Special issue

Human germline genome editing and human rights law: A "brave new world" is not here to come

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ABSTRACT: Since the dawn of genetic engineering, potential application of genome editing on the germline, implying heritable DNA alterations, has been considered extremely controversial. Unsurprisingly, therefore, limits to human germline genome editing have been envisaged in international normative instruments in the'90s. Nowadays, the rise of new technical possibilities, like CRISPR-Cas9, urges for a due regulation of basic and pre-clinical research on gametes and embryos not destined to reproduction, while reinforcing the prohibition of clinical research and clinical applications on human beings. Keeping in mind the distinction between different kind of research, the paper addresses the contribution of human rights law in the debate on legitimacy of human germline genome editing.

KEYWORDS: Human germline genome editing; right to science; eugenics; UNESCO Declaration on the Human Genome and Human Rights; Oviedo Convention

1. Introduction

Limits and restrictions to human germline genome editing (HGGE) have been envisaged in international normative instruments in the late '90s, when the public debate was dominated by worries for potential drifts like those masterfully pictured by Huxley in 1932.[1] At the emergence of genetic engineering, predetermination of individuals' abilities and societal classification of people, according to different levels of intellectual enhancement, were feared as potential results of any intervention on the human genome.

Today – as CRISPR-Cas9 has translated into reality interventions that in past could be only pictured with a powerful imagination – different voices rise, calling for due regulation of basic and pre-clinical

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The article was peer-reviewed by the editorial committee.

[1] In *Brave new world*, written in 1931 and published in 1932, A. HUXLEY describes a World State, whose citizens are environmentally conditioned to fit into an intelligence-based social hierarchy. Although the novel does not refer to genetic manipulation, but rather to sleep-learning, psychological manipulation and Pavlonial or classical conditioning, it astonishingly anticipates scientific advancements in reproductive technology.

research, rather than a total ban.[2] According to many, precluding research on gametes and embryos not destined to implantation would impede to assess the scientific feasibility and the ethical acceptability of potential clinical applications of HGGE.[3] In fact, while it is currently too early to consider human genome editing for clinical reproductive purposes, some experts consider that – when all safety, efficacy and governance needs will be duly met – certain uses of HGGE in human reproduction might be considered morally acceptable and thus applied.[4]

The paper addresses the contribution of human rights law in the debate on legitimacy of human germline genome editing, clearly keeping in mind the distinction between, on the one hand, basic research[5] and pre-clinical research on gametes and embryos not destined to reproduction and, on the other, clinical research and clinical applications on human beings.

2. Human germline genome editing: total ban or rigorous restrictions?

Since the dawn of genetic engineering technologies, it became clear that potential application of genome editing on the germline might be extremely controversial. In fact, while somatic gene editing permits to target genes in selected cells of living patients and does not imply heritable DNA alterations, genome editing applied to human embryos or gametes involves the genetic modification of germ cells. This means that this technique affects all body cells of the future individuals, including their own gametes and that, as such, these DNA modifications will be inherited by their offspring (and by the offspring of their offspring).

Many Scholars consider that germline manipulation represents an ethical limit that should never be contravened, even when it will be eventually sufficiently safe.[6] Although the arguments supporting

[2] J. HALPERN et al., *Societal and Ethical Impacts of Germline Genome Editing: How Can We Secure Human Rights?*, in *The CRISPR Journal*, 2, 5, 2019, 293-298; G. DE WERT, G. PENNINGS, A. CLARKE et al., *Human germline gene editing. Recommendations of ESHG and ESHRE*, in *Human Reproduction Open*, 2018, 1-5.

[3] Italian Committee for Bioethics (ICB), *L'editing genetico e la tecnica CRISPR-CAS9: considerazioni etiche,* 2017, 5.1; available at: http://bioetica.governo.it/italiano/documenti/pareri-e-risposte/l-editing-genetico-e-la-tecnica-crispr-cas9-considerazioni-etiche/ (last visited 4/01/2021). While urging research on gene editing on human somatic cells, the Committee unanimously rejects experimentation on gametes and embryos intended to be used in reproduction. With regard to gene editing on gametes/embryos not destined to reproduction, the Committee could not reach a unanimous view: some members encourage basic and pre-clinical research, other consider that such research is not currently justified, because gamete selection is clinically preferable to gamete editing. They also stress that assessing the effectiveness and safety of *in vitro* gene editing on embryos is not possible, since results of the genetic modification can be assessed at birth or even later ; *ibidem*, 5.2.

[4] Hinxton Group Statement, *Statement on genome editing technologies and human germline genetic modification*, 2015, http://www.hinxtongroup.org/Hinxton2015_Statement.pdf (last visited 4/01/2021).

[5] Basic research can be defined as research done in laboratory, *in vitro*, aimed at improving scientific knowledge and "performed without thought of practical ends": V. BUSH, *Science: The Endless Frontier*, United States Government Printing Office, 1945, Chapter 3, available at https://www.nsf.gov/od/lpa/nsf50/vbush1945.htm#ch3.3 (last visited 4/01/2021).
See also N. ROLL-HANSEN, *Why the Distinction between Basic (Theoretical) and Applied (Practical) Research is Important in the Politics of Science*, London School of Economics, Centre for the Philosophy of Natural and Social Science Contingency and Dissent in Science Technical, 2009.

[6] K. DRABIAK, *The Nuffield Council's green light for genome editing human embryos defies fundamental human rights law*, in *Bioethics*, 34, 2020, 223-227; M. DARNOVSKY, L. LOWTHORP, K. HASSON, *Reproductive gene editing*

this view might vary, a major idea is that human genome deserve a special protection: to some extent it is "regarded as a 'natural' connection between all human beings, as it has been handed down to us by our predecessors".[7] This principle is traceable under Art. 1 of the Universal Declaration on the Human Genome and Human Rights, adopted by UNESCO in 1997, according which human genome represents "in a symbolic sense […] the heritage of humanity", as it "underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity".[8] In 1982, in a Recommendation on genetic engineering, the Parliamentary Assembly of the Council of Europe, addressing in general terms the concerns "arising from uncertainty as to the health, safety and environmental implications of experimental research", has deeply focused on the longer-term legal, social and ethical issues of the "prospect of knowing and interfering with a person's inheritable genetic pattern".[9] In this document, the plenary organ of the Council of Europe took a clear position against HGGE, stating that "the rights to life and to human dignity protected by Articles 2 and 3 of the European Convention on Human Rights imply the right to inherit a genetic pattern which has not been artificially changed".[10] Within the Council of Europe, the same approach has been confirmed later, with the adoption of the Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine (Oviedo Convention).[11] Art. 13 of the Oviedo Convention states that "an intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants". According to someone, the reading of the norm could imply that "genome editing for therapeutic or preventive purposes where the modification in the genome of the descendants is not the aim but is incidental to the process, might still be in accordance with the Oviedo Convention";[12] nonetheless, the *ratio* of the provision seems to be indisputably focused on the ban of HGGE.

From that time, however, many scientific improvements had come, and the process is still ongoing.

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imperils universal human rights, in *OpenGlobalRights*, 15 February 2018, available at https://www.openglobalrights.org/reproductive-gene-editing-imperils-universal-human-rights/ (last visited 4/01/2021); E. ANDORNO, A.E. YAMIN, *The right to design babies? Human rights and bioethics,* in *OpenGlobalRights*, 8 January 2019, available at https://www.openglobalrights.org/the-right-to-design-babies-human-rights-and-bioethics/ (last visited 4/01/2021).

[7] N. PRIMC, *Do we have a right to an unmanipulated genome? The human genome as the common heritage of mankind*, in *Bioethics*, 34, 2020, 41-48, 41.

[8] The Universal Declaration on the Human Genome and Human Rights has been adopted at the 29th Session of the UNESCO General Conference on 11 November 1997. The United Nations General Assembly endorsed the Declaration by its Resolution 53/152 of 9 December 1998.

[9] Parliamentary Assembly of the Council of Europe (PACE), Recommendation 934 (1982) of 26 January 1982, *Genetic engineering*, para 2.

[10] *Ivi*, Art. 4 lett. a.

[11] 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*), Oviedo, 1997, European Treaty Series No.164.

[12] R. YOTOVA, *The Regulation of Genome Editing and Human Reproduction Under International Law, EU Law and Comparative Law*, Report to the Nuffield Council on Bioethics, June 2017, 4-5: available at https://www.nuffieldbioethics.org/wp-content/uploads/Report-regulation-GEHR-for-web.pdf (last visited 4/01/2021).

In 2020 the Nobel Prize in Chemistry has been awarded to Emmanuelle Charpentier and Jennifer Doudna for the development of CRISPR/Cas9. Commonly defined as "genetic scissors", this genome editing technology permits to change the DNA of animals, plants and microorganisms with extremely high precision and has therefore a revolutionary impact on life sciences, with potential applications to cancer or inherited diseases therapies. However, its application on human germline is considered highly controversial not only from a scientific perspective (as, in light of the current knowledge, it is still premature), but also from an ethical point of view. Unsurprisingly, therefore, when CRISPR-Cas9 was used to change the DNA of human embryos *in vitro* in 2015 for the first time, the disagreement about whether altering the genes of future generations should be permissible or not had strongly emerged.[13] More recently, the entire scientific community has been deeply shocked and unanimously expressed indignation and concern when, in November 2018, a Chinese biophysicist, He Jiankui, announced that two genetically modified twins had born. The embryos underwent a "genetic surgery", to become resistant to HIV infection, through the application of CRISPR/Cas9 technology, before being implanted in the maternal womb.

While the reaction of the scientific community was unanimous in blaming He Jiankui for having clearly ignored basic rules for research on humans, also violating norms and principles of medical practice, his irresponsive action also contributed to renovate the debate over the need to regulate the use of HGGE, rather than simply banning it.[14] In other words, as his misconduct proved that intervention on human germline is technically achievable and that unscrupulous and dishonest scientists may (easily) apply it, the question is whether, rather than simply placing a ban, basic and pre-clinical research should not be clearly regulated in order to make, in a near future, clinical research on humans safe, practicable and consistent with ethical standards.

If a large debate on possible regulation of human genome editing is not renounceable nor postponable nowadays, what role is played by human rights law?

3. Science and human rights law: supporting development and fixing boundaries

The effective safeguard of many fundamental human rights is strictly linked with progress in science and technology. It's undeniable, for example, that the enjoyment of the highest attainable standard of physical and mental health – protected, among other international provisions, under Art. 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) – depends, in large part,

[13] National Academies of Sciences, *Engingeering and Medicine, Human Genome Editing: Science, Ethics, and Governance*, Washington DC, 2017; Nationale Akademie der Wissenschaften Leopoldina, Deutsche Forschungsgemeinschaft, acatech – Deutsche Akademie der Technikwissenschaften, Union der deutschen Akademien der Wissenschaften, *Chancen und Grenzen des genome editing/The opportunities and limits of genome editing*, 2015, available at: https://www.leopoldina.org/uploads/tx_leopublication/2015_3Akad_Stellungnahme_Genome_Editing_01.pdf (last visited 4/01/2021); Koninklijke Nederlandse Akademie van Wetenschappen, *Genome Editing. Position Paper of the Royal Netherlands Academy of Arts and Sciences*, 2016, available at: https://knaw.nl/en/news/publications/genome-editing (last visited 4/01/2021).

[14] G. Q. Daley, R. Lovell-Badge, J. Steffann, among others, consider that halting responsible research would be unwise: *After the Storm: A Responsible Path for Genome Editing*, in *New Eng. J. Med.*, 380, 2019, 897-899.

from scientific development.[15] Moreover, science not only offers solutions to individual, social, economic, and developmental issues, but it has also an autonomous standing among other fundamental rights: Art. 15 ICESCR enshrines the right "to enjoy the benefits of scientific progress and its applications", as well as the "the freedom indispensable for scientific research and creative activity".[16] Nonetheless, while scientific development has a pivotal role in supporting the ability of people to "conceive of a better future that is not only desirable but attainable",[17] at the same time, human rights law sets boundaries that science and technology can't cross and provides guidance to balance conflicting interests. Indeed, human rights identify limits bearing upon States in regulating research on human germline genome editing.

3.1 Regulating HGGE to realize the right to science

The fundamental right to science represents a multifaceted normative basis supporting research on HGGE. Different components of this fundamental right are relevant: not only the right to enjoy the benefits of scientific progress *per se*, but also the freedom of research, as well as the right to participate in science. The three dimensions, in particular, fit perfectly with basic and pre-clinical research on human germline genome editing.

As clarified in the Venice Statement, benefits of scientific progress "encompass not only scientific results and outcomes but also the scientific process, its methodologies and tools".[18] On the same line, the General Comment n. 25 on the right to science – adopted in 2020 by the Committee on economic social and cultural rights – states that science benefits include "the scientific knowledge and information directly deriving from scientific activity".[19] The right to enjoy the benefits of scientific progress, therefore, certainly covers the general enhancement of the conditions for further scientific activity, realized through basic and pre-clinical research on HGGE.

Freedom of research is the second major component of the right to science: according to General Comment n. 25, "in order to flourish and develop, science requires the robust protection of freedom of research".[20] As clearly stated in Art. 15 para 3 ICESCR, this freedom is "indispensable", although

[15] International Covenant on Economic, Social and Cultural Rights adopted by General Assembly resolution 2200A (XXI) of 16 December 1966.

[16] A similar provision is contained under Art. 27 of the *Universal Declaration of Human Rights*, 1948.

[17] Human Rights Council, *Report of the Special Rapporteur in the Field of Cultural Rights, Farida Shaheed on the Right to Enjoy the Benefits of Scientific Progress and its Applications*, 14 May 2012 UN Doc. A/ HRC/20/26, para. 20.

[18] Venice Statement on the Right to Enjoy the Benefits of Scientific Progress and its Applications, para 8. Such Statement is the outcome of three expert meetings held between June 2007 and July 2009 under the auspices by UNESCO in collaboration with the Amsterdam Centre for International Law, the Irish Centre for Human Rights, and the European Inter-University Centre for Human Rights and Democratization.

[19] UN Committee on economic social and cultural rights, *General comment No. 25 (2020) on science and economic, social and cultural rights (article 15 (1) (b), (2), (3) and (4) of the International Covenant on Economic, Social and Cultural Rights*. 30 April 2020, UN Doc. E/C.12/GC/25, para 8, available at: https://documents-dds-ny.un.org/doc/UNDOC/GEN/G20/108/12/PDF/G2010812.pdf?OpenElement (last visited 4/01/2021).

[20] *Ivi*, para 13. According to the UN Committee on economic social and cultural rights, "this freedom includes, at the least, the following dimensions: protection of researchers from undue influence on their independent judgment; the possibility for researchers to set up autonomous research institutions and to define the aims and objectives of the research and the methods to be adopted; the freedom of researchers to freely and openly

not unlimited. Limits can be set, in particular, as long as science and its applications interfere with other economic, social and cultural rights, but most importantly, boundaries are to be fixed whenever "the research affects human beings", with the aim "to protect their dignity, their integrity and their consent when involved in the research".[21] The need to support freedom of research in the field of human genome emerges also form the provision of Art. 14 of the UNESCO Declaration on the Human Genome and Human Rights, which states that "States should take appropriate measures to foster the intellectual and material conditions favorable to freedom in the conduct of research on the human genome and to consider the ethical, legal, social and economic implications of such research […]".

Last but not least, the *enjoyment* of the benefits of scientific progress covers not only the dissemination of its outcomes, but also the participation in its development. Along with the freedom of research at the benefit of scientists, the right to science includes also the right of anyone to take part in science, that is – in the words of the Special Rapporteur in the field of cultural rights – the "participation of individuals and communities in decision-making" and, more in general, "opportunities for all to contribute to the scientific enterprise".[22] General Comment n. 25 clearly identifies this right to take part in scientific progress and in decisions concerning its direction, clarifying that the benefits of scientific advancement include "the development of the critical mind and faculties associated with doing science".[23] Therefore, if it is clear that "the incorporation of any kind of technological innovation, including genetic therapies, requires broad collective deliberation regarding its permissible uses, foreseeable effects, and regulation",[24] it is also true that the improvement of knowledge (through basic and pre-clinical research) might provide the necessary instruments and tools to involve people in a fruitful dialogue on potential clinical applications, ethical limits and normative standards for HGGE.

Indeed, the three components of the right to science militate in favor of a (proper) regulation of basic and pre-clinical research on HGGE, while a total ban (but also practical impediments like the prohibition to use supernumerary embryos in research)[25] could imply a violation of Article 15 of the ICESCR, interfering with scientific progress and impairing the right of many people to enjoy the benefits of science and its applications.

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question the ethical value of certain projects and the right to withdraw from those projects if their conscience so dictates; the freedom of researchers to cooperate with other researchers, both nationally and internationally; and the sharing of scientific data and analysis with policymakers, and with the public wherever possible".

[21] *Ivi*, para 22.

[22] Human Rights Council, *Report of the Special Rapporteur in the Field of Cultural Rights cit*., para. 25. See also UN Committee on economic social and cultural rights, *General comment No. 25* cit., para 9-11.

[23] UN Committee on economic social and cultural rights, *General comment No. 25* cit., para 10.

[24] E. ANDORNO, A.E. YAMIN, *op. cit*.

[25] L. POLI, *The Regulation of Human Germline Genome Modification in Italy*, in A. BOGGIO, C. ROMANO, J. ALMQVIST (Eds.), *Human Germline Genome Modification and the Right to Science: A Comparative Study of National Laws and Policies*, Cambridge, 2020, 335-357.

3.2 Setting limits in the name of human dignity

Current human rights law does not contain a complete ban on genome editing; it rather envisages limits that States must observe in regulating scientific research in this field.

Most importantly, Art. 13 of the Oviedo Convention, as already mentioned, prohibits any clinical research and application of human germline genome editing. Along with other provisions contained in Chapter IV of the Convention, the norm is clearly inspired by the precautionary principle and, as explained in the Explanatory Report of the Oviedo Convention, it aims at preventing misuses of scientific progress in the field of genome editing that "may endanger not only the individual but the species itself", through the "intentional modification of the human genome so as to produce individuals or entire groups endowed with particular characteristics and required qualities".[26]

Another clear ban concerns the reproductive cloning of human beings. This practice is outlawed by Art. 1 of in the Additional Protocol to the Oviedo Convention on the prohibition of cloning human beings,[27] by Art. 11 of the UNESCO Declaration on human genome as well as by Art. 3 of the Charter of fundamental rights of the European Union.[28] The Explanatory Report of the Additional Protocol to the Oviedo Convention clarifies that "deliberately cloning humans is a threat to human identity, as it would give up the indispensable protection against the predetermination of the human genetic constitution by a third party".[29] Such prohibition is clearly based on the need to preserve human dignity, which is considered to be "endangered by instrumentalization through artificial human cloning".[30] Indeed, "it is in the interest of all persons to keep the essentially random nature of the composition of their own genes", because "naturally occurring genetic recombination is likely to create more freedom for the human being than a predetermined genetic make-up".[31]

The prohibitions of clinical research and application of HGGE and of reproductive cloning of human beings are grounded on similar fears: the human species as well as humanity might be put in danger through the application of techniques aimed at predefining genetic characteristics of individuals. In other words, these bans aim at safeguarding a "collective dimension" of human dignity, namely the "long-term interests of society, future generations, and humankind" that go beyond individual rights "of prospective parents and […] future offspring".[32]

Two major concerns regard eugenics and enhancement.

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[26] Explanatory Report to the 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, para. 89.

[27] Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings, Paris, 1998, European Treaty Series No. 168.

[28] *Charter of fundamental rights of the European Union* (2000/C 364/01), Nice, 2000.

[29] Explanatory Report to the Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings, para 3.

[30] *Ibidem*.

[31] *Ibidem*.

[32] B.C. VAN BEERS, *Rewriting the human genome, rewriting human rights law? Human rights, human dignity, and human germline modification in the CRISPR era*, in *Journal of Law and the Biosciences*, 2020, 35-36.

Eugenics as a practice "aiming at the selection of persons", is explicitly prohibited under Article 3.2 of the Charter of Fundamental Rights of the European Union, which affirms the right to the integrity of the person in the fields of medicine and biology. According to the Explanations Relating to the Charter of Fundamental Rights, Article 3.2 refers to "possible situations in which selection programmes are organized and implemented, involving campaigns for sterilization, forced pregnancy, compulsory ethnic marriage among others, all acts deemed to be international crimes in the Statute of the International Criminal Court adopted in Rome on 17 July 1998".[33] While the intention of the drafters of the EU Charter was to ban projects aimed at the improvement of the human race, based on the selection by the State of who can procreate, it is true that HGGE might allow a new form of eugenics. Intended parents can know in advance the genetic makeup of their future children, and through genetic manipulation, they could make decisions about their offspring's genes in view of an improvement that goes beyond the treatment of medical disorders.

Enhancement, then, represents the second major concern about misapplication of HGGE. The potential use of germline editing to enhance traits, rather than to serve therapeutic needs, poses serious moral issues and risks to exacerbate social inequities. Additionally, it is true that setting the dividing line between healing and enhancement might not be easy in practice.[34]

As far as basic and pre-clinical research are concerned, some rules delineate general limits, mainly identifying the respect for human rights, fundamental freedoms and human dignity of individuals as prevailing over science *per se* (Art. 10 UNESCO Declaration on human genome, Art. 2 Oviedo Convention), or imposing rigorous and prior assessment of the potential risks and benefits for any research, treatment or diagnosis affecting an individual's genome (Art. 5 lett. a UNESCO Declaration on human genome). In addition, many provisions stress the key importance of free and informed consent of the person(s) involved in the research (Art. 3 Charter of fundamental rights of the EU, Art. 5 Oviedo Convention, Art. 5 UNESCO Declaration on human genome). Even with regard to basic and pre-clinical research, informed consent of people whose gametes or supernumerary embryos are to be used in research remain of crucial importance.

A stricter limit to basic and pre-clinical research is stated under Art. 18 of the Oviedo Convention, according which "[t]he creation of human embryos for research purposes is prohibited". The provision also recommends that national law ensure adequate protection of the embryos when *in vitro* research on them is allowed. Hence, to the extent that it is not prohibited, basic research on (supernumerary) embryos is to be considered permitted pursuant to the Oviedo Convention, despite the extreme cautious approach adopted in the Explanatory Report, where it is stressed that Art. 18 "does not take a stand on the admissibility of the principle of research on *in vitro* embryos".[35]

A final set of rules which appears relevant in this field of research are those concerning the respect for genetic diversity and/or the prohibition of genetic discrimination.[36] In particular, Art. 2 of the UNESCO Declaration on human genome provides that "[e]veryone has a right to respect for their

[33] Explanations Relating to the Charter of Fundamental Rights, 2007, OJ C 303.

[34] See B.C. VAN BEERS, *op. cit.*, 20-24.

[35] Expl rep 116

[36] See I.V. MOTOC, *The International Law of Genetic Discrimination: The Power of "Never Again",* in T. MURPHY (Ed.), *New Technologies and Human Rights*, Oxford, 2009, Collected Courses of the Academy of European Law, XVII/2, 222-245.

ISSN 2284-4503

dignity and for their rights regardless of their genetic characteristics. That dignity makes it imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity". In addition, according to Art. 6 of the same document, "[n]o one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity". Similarly, the Oviedo Convention bans all forms of discrimination based on a person's genetic make-up (Art. 11), allowing predictive genetic tests only for health or scientific research purposes (Art. 12). Additional documents have been adopted by the UN Economic and Social Committee[37] and the World Health Organization.[38] Finally, the 2003 UNESCO International Declaration on Human Genetic Data details principles that should govern the collection, processing, use and storage of human genetic data.[39] In particular, Art. 7 (entitled "[n]on-discrimination and non-stigmatization") states that "[e]very effort should be made to ensure that human genetic data and human proteomic data are not used for purposes that discriminate in a way that is intended to infringe, or has the effect of infringing human rights, fundamental freedoms or human dignity of an individual or for purposes that lead to the stigmatization of an individual, a family, a group or communities". With regard to HGGE, these norms will be probably relevant only when (and if) this technique will be concretely used in clinical research and practice. Moreover, the protection against genetic discrimination would be probably better applicable to individuals who do not benefit from access to HGGE, rather than to those who can use this technology to avoid genetic diseases. In any case, principles concerning genetic diversity and the prohibition of genetic discrimination still define some boundaries to basic and pre-clinical research, to the extent they consider genetic variety as an element of richness for humanity deserving special protection, net of therapeutic intervention on human genome to correct serious hereditary diseases.

4. Concluding remarks: defining values for "good" science

Pervasive individual and public interest in genetics will probably not allow unlimited impediments to the improvement of knowledge on human germline genome editing. In fact, any arbitrary obstacle to scientific developments in this field would certainly result in a violation of the right to science. While scientists' freedom of research is not without bounds, we all would significantly benefit from a deeper understanding of genome editing, also to be able to actively participate in the decision-making process, defining standards and limits for HGGE.

The Parliamentary Assembly of the Council of Europe has recognized in 2017 that, while the Oviedo Convention prohibits intervention on germline genome, nothing precludes a possible amendment of

[37] ECOSOC, Resolution 2001/39 on Genetic Privacy and Non-Discrimination, adopted on 26 July 2001. The ECOSOC urges States to ensure that no-one shall be subjected to discrimination based on genetic characteristics and to take measures to prevent the use of genetic information and testing leading to discrimination or exclusion against individuals, particularly in social, medical or employment-related areas, whether in the public or the private sector.

[38] Council for International Organizations of Medical Sciences and World Health Organization, *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, 2016.

[39] The International Declaration on Human Genetic Data was adopted at UNESCO's 32nd General Conference on 16 October 2003.

the treaty.[40] While urging "member States which have not yet ratified the Oviedo Convention to do so without further delay, or, as a minimum, to put in place a national ban on establishing a pregnancy with germline cells or human embryos having undergone intentional genome editing",[41] it has also explicitly encouraged the development of a common regulatory and legal framework to balance "potential benefits and risks of these technologies aiming to treat serious diseases, while preventing abuse or adverse effects of genetic technology on human beings".[42]

It is true that, along with potential benefits of intervening on gametes or on early-stage embryos to treat genetic diseases, germline modifications might leave room for abuses; however, concerns about eugenics and enhancement do not refer to the technique *per se*, but rather to its possible misuses. In this perspective, HGGE is not different from other scientific inventions: science in not inherently good. Along with technology, it is rather a vehicle serving whatever values and ideals it is guided by. Indeed, the law "will be the custodian of our values as we decide on the right uses of genetic technologies and knowledge".[43] The discussion on the legitimacy of human germline genome editing needs to be contextualized within the human rights framework, which will certainly contribute to trace the dividing line between Nobel prize winners and irresponsible (potentially criminal) scientists.

[40] Parliamentary Assembly of the Council of Europe (PACE), Recommendation 2115 (2017) of 12 October 2017, *The use of new genetic technologies in human beings*, para 3.
[41] *Ivi*, para 5.1.
[42] *Ivi*, para 5.2.
[43] I.V. MOTOC, *op. cit.*, 225.

ISSN 2284-4503