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Human rights in the era of emerging epigenome editing technologies

Scientific background and recent developments in epigenome editing technologies versus genome editing

Medicine and biotechnology are dynamically changing with astonishing technological advancements spanning multiple sectors. In the last decade, genome editing technology, such as Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR), has been hailed as the most revolutionary discovery in biotechnology[2]. Pioneers E. Charpentier and J.A. Doudna were awarded the 2020 Nobel Prize in Chemistry for their breakthrough research in the

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[2] J. van der Oost, C. Patinios, *The genome editing revolution*, "Trends in Biotechnology" 2023, vol. 41, no. 3, p. 396.

development of CRISPR gene-editing technology[3]. In 2012, E. Charpentier and J.A. Doudna along with four co-authors presented their landmark paper on how bacteria and archaea use CRISPR or CRISPR-associated (Cas) systems to protect themselves from viruses and plasmids[4]. Further research into the function of CRISPR-Cas and derivatives has revealed that these systems could be used as cost-effective, precise, and efficient methods of genetic engineering[5]. Scientists found that CRISPR can be used to alter a selected section of DNA or RNA by cutting the sequence at a chosen point and either deleting existing elements of the genome or introducing a new sequence[6]. Since then, CRISPR has been repurposed for the precise editing of genetic material at any selected site in different cells in humans, animals, plants, and microorganisms[7].

The revolutionary impact of gene editing has opened a new era in human somatic (cell of the body) and germline genome (eggs

[3] H. Ledford, E. Callaway, *Pioneers of revolutionary CRISPR gene editing win chemistry Nobel*, "Nature" 2020, vol. 586, issue 7829, p. 346; E. Charpentier, J.A. Doudna were awarded 'for the development of a method for genome editing', see *Press release 2020*, nobelprize.org/prizes/chemistry/2020/press-release [accessed: 12.10.2024].

[4] M. Jinek, K. Chylinski, I. Fonfara, M. Hauer, J.A. Doudna, E. Charpentier, *A programmable dual-RNA-guided DNA endonuclease in adaptive bacterial immunity*, "Science" 2012, vol. 337, no. 6096, p. 816.

[5] Cost and time effective in comparison to other genome editing techniques like ZNF, TALEN. Consequently CRISPR gene editing technology has been called 'genetic/molecular scissors' in many articles i.e. A. Azvolinsky, *Molecular scissors cut in on stem cells*, "Nature Medicine" 2019, vol. 25, no. 6, pp. 864–866. See also J.A. Doudna, E. Charpentier, *The new frontier of genome engineering with CRISPR Cas9*, "Science" 2014, vol. 346, no. 6213, 1258096; F.A. Ran, P.D. Hsu, J. Wright, V. Agarwala, D.A. Scott, J.A. Sharp, B. Konermann, Y. Liang, O. Kehayova, N.D. Le Cong, M.J. Greenleaf, F. Zhang, *Genome engineering using the CRISPR-Cas9 system*, "Nature Protocols" 2013, vol. 8, no. 11, pp. 2281–2308.

[6] S. Reardon, *Step aside CRISPR, RNA editing is taking off*, "Nature" 2020, vol. 578, no. 7794, pp. 24–27.

[7] J.Y. Wang, J.A. Doudna, *CRISPR technology: A decade of genome editing is only the beginning*, "Science" 2023, vol. 379, no. 6637, eadd8643; Y.C. Kim, Y. Kang, E.-Y. Yang, M.-C. Cho, R. Schafleitner, J.H. Lee, S. Jang, *Applications and major achievements of genome editing in vegetable crops: A review*, "Frontiers in Plant Science" 2021, vol. 12, no. 688980, p. 2281.

and sperm) editing applications, to eliminate diseases and improve public health[8]. In November 2018, during the Second International Summit on Human Genome Editing in Hong Kong, the scientist J. He sparked global outrage by announcing the birth of the first genetically engineered/edited twins in history[9]. J. He, a genome-editing researcher at the Southern University of Science and Technology of China in Shenzhen, used CRISPR-Cas5 to change both copies of the gene named CCR5, to protect the embryos from HIV infection[10]. This germline-editing intervention on humans has been widely commented on and criticized[11]. The world community pointed out that this was an experiment and not a medical, therapeutic intervention[12]. Moreover, as many authors have indicated, J. He violated several established ethical and moral norms, guidelines and international and national regulations[13]. This story and the rapidly growing studies of somatic and germline genome editing triggered discussions and implications on international and country-level

[8] Human germline genome editing (HGGE) refers to germ cells, or embryo and results could be transferred to offspring. See more J. Ryu, E.Y. Adashi, J.D. Hennebold, *The history, use, and challenges of therapeutic somatic cell and germline gene editing*, "Fertility and Sterility" 2023, vol. 120, no. 3, Pt 1, pp. 528–538; B.C. van Beers, *Rewriting the human genome, rewriting human rights law? Human rights, human dignity, and human germline modification in the CRISPR era*, "Journal of Law and the Biosciences" 2020, vol. 7, issue 1, p. 3.

[9] The story in details is presented in many articles i.e. H.T. Greely, *CRISPR'd babies: human germline genome editing in the 'He Jiankui affair'*, "Journal of Law and the Biosciences" 2019, vol. 6, issue 1, pp. 111–120; V.L. Raposo, *The first Chinese edited babies: a leap of faith in science*, "JBRA Assisted Reproduction" 2019, vol. 23, no. 3, pp. 197–199.

[10] M. Alonso, J. Savulescu, *He Jiankui´s gene-editing experiment and the non-identity problem*, "Bioethics" 2021, vol. 35, issue 6, pp. 563–564.

[11] B.C. van Beers, *Rewriting the human genome*, *op. cit.*, pp. 2–3; V.L. Raposo, *The first Chinese edited babies*…, *op. cit.*, pp. 197–199.

[12] V.L. Raposo, *The first Chinese edited babies*…, *op. cit.*

[13] J.R. Li, S. Walker, J.B. Nie, X.Q. Zhang, *Experiments that led to the first gene-edited babies: The ethical failings and the urgent need for better governance*, "The Journal of Zhejiang University Science B" 2019, vol. 20, issue 1, pp. 32–33; B.C. van Beers, *Rewriting the human genome*, *op. cit.*, p. 7. Authors commented that J. He ignored and violated basic long-term rules established in biological and medical science.

regulations, patentees, licensing models, worldwide commercialization, and access to this technology[14].

While canonical somatic genome editing, which is less controversial than germline editing for therapeutic purposes, has been developed and continues to be applied, new ethical and legal issues arise for epigenome editing studies and applications. In epigenome editing (also called genetic tuning), the particular expression of a gene is controlled/influenced by modifying chromatin components without altering the genome nucleotide sequence[15]. Epigenome editing is an entirely 'no-cut' process, leaving the DNA untouched. It is therefore significantly distinct from genome editing. Among many mechanisms, chemical modifications of DNA (DNA methylation), histone post-translation modifications, chromatin proteins, RNA interference, and noncoding RNAs are involved in the epigenetic regulation of the gene expressions associated with many genetic diseases and cancers[16]. The effectiveness of epigenome editing depends on many factors, which are not yet fully understood[17]. The epigenetics processes are unique for each cell type in an organism (i.e. blood, skin, brain cells) and can turn genes on or off[18]. Sometimes epigenetic changes might be induced by social

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14 J.L. Contreras, J.S. Sherkow, *CRISPR, surrogate licensing, and scientific discovery*, "Science" 2017, vol. 355, issue 6326, p. 698; D. Matthews, *Access to CRISPR genome editing technologies: patents, human rights and the public interest*, [in:] *Access to medicines and vaccines*, eds C.M. Correa, R.M. Hilty, Cham 2022, pp. 106–108.

15 See more details about epigenome editing in article: J.H. Goell, I.B. Hilton, *CRISPR/Cas-based epigenome editing: advances, applications, and clinical utility*, "Trends in Biotechnology" 2021, vol. 39, issue 7, pp. 678–691.

16 J. Ueda, T. Yamazaki, H. Funakoshi, *Toward the development of epigenome editing-based therapeutics: Potentials and challenges*, "International Journal of Molecular Sciences" 2023, vol. 24, issue 5, p. 4778.

17 T. Weiss, J. Malabarba, Y. Mitsuya, A. Sharma, P. Nielsen, J. Wang, *Epigenetic features drastically impact CRISPR–Cas9 efficacy in plants*, "Plant Physiology" 2022, vol. 190, issue 2, p. 1154; G. Kungulovski, A Jeltsch, *Epigenome editing: State of the art, concepts, and perspectives*, "Trends in Genetics" 2022, vol. 32, issue 2, pp. 101–102.

18 J.K. Nuñez, J. Chen, G.C. Pommier, J.Z. Cogan, J.M. Replogle, C. Adriaens, G.N. Ramadoss, Q. Shi, K.L. Hung, A.J. Samelson, A.N. Pogson, J.Y.S. Kim, A. Chung, M.D. Leonetti, H.Y. Chang, M. Kampmann, B.E. Bernstein,

or environmental factors[19]. They therefore are recognised as reversible but at the same time more stable than others and heritable[20].

This study's discussion of issues related to human rights will focus on CRISPR-Cas (and its follow-on techniques, such as the FIRECas9 system, dCas9, CHARM, or the CRISPRon/CRISPRoff system), as it is the most developed and popular epigenetic tool in epigenome-editing technologies[21]. However, the considerations presented here may be relevant to other types/modalities/effectors of epigenetic editing. Epigenome-like genome editing can be performed both on somatic and germline cells. Mostly, this process – called site-specific epigenetic editing – is based on the fusion of designed DNA recognition domains (catalytically inactive CRISPR complex) with catalytic domains of a chromatin-modifying enzyme, to generate targeted EpiEffectors[22]. This mechanism

V. Hovestadt, L.A. Gilbert, J.S. Weissman, *Genome-wide programmable transcriptional memory by CRISPR-based epigenome editing*, "Cell" 2021, vol. 184, issue 9, p. 2504.

19 C. Dupras, Y. Joly, E. Rial-Sebbag, *Human rights in the postgenomic era: Challenges and opportunities arising with epigenetics*, "Social Science Information" 2020, vol. 59, issue 1, pp. 14–15.

20 E.A. Saunderson, H. Huerga Encabo, J. Devis, K. Rouault-Pierre, M. Piganeau, C.G. Bell, J.G. Gribben, D. Bonnet, G. Ficz, *CRISPR/dCas9 DNA methylation editing is heritable during human hematopoiesis and shapes immune progeny*, "Proceedings of the National Academy of Sciences (PNAS)" 2023, vol. 120, issue 34, p. e2300224120; C. Dupras, Y. Joly, E. Rial-Sebbag, *Human rights in the postgenomic era*…, *op. cit.*, pp. 14–15.

21 Studies concerning epigenome editing using zinc fingers, TAL effector, TetR coupled to EpiEffectors have shown also feasibility of the planned experiments. See more G. Kungulovski, A. Jeltsch, *Epigenome editing*…, *op. cit.*, p. 101. However, more promising and effectively in epigenome editing are CRISPR and follow-on (derivative) techniques. See state of the art epigenome editing technology presented by A. Sgro, P. Blancafort, *Epigenome engineering: New technologies for precision medicine*, "Nucleic Acids Research" 2020, vol. 48, issue 22, pp. 12453–12475 and G.V Roth, I.R. Gengaro, L.S. Qi, *Precision epigenetic editing: Technological advances, enduring challenges, and therapeutic applications*, "Cell Chemical Biology" 2024, vol. 31, issue 7, pp. 1012–1028.

22 Modalities through methylation-specific epigenome edition called epigenomic-modifying enzymes (EpiEffectors) and CRISPRon/CRISPRoff, a programmable epigenetic memory writer are very promising and exciting

(without cutting DNA) creates a false perception that epigenome editing is considered safer and less ethically controversial for human applications than traditional genome editions.

Although most studies are concentrated on basic research, considerable interest exists in translating this technology into medicine and agriculture, or even to military, defense, and security contexts[23]. The clinical applications of epigenome editing are numerous. It can be used in prediction and diagnostic tools, to prevent or cure diseases according to patient epigenetic profiles, applied in drug development, as well as for more specific and less toxic to specific cells or tissue[24]. Over the past few years, epigenetic tools have been commercialized and offered by various companies. For example, EpiCrop Technologies, founded in 2013, utilizes epigenetic editing technology to improve yields, resilience, and stress tolerances of crops (including tomato, soy, and strawberry)[25]. Chroma Medicine has announced on its website that is 'pioneering a new class of single-dose genomic medicines that harness epigenetics'[26].

approaches to regulate gene function and expression. See K. Huerne, N. Palmour, A.R. Wu, S. Beck, A. Berner, R. Siebert, Y. Joly, *Auditing the editor: a review of key translational issues in epigenetic editing*, "The CRISPR Journal" 2022, vol. 5, issue 2, pp. 203; G. Kungulovski, A. Jeltsch, *Epigenome editing*…, *op. cit.*, p. 101. See also examples of EpiEffectors presented by K.D. Rienecker, M.J. Hill, A.R. Isles, *Methods of epigenome editing for probing the function of genomic imprinting*, "Epigenomics" 2016, vol. 8, issue 10, pp. 1391 and 1393.

[23] K. Huerne *et al.*, *Auditing the editor*…, *op. cit.*, pp. 204–205; H. Shin, W.L. Choi, J.Y. Lim, J.H. Huh, *Epigenome editing: Targeted manipulation of epigenetic modifications in plants*, "Genes Genomics" 2022, vol. 44, issue 3, pp. 307–310; G. Dalpé, K. Huerne, C. Dupras, K. Cheung, N. Palmour, E. Winkler, K. Alex, M. Mehlman, J.W. Holloway, E. Bunnik, H. König, I.M. Mansuy, M.G. Rots, C. Erwin, A. Erler, E. Libertini, Y. Joly, *Defusing the legal and ethical minefield of epigenetic applications in the military, defense, and security context*, "Journal of Law Biosciences" 2023, vol. 10, issue 2, lsad034.

[24] C. Dupras, Y. Joly, E. Rial-Sebbag, *Human rights in the postgenomic era*…, *op. cit.*, pp. 14–15.

[25] See *This is the future of agriculture*, 2023, epicrop.com [accessed: 10.11.2024]; also K. Huerne *et al.*, *Auditing the editor*…, *op. cit.*, pp. 209–210.

[26] See *Reimagining genome regulation*, 2023, chromamedicine.com [accessed: 10.11.2024]. Selected epigenome editing companies are summarized in article prepared by I. Clift, *Epigenome editing companies mark preclinical prog-*

As suggested in the literature, the potential but also controversial military applications of such technology are stratifying soldiers' health, measuring exposure to trauma using epigenetic testing, collecting information about biological clocks, and confirming child soldiers' minor status[27].

Despite the promising applications of epigenome editing, the outcomes of this technology compared to genetic editing are presently not clear[28]. Even if a desirable effect was observed in the cell line model, limited data are accessible for tissues or whole organisms. Notable, in epigenetics studies, applying the strategy to one type of cell might be harmful or even affects the same cell, neighboring cells, far located cells, or tissue[29].

In particular, the use of epigenome editing inventions on germ cells is not fully known and predictable. Even if embryo and germline gene editing manipulations are banned and/or discouraged in guidelines, the 'non-invasive', reversible nature of epigenetic editing may lead to wider applications and public acceptance[30]. That wide acceptance might be observed when epigenetic editing techniques become suitable and effective in removing or neutralizing serious

ress, 1.09.2023, genengnews.com/topics/genome-editing/epigenome-editing-companies-mark-preclinical-progress [accessed: 2.12.2024].

27 G. Dalpé *et al.*, *Defusing the legal and ethical*…, *op. cit.*

28 Severity of risks associated with epigenome editing versus genome editing is presented in article prepared by K. Alex, E.C. Winkler, *Comparative ethical evaluation*…, *op. cit.*, pp. 398–406; K. Huerne *et al.*, *Auditing the editor*…, *op. cit.*, p. 210. Importantly, genome editing (not epigenome) after a long time got its first FDA scrutiny for sickle-cell disease in October 2023. See H. Ledford, *Is CRISPR safe? Genome editing gets its first FDA scrutiny*, "Nature" 2023, vol. 623, issue 7986, pp. 234–235.

29 See K. Huerne *et al.*, *Auditing the editor*…, *op. cit.*, pp. 204 and 205; also J.H. Goell, I.B. Hilton, *CRISPR/Cas-based epigenome*…, *op. cit.*, pp. 686–687. Significantly promise for the treatment of cancer via the epigenetic editing method is noted. However, in contrast to standard photon or proton radiotherapy, serious difficulties remain in epigenome editing for cancer like off-target effects, delivery efficiency, and enormous cancer cell resistance i.e. in glioblastoma multiforme treatment.

30 See similar opinion posted by K. Huerne *et al.*, *Auditing the editor*…, *op. cit.*, p. 205.

inherited diseases[31]. Through epigenetic editing sex/gender-related characteristics as well as sexual differentiation of a male embryo into a female is possible[32]. Before the era of epigenetic editing, one of the biggest expectations in epigenetics was the possibility of altering biological aging (biological clock)[33]. Epigenetic editing has been shown to be highly relevant in anti-aging research, not only as previously mentioned for military purposes[34].

However, these applications might not only be used in the treatment process but might also be abused in practices called 'human enhancement' and 'selection of persons'[35]. Importantly, the application of epigenetic editing for enhancement purposes would conflict with human rights, whereas employing it to prevent or cure diseases would not. Without definitions and distinctions between these practices, the blurring boundary exists[36]. For instance, drugs could be designed to improve or enhance human bodily functions (muscle strength). Furthermore, companies such as EpigenCare collect clients' saliva samples to evaluate their biological age, quality of skin, and smoke exposure[37]. It is unclear in the scope of human

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31 L. Zhu, S.L. Marjani, Z. Jiang, *The epigenetics of gametes and early embryos and potential long-range consequences in livestock species – Filling in the picture with epigenomic analyses*, "Frontiers in Genetics" 2021, vol. 12, art. 557934, pp. 1–2.

32 K. Huerne *et al.*, *Auditing the editor*…, *op. cit.*, p. 208.

33 C. Pagiatakis, E. Musolino, R. Gornati, G. Bernardini, R. Papait, *Epigenetics of aging and disease: A brief overview*, "Aging Clinical and Experimental Research" 2021, vol. 33, issue 4, pp. 739–740.

34 EA. Saunderson *et al.*, *CRISPR/dCas9 DNA methylation editing*…, *op. cit.*, pp. 1–2.

35 M. Mandrioli, *Genome editing among bioethics and regulatory practices*, "Biomolecules" 2021, vol. 12, issue 1, p. 6; M.M. Spaander, *The European Court of Human Rights and the emergence of human germline genome editing*, "European Journal of Health Law" 2022, vol. 29, issues 3–5, p. 459.

36 For example, as M. Mandrioli rightly asked in term of epigenome editing "[…] is preventing obesity a cure or enhancement?", see *idem*, *Genome editing among bioethics*…, *op. cit*., p. 6; see also B.C. van Beers, *Rewriting the human genome*…, *op. cit.*, pp. 20–24.

37 See K. Ahern, *About face: How two digital beauty companies plan to give skincare a makeover*, 10.04.2018, jnj.com/innovation/epigencare-skingenie-using-ai-and-dna-to-innovate-your-beauty-routine [accessed: 7.04.2025].

rights whether private companies can collect and use genetic and epigenetic data. This might be particularly interesting for insurance companies, but there is no guidance for epigenetic individual data collecting and use[38].

Other concerns include the risk of using or misusing the technology, with or without other treatments, to alter human health. As mentioned in the literature, this technology can cause off-target effects which could influence clinical outcomes[39]. The specific ethical dilemmas and some plausible scenarios like epigenetic-editing sex/gender-related traits in embryo or adult development are presented, respectively[40]. Moreover, the latest studies might reverse the molecular biology dogma indicating that epigenetic inheritance across generations is possible in gene-edited mammals[41]. Therefore, more methodological studies are needed for a better understanding of the epigenetic mechanisms in humans from in vitro to in vivo that will guide the next applications, ethical principles, and legal status.

This section has illustrated various promises and some unresolved concerns observed previously for genome editing that presently apply to epigenetic tools. In addition, new problems signaled here arise for epigenetic studies and applications. Despite ongoing debate and studies, discussion on the safety, equity, access, ethics, and risk of epigenome editing for various applications is relatively

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See also C. Dupras, Y. Joly, E. Rial-Sebbag, *Human rights in the postgenomic era*…, *op. cit.*, p. 20.

38 See above at 17 and 18. This problem is widely discussed by N. Shapo, M.S. Masar III, *Modern regulatory frameworks for the use of genetic and epigenetic underwriting technology in life insurance*, "Journal of Insurance Regulation" 2020, vol. 39, issue 10, p. 11.

39 K. Huerne *et al.*, *Auditing the editor*…, *op. cit.*, p. 205; Editorial, *Off-targets in epigenome editing*, "Nature Methods" 2018, vol. 15, p. 246. Authors indicated off-targets effects like 'unexpectedly high background methylation', 'high genome-wide off-target activity'.

40 K. Alex, E.C. Winkler, *Comparative ethical evaluation of epigenome editing and genome editing in medicine: first steps and future directions*, "Journal of Medical Ethics" 2024, vol. 50, issue 6, pp. 398–406; K. Huerne *et al.*, *Auditing the editor*…, *op. cit.*, pp. 203–212.

41 See M. Sasaki-Honda, K. Akatsuka, T. Sawai, *Is epigenome editing non-inheritable? Implications for ethics and the regulation of human applications*, "Stem Cell Reports" 2023, vol. 18, issue 11, pp. 2005–2009.

sparse and fragmented. Therefore, there is still a need to evaluate the existing human rights frameworks for epigenetic genome research and translation for medical and abroad applications.

International and selected regional regulatory human rights framework in epigenome editing techniques

Epigenome editing technology and applications hold unprecedented power to shape the future of human rights. The key question is whether epigenome editing is currently prohibited or otherwise regulated under international human rights law? It is not clear whether the existing international regulatory human rights framework sufficiently and adequately addresses epigenome editing technologies. The human rights that are most relevant to epigenome editing are the rights to health and life, human dignity, the right to benefit from science, the right to habilitation, and the prohibition against discrimination[42]. They guarantee the rights not only of members of the present generation but also the interests of the next generation[43]. Human rights might be used as an argument not only against using epigenome technology but in favor of the rights of disabled people to new promising treatment. Importantly, epigenetics findings could contribute to the rise of second-generation (social, economic, cultural rights) and third-generation human rights (solidarity rights)[44].

Due to the lack of an international consensus that would establish an effective regulatory framework designed specifically to govern genome editing, there is no international treaty of general

[42] Selected based on articles i.e. R. Yotova, *Regulating genome editing under international human rights law*, "International & Comparative Law Quarterly" 2020, vol. 69, issue 3, pp. 664–665; S. Slokenberga, T. Minssen, A. Nordberg, *Governing, protecting, and regulating the future of genome editing: the significance of ELSPI perspectives*, "European Journal of Health Law" 2022, vol. 29, issues 3–5, pp. 335–336.

[43] B.C. van Beers, *Rewriting the human genome*…, *op. cit.*, p. 23.

[44] This opinion is rightly presented i.e. by C. Dupras, Y. Joly, E. Rial-Sebbag, *Human rights in the postgenomic era*…, *op. cit.*, p. 16. Apart this article, this aspect is not commented extensively.

application that directly addresses epigenome editing. However, human rights instruments should play an immense role in shaping epigenome editing regulations and applications. In the absence of an international treaty, international regulation of interventions in the human genome is currently approached through the framework of human rights law. Several international instruments describe the human rights relating to their genome.

Firstly, the 1948 Universal Declaration of Human Rights declares the rights to health – in particular, that "everyone has the right to a standard of living adequate for the health of himself and his family […]"[45]. The two leading human rights treaties adopted in 1966 are the International Covenant on Civil and Political Rights (ICCPR) and the International Covenant on Economic, Social and Cultural Rights (ICESCR). They form the international consensus in fundamental human rights standards, called the International Bill of Human Rights (also referred to as 'the International Covenants'), which apply to all states[46]. This act does not explicitly mention epigenome interventions, but it sets out the human rights that must be taken into consideration during discussions of new technologies

[45] Article 25(1), Universal Declaration of Human Rights – a set of human rights and principles for their application, adopted on 10 December 1948, France, United Nations Document A/RES/217(III). The Universal Declaration of Human Rights (UDHR) was proclaimed by the United Nations General Assembly in Paris on 10 December 1948 and is recognized as a milestone in the human rights history. See also L. Wang, X. Liang, W. Zhang, *Genome editing and human rights: Implications of the UNGPs*, "Biosafety and Health" 2022, vol. 4, issue 6, p. 387 and P.L. Lau, *Addressing cognitive vulnerabilities through genome and epigenome editing: Techno-legal adaptations for persons with intellectual disabilities*, "European Journal of Health Law" 2022, vol. 29, issue 3–5, p. 416.

[46] International Covenant on Civil and Political Rights, adopted by the United Nations General Assembly on 16 December 1966, United Nations, Treaty Series, vol. 999, p. 171, entered into force on 23 March 1976 and International Covenant on Economic, Social and Cultural Rights, adopted by the United Nations General Assembly on 16 December 1966, United Nations, Treaty Series, vol. 993, p. 3, entered into force on 3 January 1976; see also A. Boggio, R. Yotova, *Gene editing of human embryos is not contrary to human rights law: A reply to Drabiak*, "Bioethics" 2021, vol. 35, no. 9, p. 957. The ICESCR has 171 States Parties and the ICCPR 173, respectively.

involving human embryos that can positively or negatively affect humans. Three important rights of everyone are recognized, including 'the inherent right to life [which] shall be protected by law' (ICCPR, Art. 6(1)), the right 'to the enjoyment of the highest attainable standard of physical and mental health' (ICESCR, Art. 12(1)) and the right 'to enjoy the benefits of scientific progress and its applications' (ICESCR, Art. 15(1)(b)). These provisions (mostly Art. 15(1)(b)) might be viewed as supporting epigenome editing studies that are compatible with human rights law.

Currently, the most important international soft law human rights instruments (not legally binding themselves) in the field of genome studies are the 1997 UNESCO Universal Declaration on the Human Genome and Human Rights (UNESCO 1997 Declaration)[47], the 2003 UNESCO International Declaration on Human Genetic Data (UNESCO 2003 Declaration)[48] and the 2005 UNESCO Declaration on Bioethics and Human Rights[49]. Adopted in the last century, UNESCO Declarations set out standards and good practices on human rights in the genetic field[50]. This achieved consensus by the UN General Assembly and adoption of the UNESCO 1997 Declaration by the 184 Member States of UNESCO at the time, thus leading to Article 1, which characterized the human genome as the heritage of society that should be protected[51]. For that reason, research and

[47] UNESCO Universal Declaration on the Human Genome and Human Rights (11 November 1997), unesco.org/en/legal-affairs/universal-declaration-human-genome-and-human-rights [accessed: 12.11.2024].

[48] UNESCO International Declaration on Human Genetic Data (16 October 2003), unesco.org/en/legal-affairs/international-declaration-human-genetic-data?hub=66535 [accessed: 12.11.2024].

[49] UNESCO Universal Declaration on Bioethics and Human Rights (19 October 2005), unesco.org/en/legal-affairs/universal-declaration-bioethics-and-human-rights?hub=66535 [accessed: 12.11.2024]; see also R. Yotova, *Regulating genome*…, *op. cit.*, p. 658.

[50] This opinion is propagated widely i.e. R. Yotova, *Regulating genome*…, *op. cit.*, p. 671; C. Dupras, Y. Joly, E. Rial-Sebbag, *Human rights in the postgenomic era*…, *op. cit.*, pp. 16–17; J. Symonides, *UNESCO's contribution to the progressive development of human rights*, "Max Planck Yearbook of United Nations Law" 2021, vol. 5, no. 1, p. 337.

[51] According with Art. 1 UNESCO 1997 Declaration "the human genome underlies the fundamental unity […] as well as the recognition of their inher-

technologies applied to the genome should be viewed with special scrutiny in light of human rights. The provisions of the UNESCO 1997 Declaration address genetic intervention studies from the perspective of human dignity, diversity, and human rights. For that reason, those provisions do not afford human rights normative guidance for epigenome science[52]. However as suggested in the literature, Article 3 might be interpreted as capable of providing guidance in the regulation of epigenome studies[53]. In the context of epigenome editing, it seems that Article 5(a) enumerates the rights of the person concerned that might be used as a test in applying this technology in research and translational studies. According to Article 5(a) 'research, treatment or diagnosis affecting an individual's genome shall be undertaken only after rigorous and prior assessment of the potential risks and benefit'. Given this requirement, more bioinformatic studies (without experimental steps) about potential off-target effects should be propagated and undertaken. However, it is not clear if 'genome' should be identified/unified with 'epigenome'.

Next, the UNESCO 2003 Declaration also focused on genetic data with a broad scope of human rights including 'the collection, processing, use and storage of human genetic data, human proteomic data and biological samples' (Art. 1(c))[54]. This declaration includes particular articles enumerating the right to consent (Art. 8), the right to withdraw consent (Art. 9), the right to decide to be informed about research results (Art. 10), and the right to genetic counseling (Art. 11). Important for this analysis are non-discrimination procedures discussed in Art. 6, which include provisions against potential discrimination on human proteomic data (during collecting, processing, using and storing). In some sense, proteomic

ent dignity and diversity". A. Boggio, R. Yotova, *Gene editing of human embryos*…, *op. cit.*, p. 957.

52 Similar conclusion presents C. Dupras, Y. Joly, E. Rial-Sebbag, *Human rights in the postgenomic era*…, *op. cit.*, p. 18.

53 Importantly, UNESCO 1997 Declaration does not prohibit germline modification, whereas 'practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted' (Art. 11). See also opinion provided by R. Yotova, *Regulating genome*…, *op. cit.*, p. 660.

54 C. Dupras, Y. Joly, E. Rial-Sebbag, *Human rights in the postgenomic era*…, *op. cit.*, p. 18.

data might include protein-epigenetic data (such as modification of histone proteins)[55].

The UNESCO 2005 Declaration aimed to "promote respect for human dignity and protect human rights" (Art. 2(c)). They constitute 'fundamental freedoms' that must be respected (Art. 3). Any medical intervention may only be carried out on the basis of adequate information. According to Art. 15 of the UNESCO 2005 Declaration, it is clear that benefits from any scientific research should be propagated in society. Moreover, it states that future generations (Art. 16), the environment, the biosphere, and biodiversity must be protected.

The absence of provisions about epigenetic data in the discussed declarations is likely due to the time at which they were prepared and adopted[56]. Therefore, the International Bioethics Committee (IBC) in 2015 published a report with suggestions about updating the UNESCO declarations, in light of developments in genetics. One important statement regarding epigenome is that it "add[s] to the complexity of genomic information and human diversity"[57]. For this reason, it should be clear that UNESCO should consider reframing human rights approaches in the Declarations during the era of epigenetic editing[58].

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55 See S.B. Zaghlool, B. Kühnel, M.A. Elhadad, S. Kader, A. Halama, G. Thareja, M. Bayoumi, S. Alcaraz, K.G. Staab-Weijnitz, T. Prasse, T. Schäfer, S. Mohamed, M. Al-Dous, A.G. Nietert, S. Suhre, T. Ghanem, *Epigenetics meets proteomics in an epigenome-wide association study with circulating blood plasma protein traits*, "Nature Communications" 2020, vol. 11, no. 1, pp. 1–12 in context of Art. 2(ii) UNESCO 2003 Declaration defining human proteomic data.

56 Mostly, discussion about ethical and legal implications in epigenetics began around 2005. Based on C. Dupras, Y. Joly, E. Rial-Sebbag, *Human rights in the postgenomic era…*, *op. cit.*, p. 19.

57 UNESCO, International Bioethics Committee, *Report of the IBC on updating its reflection on the Human Genome and Human Rights*, unesdoc.unesco.org/ark:/48223/pf0000233258 [accessed: 14.11.2024]; International Bioethics Committee created in 1993 consists of 36 independent experts. They follow progress in life sciences for human dignity.

58 See conclusions presented by C. Dupras, Y. Joly, E. Rial-Sebbag, *Human rights in the postgenomic era…*, *op. cit.*, p. 29 and the latest article published by O. Feeney, *Catching the next wave? The relationship between UNESCO and developments in genomics*, "European Journal of Human Genetics" 2024, vol. 32, no. 6, pp. 605–606.

Two regional European human rights treaties regulate genetic interventions directly: the 1997 Council of Europe's Oviedo Convention on Human Rights and Biomedicine (Oviedo Convention)[59] and the EU Charter of Fundamental Rights (EU Charter)[60]. These treaties contribute to the fundamental human rights law but only in countries that ratified them[61]. The Oviedo Convention adopted a restrictive approach and has provisions that can be directly applied to epigenome editing. In the literature, the Oviedo Convention is viewed as the "first international legally binding instrument addressing human rights in the biomedical field"[62]. Particularly, Article 13 prohibits interventions aimed at modifying the human genome for purposes such as prevention, diagnosis, and therapy[63].

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59 Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (European Treaty Series, No. 164) was opened for signature on 4 April 1997 in Oviedo (Spain). It should be noted that the Oviedo Convention has been signed by 35 but adopted only by 29 of the 47 Members of the Council of Europe due of diverging reasons. For Germany Oviedo Convention was deemed too permissive, for UK was too restrictive. Some countries like Poland, Ukraine signed the Oviedo Convention but without ratification. See B.C. van Beers, *Rewriting the human genome*…, *op. cit.*, p. 12.

60 Charter of Fundamental Rights of the European Union (2012/C 326/02), Official Journal of the European Union C 326, 26.11.2012; A. Mahalatchimy, E. Rial-Sebbag, *Deciphering the fragmentation of the human genome editing regulatory landscape*, "Frontiers in Political Science" 2022, vol. 3, 793134, p. 5.

61 A. Boggio, R. Yotova, *Gene editing of human embryos*…, *op. cit.*, p. 959.

62 B.C. van Beers, *Rewriting the human genome*…, *op. cit.*, p. 11.

63 During the OVIEDO Convention drafting, the Article 13 was the most controversial part which states that "»[…] '[a]n intervention seeking to modify the human genome may only be undertaken […] if its aim is not to introduce any modification in the genome of any descendants«" from R. Yotova, *Regulating genome*…, *op. cit.*, p. 669; see also Council of Europe, Genome editing technologies: final conclusions of the re-examination of Article 13 of the Oviedo Convention", Genome editing technologies: final conclusions of the re-examination of Article 13 of the Oviedo Convention", 11.10.2022, coe.int/en/web/bioethics/-/genome-editing-technologies-final-conclusions-of-the-re-examination-of-article-13-of-the-oviedo-convention [accessed: 12.11.2024] and B.C. van Beers, *Rewriting the human genome*…, *op. cit.*, pp. 11–12.

Moreover, Article 13 was proposed to be re-examined within the framework of the Strategic Action Plan on Human Rights Technologies (2020–2025), emphasizing that human rights should govern biomedicine technologies in light of progress in gene editing technologies[64]. However, the Committee of Bioethics did not explicitly list epigenome technologies in SAPHRTB. Finally, the Steering Committee for Human Rights in the fields of Biomedicine and Health re-examined the Article 13 of Oviedo Convention to reflect advances in genome editing technology, but only minimal changes in the form of clarifications (in particular on the terms "preventive, diagnostic and therapeutic" were deemed[65]. Even if necessary – in my opinion – it is unlikely that in the coming years, the Article 13 will be revised addressing the epigenome editing developments and threats.

On the other hand, Art. 15 as a general rule affirms that, because of human rights, the freedom of scientific research exists in biology and medicine. According to Art. 18, research on embryos in vitro is permissible when the law adequately protects them. Importantly, the European Court of Human Rights case law on that topic serves as the guiding principle of human rights, 'right to life' and 'right to respect for private and family life'[66]. In terms of genome editing processes, some discussions revealed the opinion that interventions

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[64] The Committee of Bioethics in the Council of Europe, Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020–2025) [SAPHRTB], 2019, rm.coe.int/strategic-action-plan-final-e/1680a2c5d2 [accessed: 12.11.2024]; based on L. Wang, X. Liang, W. Zhang, *Genome editing and human rights*…, *op. cit.*, p. 387. On the page 8 of SAPHRTB genome editing is mention as one of major breakthroughs in biomedicine. However, uncertainty exists in the development of this technology.

[65] See *Steering Committee for Human Rights in the Fields of Biomedicine and Health (CDBIO), Intervention on the Human Genome. Re-examination Process of Article 13 of the Oviedo Convention. Conclusions and Clarifications*, 2022, rm.coe.int/cdbio-2022-7-nal-claricationsер-art-13-e-/1680a8736c [accessed: 12.02.2025].

[66] See the role of the European Court of Human Rights (ECHR) in genome editing, mostly germline edition presented by M.M. Spaander, *The European Court of Human Rights*…, *op. cit.*, pp. 458–483; R. Yotova, *Regulating genome*…, *op. cit.*, p. 670.

on human embryos are contrary to human rights, such as the fundamental right to inherit a genome[67].

Consequently, if not exactly the Oviedo Convention, the European Court of Human Rights might be a key player with a pivotal role in interpreting and guiding human rights in epigenome interventions. Apart from the Oviedo Convention, the EU Charter has provisions that can apply to epigenome editing (Art. 1 'human dignity', Art. 2 'right to life', Art. 37 'environmental protection'). However, Art. 51 applies only "to the institutions and bodies of the Union" and "to the Member States only when they are implementing Union law"[68].

Several scholars have focused on the role of intellectual property (IP), mostly patent systems in the governance of genome editing. It therefore seems that IP might be applicable in the governance of human rights in epigenetics[69]. In the international arena, the TRIPS Agreement obstructs human rights[70]. At the regional level, however, the Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973[71] and European Union Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions (Biotech Directive) might be used as supplementary

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67 K. Drabiak, *The Nuffield Council's green light for genome editing human embryos defies fundamental human rights law*, "Bioethics" 2020, vol. 34, no. 3, p. 223; also A. Boggio, R. Yotova, *Gene editing of human embryos…*, *op. cit.*, p. 956.

68 *Ibidem*.

69 For example authors indicate ICESCR, Art. 15(1)(b), see C. Bodimeade, F. Deane, *Evolving theory of IP rights: promoting human rights in the Agreement on Trade-Related Aspects of Intellectual Property Rights*, "Journal of Intellectual Property Law & Practice" 2023, vol. 18, no. 8, pp. 603–614. See also S. Slokenberga, T. Minssen, A. Nordberg, *Governing, protecting, and regulating…*, *op. cit.*, p. 338; W. Noonan, A.D. Dismuke, M.S. Turker, *Epigenetic patents: A stressful environment for an emerging science*, "Biotechnology Law Report" 2013, vol. 32, no. 5, pp. 302–312.

70 *Overview: the TRIPS Agreement*, wto.org/english/tratop_e/trips_e/intel2_e.htm [accessed: 14.11.2024]; C. Bodimeade, F. Deane, *Evolving theory of IP rights…*, *op. cit.*, p. 609.

71 Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973 as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000.

legal acts that can be used in the indirect protection of human rights[72]. The Preamble of the Biotech Directive asserts that

> there is a consensus within the Community that interventions in the human germ line and the cloning of human beings offend against *ordre public* and morality; whereas it is therefore important to exclude unequivocally from patentability processes for modifying the germ line genetic identity of human beings and processes for cloning human beings.

Therefore, the Biotech directive excludes biotechnological inventions from patentability, in cases where moral and ethical reasons are obtained that would be contrary to 'order public or morality'. For example, Art. 6(2)(a) excludes 'processes for cloning human beings' from patentability, and Art. 6(2)(b) excludes 'processes for modifying the germ line genetic identity of human beings'. What these words mean in the context of epigenome editing is unknown.

Currently, when the human rights debate and basic research do not provide sufficient information about epigenome editing, one of the main human rights invoked by opponents of this technology is respect for human health and dignity, especially for reproductive purposes. Disagreement in that domain was previously observed for genome editing[73]. As observed, some states are in favor of allowing research involving germline editing (depending on the therapeutic or reproductive purposes), while some ban it (many European countries, Australia, Canada, and Brazil) and others impose strict limitations on this technology (China, the USA, the UK)[74].

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[72] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, Official Journal of the European Union, 30.7.1998.

[73] L. Wang, X. Liang, W. Zhang, *Genome editing and human rights*…, *op. cit.*, 389; S. Schleidgen *et al.*, *Human germline editing*…, *op. cit.*, p. 2; N. Coghlan, F. Barrister, K. Inns, *Heritable human genome editing: the bioethical battle for the basis and future of human rights*, printfriendly.com/p/g/hpiVmb [accessed: 12.10.2024].

[74] See F. Baylis, M. Darnovsky, K. Hasson, T.M. Krahn, *Human germline and heritable genome editing: The global policy landscape*, "CRISPR Journal" 2020, vol. 3, no. 5, p. 370; B.C. van Beers, *Rewriting the human genome*…, *op. cit.*, p. 8; R. Yotova, *Regulating genome*…, *op. cit.*, p. 660. Importantly,

On the other hand, in the USA, no law or regulation bans germline gene editing conducted through private funding. In light of this, it is indeed hard to imagine an international consensus against epigenome germline editing and this technology not being permitted in instances of therapeutic applications. The point of criticism is that most cases of germline editing take place in low-income countries which do not explicitly permit this practice[75]. In clinical practice, the regulation of clinical trials prohibits gene therapy interventions "which result in a modification of the subject's germline genetic identity"[76]. However, in the case of the corresponding epigenome mechanism, there is no clear arbiter on whether applied epigenetic intervention could modify germline identity.

Nowadays, many authors discuss the applicability of the European genetically modified organisms (GMOs) legislation to epigenetically modified or adapting regulatory frameworks for edited organisms[77]. Moving foreward, it can be speculated that for the process of controlling epigenome editing interventions and techniques, the legislation on GMOs and genetically modified micro-organisms

UK government considering amends in law to allow embryos gene editing. Based on R. McKie, *UK government urged to consider changing law to allow gene editing of embryos*, 4.03.2023, theguardian.com/science/2023/mar/04/uk-government-urged-to-consider-changing-law-to-allow-gene-editing-of-embryos [accessed: 12.10.2024].

[75] *Ibidem*.

[76] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance, Official Journal of the European Union, L 158, 27.05.2014, pp. 1–76. See Art 90 last sentence "No gene therapy clinical trials may be carried out which result in modifications to the subject's germ line genetic identity". S. Schleidgen, H.-G. Dederer, S. Sgodda, S. Cravcisin, L. Lüneburg, T. Cantz, T. Heinemann, *Human germline editing in the era of CRISPR-Cas: Risk and uncertainty, inter- generational responsibility, therapeutic* legitimacy, "BMC Medical Ethics" 2020, vol. 21, no. 87, p. 2.

[77] See for example T. Faltus, *The applicability of the European GMO legislation to epigenetically modified organisms*, "Frontiers in Bioengineering and Biotechnology" 2023, vol. 11, no. 27, pp. 1–12; P. Rozas, E.I. Kessi-Pérez, C. Martínez, *Genetically modified organisms: adapting regulatory frameworks for evolving genome editing technologies*, "Biological Research" 2022, vol. 55, no. 1, p. 31.

may apply[78]. However, based on different legal and scientific arguments, it is clear that epigenome editing modalities might not be limited by the legal definition of GMOs (Art. 2(a)), as "any microbiological entity, cellular or noncellular, capable of replication or of transferring genetic material, including viruses, viroids and animal and plant cells in culture". Once again, it is unclear whether the epigenome techniques are covered by the definition in this directive.

On one hand, 'human beings' are excluded from the GMO's legal definition. However, the Court of Justice of the European Union, in *Confédération paysanne and Others v. Premier ministre and Ministre de l'agriculture, de l'agroalimentaire et de la forêt*, precludes organisms obtained by mutagenesis from being classified as GMOs, as the genetic material of an organism is altered by the techniques and methods of mutagenesis in a way that does not occur naturally[79]. Consequently, if the Court has clarified that genome editing techniques are covered by the directive, and the law applies only to plants, it is unclear what this interpretation implies for epigenome editing techniques[80]. Therefore, it should be noted that simply applying GMOs legislation to epigenome editing might lead to many legal assumptions (i.e. construction of the same legal definitions for genetic modification, epigenetic modification and edition or using the same legal interpretation) and regulatory mismatches which further overlook the unique aspects and implications of this emerging technology.

Within this debate in genome editing – in contrast to epigenome editing – many international organizations have issued reports and statements highlighting the challenges and limitations[81].

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78 Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms, Official Journal of the European Union, L 125, 21.05.2009, pp. 75–97.

79 Judgment of the Court (Grand Chamber) of 25 July 2018 *Confédération paysanne and Others v Premier ministre and Ministre de l'agriculture, de l'agroalimentaire et de la forêt*, C-528/16.

80 A. Mahalatchimy, E. Rial-Sebbag, *Deciphering the fragmentation…*, *op. cit.*, p. 6.

81 The European Group on Ethics in Science and New Technologies is the one that has gone deeper on these aspects with a 2016 and 2021 statements, see *European Group on Ethics in Science and New Technologies (EGE) State-*

To illustrate, the National Academies of Sciences, Engineering, and Medicine (NASEM 2017) and the Nuffield Council (2018) have both called for public debate in their reports but have also admitted that, in some scenarios, germline editing might be ethically possible.

International law, by setting out common minimum standards and centralized oversight, should be the most effective way to develop a regulatory framework for epigenome editing, to harmonize international consensus and domestic laws and procedures. As suggested in the literature, the optimum guarantee in scenarios of unethical or unsafe uses of epigenome techniques consists in agreeing on minimum regulatory standards through international law[82]. Overall, the current legal landscape on human rights does not address any of the key concerns raised by epigenome editing. As advances are presented, they should trigger debate about epigenome editing not only in humans but also in relation to the environment, among lawmakers, scientists, and policymakers, at the international and national levels. Due to the comparative lack of experience in this field, there is an urgent need for policy regarding basic research. Therefore, in the case of epigenome editing, it can be said that the regulatory landscape is fragmented at the international and national levels[83]. Moreover, due to a lack of consensus on crucial definitions (e.g. of 'genome', 'modification', 'edition' and 'epigenome') in law acts, there is no guarantee that these acts apply to epigenome editing.

ment on gene editing, "Jahrbuch für Wissenschaft und Ethik" 2017, vol. 21, no. 1, 2017, pp. 241–244 and European Group on Ethics in Science and New Technologies, *Opinion on ethics of genome editing*, opinion No. 32, 19 March 2021, euroseeds.eu/app/uploads/2021/03/ege_ethics_of_genome_editing-opinion_publication.pdf. See also A. Mahalatchimy, E. Rial-Sebbag, *Deciphering the fragmentation*…, *op. cit.*, p. 8.

82 R. Yotova, *Regulating genome*…, *op. cit.*, p. 664.

83 A. Mahalatchimy, E. Rial-Sebbag, *Deciphering the fragmentation*…, *op. cit.*, p. 1.

Landscape in the approaches of epigenome editing under human rights law – the road ahead

One of the biggest concerns seems to be that epigenetic editing and techniques are safer than traditional genome editing[84]. The current state of scientific knowledge is relatively sparse and could be contrary to human rights such as those concerning human health and dignity. Based on the presented scientific background, recent developments and international and selected regional regulatory human rights framework in the era of epigenome editing technologies several crucial open questions should be pointed out and addressed in the future. Some are indicated below, but it seems clear that each of them should be the subject of a separate article. Should this technology be rather regulated by national or international regulations? Can we apply opinions and recommendations concerning genetic editing to epigenome editing? What are the relevant human rights norms and standards that apply to it? In light of human health and dignity, the question arises about the criteria for distinguishing between 'therapy' and 'enhancement'? Even if epigenome editing does not touch the DNA strand, what is the acceptable level of risk of harm to the future person and their future generations, offspring generated by epigenome editing? Should germline epigenetic editing be allowed for therapeutic as well as for reproductive application – and if so, under what conditions? Finally, how can international or national law help balance the risks and benefits of this technology, for individuals and society?

One thing seems to be clear, namely that what is contained in the international landscape in the regulation of genome editing would certainly not be sufficient for the protection of human rights. As a starting point, more highly regulated freedom in basic research should be achieved, to deliver data from basic and preclinical research about epigenome editing risks, including risks to future

[84] K. Huerne *et al.*, *Auditing the editor*…, *op. cit.*, p. 205; J. Kaiser, *Better than CRISPR? Another way to fix gene problems may be safer and more versatile*, 1.03.2022, science.org/content/article/better-crispr-another-way-fix-gene-problems-may-be-safer-and-more-versatile [accessed: 12.10.2024].

generations, comparable to genetic edition[85]. The risks of these studies should be assessed each time, firstly by bioinformatics studies. Without understanding the risks and benefits for individuals, society, and the environment, human rights may constitute an obstacle. It is widely known that the interpretation of human rights and the underlying principles may evolve accordingly with accessible data and public opinion. The basic research should be performed mostly in medical and environmental epigenetics. They would provide the additional sort of evidence that seems to be needed for the governance of this technology.

Given the easier accessibility to epigenome editing, basic research would give data that might be advisable for law and policymakers through international standards. Existing international organizations, such as the WHO and UNESCO, should put forward opinions (i.e. in reports or in the form of a treaty) and should propose potential mechanisms. Such proposals might be also discussed during such conferences as the International Summit on Human Genome Editing[86]. The relevant opinions should be prepared by interdisciplinary bodies comprised of lawyers, scientists, and ethicists. Also, public engagement, e.g. debates, would be of great importance. Social, statistical, and epidemiological studies should be performed on public opinion about epigenome editing. These studies should focus on the conditions under which somatic/germline (reproductive vs. therapeutic) epigenome editing should be allowed. Importantly, public opinion should discuss whether that technology can be used for enhancement purposes (non-therapeutic) or only therapeutic applications. The distinctions between them should be enumerated by organizations such as the Nuffield Council of Bioethics, and NASEM. Stakeholders should subsequently revisit existing policies and governance in the scope of epigenetic editing, taking into account the various considerations raised.

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[85] J. Halpern, S.E. O'Hara, K.W. Doxzen, L.B. Witkowsky, A.L. Owen, *Societal and ethical impacts of germline genome editing: How can we secure human rights?*, "The CRISPR Journal" 2019, vol. 2, no. 5, p. 297.

[86] *The Third International Summit on Human Genome Editing*, royalsociety.org/science-events-and-lectures/2023/03/2023-human-genome-editing-summit [accessed: 12.10.2024].

In such discussions, importantly, the consensus should be presented in terms of international treaties about human rights and somatic/germline epigenome editing for therapeutic and reproductive purposes. To date, due to insufficient data, the ban on uses of this technology for reproductive purposes should be maintained. By developing a pathway to effective and safe epigenome editing, its commercial application should be strictly regulated. Taking all necessary measures to minimize the risks will be one of the options in that topic[87]. In that debate, human rights and standards must apply not only to the public but also to the private sector.

Regulations pertaining to human rights should be prepared based on balanced interests between individuals and fair access for society[88]. Without basic scientific data, it could be difficult to propose and decide upon balanced rules. Apart from human rights law, the story of J. He reveals the failure of ethical scientists' self-regulation and institutional supervision[89]. Therefore, the revision of current ethical guidelines and informed consent at universities and scientific institutions is needed[90]. However, in my opinion, self-regulation alone is not sufficient to protect against human rights violations and to guide research development in the case of new epigenome technologies. It is not sufficient for protecting the most vulnerable members of society (sick people, children) who seek every chance to prolong their lives. The danger of self-regulation is the recklessness of a scientist or member of the private sector whose ambition, fame, and success may motivate them to start research and move the boundary to the unethically or morally outrageous[91]. For example, in Nuffield's report on germline editing can be ethically acceptable when important principles (the welfare of future people,

87 R. Yotova, *Regulating genome*…, *op. cit.*, p. 667.

88 *Ibidem*, p. 666.

89 See footnote 8.

90 J.R. Li, S. Walker, J.B. Nie, X.Q. Zhang, *Experiments that led*…, *op. cit.*, pp. 36–37.

91 Like J. Hu who after realized from prison announced on social media that he had opened a lab in Beijing to develop gene therapies for rare diseases like Duchenne muscular dystrophy. Previously, he successfully raised millions of dollars from investors for biotech start-ups, see B.C. van Beers, *Rewriting the human genome*…, *op. cit.*, p. 33.

upholding justice and solidarity) are properly weighed[92]. Based on collected data – in my opinion – in the next step it seems appropriate to revise and clarify UNESCO Declarations[93]. All these enumerated components are necessary for human rights and the autonomy of individuals while respecting diverse values in society.

Conclusions

Due to the promising opportunities, the research and translational studies of epigenome editing are highly anticipated by science, industry and society. However, the legal framework should be shaped based on human rights, particularly those concerning health and dignity.

This article has provided insights into human rights at the international and regional levels. Overall, it can be concluded that epigenome editing, including germline intervention, is presently not explicitly prohibited under human rights law. Furthermore, analysis indicates that laws applicable to human rights in epigenome editing technology are fragmented and consistently broadened. Processes observed for genome editing show that developing regulation in genetics is a complex, balanced interaction between human rights. The article also presents the challenges and future landscape arising from epigenome editing for international human rights. Several questions have been posted and still need to be addressed, as summarised in the last part of the article. A few recommendations have been offered; however, greater attention to epigenetic editing should be paid in the coming years.

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92 See J. Halpern *et al.*, *Societal and ethical impacts*…, *op. cit.*, p. 295.

93 The same opinion is presented by O. Feeney, *Catching the next wave?*, *op. cit.*, pp. 605–606 in the light of arguments presented by H. Gaydarska, K. Takashima, S. Shahrier, A. Raz, J. Minari, *The interplay of ethics and genetic technologies in balancing the social valuation of the human genome in UNESCO declarations*, "European Journal of Human Genetics" 2024, vol. 32, pp. 725–730. Authors pointed out that UNESCO/Universal Declaration on Bioethics and Human Rights is 20 years old. Therefore, emerging medicinal developments should be addressed in revised declarations.

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Abstract

Human rights in the era of emerging epigenome editing technologies

Genome and epigenome editing technologies have been hailed as the most revolutionary discoveries in the natural and medical sciences. These achievements were confirmed by the 2020 Nobel Prize in chem-

istry. In contrast to genome editing, epigenetic regulation involves controlling the particular expression of a gene by modifying chromatin components without altering the genome nucleotide sequence. Despite many promising results and applications, the effects of epigenome editing interventions are not fully known. For example, potential irrevocable and transgenerational events are possible and might be heritable. Other concerns include the risk of using or misusing this technology in agriculture and, the military as well as using it with or without other treatments to alter human health and body.

Despite ongoing debate and studies on human genome editing, especially germline, the discussion regarding human rights and the ethics of epigenome editing for different applications is at a relatively early stage and therefore sparse. Furthermore, in the context of possible infringements on human dignity and integrity, critical consideration is warranted as to whether the uses of these technologies are acceptable or should be banned in some countries.

The first part of this article presents a short review of the epigenome versus genome editing field. Particular emphasis is placed on epigenome editing advances and threats, to draw open questions in epigenetic human rights status and regulation. The second part presents the analyses of international human rights law with other possible normative law acts that can influence the status of epigenome editing technologies, mostly in Europe. Their strengths and limitations are highlighted, to present raised open questions and gaps in the last part. The normative question is whether the existing international law regulations are sufficient to address a wide number of implications and to protect human rights in the face of this emerging technology. Furthermore, some gaps and flaws are pointed out in current regulation policy, as regards epigenetic editing. Accordingly, this study aims to present further guidance and questions by exploring the implications of the human rights framework for research and the application of epigenome editing. This article then lays down the landscape in the possible approaches of genome editing under human rights law – and argues that new regulations or updated international standards are needed, in combination with the institutional framework. Lastly, the concluding section situates this study's findings within the relevant epigenome editing context.

Key words: epigenetics, ethics, human rights, epigenome editing, genome editing, germline editing, CRISPR, human dignity, human health

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