

DAFTAR PUSTAKA

- Agita, Petra, and Dyah Ersita Yustanti. "Efektivitas Penerapan Persetujuan Tindakan Media (Informed Consent) sebagai Perlindungan Hukum bagi Pasien dan Tenaga Kesehatan dalam Pelayanan Medis di Rumah Sakit." *JIMU: Jurnal Ilmiah Multi Disiplin* 04, no. 01 (2026). <https://ojs.smkmerahputih.com/index.php/jimu/article/view/2044>.
- Agustin, Heidy, Triya Damayanti, Arini Purwono, et al. "Genomic and Stem Cell Research for Tuberculosis and Pulmonary Diseases: Experience from Persahabatan Hospital." *Persahabatan Resporology Journal* 1, no. 1 (2025). <https://doi.org/https://doi.org/10.67483/prj.v1.i1.4>.
- Agustin, Ruli, and Taufiqurrohman Syahuri. "Implementasi Undang-Undang Kesehatan: Implikasi Terhadap Kesejahteraan Masyarakat Dan Perspektif Tenaga Kesehatan Di Indonesia." *Bacarita Law Journal* 4, no. 2 (2024): 64–76. <https://doi.org/10.30598/bacarita.v4i2.12362>.
- Alberts, Bruce, Alexander Johnson, Julian Lewis, Martin Raff, Keith Roberts, and Peter Walter. *Molecular Biology of the Cell*. 6th ed. Garland Science, 2014. <https://www.ncbi.nlm.nih.gov/books/NBK21054/>.
- Arias, Luis Gerardo Jiménez. "Ethical Consideration of Stem Cell Transplantation." In *Biochemistry*, vol. 62. IntechOpen, 2024. <https://doi.org/10.5772/intechopen.1007415>.
- Azuma, Kentaro, and Shinya Yamanaka. "Recent Policies That Support Clinical Application of Induced Pluripotent Stem Cell-Based Regenerative

Therapies.” *Regenerative Therapy* 4 (June 2016): 36–47.
<https://doi.org/10.1016/j.reth.2016.01.009>.

Biro Kerja Sama dan Hubungan Masyarakat Badan POM. “BPOM Bongkar Praktik Ilegal Terapi Sekretom Oleh Dokter Hewan Di Magelang.” Badan POM, Badan Pengawasan Obat dan Makanan, August 27, 2025.
<https://www.pom.go.id/berita/bpom-bongkar-praktik-ilegal-terapi-sekretom-oleh-dokter-hewan-di-magelang>.

Danil, Tamaulina Br Sembiring, and Bambang Fitrianto. “Juridical Analysis of Informed Consent and Ownership Rights Reviewed from Law No 17 of 2023 Concerning Health.” *Asian Journal of Multidisciplinary Research and Analysis* 1, no. 2 (2023).
<https://journal.berpusi.co.id/index.php/Ajomra/article/view/588>.

Debie, Ayal, Resham B. Khatri, and Yibeltal Assefa. “Successes and Challenges of Health Systems Governance towards Universal Health Coverage and Global Health Security: A Narrative Review and Synthesis of the Literature.” *Health Research Policy and Systems* 20, no. 1 (2022): 50.
<https://doi.org/10.1186/s12961-022-00858-7>.

Dewi, Dian Andriani Ratna, Tiarsen Buaton, and Topane Gayus. “Stem Cells Service Legality Post-Application of Law Number 36 Year 2009 About Health.” *Eduvest - Journal of Universal Studies* 2, no. 7 (2022).
<https://doi.org/https://doi.org/10.59188/eduvest.v2i7.508>.

Dhingra-Kumar, Neelam, Silvio Brusaferrero, Luca Arnaldo, et al. “Patient Safety in the World.” In *Textbook of Patient Safety and Clinical Risk Management*,

Chapter 8. Springer, 2021. https://doi.org/https://doi.org/10.1007/978-3-030-59403-9_8.

European Commission. *Guidelines on Good Clinical Practice Specific to Advanced Therapy Medicinal Products*. European Commission, 2019. https://health.ec.europa.eu/document/download/2d8842cb-e785-488f-bfd0-bf8f2dab1efe_en?filename=atmp_guidelines_en.pdf.

European Medicines Agency. “Advanced Therapy Medicinal Products: Overview.” European Medicines Agency: Science Medicines Health, 2023. <https://www.ema.europa.eu/en/human-regulatory-overview/advanced-therapy-medicinal-products-overview>.

Fitira, Annisa, and Rahayu Subekti. “Informed Consent sebagai Perlindungan Hukum bagi Dokter dan Pasien dalam Langkah Antisipasi Potensi Terjadinya Sengketa Medis di Rumah Sakit.” *Prosiding Seminar Nasional Ilmu Hukum* (Demak), 2025. <https://doi.org/https://doi.org/10.62383/prosemnashuk.v2i2.74>.

Food and Drug Administration. “Regenerative Medicine Advanced Therapy Designation.” Food and Drug Administration (FDA), 2024. <https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/regenerative-medicine-advanced-therapy-designation>.

Gurusamy, Narasimman, Abdulrhman Alsayari, Sheeja Rajasingh, and Johnson Rajasingh. “Adult Stem Cells for Regenerative Therapy.” In *Progress in Molecular Biology and Translational Science*, vol. 160. Elsevier, 2018. <https://doi.org/10.1016/bs.pmbts.2018.07.009>.

Haase, Alexandra, Arjang Ruhparwar, and Ulrich Martin. "GMP-Compliant Manufacturing of iPSC-Derived Therapeutic Cell Products: Technologies, Applications, Risks and Limitations." *Advanced Drug Delivery Reviews* 229 (February 2026): 115744. <https://doi.org/10.1016/j.addr.2025.115744>.

Harris, Alexander R., Mary Jean Walker, and Frederic Gilbert. "Ethical and Regulatory Issues of Stem Cell-Derived 3-Dimensional Organoid and Tissue Therapy for Personalised Regenerative Medicine." *BMC Medicine* 20, no. 1 (2022). <https://doi.org/10.1186/s12916-022-02710-9>.

Hoang, Duc M., Phuong T. Pham, Trung Q. Bach, et al. "Stem Cell-Based Therapy for Human Diseases." *Signal Transduction and Targeted Therapy* 7, no. 1 (2022): 272. <https://doi.org/10.1038/s41392-022-01134-4>.

Human Fertilisation and Embryology Authority. *The Code of Practice*. 9.4. Human Fertilisation and Embryology Authority, 2023.

Iglesias-Lopez, Carolina, Antonia Agustí, Mercè Obach, and Antonio Vallano. "Regulatory Framework for Advanced Therapy Medicinal Products in Europe and United States." *Frontiers in Pharmacology* 10 (August 2019): 921. <https://doi.org/10.3389/fphar.2019.00921>.

Immanuela, Joanne Krisna. "Perlindungan Hukum Bagi Pasien Dalam Penggunaan Terapi Sel Punca (Stem Cell) Pada Pelayanan Kesehatan Di Indonesia." *Law and Humanity* 3, no. 3 (2025): 201–14. <https://doi.org/10.37504/lh.v3i3.773>.

Indina, Fila. "Kajian Yuridis Persetujuan Tindakan Medis (Informed Consent) Dalam Perspektif Undang-Undang No 17 Tahun 2023 Tentang Kesehatan."

Jurnal Cahaya Mandalika ISSN 2721-4796 (online) 3, no. 1 (2024): 633–38. <https://doi.org/10.36312/jcm.v3i1.3499>.

International Society for Stem Cell Research. *Guidelines for Stem Cell Research and Clinical Translation*. Version 1.2. International Society for Stem Cell Research (ISSCRs), 2025. <https://www.isscr.org/guidelines>.

Jiang, Lin-Li, Hui Li, and Lei Liu. “Xenogeneic Stem Cell Transplantation: Research Progress and Clinical Prospects.” *World Journal of Clinical Cases* 9, no. 16 (2021): 3826–37. <https://doi.org/10.12998/wjcc.v9.i16.3826>.

Karwiti, Witi, Sholeha Rezekiyah, Nasrazuhdy Nasrazuhdy, Wuni Sri Lestari, Nurhayati Nurhayati, and Asrori Asrori. “Profil Kimia Darah sebagai Deteksi Dini Penyakit Degeneratif Pada Kelompok Usia Produktif.” *Jurnal Kesehatan Komunitas* 9, no. 3 (2023): 494–503. <https://doi.org/10.25311/keskom.Vol9.Iss3.1389>.

Keputusan Menteri Kesehatan Nomor 01.07/MENKES/1200/2025 tentang Pedoman Penyelenggaraan Terapi Sel dan/atau Sel Punca di Bidang Bedah Plastik Rekonstruksi dan Estetika.

Keputusan Menteri Kesehatan Nomor 01.07/MENKES/1359/2024 tentang Pedoman Penyelenggaraan Terapi Sel Punca di Bidang Orthopedi dan Traumatologi.

Kurniawan, Franky, Hendry Aspan, and Andoko Andoko. “A Juridical Review of Informed Consent Based on Law Number 17 of 2023 Concerning Health as a Replacement for Law Number 36 of 2009.” *Bengkoelen Justice: Jurnal*

Ilmu Hukum 14, no. 1 (2024): 85–100.
<https://doi.org/10.33369/jbengkoelenjust.v14i1.33564>.

Kurniawan, I. Gede Agus, and Ade Chandra. “The Civil Law Aspects of Informed Consent to Medical Procedures.” *SASI*, September 30, 2024, 326–38.
<https://doi.org/10.47268/sasi.v30i3.2277>.

Lebang, Nonia Sakka, and Haeruddin. “Nonia Sakka Lebang.” *Sultra Journal of Political Science* 4, no. 1 (2022): 1–11. <http://jurnal-unsultra.ac.id/index.php/sulrev>.

Mahendra, Cipta. “Terapi Berbasis Sel: Perkembangan Terkini.” *Cermin Dunia Kedokteran* 49, no. 3 (2022).
<https://doi.org/https://doi.org/10.55175/cdk.v49i3.207>.

Mayring, Philipp. *Qualitative Content Analysis: Theoretical Foundation, Basic Procedures and Software Solution*. Klagenfurt, 2014.
<https://www.ssoar.info/ssoar/handle/document/39517>.

Mazini, Loubna, Mohamed Ezzoubi, and Gabriel Malka. “Overview of Current Adipose-Derived Stem Cell (ADSCs) Processing Involved in Therapeutic Advancements: Flow Chart and Regulation Updates before and after COVID-19.” *Stem Cell Research & Therapy* 12, no. 1 (2021): 1.
<https://doi.org/10.1186/s13287-020-02006-w>.

Muhaimin. *Metode Penelitian Hukum*. Mataram University Press, 2020.

Nasir, Mohammad, Kaif Siddiqui, and Samreen Ahmed. “Ethical-Legal Implications of AI-Powered Healthcare in Critical Perspective.” *Frontiers*

in *Artificial Intelligence* 8 (July 2025): 1619463.
<https://doi.org/10.3389/frai.2025.1619463>.

Nur, Iffatin. "Stem Cell Therapy: Its Legality in the Perspectives of Indonesian Law and Progressive Islamic Jurisprudence." *International Journal of Advanced Research* 8, no. 02 (2020): 202–12.
<https://doi.org/10.21474/IJAR01/10455>.

Pamuji, Kadar, Abdul Aziz Nasihuddi, Kartono, et al. *Buku Ajar Hukum Administrasi Negara*. Unsoed Press, 2023.

Peraturan Badan Pengawas Obat dan Makanan Nomor 18 Tahun 2020 tentang Pedoman Penilaian Obat Berbasis Sel Manusia.

Peraturan Badan Pengawas Obat dan Makanan Nomor 24 Tahun 2025 tentang Tata Laksana Persetujuan Obat Pengembangan Baru.

Peraturan Badan Pengawas Obat dan Makanan Nomor 8 Tahun 2025 tentang Pedoman Penilaian Produk Terapi Advanced.

Peraturan Menteri Kesehatan Nomor 11 Tahun 2025 tentang Standar Kegiatan Usaha dan Standar Produk/Jasa pada Penyelenggaraan Perizinan Berusaha Berbasis Risiko Subsektor Kesehatan.

Peraturan Menteri Kesehatan Nomor 32 Tahun 2018 tentang Penyelenggaraan Pelayanan Sel Punca dan/atau Sel.

Peraturan Menteri Kesehatan Nomor 50 Tahun 2012 tentang Laboratorium Pengolahan Sel Punca Untuk Aplikasi Klinis.

Peraturan Menteri Kesehatan Nomor 62 Tahun 2013 tentang Penyelenggaraan Bank Jaringan dan/atau Sel.

Peraturan Pemerintah Nomor 28 Tahun 2024 tentang Peraturan Pelaksanaan Undang-Undang Nomor 17 Tahun 2023 tentang Kesehatan.

Pirsadeghi, Ali, Negar Namakkoobi, Mahtab Sharifzadeh Behzadi, et al.

“Therapeutic Approaches of Cell Therapy Based on Stem Cells and Terminally Differentiated Cells: Potential and Effectiveness.” *Cells & Development* 177 (March 2024): 203904.
<https://doi.org/10.1016/j.cdev.2024.203904>.

Poliwoda, Salomon, Nazir Noor, Evan Downs, et al. “Stem Cells: A Comprehensive Review of Origins and Emerging Clinical Roles in Medical Practice.” *Orthopedic Reviews* 14, no. 3 (2022).
<https://doi.org/10.52965/001c.37498>.

Prabowo, Bambang Hadi. “Apa Itu Terapi Stem Cell? Ini Penjelasannya.” *Regenic*, May 13, 2025. <https://www.regenic.co.id/en/article/umum/apa-itu-terapi-stem-cell-ini-penjelasannya>.

Priyadarshini, Ni Putu Parvathi, and I. Gusti Ayu Putri Kartika. “Patient’s Right to Consent to Medical Procedures from the Perspective of Health Law, Bioethics, and Human Rights.” *Journal of Law, Politic and Humanities* 5, no. 4 (2025): 2429–35. <https://doi.org/10.38035/jlph.v5i4.1505>.

Revon, Gabriel, and Michael J. Reiss. “Principlism in Bioethics: How to Consolidate Autonomy? A Scoping Review.” *Bioethics Open Research* 3 (June 2025). <https://doi.org/10.12688/bioethopenres.17704.1>.

RI, Undang-Undang Dasar Republik Indonesia Tahun 1945.

RI, Undang-Undang Nomor 17 Tahun 2023 tentang Kesehatan.

Ryansyah, Ahmad, Halimah Zahra, Berdhy Ursila Djamil, and Muhammad Irfan Fauzan. "Efektivitas Perlindungan Hukum Konsumen dalam Kasus Malpraktik Medis pada Jasa Pelayanan Kesehatan di Indonesia." *PENG: Jurnal Ekonomi dan Manajemen* 2, no. 4 (2025): 4158–66. <https://doi.org/10.62710/htt84329>.

Saputra, Juliansyah Yugis, and Dyah Ersita Yustanti. "Peran Hukum Kesehatan dalam Penyelenggaraan Pelayanan Kesehatan di Indonesia pada Layanan Telemedicine." *Desentralisasi: Jurnal Hukum, Kebijakan Publik, dan Pemerintahan* 3, no. 1 (2026). <https://doi.org/10.62383/desentralisasi.v3i1.1526>.

Sari, Restiana Mustika. "Bioethics and Patient Involvement in Medical Decision-Making: Challenges And Ethical Implications In Clinical Practice." *International Journal of Patient Safety and Quality* 1, no. 1 (2024): 73–81. <https://doi.org/10.20473/ijpsq.v1i1.55991>.

Schultz, Timothy J., Michael Zhou, Jodi Gray, et al. "Patient Characteristics of, and Remedial Interventions for, Complaints and Medico-Legal Claims against Doctors: A Rapid Review of the Literature." *BMC Journals* 13, no. 1 (2024). <https://doi.org/10.1186/s13643-024-02501-8>.

Soetisna, Tri Wisesa, Ahmad Muslim Hidayat Thamrin, Andi Nurul Erisya Ramadhani, Diajeng Permadijana, Muhammad Alghifari Elfian, and Hari Hendarto. "Systematic Review of Stem Cell Therapy for Ischemic Heart Disease in Indonesia: Where Are We Now?" *Malaysian Journal of*

Medicine and Health Sciences 20, no. 3 (2024): 298–306.
<https://doi.org/10.47836/mjmhs.20.3.40>.

Song, Seohyun Jennie, Yoojun Nam, Yeri Alice Rim, Ji Hyeon Ju, and Yeowon Sohn. “Comparative Analysis of Regulations and Studies on Stem Cell Therapies: Focusing on Induced Pluripotent Stem Cell (iPSC)-Based Treatments.” *Stem Cell Research & Therapy* 15, no. 1 (2024): 447.
<https://doi.org/10.1186/s13287-024-04065-9>.

Suni, Nur Sholikhah Putri. “Pengawasan Pelayanan Terapi Sel Punca.” *Info Singkat* XVII, no. 17 (2025).
https://berkas.dpr.go.id/pusaka/files/info_singkat/Info%20Singkat-XVII-17-I-P3DI-September-2025-1957.pdf.

Suprpto. *Kebijakan Kesehatan Dan Keperawatan: Teori, Implementasi, Dan Transformasi Sistem Pelayanan*. Edited Book. Edukasi Ilmiah Indonesia, 2026.

Suryanto, Muhammad Handika, Fatma Tria Arresti, and Aisyunnada Makky. “No Viral No Justice Perspektif Teori Efektivitas Hukum Soerjono Soekanto.” *Widya Yuridika* 7, no. 3 (2024): 513–22.
<https://doi.org/10.31328/wy.v7i3.5076>.

Syahrani, Aqilla Nur, and 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>.

Tian, Zeyu, Tao Yu, Jun Liu, Ting Wang, and Akon Higuchi. "Introduction to Stem Cells." In *Progress in Molecular Biology and Translational Science*, vol. 199. Elsevier, 2023. <https://doi.org/10.1016/bs.pmbts.2023.02.012>.

Urahn, Susan K., Allan Coukell, Liz Richardson, et al. *FDA's Framework for Regulating Regenerative Medicine Will Improve Oversight: Further Action Needed to Facilitate Development of Safe, Effective Treatments*. The PEW Charitable Trust, 2019. https://www.pew.org/-/media/assets/2019/10/fdasframeworkforregulatingregenerativemedicine_v2.pdf.

Wang, Jipeng, Gang Deng, Shuyi Wang, et al. "Enhancing Regenerative Medicine: The Crucial Role of Stem Cell Therapy." *Frontiers in Neuroscience* 18 (February 2024): 1269577. <https://doi.org/10.3389/fnins.2024.1269577>.

Waterworth, Christopher James, Fleur Smith, Felix Kiefel-Johnson, Wesley Pryor, and Manjula Marella. "Integration of Rehabilitation Services in Primary, Secondary, and Tertiary Levels of Health Care Systems in Low- and Middle-Income Countries: A Scoping Review." *Disability and Rehabilitation* 46, no. 25 (2024): 5965–76. <https://doi.org/10.1080/09638288.2024.2317422>.

Widyawati. "Praktik Stem Cell Ilegal, Dokter Sekaligus Pemilik Klinik Tak Punya Kompetensi." *Kemenkes*, January 16, 2020. <https://kemkes.go.id/eng/%20praktik-stem-cell-ilegal-dokter-sekaligus-pemilik-klinik-tak-punya-kompetensi>.

World Health Organization (WHO). “Noncommunicable Diseases.” World Health Organization (WHO), World Health Organization (WHO), September 25, 2025. <https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases>.

World Health Organization (WHO). *Role of Policy-Makers and Health Care Leaders in Implementation of the Global Patient Safety Action Plan 2021–2030*. Consensus Statement. World Health Organization (WHO), 2022. <https://www.who.int/publications/i/item/WHO-UHL-IHS-PSF-2022.3>.

Zakrzewski, Wojciech, Maciej Dobrzyński, Maria Szymonowicz, and Zbigniew Rybak. “Stem Cells: Past, Present, and Future.” *Stem Cell Research & Therapy* 10, no. 1 (2019). <https://doi.org/10.1186/s13287-019-1165-5>.

Zhao, Shengyu, Giles Birchley, and Richard Huxtable. “Translation of Bioethics across Cultural Borders: Exploring the Adoption of the Four-Principles Approach in Palliative Care Provision on the Chinese Mainland.” *BMC Palliative Care* 24, no. 1 (2025): 100. <https://doi.org/10.1186/s12904-025-01733-2>.