damaged organs.

In general, stem cells are classified into embryonic and non-embryonic types that are specifically derived from bone marrow myoblasts, bone marrow-derived mononuclear cells (BMMNC), hematopoietic stem cells (HSC), endothelial stem cells (EPC), mesenchymal stem cells (MSC), embryonic stem cells (ESC), and induced pluripotent stem cells (iPSC).[9] iPSC stem cells have similarities to embryonic stem cells, but are not derived from embryos, which is not a problem. Stem cells have various uses, including for research purposes that benefit the development of the basic biology of life in various cell types in the event of disruption, replacement therapy for damaged or lost cells.[10] Stem cells can be replicated to produce new cells, tissues and organs. Tissues or organs formed from stem cells can be transplanted into the body to replace cells that are no longer functioning properly. Stem cells are used in the field of medical research for the treatment of various diseases viz: Burkitt's lymphoma, leukemia, leukocyte adhesion deficiency, sickle cell anemia, B-thalassemia, liver cirrhosis, aplastic anemia, red blood cell aplasia, paroxysmal nocturnal hemoglobinuria, heart disease, type 1 diabetes, lupus erythematosus, inherited metabolic diseases, alzheimer's, parkinson's, rheumatoid arthritis, spinal cord injury, stroke, and others.[11]

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[3] Murti Ani, et al., *Reproductive Biology and Microbiology*, (Jakarta: Yayasan Kita Tulis, 2021).

[4] T. Editors of Encyclopaedia Britannica. "Genetic Engineering." Britannica, 2024. https://www.britannica.com/science/genetic-engineering.

[5] Desmond ST Nicholl, *An introduction to genetic engineering* (United Kingdom: Cambridge University Press, 2023), pp. 3.

[6] Ryota Tamura, and Masahiro Toda, "Historical Overview of Genetic Engineering Technologies for Human Gene Therapy." *Japan Neurologia Medico-Chirurgica. Japan Neurosurgical Society* 60, no. 10 (2020): 483-491. doi:10.2176/nmc.ra.2020-0049.

[7] Emina Karahmet Sher, et al., "Cellular Therapeutic Potential of Genetically Engineered Stem Cells in Cancer Treatment." *Biotechnology and Genetic Engineering Reviews* (2023): 1–36. doi:10.1080/02648725.2023.2204720.

[8] Tita Yunia Zalni, et al., "Stem Cell Therapy in Stroke." *Journal of Stem Cell Research & Tissue Engineering* 7, no. 1 (2023): 1-6, https://doi.org/10.20473/jscrte.v7i1.36443

[9] Dian Andriani Ratna Dewi, et al., "Stem Cells Service Legality Post-Application of Law Number 36 Year 2009 About Health." *Eduvest-Journal of Universal Studies* 2, no. 7 (2022): 1-270, http://dx.doi.org/10.59188/eduvest.v2i7.508.

[10] Arif, Tuba, Selva Bilge et al., "Biosensors for stem cell-based applications: Current trends and future prospects." *Microchemical Journal* (2024): 110141.

[11] Widyastuti, Dyah Ayu. "Gene Therapy: From Biotechnology to Health." *Al-Kauniyah: Journal of Biology 10*, no. 1 (2017): 59-72.

Stem cell research began in 1908 by Russian histologist Alexander Maksimov. In 1995, Dr. B.G. Matapurkar demonstrated the technique on over 60 patients and was subsequently granted a patent by the United State Patent Office in 2001. Modern stem cell research has come a long way, with studies showing that different types of stem cells can be created, leading to greater control and differentiation in stem cell research.[12]

The right to health of every person is recognized by the whole world, including Indonesia. One of the basic rights of citizens that must be organized by the Government as mandated in the 1945 Constitution Article 28H paragraph (1) that everyone has the right to live a prosperous life physically and mentally with a good and healthy living environment and obtain health services, besides that the state is also responsible for providing health care facilities and public facilities that are suitable for the community without discrimination as mandated in the 1945 Constitution Article 34 paragraph (3).[13] The mandate has been reviewed and responded to by the Government together with the House of Representatives as outlined in Law No. 17 of 2023 concerning Health (hereinafter referred to as Health Law No. 17 of 2023) so that the community can obtain fair, quality and equitable health services.[14]

In its implementation, the Indonesian people still have difficulty accessing health services. Although policies and regulations have been established to guide various health services and programs, the community is still faced with health service problems, both in rural and urban areas. Existing facilities are also not yet available in full and meet health standards adequately. In providing the best health services, hospitals must have their own service characteristics because hospitals are complex organizations.[15] This needs to be understood and known by everyone who has responsibilities and duties in the organization and development of hospitals.

The government has developed specific regulations related to human-derived stem cells therapy to ensure stem cells treatment is safe, ethical, and based on the latest scientific data, with clear standards for research and application. This regulation applies to all stem cell therapy processes, including minimum service standards (MSS), patient safety protection that aims to provide quality assurance of services, both in health service facilities, processing laboratories, storage facilities, and stem cell production facilities.[16] Health development is one of the important responsibilities of the Government in ensuring public health that affects the quality of human resources, when a person is healthy then he is able to optimize the ability of his body.[17]

Regulation of the Minister of Health No. 6 of 2024 is an improvement of Regulation of the Minister of Health No. 4 of 2019 as the Government's commitment to fulfill and improve the quality of public health services through changes and implementation of Health Law

[12] Sagita, Sylva. "The controversy of stem cells research and therapy in the view of science ethics." *Indonesian Journal of Philosophy 3*, no. 2 (2020): 54-52.

[13] Secretariat General of the People's Consultative Assembly, *Guidelines for the Correction of the 1945 Constitution of the Republic of Indonesia* (Jakarta: MPR, 2009), pp. 112.

[14] Mikho Ardinata, "State Responsibility for Health Insurance in the Perspective of Human Rights," *Journal of Ham* 11, no. 2 (2020): 319-332, http://dx.doi.org/10.30641/ham.2020.11.319-332.

[15] Ministry of Health of the Republic of Indonesia, *Academic Paper on Draft Hospital Law* (Jakarta: Legal Bureau, 2020). p. 1.

[16] Medical Tourism Magazine. "Venturing Into Stem Cell Therapy In Indonesia: A First-Time Consumer's Comprehensive Guide." Medical Tourism, 2020. https://www.magazine.medicaltourism.com/article/venturing-into-stem-cell-therapy-in-indonesia-a-first-time-consumers-comprehensive-guide.

[17] Hernadi Affandi, "Implementation of the Right to Health According to the 1945 Constitution: Between Regulation and Realization of State Responsibility," *Positum Law Journal* 4, no. 1 (2019): 36-56, doi:10.35706/positum.v4i1.3006.

No. 17 of 2023.[18] The government already has positive Indonesian legal regulations to regulate the implementation of stem cells therapy as a health service effort in Indonesia, which is covered by Minister of Health Regulation No. 32 of 2018 concerning the implementation of stem cell services (hereinafter referred to as PMK No. 32 of 2018) specifically regulates the processing, service, use, organizers, requirements, procedures, storage, and supervision of stem cell therapy in Indonesia.[19] This regulation aims to provide guidelines for a clear and structured legal framework for the development and implementation of stem cells practices in Indonesia. Therefore, the state holds the authority and responsibility to regulate and organize health services in accordance with minimum service standards that provide health insurance as part of human rights.

Although it is still a controversial practice in Indonesia, there are currently several hospitals that have the technology and human resources for stem cell therapy. Based on the Decree of the Minister of Health No. HK.02.02/1/0197/2020, Cipto Mangunkusumo Hospital as the main supervisor and Dr. Soetomo Hospital as the second supervisor of stem cells medical practice in Indonesia, which oversees nine other hospitals namely: Harapan Kita Heart Hospital, Jakarta; Fatmawati Hospital; Dharmais Cancer Hospital; Persahabatan Hospital; Dr. Hasan Sadikin Hospital, Bandung; Dr. M. Djamil Hospital, Padang; Dr. Sardjito Hospital, Yogyakarta; Sanglah Hospital, Bali; and Dr. Kariadi Hospital, Semarang.[20] Indonesia began conducting stem cells research in 2008, supported by the National Research and Innovation Agency with a commitment to advancing research by providing facilities and funds as well as an innovation research platform. Harapan Kita Hospital is one of those granted permission to conduct service-based research and has the function of carrying out management and services as a form of utilization of the results of research and development of stem cells medical technology.[21] This development is an example of the Government's commitment to continue to innovate and improve the quality of health in Indonesia.

This research aims to analyze health law related to the development of stem cells therapy in Indonesia in general and at Harapan Kita Hospital in particular. This phenomenon will be studied with the theory of legal certainty and data focusing on health law based on the 1954 Constitution to answer problems related to legal protection and safety of the use of genetic engineering technology in the medical field. As well as knowing the implementation of PMK No. 32/2018 whether it has gone well and whether the existing policy protects the entire scope of the stem cells practice process for health purposes. Therefore, this research has the following problem formulations: (1) How is the legal protection of the practice of stem cells therapy according to PMK No. 32/2018 and (2) How are the problems and solutions in the practice of stem cell therapy at Harapan Kita Hospital.

METHODS OF THE RESEARCH

This research uses a juridical-normative method in the form of searching and collecting literature with a statutory approach that analyzes all regulations related to the legal issues

[18] Fachrudin Ali. "Minimum Health Service Standards, the Right of Every Citizen." BKPK, 2024. https://www.badankebijakan.kemkes.go.id/

[19] Jayanti Purnama Sari et al., "Utilization of Frozen Embryo Remnants from IVF Program as Stem Cell Transplant Therapy in Indonesia," *Journal of USM Law Review* 7, no. 1 (2024): 300-313, http://dx.doi.org/10.26623/julr.v7i1.8286

[20] Ministry of Health Cipto Mangunkusumo Hospital. "Stem Cells." KEMENKES RSCM, 2022. https://www.rscm.co.id/index.php?XP_webview_menu=0&pageid=8

[21] Ministry of Health RSJPD Harapan Kita. "Molecular Laboratory Unit and SCF." RSJPDHK. https://pjnhk.go.id/informasi/unit-laboratorium-molekular-dan-scf

to be studied.[22] Supported by empirical data that combines literature studies and case studies involving resource persons from Harapan Kita Hospital. The method of collecting legal materials uses data obtained from the analysis of studies of scientific journals, articles, and supporting documents from various valid sources with qualitative research types to understand the phenomena that occur in the form of descriptions and narratives that describe the results of research according to the problems and objectives, then examine the applicable laws and regulations by utilizing various scientific methods, to analyze legal aspects in the application of stem cells therapy.[23] So that the data generated will be more valid, comprehensive, objective and reliable.[24]

RESULTS AND DISCUSSION

The findings of this study provide in-depth insight into existing policies, the extent to which the government regulates stem cell practice and the sustainability of Indonesian health with the rights and needs of the community. The implications of this research can help the government and stem cell service providers to improve their policies and practices. The importance of this research is to explore novelty in science by looking for studies that have not existed in previous research. The results of this study are expected to be developed for further research and used as scientific reference material.

A. Legal Protection of Stem Cell Therapy Practices According to Minister of Health Regulation No. 32/2018

Legal protection aims to ensure legal certainty, justice, and benefits to patients, donors, and health care facilities as organizers of stem cells services.[25] This is regulated in Article 2 letter b of PMK No. 32/2018 to implement the provisions of Article 135 paragraphs (1) and (2) of Health Law No. 17 of 2023. Stem cells practice activities consisting of retrieval, storage, processing, and clinical application are carried out by paying attention to standard procedures so as not to result in blurring of norms and ethical violations. Based on the basis of positive legal theory, legal certainty and legal protection are derived from the Health Law used in this study.[26]

Legal protection for patients consists of preventive and repressive protection which can be found in Health Law No. 17 of 2023, PMK No. 32 of 2018, and *informed consent* forms.[27] Meanwhile, repressive legal protection is found in Health Law No. 17 of 2023, PMK No. 32 of 2018, KUHPer, and Harapan Kita Hospital Regulations. Qualification of laboratory facilities and equipment must also be completed with validation of the manufacturing process. The validation process includes donor qualification, stem cell isolation and

[22] Zainuddin, Muhammad, and Aisyah Dinda Karina, "The Use of Normative Juridical Methods in Proving Truth in Legal Research." *Smart Law Journal* 2, no. 2 (2023): 114-123.

[23] Dr. Sigit Sapto Nugroho, et al., Legal Research Methodology, (Surakarta: Oase Pustaka, 2020)

[24] Devi Syukri Azhari et al., "Mixed Method Research for Dissertation." *Innovative: Journal Of Social Science Research* 3, no. 2 (2023): 8010-8025. https://doi.org/10.31004/innovative.v3i2.1339.

[25] Riski Saputra 'Regulation of Stem Cell Utilization as a Rehabilitative Health Effort Based on Bioethical Principles' (thesis: Jambi University, 2022).

[26] Fajriyanti, Dwi Nory. "The Law of Treatment Using Embryonic Stem Cells (Comparative Analysis of Positive Law and Islamic Law) in Indonesia." PhD diss., UIN Sunan Kalijaga Yogyakarta, 2021.

[27] Sang Ayu Made Tamara, 'Juridical Review of the Implementation of Therapeutic Agreements for Stem Cell Therapy for COVID-19 Patients at Dr. Sardjito Central General Hospital Yogyakarta' (Thesis: Gajah Mada University, 2023).

expansion, cryopreservation and thawing, packaging, and shipping processes.[28] All processes must comply with local standards to ensure product quality and patient safety.

Articles 273 to 275 of Health Law No. 17 of 2023 can be used as guidelines in medical practice. The procedure carried out in the hospital before undergoing stem cells therapy requires a patient interview, physical examination to diagnose the disease and find out the condition of the body, informed consent, then therapeutic actions can be carried out and after that a prognosis will be carried out.[29] Informed consent in health law is the consent of the patient (or the patient's family if the patient cannot be asked for consent) freely and consciously for the actions performed by the doctor on the patient's body or for diagnostic, therapeutic and palliative.[30] After consent is obtained, the doctor can provide an explanation including preparation before therapy, the purpose and objectives of therapy, procedure techniques along with risks and side effects in a language that is easy for the patient to understand so that the patient knows that all actions taken by the doctor are with his consent. Patients give consent according to their right to determine what will happen to their body condition *(self determination)*. The same thing also needs to be done to donors, which includes explanations related to the selection process and requirements as a donor, conducting body and laboratory examinations.[31] Informed consent is one of the main elements before following up on stem cell therapy as mentioned in Article 276 of Health Law No. 17 of 2023.

When donor-derived stem cells enter the laboratory, care needs to be taken to ensure that the material is transferred with the appropriate permissions and used in accordance with the donor's consent.[32] Each individual must understand any restrictions for use of the material and data reporting. The researcher's responsibility to the donor providing the material is critical, and adhering well to their restrictions is essential to maintaining the integrity of the study. For this reason, materials should not be brought into the laboratory without knowing the rights and restrictions associated with them, which are generally stated in the transfer agreement or informed consent. When setting quality standards within the laboratory for stem cells, this cannot be overlooked. These standardization documents should be available within the laboratory, and all researchers should read and understand the conditions or restrictions associated with a particular line before starting any work.

A doctor also has rights, obligations, and authorities when practicing that are related to legal aspects. Health workers are obliged to conduct health checks professionally and provide services according to standard procedures. The doctor's role is very important in directing patients during the implementation of treatment, both before, during, and after the procedure is completed. As a legal subject in health services, doctors are bound and obliged to be responsible for all things that will result from their profession. There are several stem cell therapies that doctors can provide, namely: *autologous* stem cell transplantation (cells taken from the patient's body), and *allogenic* (cells taken from another

[28] Angliana Chouw et al., "Standard Regulation for Stem Cell Products in Indonesia." *Cytotherapy* 23, no. 5 (2021): S17-S2071, Elsevier BV: S206. doi:10.1016/s146532492100637x.

[29] Wind Astuti, "Doctor's Responsibility to Patients for Stem Cell Therapy Services." (2021).

[30] Dewi Atriani, and Ade Yusuf Yulianto. "The Legal Power of Informed Consent in the Practice of Euthanasia in Indonesia." *Legal Treatise* 20, no. 2 (2023): 101-111.

[31] Kastania Lintang. "Juridical Review of the Implementation of Informed Consent in Therapeutic Agreements." *Lex Generalis Law Journal* 2, no. 4 (2021): 296-308.

[32] Oktariana, Desi, Legiran, et al., "Stem Cell Transplantation for Hematologic Malignancies." *eJournal Kedokteran Indonesia* (2022): 186-93.

person's body), cells injected into the patient's body will succeed if they develop properly, but possible risks can also occur which cause complications in the future.

The legal relationship created by the agreement between the patient and the doctor is a *therapeutic* agreement formed on the basis of the fulfillment of the rights and obligations of each party.[33] If the doctor is suspected or found to have violated the code of ethics, the doctor will be required to be responsible for the existing problems and guidance will be carried out by the Indonesian Medical Association as a form of disciplining its members. Negligence committed by doctors during the practice of stem cells therapy can be held legally responsible which is divided into three, namely: civil, criminal and administrative responsibility.[34]

The Government's responsibility is seen in the fulfillment of the right to health in accordance with the 1945 Constitution which has an impact on legal protection in the practice of stem cells therapy, this can be realized especially after the issuance of Health Law No. 17 of 2023 and PMK No. 32 of 2018 which shows that the Government pays attention to the development of stem cells therapy. Informed consent shows the legality and importance of patient consent which has the power in the eyes of the law. The legal relationship formed from informed consent becomes the basis for the fulfillment of patient rights and legal protection to doctors who create rights and obligations that must be fulfilled by each subject. So that if a problem occurs in the hospital caused by the fault of health workers who work and are bound, it will be easier to determine which party will be responsible for the problem. The practice of stem cells therapy prioritizes patient safety by providing clinical guidance information so that the patient understands thoroughly, not only the benefits obtained but also the accompanying risks.[35]

The meaning of legal protection in the fulfillment of the right to health for stem cells therapy services can be done through regulatory efforts, setting service standards, mechanisms, institutions and guarantees for the community.[36] With competent human resources and implementing strict procedures in ensuring the safety and effectiveness of therapy, Harapan Kita Hospital has implemented regulations well so that legal protection is created for patients, donors, health workers, and the hospital itself as a facility organizer.[37] Although Indonesia already has PMK No. 32 of 2018 and Health Law No. 17 of 2023 that guide the practice of stem cells therapy, there is an urgency for the Government to immediately create and ratify minimum service standards to provide a quality maintenance and patient safety guarantee for the quality of therapy implementation. Because it has been almost about 10 or 15 years that stem cells have developed in Indonesia, but until now it does not have clear service standards because it is still service-based research.[38] The

[33] Pirsadeghi, Ali, et al., "Therapeutic approaches of cell therapy based on stem cells and terminally differentiated cells: Potential and effectiveness." *Cells & Development* (2024): 203904.

[34] Aroma Elmina Martha, 'Limitations of Doctors in Performing Medical Actions that are not the Authority of their Professional Competence' (Thesis: Universitas Islam Indonesia, 2020).

[35] Niu, Yifei, et al., "Regenerative treatment of ophthalmic diseases with stem cells: Principles, progress, and challenges." *Advances in Ophthalmology Practice and Research* (2024).

[36] Susanti, Dyah Ochtorina, and Nuzulia Kumala Sari. "The Model Of Legal Protection For Products Of Genetic Engineering In Agricultural Technology." *Trunojoyo Law Review* 1, no. 1 (2019): 30-45.

[37] Budiarsih, "Legal Liability of Doctors for Errors in Diagnosis in Medical Services in Hospitals." *Indonesian Health Law Journal* 1, no. 01 (2021): 49-58.

[38] Iffatin Nur, "Stem Cell Therapy: Its Legality In The Perspective Of Indonesian Law And Progressive Islamic Jurisprudence." *International Journal of Advanced Research 8*, no. 2 (2020): 202–12. doi:10.21474/ijar01/10455.

minimum service standard will be evidence of safety effectiveness and efficiency and will be ratified by the minister of health who sets the standard.

The effectiveness of the standards will improve the quality of research, and these standards should be adopted by the scientific community. While overall these recommendations are designed to be technically and financially feasible for any laboratory, they are not without cost. However, the costs associated with the recommended characterization strategies are minimal when compared to overall research costs and can ultimately save research costs by reducing the need to repeat experiments and by helping to ensure the validity of results.

The government does not yet have laws and regulations derived from PMK No. 32/2018, this creates an urgency for Indonesia to immediately design service standards to ensure correct and good standard operating procedures (SOPs).[39] The main objective of drafting this standard is to create a set of practical recommendations that establish minimum characterization and reporting criteria for basic research using human stem cells.[40] While standards have previously been proposed for repositories, distribution centers, and clinical applications, these standards are not focused on the issues of laboratory research with human stem cells and tissue stem cells. There is also an aspirational component to the development of laboratory standards, a natural consequence of the need to change or improve current standard practices, some of which may not be sufficient to ensure rigor and research. The challenge for Governments is to strike a balance so that these standards are practical enough to be widely implemented, and that society recognizes their value (aspirational) and adopts them for the common good of the field. Ethics will serve as a basis for standard-setting so as not to override normative values and be responsible for quality survival.[41]

B. The Role of Harapan Kita Hospital in the Development of Stem Cells Technology in Indonesia

Harapan Kita Hospital has a Molecular Laboratory Unit and Stem Cell Facility (SCF) in the Research and Development Installation Building which functions as a molecular examination service and breeding of stem cells. SCF is used to accommodate services in the development and growth of stem cells consisting of cardiac resident stem cells, bone marrow stem cells, mesenchymal stem cells, cell sorting, immunophenotyping, and immunocytokines. Facilities in the SCF are: general room is used for the manufacture of basic reagents, sample centrifuge and storage of regensia with specific properties; Flow Cyto room is used for the analysis of cell samples resulting from stem cell proliferation; stem cell room is used for the isolation of stem cells from tissues and their proliferation; dark room is used for the analysis and reading of samples with a fluoresece microscope; and sample storage room is used to store samples in minus 20 and minus 80 freezers and liquid nitrogen. Marker flowsitometry examination for characterization of CD 133 bone marrow stem cell viability test, characterization of Sca-1 cardiac stem cell population, characterization of C-Kit cardiac resident stem cell population. The duties and functions of this unit as a genomic and metabolomic stem cell-based research service and maintenance of instruments and

[39] Hernawati, Elly. "Legal Aspects of Standardization on Genetically Engineered Food Products." *Yustika Journal: Media of Law and Justice* 25, no. 02 (2022): 104-120.

[40] Ibrahim, Sukaeni, and Marhaen Hardjo. Health Research Methodology. NEM Publisher, 2023.

[41] Dewi, Dian Andriani Ratna, Nasser, Tiarsen Buaton, and Topane Gayus Lumbuun. "Stem Cells Service Legality Post-Application of Law Number 36 Year 2009 about Health." Eduvest-Journal of Universal Studies 2, no. 7 (2022): 1-270.

facilities that are medical and non-medical in coordination with certain units. The types of services performed in this unit include advanced stem cell isolation services related to the development and research activities of cell culture examination. This facility is used to support quality research and prospects for international publications. In 2020 this unit focuses on COVID-19 examination to support hospital services and government programs in overcoming COVID-19.

There is a Biomedical & Genome Science initiative (BGSi) facility as a program of the Ministry of Health in carrying out genetic-based national initiatives in developing more appropriate treatments for the community. Harapan Kita Hospital is one of the vertical hospitals incorporated in the BGSi Hubs, so the activity plan for the Molecular Biology Laboratory Unit and SCF will be provided in the form of Biobank and Sequencing services. Biobank is a storage facility that stores and manages high-quality biological specimens (organ tissue, blood, serum, plasma, urine, genetic material, and others) for future use.

Clinical applications of stem cells therapy have been conducted in patients with diabetes, bone fractures, arthritis, burns, decreased vision, heart failure and paralysis due to accidents. Cases in Indonesia are dominated by heart failure and arthritis patients, it is generally recognized that preclinical cell-based therapies are effective and have provided significant results, involving prevention or reduction of myocardial cell death, inhibiting scar formation, increasing angiogenesis, and improving cardiac function.[42] Stem cells that develop into heart muscle cells will provide clues on how to induce the heart muscle to repair itself after a heart attack. The cells can be used to study diseases, identify new drugs, or screen drugs for toxic side effects.[43] Patients with chronic heart conditions can be given stem cell therapy, but not all cases can be treated with this treatment. Clinical studies have not achieved maximum results because some show paradoxical results, but it is known that MSC and iPSC are the most promising cell types for coronary heart disease in clinical settings. As a heart center hospital that provides cardiac health services, Harapan Kita also develops its knowledge as a facilitator of education and training, by assisting the development of cardiovascular research. Good Corporate Governance is used as a guideline in carrying out all its activities, starting from upstream to downstream, namely: responsibility, accountability, independence, transparency, and normalcy. The goal is to improve the quality of services and be able to compete with the quality of overseas hospitals.

Health workers and researchers at Harapan Kita Hospital are trying to improve stem cell therapy services for the treatment and recovery of patients, but the implementation of clinical applications is not as much as the research conducted because it is still service-based research. Harapan Kita Hospital does not use embryonic stem cells because this type conflicts with the law on the status of the embryo whether as a subject or object, religiously, norms, and ethics whether embryonic stem cells can be used as a source of research and treatment. Although the benefits derived from embryonic stem cells are enormous, this needs attention because the source of the cells taken has damaged the potential of human life. This controversial issue is related to the beginning of life and the human right to life

[42] Chuanbin Liu et al., "The Current Dilemma and Breakthrough of Stem Cell Therapy in Ischemic Heart Disease." *Front Cell Dev Biol* 9 (2021):1-12.

[43] California Institute for Regenerative Medicine. "Myths and Misconceptions About Stem Cell Research". CIRM, 2021. https://www.cirm.ca.gov/patients/myths-and-misconceptions-about-stem-cell-research

because the source comes from zygotes left over from IVF, cloned embryos, and miscarried fetuses.[44]

Based on the research results, it is known that: (1) Lack of shared understanding among researchers due to the diversity of scientific backgrounds which may not always be the case. With the influx of new researchers, there may not always be a clear understanding of the history of the field and terminology, therefore specific definitions or contextual meanings of language and concepts may not be universal. Achieving a common understanding will reduce confusion and increase clarity in the design, application and reporting of the science; (2) Issues in material integrity as consistency in research requires consistency in materials. Problems affecting cell quality can affect experimental results, resulting in inconsistent data and invalid conclusions. For this reason, it is important to identify practical steps that each laboratory can take to help ensure that the materials they use are of good quality and unaffected by factors that could render the data collected using those materials dubious; (3) Non-reproducibility as the lack of reproducibility both within and between laboratories impacts the pace of research progress and erodes confidence in the scientific method.

At the same time, there are ongoing debates regarding the safety and efficacy of the treatment, as well as the patient's understanding of the origin of the materials used in the treatment. For stem cells isolated from the umbilical cord, there are two main issues regarding the appropriate time at which donor consent should be obtained for the use of the resulting medical data and related issues regarding maintenance and cold storage in certain banks. Regarding bone marrow mesenchymal stem cells, questions arise regarding the pain and risk to the donor during the cell isolation process. Then there are questions relating to the full informed consent of participants throughout the experimental process. The importance of some institutional issues concerns the careful consideration of intellectual property rights governing stem cell research in relation to medical care and ethics. Finally, questions arise about intellectual property limitations on the use of research materials and how to access medical and therapeutic technologies.

Public interest in stem cells therapy is quite high in Indonesia despite the high cost and lack of information regarding the practice of stem cells therapy. There are still many people or patients who lack education related to stem cells, this is a gap for people who take advantage of the ignorance of the public or patients to rob them of their money. Problems that generally occur in fact are carried out by illegal stem cells clinics using products that are not standardized because they do not obtain BPOM distribution permits as products that can be used en masse. As a result of these actions, legal problems arise for consumers, as parties who tend to be seen as having a weak legal position compared to producers of goods and entrepreneurs or traders in trade activities.[45] Due to the weak position of consumers, the government needs to realize that there is an urgency for the Law to provide legal protection to consumers. One form of consumer protection is the protection provided as mentioned in Article 204 and Article 205 of the Criminal Code.[46] Article 204 and Article 205 of the Criminal Code relate to goods that threaten life or damage people's health, such

[44] Ahdiana Yuni Lestari et al., "Legality of Therapeutic Contract of Stem Cell Treatment in Indonesia." *International Journal of Public Health Science* 12, no. 1 (2023): 215–24. doi:10.11591/ijphs.v12i1.22498

[45] Tursina, Alya. "Stem Cell Transplant Therapy as a Health Service Effort in Indonesia in the Perspective of Health Law and Islamic Law." *Aktualita: Journal of Law* 2, no. 1 (2019): 59-86.

[46] Rimbawan, Andhika Yuli. "Therapeutics in Health Services from the Perspective of Legal Protection." *Legal Standing: Journal of Legal Science* 4, no. 2 (2020): 64-69.

goods will be sold, disseminated, and so on to consumers, including patients.[47] The difference between Article 204 and Article 205 is that Article 204 is a criminal offense with intent *(dolus)*, while Article 205 is a criminal offense of negligence *(culpa)*.[48] Although not directly related to Article 204 and Article 205 of the Criminal Code, PMK No. 32 of 2018 and Health Law No. 17 of 2023 strengthen consumer protection in public health services as a whole. Therefore, these three regulations complement each other in an effort to protect people's lives and health and regulate actions that endanger the public.

CONCLUSION

The development of research and use of stem cells for degenerative diseases makes them a potential solution for healthcare in the future. However, it faces challenges in terms of regulation as the Government lacks the necessary standards to ensure the safe implementation of stem cell therapy. The lack of minimum standards and an enabling environment can cause problems in the research process. This will greatly affect hospitals and laboratories that have been licensed by the Minister of Health to safely carry out stem cell therapy. Because the standards established will be the solution to determine the success rate of research and therapy services carried out, patient understanding of stem cell therapy treatment, maintenance and storage of stem cells that have been produced, the level of pain caused by therapy actions, the risks experienced by donors, and the limitations of research materials. Researchers and health workers significantly provide strong evidence to support decision-making in policy formulation and can ensure that the standards established are relevant to the research findings.

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[47] Yeni Triana et al. "Relationship between Legal Protection of Patients in Health Services in Public Hospitals." *Journal of Education and Counseling* (JPDK) 5, no. 1 (2023): 1274-1279.

[48] Yulio Tubongkasi. "Articles 204 and 205 of the Criminal Code in Relation to Law Number 8 Year 1999." *LEX CRIMEN* 11, no. 5 (2022).

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