REPORT ON REGULATION

The Regulation of Genome Editing and Human Reproduction Under International Law, EU Law and Comparative Law

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Note
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I. INTRODUCTION AND METHODOLOGY

The aim of this report is to identify and analyse the relevant legal frameworks governing the research and possible clinical applications of human genome editing on the levels of public international law, EU law and the comparison between selected domestic jurisdictions. The report will focus in particular on the requirements and restrictions imposed by these legal frameworks, as well as on the existing mechanisms for oversight, compliance and sanctions in cases of violations. Together with the black letter law, the report will also assess the soft law instruments, including guidelines, recommendations and non-binding declarations of competent international and domestic agencies.

In terms of methodology, the report will focus on identifying and interpreting the primary sources of law, including international treaties of general and regional application, resolutions of competent international organisations, EU regulations and directives, domestic laws, relevant case law, as well as soft law instruments. These will be supplemented by a review of the relevant literature that helps understand the regulatory frameworks and their operation in practice.

II. GENOME EDITING UNDER INTERNATIONAL LAW

While there are no international treaties of general application that directly regulate the human genome or the possibilities for its modification, there are three legal frameworks that would apply to the activities of a State engaging in genome editing given its object and potential effects. These include the protection of human rights and fundamental freedoms, the general principles of environmental law and possibly, certain aspects of the common heritage regime. It should be stressed at the outset that none of these frameworks contain an outright prohibition of genome editing but instead impose requirements on the conduct of States who might engage with it. Furthermore, international human rights law provides for special protections of the freedom of scientific research that would likely extend to genome editing.

Genome editing and human rights law

Human rights treaties directly regulating genome editing

There are two regional human rights treaties that regulate genetic interventions directly, namely, the 1997 European Convention on Human Rights and Biomedicine (Oviedo Convention)[2] and the EU Charter of Fundamental Rights (EU Charter).[3]

[2] Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, Oviedo, 4 April 1997, ETS No. 164, Council of Europe.
[3] Charter of Fundamental Rights of the European Union, 2000/C 364/01.

These will be addressed in turn. While the UK is not a State party to the Oviedo Convention and thus not bound by it, at present, it is bound by the EU Charter, which forms part of the Founding Treaties of the European Union and whose provisions relevant to genome editing were based on the Oviedo Convention.

Oviedo Convention

The Oviedo Convention has 29 States parties, all of which are members of the Council of Europe, making it an international treaty of regional rather than general application. Notably, its States parties do not include technologically advanced States like the UK, Germany, Sweden, the Netherlands, Spain, Russia, Italy, Belgium and Austria. In order for a treaty to generate obligations under customary international law, it needs both widespread and representative participation, including by the States that would be specially affected by its provisions,[4] here States with advanced biomedicine. This means that the principles incorporated in the Oviedo Convention have not yet become generally accepted in Europe and thus become binding as a matter of customary international law, i.e. without a treaty obligation. Nonetheless, these principles should be taken into account as authoritative guidance given that they incorporate agreed international standards and good practices in the area of biomedicine.

The Oviedo Convention affirms the obligation of States legislate to protect the dignity, identity and human rights of all human beings with respect to the application of biology and medicine.[5] Chapter IV of the Convention regulates the human genome by prohibiting any form of discrimination against the person based on their genetic heritage, as well as the use of procreation techniques to choose the sex of the child, except for the avoidance of serious hereditary sex-related disease.[6] The most important provision for the purposes of the present study is Article 13 Interventions on the human genome which provides 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.

The implications of this provision for genome editing are three-fold: first, it can only be undertaken for preventive, diagnostic or therapeutic purposes as opposed to enhancement. Second, genome editing that has as its aim germline modifications is prohibited. This could in effect preclude the legality of genome editing on embryos for the State parties to the Convention. However, it is possible that genome editing for therapeutic or preventive purposes where the modification in the genome of the

[4] *North Sea Continental Shelf Cases (Federal Republic of Germany/Denmark/Netherlands),* Judgment, ICJ Reports 1969, p. 3, paras 60-82.
[5] Art. 1, Oviedo Convention.
[6] Ibid, Art. 11 and 14.

descendants is not the aim but is incidental to the process, might still be in accordance with the Oviedo Convention. Thirdly, neither Article 13 nor Part IV of the Convention regulating the human genome prohibit research involving modifications of the genome.

Also relevant in this context is Article 15 of the Convention, which provides for the freedom of scientific research in the fields of biology and medicine, subject to the protection of human rights. This provision is one of the many instances in human rights treaties affirming the freedom of scientific research as a human right. It can now be said that the freedom of research is part of custom as a source of international law within the meaning of Article 38(1)(b) of the Statute of the International Court of Justice. As such, it is binding upon all States without the need of a treaty obligation. This means that the freedom to conduct research into genome editing is protected under international human rights law so long as it is not in violation of other human rights.

According to the Oviedo Convention, the creation of human embryos solely for research purposes is prohibited, as is the financial gain from the human body and its parts,[7] arguably including the genome. This provision was originally inspired by the 1994 French legislation on the respect for the human body aimed primarily against the sale of human organs and tissues. However, it can be interpreted evolutionary in light of the developments of science and technology to cover genetic material under its protection.

Last but not least, Article 28 of the Oviedo Convention requires public debate on "the fundamental questions raised by the developments of biology and medicine… in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate consultation." Accordingly, the States Parties to the Convention would need to engage in public consultation before regulating genome editing. Arguably, this is an example of good practice that should be considered by all States.

EU Charter of Fundamental Rights

The EU Charter is binding on the UK by virtue of its membership in the European Union. Given the status of the Charter as being part of and having equal legal force to the Founding Treaties of the EU, it enjoys primacy in domestic law over any conflicting statutes or rules, as well as a direct effect, meaning that it can be relied upon by individuals directly before domestic courts. It should be noted in this context, however, that upon signing the Lisbon Treaty, the UK together with Poland appended a Protocol on the Application of the EU Charter, aimed particularly at limiting the ability of individuals to invoke before domestic courts Title IV of the Charter on worker's rights.

[7] Ibid, Art. 18 and 21.

However, the Protocol purports to have broader implications by stating that the Charter does not extend the ability of the Court of Justice of the EU or any court or tribunal of the UK "to find that the laws, regulations or administrative provisions, practices or action … of the United Kingdom are inconsistent with the fundamental rights, freedoms and principles that it reaffirms."[8] It should be noted that the legal effects of this protocol are somewhat controversial and that in any case, its sphere of operation is limited to restricting the ability of the CJEU and domestic courts to find inconsistencies between the Charter and UK law. This is without prejudice to the fact that the UK would still incur responsibility on the international plane and under EU law in case of violating the provisions of the Charter, i.e. by passing inconsistent laws.

Turning to the substantive obligations under the EU Charter, the provision most relevant for genome editing is Article 3 on the right to integrity of the person:

> 1. Everyone has the right to respect for his or her physical and mental integrity.
>
> 2. In the fields of medicine and biology, the following must be respected in particular:
>
> (a) the free and informed consent of the person concerned, according to the procedures laid down by law;
> (b) the prohibition of eugenic practices, in particular those aiming at the selection of persons;
> (c) the prohibition on making the human body and its parts as such a source of financial gain;
> (d) the prohibition of the reproductive cloning of human beings.

The EU Network of Independent Experts on Fundamental Rights prepared an authoritative Commentary to the EU Charter at the request of the European Commission and Parliament to serve as guidance on its implementation by the Member States and the EU institutions.[9] According to the Commentary on Article 3, the right to personal integrity, both physical and mental, should be interpreted broadly as including not only the prohibition of torture and inhuman treatment, but also a broad range of other less serious forms of interference with a person's body, including any form of medical treatment absent or against their will.[10] Accordingly, it is likely that genome editing without or against the will of the person involved would violate their right to physical integrity. This brings the controversial question as to when one becomes 'a person'. According to the Commentary to Article 2 of the Charter on the

[8] Protocol on the Application of the Charter of Fundamental Rights of the European Union to Poland and to the United Kingdom, *Official Journal of the European Union*, C 306/157, Article 1(1).
[9] The Network consists of one expert per Member State and set up by the European Commission at the request of the Parliament to monitor the implementation of fundamental rights in Member States and the Union.
[10] EU Network of Independent Experts on Fundamental Rights, Commentary of the Charter of Fundamental Rights of the European Union, June 2006, p. 36.

right to life, despite the various attempts during the drafting to provide explicit protection to the unborn child, the presidium decided to keep the provision vague and tied to the corresponding provision in the European Convention of Human Rights (ECHR), thus open to development by the European Court of Human Rights.[11] Nonetheless, based on the existing case law under the ECHR, it can be observed that "the full protection of the right to life starts only with the birth of the child".[12] Accordingly, the other rights of the person, including the right to physical integrity, arguably also gain legal protection at the time of birth and genome editing before that would not be a violation. Indeed, this is one of the main difficulties of adopting a human rights approach when regulating the editing of the genome in embryos.

With respect to the prohibition of eugenic practices, the explanations of the presidium during the drafting of Article 3(2) stated that the reference to 'eugenic practices' refers to those aiming at the selection of persons in more serious situations involving "campaigns for sterilisation, forced pregnancy, compulsory ethnic marriage" carried out in Nazi Germany and as part of the ethnic cleansing in Bosnia and Herzegovina.[13] According to the Commentary, however, less serious forms of eugenic practices would be covered under the Charter too and furthermore, the prohibition should apply not only to States, but also to non-State actors.[14] Given that the term "eugenic practices" is not defined in the text of the EU Charter or in its Commentary, and in light of the illustrative examples given by the presidium, it is not clear whether and what lesser forms might fall under the prohibition. It is also doubtful that it could apply horizontally to non-State actors without further domestic legislation to this effect. Nonetheless, the prohibition against eugenics forms part of the crimes against humanity as set out in Article 7(1)(g) of the Rome Statute of the International Criminal Court and serves as a limit to genome editing aimed at the selection of persons where committed systemically or on a large scale against civilian population.

Article 3(2)(c) of the EU Charter can have important implications with respect to the patentability of genome editing technology and the edited genomes themselves. The case of *The Netherlands v European Parliament and Council* relating to Directive 98/44 on the legal protection of biotechnological inventions sheds some light on the interpretation of this provision. The Directive provides in the relevant part that "inventions which combine a natural element with a technical process enabling it to be isolated or produced for an industrial application can be subject of an application for a patent". The Court interpreted this to mean that "the Directive frames the law on patents in a manner sufficiently rigorous to ensure that the human body effectively remains unavailable and inalienable and that human dignity is safeguarded."[15]

[11] Ibid, pp 33-4.
[12] Ibid, 33 quoting the report of the European Commission of Human Rights in *Brüggemann and Scheuten v Germany,* 12 July 1977, DR 10, 100.
[13] Ibid, p. 40.
[14] Ibid.
[15] Ibid, pp 40-1, quoting ECJ, Case C-377/98, The Netherlands v European Parliament and Council of the European Union, [2001] ECR I-07079, Judgment of 9 October 2001, paras 69-77.

Also important is Article 21, which prohibits discrimination based, *inter alia*, on genetic features, inspired by Article 11 of the Oviedo Convention.[16] This specification is significant since the first reported case of genetic discrimination in China failed on the ground that genetic features were not considered to be a legally recognised basis for prohibited discrimination.[17]

Finally, it should be noted that the scope of application of the EU Charter is limited. According to Article 51 it applies "to the institutions, bodies, offices and agencies of the Union" and "to the Member States only when they are implementing Union law." As will be discussed later, the EU has so far issued very few rules pertaining to genome modification given its lack of exclusive competence in the area of public health. Therefore the Charter, however progressive in substance, has limited potential to regulate genome editing in the Member States.

Overall the EU Charter places the most significant and direct restrictions on the regulation of genome editing in the UK but only in the context of implementing EU law. The sanctions for non-compliance could include the bringing of infringement proceedings by the European Commission or another EU Member State before the Court of Justice of the EU. Given that these proceedings are provided for and binding under the Treaty on the Functioning of the European Union (TFEU),[18] it is unlikely that the CJEU would give effect to the UK Protocol to the Charter in this context.

The next section will focus on specific human rights that are relevant to genome editing and that should be taken into account in future domestic regulation.

Human rights relevant to genome editing

Human dignity

The respect for human dignity is often defined as the foundation of all human rights. It is also one of the key legal arguments used by courts and set out in international treaties in the context of germline editing.

Human dignity features in a number of international human rights treaties. Article 1 of the 1948 Universal Declaration of Human Rights (UDHR) affirms that "[a]ll human beings are born free and equal in dignity and rights." Even though not legally binding itself, the majority of the provisions of the UDHR are now seen to reflect custom. "[T]he dignity and worth of the human person" as the foundation of all human rights are also reaffirmed in the Preamble of the UN Charter,[19] the Preambles of the UNESCO

[16] EU Charter Commentary, p. 191.
[17] Tang, Zhou, Xie v Human Resources and Social Security Bureau in Foshan City, 2010, Foshan, Intermediate, Administrative, Final reported in Z Xie, *Labour Law in China: Progress and Challenges* (Springer, 2015), p. 45.
[18] Articles 258-260 TFEU.
[19] Charter of the United Nations, 892 UNTS 119, 24 October 1945, Preamble, para. 2.

Constitution,[20] the International Covenant on Civil and Political Rights (ICCPR),[21] the International Covenant on Economic, Social and Cultural Rights (ICESCR),[22] the International Convention on the Rights of the Child (CRC),[23] the International Convention on the Elimination of All Forms of Racial Discrimination (CERD),[24] the Convention on the Elimination of All Forms of Discrimination Against Women, (CEDAW)[25] as well as the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment and Punishment (CAT).[26]

While the preambles of international treaties do not impose legal obligations directly, they are an important part of the process of treaty interpretation as they commonly set out the object and purpose of the treaty, as well as form part of its context.[27] Therefore, the preambles of treaties and the principles they set out can affect the interpretation of all their provisions.

Express references to human dignity can be found in a number of UNESCO declarations relating specifically to the human genome and science, indicating the implications of the principle in these areas of regulation. The respect for human dignity lies at the heart of the prohibition against genetic discrimination and the obligation to respect genetic diversity. For example, the UNESCO Universal Declaration on the Human Genome and Human Rights stresses that "the recognition of the genetic diversity of humanity must not give rise to any interpretation of social or political nature which could call into question "the inherent dignity" of all members of the human family.[28] Furthermore, while recognizing that the research on the human genome and the resulting applications can lead to significant progress in improving the health of individuals and of humanity as a whole, the Human Genome Declaration emphasizes that such research should fully respect human dignity, freedom and human rights.[29] Notably, the very first section of the Declaration is entitled "human dignity and the human genome" with Article 1 and 2 fleshing out the relationship between the two in the following terms:

> Article 1
>
> The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity.

[20] Constitution of UNESCO, 4 November 1946, Preamble, para. 3.
[21] ICCPR, 999 UNTS 171, 23 March 1976, Preamble, para. 2.
[22] CESCR, 993 UNTS 3, 3 January 1976, Preamble, para. 2.
[23] CRC, 2 September 1990, Preamble, paras 2, 3, 7, Art. 23(1), 28(2), 37(c), 39, 40(1).
[24] CERD, 660 UNTS 195, 4 January 1969, Preamble, paras 1, 2, 5.
[25] CEDAW, 1249 UNTS 13, 3 September 1981, Preamble, paras 1, 2, 7.
[26] CAT, 1465 UNTS 85, 10 December 1948, Preamble, para. 2.
[27] Art. 31(1) and (2) General rule of interpretation, Vienna Convention on the Law of Treaties, 1155 UNTS 331, 22 May 1969.
[28] UNESCO Universal Declaration on the Human Genome and Human Rights, 1997, Preamble, para. 4.
[29] Ibid, Preamble, para. 6.

Article 2

(a) Everyone has a right to respect for their dignity and for their rights regardless of their genetic characteristics.

(b) That dignity makes it imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity.

Human dignity is relevant to the scientific research in genome editing, as well as to its clinical applications. The UNESCO Declaration on Science and the Use of Scientific Knowledge affirms specifically that both "scientific research and the use of scientific knowledge should respect human rights and the dignity of human beings".[30] The UNESCO Declaration on Bioethics and Human Rights specifies further that the "ethical issues raised by the rapid advances in science and their technological applications should be examined with due respect to the dignity of the human person and universal respect for, and observance of, human rights".[31] According to Article 3 of this Declaration on human dignity and human rights, these are to be fully respected and further, they entail that the interests and welfare of the individual should have priority over the sole interest of science and society,[32] and that discrimination or stigmatization based on any grounds violates human dignity.[33]

The respect for human dignity is also central to the Oviedo Convention, whose Article 1 sets out that the obligation of the Parties to protect the dignity and identity of all human beings in the application of biology and medicine. The inviolability, respect for and protection of human dignity are also set out in Article 1 of the EU Charter of Human Rights. The Commentary to the Charter defines human dignity by reference to a holding of the German Federal Constitutional Court as meaning "that the human being has a right to 'social value and respect'. Everyone possesses dignity as a human creature 'regardless of his/her innate characteristics, achievements and social status…It cannot be taken away from any human being." [34] According to the Commentary, while human dignity in Article 1 is a legal term:

> Its range…is connected with ethical assessments. This applies, for instance to the question whether developing life already has human dignity. In the Member States partly different traditions and ideas exist. Moreover the ideas can change regarding to what human dignity applies to. This especially happens if the ethical question is a subject of intensive public discussion. It always depends on the concrete issue. In rather problematic issues on the European level,

[30] UNESCO Declaration on Science and the Use of Scientific Knowledge, 1999, para. 19.
[31] UNESCO Universal Declaration on Bioethics and Human Rights, 1998, Preamble, para. 3.
[32] Ibid, Art. 3(2).
[33] Ibid, Art. 11.
[34] EU Charter Commentary, p. 26 quoting Decision of 20 October 1992, BVerfGE 87, 209.

> therefore, it will be important to begin with looking for communication by ethical criteria.[35]

Notably, the CJEU has affirmed that human dignity is a general principle of EU law, which as such has a high rank in the hierarchy of EU law, justifying restrictions of the obligations imposed by EU law, even the four freedoms.[36] Also important is a judgment concerning the Directive on the legal protection of biotechnical inventions, which was challenged by the Netherlands, *inter alia*, for being contrary to human dignity by allowing the patenting of parts of the human body. The CJEU agreed that it is its role to review the compatibility of the acts of the EU institutions with the general principles of EU law in order to ensure observance of the fundamental human rights to dignity and integrity.[37] It held that human dignity was guaranteed by Article 5(1) of the Directive providing that the human body at the various stages of its formation and development cannot constitute a patentable invention. Notably, the CJEU also relied on Article 6 of the Directive setting out the public order and morality exception to conclude that "processes for cloning human beings, processes for modifying the germ line genetic identity of human beings and uses of human embryos for industrial or commercial purposes" would be excluded from patentability.[38]

Even though human dignity is not expressly referred to in the European Convention of Human Rights, it has been used as a guiding principle by the European Court of Human Rights (ECtHR), including as a reason for extending human rights protections to the embryo and/or foetus as belonging to the human race even without qualifying as a 'person' with a 'right to life' under Article 2 of the ECHR.[39] The Court noted:

> At European level, …there is no consensus on the nature and status of the embryo and/or foetus, although they are beginning to receive some protection in the light of scientific progress and the potential consequences of research into genetic engineering, medically assisted procreation or embryo experimentation. At best, it may be regarded as common ground between States that the embryo/foetus belongs to the human race. The potentiality of that being and its capacity to become a person – enjoying protection under the civil law, moreover, in many States, such as France, in the context of inheritance and gifts, and also in the United Kingdom– require protection in the name of human dignity, without making it a "person" with the "right to life" for the purposes of Article 2. The Oviedo Convention on Human Rights and Biomedicine, indeed, is careful not to give a definition of the term "everyone",

[35] Ibid, p. 28.
[36] Case C-36/02, *Omega Spielhallen und Automatenaufstellungs GmbH v Oberbürgermeisterin der Bundesstadt Bonn* [2004] ECR I-9609, paras 34-5.
[37] Case C-377/98, *The Netherlands v Parliament and Council,* [2001] ECR I-07079, Judgment of 9 October 2001, para. 70. See also Opinion of Advocate General Jacobs, 14 June 2001.
[38] Ibid, para. 76.
[39] *Vo v France*, Judgment, Merits, App No 53924/00, ECHR 2004-VIII, [2004] ECHR 326, 8th July 2004, ECtHR, Grand Chamber, para. 84.

> and its explanatory report indicates that, in the absence of a unanimous agreement on the definition, the member States decided to allow domestic law to provide clarification for the purposes of the application of that Convention.[40]

Notably, the German Federal Constitutional Court held similarly that embryos and developing life are included in the protection of human dignity based on the potential abilities in the human existence, reasoning that:

> Where there is life, human dignity is due; it is not significant whether or not the bearer of life is conscious of his dignity and how to safeguard it him/herself.[41]

Article 5 of the African Charter on Human and People's Rights links the right to respect of the dignity inherent in the human being with the recognition of their legal status. According to the African Commission on Human Rights, "[t]he respect of the dignity inherent in the human person informs the content of all the personal rights protected in the Charter" and is inherently linked to the recognition of their juridical personality as a prerequisite of one's capacity to hold rights and obligations.[42] The Inter-American Court of Human Rights held too that "failure to recognize juridical personality harms human dignity, because it denies absolutely an individual's condition of being a subject of rights and renders him vulnerable to non-observance of his rights by the State and other individuals."[43]

The UK Supreme Court in the case of *Ghaidan v Godin-Mendoza,* decided under the Human Rights Act, gave as an example of a violation of human dignity "[t]reating someone as automatically having less value than others not only causes pain and distress to that person but also violates his or her dignity as a human being".[44] The link between human dignity and equality was also at the centre of the reasoning of the Canadian Supreme Court's judgment in *R v Ewanchuk.*[45] The German Federal Constitutional Court decided that human dignity is violated "if, by the kind of measure taken, the quality of the person concerned as a subject is questioned in principle".[46]

The African Commission on Human Rights held in *Purohit and Moore v Gambia* that:

> Human dignity is an inherent basic right to which all human beings, regardless of their mental capabilities or disabilities as the case may be, are entitled to without discrimination. It is therefore an inherent right which every human being

[40] Ibid.
[41] Judgment of 25 February 1975, BVerfGE 39, 1 and Judgment of 28 May 1993, BVerfGE 88, 203 both concerning abortion.
[42] Communication No 317/06 *Nubian Community in Kenya v Kenya,* 30 May 2016, paras 137-8.
[43] *Yean Bosico v Dominican Republic,* IACtHR, Judgment of 8 September 2005, para. 178.
[44] *Ghaidan v Godin-Mendoza,* [2004] UKHL 30, 2 AC 557, per Baroness Hale of Richmon, para. 132.
[45] [1999] 1 SCR 330.
[46] Judgment of 3 March 2004, BVerfGE 109, 279, 313.

> is obliged to respect by all means possible and on the other hand it confers a duty on every human being to respect this right.[47]

These cases raise the question as to whether the use of genome editing aimed at eliminating certain conditions could be incompatible with the human dignity of those affected by them, i.e. the editing out of certain mental health issues, such as autism, which could lead to stigmatization. This will be discussed further in the section on the rights of persons with disabilities.

Based on the coinciding approaches of regional human rights courts and domestic bodies, it can be concluded that there is a trend of acknowledging that while embryos and foetuses are not generally recognised as holders of human rights, they are becoming increasingly recognised as having human dignity. While the full consequences of such recognition are not yet clear, they seem to include the prohibition against discrimination and stigmatization based on genetic traits, the respect for genetic uniqueness and diversity, as well as the prioritization of the welfare and interests of the individual over the sole interests of science and society. Human dignity is inviolable and hence ought to be respected both in the research and the clinical applications of genome editing. It has been used as an argument for extending certain human rights and legal protections to the embryo and the foetus.

Right to physical integrity

The right to personal integrity is probably the second most important human right with implications for genome editing. This is due one the one side to the fundamental character of the right itself and on the other, to the specific implications it has in the fields of medicine, research and technology, which are recognised on the international plane.

The right to “corporal integrity” featured prominently in the negotiations of the Genocide Convention.[48] The early drafts of Article 1 provided that the material element of genocide includes “any act directed against the corporal integrity of members of the group”, which was adopted by five votes to one with one abstention. [49] The commentary to the provision suggested that the formula covered acts including “biological experiments conducted with no useful end in view”.[50] The final version of the Genocide Convention includes an indicative though non-exhaustive list of acts, which may constitute genocide, including the causing of serious bodily harm, the imposition of measures intended to prevent births within a group and the deliberate infliction of conditions of life calculated to bring about the physical destruction of the

[47] Communication No. 241/01 (2003) AHRRL 96, para. 57.
[48] Convention on the Prevention and Punishment of the Crime of Genocide, 78 UNTS 277, 9 December 1948.
[49] Ad Hoc Committee on Genocide: Commentary on Articles Adopted by the Committee, UN Doc E/AC.25/W.1, Article 1.
[50] Ibid, Observations, para. 2.

group.[51] Even though the final text of Article 2 of the Genocide Convention no longer expressly refers to physical integrity, the principle clearly underlines its provisions. This, coupled with the preparatory works and the non-exhaustive character of the listed acts indicates that certain extreme applications of genome editing, if accompanied by the intent to destroy a protected group, could indeed amount to genocide, which is the most heinous crime prohibited under peremptory norms of international law. The question as to what constitutes a protected group for the purposes of genocide is somewhat open. The Genocide Convention itself refers to national, ethnical, racial or religious groups[52] but it is possible that the law has developed since 1948 and now protects more groups.

The right to physical integrity is expressly protected under regional and specialised human rights treaties, including Article 5 of the American Convention on Human Rights; Article 4 of the African Charter on Human and People's Rights; Article 3 of the EU Charter of Fundamental Rights; Article 17 of the Convention on the Rights of Persons with Disabilities and Article 1 of the Oviedo Convention on Human Rights and Biomedicine. The right is also affirmed in the EU Clinical Trials Regulation[53] and in soft law instruments, such as the Declaration on the Use of Scientific and Technological Progress for the Benefit of Mankind.[54]

Notably, the main practical significance of the right to personal integrity in the EU Charter is described as one of placing specific limitations on medicine, biology and the freedom of scientific research.[55] It is defined broadly which could be interpreted as covering a range of serious and less serious forms of interference with the person's physical and mental integrity, as well as any for of medical treatment without consent.[56] The right to physical integrity is formulated as an express limitation on the freedom of scientific research.[57] In this context, it should be noted that during the drafting of Article 3 of the Charter it was repeatedly stated that its principles are already included in the Oviedo Convention and that the Charter does not depart from those principles.[58] Indeed, the prohibition against any germline modifications under Article 13 of the Oviedo Convention can be seen as an expression of the right to physical integrity. Therefore, it is not entirely surprising that the Commentary concludes that:

> The protection of the embryo against genetic engineering and other unlawful research and the absolute prohibition of any modification in the genome of any descendants illustrates that the protection of the right to personal integrity extends to the unborn children and even to future generations. This represents

[51] Genocide Convention, Article 2(b), (d) and (c).
[52] Ibid, Art. 2.
[53] Clinical Trials Regulation, EU No. 536/2014, Art. 28 (d) General Rules and previously, EU Clinical Trials Directive, 2001/20/EC, Art. 3(2)(c).
[54] UN GA Res. 3384 (XXX), 10 November 1975, Section 6.
[55] Ibid, p. 37.
[56] Commentary of the EU Charter, p. 36.
[57] Ibid, p. 37.
[58] ETS No. 164.

an important difference to the right to life in Article 2, which in principle is only protected as from birth.[59]

While based on the Oviedo Convention's prohibition of germline editing, this conclusion goes significantly beyond it by extending the prohibition to the conduct of research and to the protection of future generations. It should be noted, however, that the Commentary is not obviously grounded on the actual wording of Article 3 of the EU Charter and in any event, cannot be regarded as a binding interpretation. Had the drafters wished to prohibit the genetic engineering of embryos and to protect the personal integrity of unborn children, they should have done so expressly.

Finally, it should be noted that the right to physical integrity, in contrast to the right to life, for instance, is not defined as an absolute right and that States could derogate from it, i.e., in accordance with the general limitations clause in Article 52(1) of the EU Charter, i.e. provided that the limitations respect the essence of the right, are proportionate and "are necessary and genuinely meet objectives of general interest recognised by the Union or the need to protect the rights and freedoms of others."[60] Rights which could conceivably be in tension with the right to physical integrity in the context of genome editing include the right to health, the freedom of scientific research and the right to enjoy the benefits of science.

Overall, the right to physical integrity is defined broadly and extends to the genetic integrity of the individual. Interference with the right is subject to the principle of express consent. The question of germlie editing is treated as prohibited interference with the right to physical integrity of future generations under the Oviedo Convention and the Commentary to the EU Charter of Fundamental Rights. It is unclear, however, whether in the absence of an express prohibition of germline editing, the right to physical integrity could be extended to cover situations not only before the birth but even before the conception of an individual. If this is indeed the case, it is also open to debate how is one to weigh the right to health of an existing individual with the right to physical integrity of future generations.

Right to life

The question as to when the right to life begins is controversial and subject to varying treatment by different States. This lack of common agreement is also reflected in international treaties, most of which leave the question open.

The right to life is set out in most if not all human rights treaties, including Article 2 of the ECHR, Article 4 of the African Charter on Human and People's Rights, Article 5 of the Arab Charter on Human Rights, Article 6 of the ICCPR, Article 2 of the EU Charter, Article 3 UDHR, Article 6 of the CRC and others. The American Convention on Human

[59] Commentary of the EU Charter, p. 39.
[60] EU Charter of Fundamental Rights, Art. 52(1).

Rights is exceptional in specifying that the right to life "shall be protected by law and, in general, from the moment of conception."[61]

The right to life can be relevant to genome editing in two ways. First, as an argument against it in order to protect the life of the embryo or foetus (if these are indeed entitled to human rights) and second, as an argument in favour of genome editing, requiring the State to take positive measures to enable the right to life by decreasing infant mortality.

According to General Comment No. 6 on the Right to Life by the Human Rights Committee (HRC), which is the treaty monitoring body to the ICCPR, the right to life "is the supreme right from which no derogation is permitted even in time of public emergency which threatens the life of the nation" and "the protection of this right requires positive measures".[62] The Commentary goes on to suggest that "it would be desirable for States parties to take all possible measures to reduce infant mortality and to increase life expectancy",[63] including, arguably, by research into and the clinical application of genome editing. In this context, it should be noted that Article 6 of the CRC imposes an obligation on the States Parties to "ensure to the maximum extent possible the survival and development of the child."

Interestingly, the Draft General Comment No. 6 addressed explicitly the question of the rights of unborn children and their right to life, noting the absence of subsequent agreements regarding the inclusion of the rights of the unborn within article 6 and the absence of uniform State practice to this effect to conclude that "the Committee cannot assume that article 6 imposes on States parties an obligation to recognize the right of life to unborn children."[64] The HRC also stressed that the absence of an express reference to the rights of unborn children in the ICCPR was deliberate as the proposals to include the right to life for the unborn were rejected during the drafting of the ICCPR.[65] Indeed, the amendment to this effect proposed by Belgium, Brazil, El Salvador, Mexico and Morocco was rejected by 31 votes to 20 with 14 abstentions.[66] Furthermore, the Draft General Comment No. 6 noted that the ICCPR does not regulate the right to life of frozen embryos, eggs, sperm, stem cells or human clones and that it is for States to decide whether to regulate the protection of these forms of potential life.[67]

Similar discussions took place during the negotiations of the Convention on the Rights of the Child. Its Preamble does refer to the Declaration on the Rights of the Child noting that "the child, by reason of his physical and mental immaturity, needs special

[61] American Convention on Human Rights, 22 November 1969, Article 4(1).
[62] General Comment No. 6 to the ICCPR: Article 6 (Right to Life), Human Rights Committee, paras 1 and 5.
[63] Ibid, para. 5.
[64] Draft General Comment No. 6 to the ICCPR, HRC, para. 7.
[65] UN Doc. E/CN.4/21, UN Doc. E/CN.4/SR.35, p. 16.
[66] UN GAOR, 12th Session, UN Doc. A/3764, 1957 and A/C.3/L.654.
[67] Draft General Comment No. 6, para. 8.

safeguards and care, including appropriate legal protection before as well as after birth".[68] Due to the controversies surrounding this paragraph and the insistence by States, including Italy, Malta, Venezuela, Senegal, Kuwait, Argentina, Austria, Colombia and Egypt to include the protection of unborn children in the operative text of the Convention, an interpretative statement was appended to paragraph 9 of the Preamble stating that:

> In adopting this preambular paragraph, the Working Group does not intend to prejudice the interpretation of article 1 [definition of 'child'] or any other provision of the Convention by States Parties.[69]

The European Court of Human Rights has not yet determined the issue of the beginning of everyone's right to life under the ECHR either,[70] though it has not excluded the possibility that the foetus may enjoy certain protection under Article 2 ECHR, noting that "in certain circumstances this may be the case notwithstanding that there is in the Contracting States a considerable divergence of views on whether and to what extent Article 2 protects unborn life."[71] Overall, however, the ECtHR adopts the view that the determination of the issue as to when the right to life begins is within the margin of appreciation that States enjoy, reasoning that:

> At European level, the Court observes that there is no consensus on the nature and status of the embryo and/or foetus, although they are beginning to receive some protection in the light of scientific progress and the potential consequences of research into genetic engineering, medically assisted procreation or embryo experimentation. At best, it may be regarded as common ground between States that the embryo/foetus belongs to the human race. The potentiality of that being and its capacity to become a person … require protection in the name of human dignity, without making it a "person" with the "right to life" for the purposes of Article 2. [72]

It should be noted that the interpretation of Article 2 of the ECHR by the ECtHR is directly relevant to the interpretation of Article 2 of the EU Charter, as was the intention of the presidium, which deliberately kept the provision vague explaining that it corresponds to the ECHR.[73] Accordingly, any development in this respect is likely to come from the ECtHR, which also has the power to give advisory opinions on the interpretation of the Oviedo Convention pursuant to its Article 29.

[68] CRC, Preamble, para. 9.
[69] Report of the Working Group on a draft convention on the rights of the child, UN Doc. E/CN.4/1989/48, para. 43.
[70] *Vo v France,* 2004, para. 75.
[71] H v Norway, Application No. 17004/90 (1992), para. 167.
[72] *Vo v France,* para. 84.
[73] EU Charter, Commentary, p. 34.

Right to health

The right to health has significant implications for genome editing, especially for the obligations of States who choose to introduce its clinical application.

The right to health is a fundamental human right of the sub-category of social rights. It is set out in numerous universal, regional and specialised human rights treaties, arguably making it binding not only under treaty but also under customary international law. The right to health can be traced back to Article 25 of the UDHR and is set out expressly in: Article 12 of the widely-ratified International Covenant on Economic, Social and Cultural Rights to which the UK is a party; Article 55(b) of the UN Charter; the Preamble and Article 1 of the Constitution of the World Health Organisation; Article 35 of the EU Charter; Article 11 of the European Social Charter; Article 24(1) of the Convention on the Rights of the Child; Article 5(e)(iv) of the Convention on the Elimination of All Forms of Racial Discrimination; in Article 11(1)(f) of the Convention on the Elimination of All Forms of Discrimination against Women; Article 16 of the African Charter on Human and People's Rights and Article 14 of the Protocol to the African Charter on the Rights of Women in Africa; Article 10 of the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights;; and Article 3 of the Oviedo Convention.

"Health" is defined in the Constitution of the WHO as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."[74] This definition was affirmed in the Alma-Ata Declaration of the WHO, which is a soft law instrument.[75] The Declaration stressed that "the attainment of the highest possible level of health is a most important world-wide social goal whose realization requires the action of many other social and economic sectors in addition to the health sector."[76]

According to Article 12 of the ICESCR:

> 1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
>
> 2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:
>
> (a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
> …

[74] Constitution of the World Health Organisation, 22 July 1946, Preamble, para. 2.
[75] Alma-Ata Declaration, International Conference on Primary Health Care, Alma-Ata, USSR, 6-12 September 1978**,** para. 1.
[76] Ibid.

(d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

The rights and obligations under this provision are two-fold. On the one side, Article 12(1) formulates health as an individual right and on the other, Article 12(2) imposes specific obligations on the States Parties in order to realise the right to health.[77] As described by Audrey Chapman, "medicine focuses primarily on the health status of the individual, generally in the context of physical (and to a lesser extent mental) illness and disability, in contrast, public health is concerned with protecting the health of populations and ensuring conditions in which people can be healthy."[78] Scholars have observed the tension between individual rights and public policy objectives in the context of health.[79]

The inclusion of the right in the ICESCR is significant given that the Covenant includes human rights of the so-called 'second generation',[80] which in contrast to the 'first generation' of civil and political rights, is not subject to immediate application, but to progressive realization instead. Indeed, according to Article 2(1) of the ICESCR, the States Parties undertake to "take steps…to the maximum of [their] available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures." As observed by Canada during the negotiations of the ICESCR, economic, social and cultural rights are in effect "responsibilities of the state in the field of economic policy and social welfare which usually require for their effective implementation detailed social legislation and the creation of appropriate administrative machinery."[81]

The Committee on Economic, Social and Cultural Rights (CESCR), which is the treaty-monitoring body under the ICESCR, issued an authoritative interpretation of Article 12 in its General Comment No. 14 on the right to the highest attainable standard of health. According to the CESCR, the right to health includes legally-enforceable components, including the principle of non-discrimination in relation to health facilities, goods and services.[82] As will be discussed below, this is particularly significant for the future clinical application of genome editing.

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[77] B Saul, D Kinley and J Mowbray, *The International Covenant on Economic, Social and Cultural Rights: Commentary, Cases and Materials* (2014, OUP), 979.
[78] A Chapman, 'Core Obligations Related to the Right to Health' in A Chapman and S Russed (eds), *Core Obligations: Building a Framework for Economic, Social and Cultural Rights* (Intersentia, 2002), 187.
[79] Saul, Kinley and Mowbray, note 77 above, 982.
[80] UN Chronicle 'International Human Rights Law: A Short History' Vol. XLVI No. 1 & 2 2009, available at: https://unchronicle.un.org/article/international-human-rights-law-short-history (accessed 12 April 2017).
[81] Complication of the Observations of Governments of Member States on the Draft International Covenant on Human Rights and Measures of Implementation, as Drafted at the Sixth Session of the Commission on Human Rights: Memorandum by the Secretary-General, E/CN.4/552 (24 April 1951).
[82] CESCR, General Comment No. 14 (2000): The right to the highest attainable standard of health, E/C.12/2000/4, para. 1, note 1.

The CESCR stresses that the right to health is not a right to be healthy and defines the normative content of the right to health as containing both freedoms and entitlements:

> The freedoms include the right to control one's health and body, including sexual and reproductive freedom, and the right to be free from interference, such as the right to be free from torture, non-consensual medical treatment and experimentation. By contrast, the entitlements include the right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health. [83]

According to the Committee, the essential elements of the right to health include the availability of functioning health-care facilities, their scientific and medical quality and notably, their accessibility to everyone without discrimination, especially the most vulnerable or marginalized sections of the population.[84] Accessibility is defined as both physical but also economic, i.e. affordability:

> health facilities, goods and services must be affordable for all. Payment for health-care services, as well as services related to the underlying determinants of health, has to be based on the principle of equity, ensuring that these services, whether privately or publicly provided, are affordable for all, including socially disadvantaged groups. Equity demands that poorer households should not be disproportionately burdened with health expenses as compared to richer households…[85]

The obligation of equal treatment and the prohibition against discrimination are important aspects of the right to health. The CESCR emphasises that "States have a special obligation to provide those who do not have sufficient means with the necessary…health care facilities, and to prevent any discrimination on internationally prohibited grounds in the provision of health care and health services".[86]

Therefore, the obligation of equitable accessibility of health facilities could have important financial implications for States who introduce genome editing at the clinical level as they would have to make it affordable to the socially disadvantaged groups irrespective of whether it is a publicly or privately provided service.

The right to health imposes on States an obligation to respect, to protect and to fulfill it. The obligation to respect includes refraining from denying or limiting equal access, as discussed above, but also very importantly, an obligation to refrain from marketing

[83] Ibid, para. 8.
[84] Ibid, para. 12.
[85] Ibid.
[86] Ibid, para. 19.

unsafe drugs or services.[87] This would mean that allowing genome editing before it is proven to be "safe" would put the State in violation of respecting the right to health.

The obligation to protect entails a duty to regulate the provision of health-care services by third, i.e. private, parties, including by ensuring equal access to health care and services but also to control the marketing of medical equipment and medicines by third parties.[88] This means that the obligations of States with respect to the right to health apply irrespective of whether the health services are provided by the State itself or by third parties, i.e. corporations. It is incumbent on the State to ensure equal access and the quality of the service provided. According to the CESCR, violations of the right to health can occur through the direct action of States but also through the actions of other entities insufficiently regulated by the State.[89] With respect to genome editing, this would entail an obligation on the State on whose territory it is performed, an obligation to regulate the conduct of private providers and to ensure both its quality and accessibility.

The specific right to maternal, child and reproductive health could be a strong argument in favour of introducing genome editing. Indeed, the promotion of maternal health and the reduction of child mortality form part of the Millennium Development Goals.[90] Reproductive health is defined by the CESCR:

> Reproductive health means that women and men have the freedom to decide if and when to reproduce and the right to be informed and to have access to safe, effective, affordable and acceptable methods of family planning of their choice as well as the right of access to appropriate health-care services that will, for example enable women to go safely through pregnancy and childbirth.[91]

According to the Committee, the provision requiring the reduction of stillbirth and infant mortality requires measures to improve child and maternal health, sexual and reproductive health services, access to information and resources to act on that information. Accordingly, once safe and clinically available, genome editing would likely qualify as a measure that enables the right to maternal, child and reproductive health.

Notably, the right to sexual and reproductive health under Article 12 of the ICESCR was elaborated in General Comment No. 22 of 2016, defining the rights as including the following freedoms and entitlements:

[87] Ibid, para. 34.
[88] Ibid, para. 35.
[89] Ibid, para. 48.
[90] Millennium Development Goals No. 4 and 5, United Nations Millennium Declaration, GA Re. 55/2 (2000).
[91] Ibid, note 12.

> The freedoms include the right to make free and responsible decisions and choices, free of violence, coercion and discrimination, regarding matters concerning one's body and sexual and reproductive health. The entitlements include unhindered access to a whole range of health facilities, goods, services and information, which ensure all people full enjoyment of the right to sexual and reproductive health under article 12 of the Covenant.[92]

In his reports, the UN Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health stressed:

> [T]he right of men and women to be informed and have access to safe, affordable and acceptable methods of family planning of their choice, as well as other methods of their choice for regulation of fertility which are not against the law, and the right of access to appropriate health care services that will enable women to go safely through pregnancy and childbirth and provide couples with the best chance of having a healthy infant.
>
> In line with the above definition of reproductive health, reproductive health care is defined as the constellation of methods, techniques and services that contribute to reproductive health and well-being by preventing and solving reproductive health problems.[93]

The CESCR stresses that the failure or refusal to incorporate technological advances and innovations in sexual and reproductive health services jeopardizes the quality of care and the right to reproductive health.[94] This could mean that once safe to use in clinical context, States might have a positive obligation to introduce genome editing, at least for the purposes of enabling women to go safely through pregnancy but also for improving their chances to have a healthy infant. In the *Artavia Murillo v Costa Rica* case where couples challenged the blank prohibition against IVF in Costa Rica, the Inter-American Court of Human Rights held in similar vein that:

> The right to reproductive health entails the rights of men and women to be informed and to have free choice of and access to methods to regulate fertility, that are safe, effective, easily accessible and acceptable…the right to private life and reproductive freedom is related to the right to have access to the medical technology necessary to exercise that right.[95]

[92] CESCR, General Comment No. 22(2016) on the right to sexual and reproductive health, para. 5.
[93] Commission on Human Rights, Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, E/CN.4/2004/49, 16 February 2004, para. 18 (emphasis added).
[94] Ibid, para. 21.
[95] *Artavia Murillo v Costa Rica,* IACtHR (2012), 165 ILR 1, 159, paras 149-50.

Finally, the right to health has trans-national aspects:

> To comply with their international obligations in relation to article 12, States parties have to respect the enjoyment of the right to health in other countries, and to prevent third parties from violating the right in other countries, if they are able to influence these third parties by way of legal or political means, in accordance with the Charter of the United Nations and applicable international law. Depending on the availability of resources, States should facilitate access to essential health facilities, goods and services in other countries, wherever possible and provide the necessary aid when required.
> …
> For the avoidance of any doubt, the Committee wishes to emphasize that it is particularly incumbent on States parties and other actors in a position to assist, to provide "international assistance and cooperation, especially economic and technical" which enable developing countries to fulfill their core and other obligations.[96]

In practice, the trans-national aspect of the right to health imposes an obligation on States to regulate the behaviour of their subjects abroad and make sure that they are prohibited from circumventing the legal restrictions on genome editing by performing or receiving such services abroad, including by providing appropriate sanctions if this happens. Secondly, developed States are actively encouraged to provide international economic and technical assistance to developing States in the field of health, i.e. to help them introduce genome editing in their respective health systems.

Similarly, the right to health was discussed by Judge Weeramantry of the International Court of Justice in his Separate Opinion in the *Legality of the Threat or Use of Nuclear Weapons* Advisory Opinion. Judge Weeramantry interpreted Article 12 of the ICESCR, to mean that the recognition by States of the right to health to "everyone" and not merely of their own subjects to mean that "each State is under an obligation to respect the right to health of all members of the international community."[97] He thought that the right to health entails obligations *erga omnes* (owed to the international community as a whole), towards the entire global population, including an obligation "to take active steps towards guaranteeing this right to health of the global population."[98]

There have been non-binding but authoritative recommendations from the UN agency specializing in the area of health to introduce medical generic services at the level of primary healthcare with specific focus on the prevention of certain genetic diseases. In its resolutions, the WHO has stressed the significant contribution that genomics can have on the right to health and the need to promote their potential benefits in

[96] Ibid, paras 39 and 45.
[97] *Legality of the Use by a State of Nuclear Weapons in Armed Conflict,* Advisory Opinion, ICJ Reports 1996, p. 66, Dissenting Opinion Judge Weeramantry, p. 144.
[98] Ibid.

developed and developing countries alike.[99] The WHO defines genomics broadly as "the study of genes and their functions, and related techniques".[100] Genome editing techniques would certainly fall within this definition. The WHO urges its Member States (including the UK) to set up regulatory systems on genomics with particular regard to safety and the need for public awareness.[101] Indeed, the Executive Board of the WHO called on the Member States to develop and strengthen medical genetic services, within their existing primary health systems, to prevent and manage genetic diseases so, including sickle-cell anaemia and thalassemia, in order to reduce morbidity and mortality.[102] Primary health care was defined by the WHO Alma-Ata declaration as "essential health care based on practical, scientifically sound and socially acceptable methods and technology made universally accessible to individuals and families in the community through their full participation and at a cost that the community and country can afford to maintain at every stage of their development in the spirit of self-reliance and self-determination".[103]

Right to enjoy the benefits from scientific progress and the freedom of scientific research

The right to enjoy the benefits from scientific progress is relevant to both the research and the potential clinical application of genome editing. One aspect of the right particularly significant for genome editing research (and funding) is the principle of freedom of scientific research.

The right to enjoy the benefits of scientific progress and its applications (in short, "the right to benefit from science") was set out in the UDHR and later in the ICESCR, providing in Article 15 that:

> 1. (b) The States Parties to the present Covenant recognize the right of everyone to enjoy the benefits of scientific progress and its applications.
>
> 2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for the conservation, the development and the diffusion of science and culture.
>
> 3. The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity.

[99] WHO, Resolution WHA57.13 (2004), Genomics and World Health, Preamble, paras 3 and 7.
[100] Ibid, para. 2.
[101] Ibid, para. 3(1).
[102] WHO, Executive Board Resolutions EB117R3 and EB118.R1.
[103] Declaration of Alma-Ata, International Conference on Primary Health Care, 1978, para. VI.

> 4. The States Parties to the present Covenant recognize the benefits to be derived from the encouragement and development of international contacts and co-operation in the scientific and cultural fields.

The right to benefit from science can also be found in varying formulations in some though not all regional human rights instruments, including Article 38 of the Charter of the Organisation of American States; Article 14(2) of the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights; Article 32 of the ASEAN Human Rights Declaration; and Article 42 of the Arab Charter on Human Rights. Notably, the EU approach towards science is one of conceptualizing it as a freedom rather than as a positive right. The EU Charter of Fundamental Rights defines scientific freedom very narrowly as freedom of scientific research.[104] The Commentary to the Charter clarifies that the provision is based on the freedom of expression set out in Article 10 of the ECHR and the case law of the European Court on Human Rights on the freedom of expression.[105] Somewhat disappointingly, the ECHR itself does not contain any provisions on the right to science or on cultural rights. The African Charter on Human and People's Rights contains a general reference to cultural development but does not contain a reference to science.[106]

Overall, the regional treaties providing for the right to benefit from science are similar to the ICESCR. One of the main differences is that many of them refer to technological progress rather than to the benefits of scientific applications, which indicates a narrower understanding that the applications of science necessarily imply technological benefits.

Unlike most other rights in the ICESCR, the right to benefit from science has not yet been clarified in a General Comment. However, UNESCO and the UN Special Rapporteur in the Field of Cultural Rights have issued similar interpretations of the normative content of the right, which will no doubt inform the future general comment.

Still, in General Comment No. 17 on the right of everyone to benefit from the protection of the moral and material interests resulting from any scientific production under Article 15(1)(c) of the ICESCR, the CESCR clarifies with respect to the right to benefit from science that:

> States parties should prevent the use of scientific and technical progress for purposes contrary to human rights and dignity, including the rights to life, health and privacy, e.g. by excluding inventions from patentability whenever their

[104] Art. 13 Freedom of the Arts and Sciences, Charter of Fundamental Rights of the European Union, 2007.
[105] Commentary of the Charter of Fundamental Rights of the EU, EU Network of Independent Experts on Fundamental Rights (2006), pp 134-8.
[106] Art. 22, African Charter on Human and People's Rights 1981. See also Art. 12(2) of the Protocol to the African Charter on Human and People's Rights on the Rights of Women in Africa requiring States to promote the education of women particularly in the fields of science and technology.

> commercialization would jeopardize the full realization of these rights. States parties should, in particular, consider to what extent the patenting of the human body and its parts would affect their obligations under the Covenant or under other relevant international human rights instruments. States parties should also consider undertaking human rights impact assessments prior to the adoption and after a period of implementation of legislation for the protection of the moral and material interests resulting from one's scientific, literary or artistic productions.[107]

This commentary highlights an important aspect of the right to benefit from science, namely, that science and its applications should not be used in a way contrary to human rights. The Comment also provides for two mechanisms for preventing such an occurrence, both of which could be used when regulating genome editing. First, the denying of IP-rights protection of genome-editing technologies which could result in violations of human rights, for example because they are not safe. Indeed, this is the regulatory approach adopted by the EU with respect to the patentability of processes for modifying the germline. Second, the application of science in compliance with human rights can also be assured by conducting human rights impact assessment prior to the adoption of legislation on genome editing.

The UNESCO Venice Statement on the Right to Enjoy the Benefits of Scientific Progress and Its Applications elaborates in similar vein that the normative content of the right includes:

a) Creation of an enabling and participatory environment for the conservation, development and diffusion of science and technology, which implies inter alia academic and scientific freedom, including freedoms of opinion and expression, to seek, receive and impart information, association and movement; equal access and participation of all public and private actors; and capacity-building and education.

b) Enjoyment of the applications of the benefits of scientific progress, which implies inter alia non-discriminatory access to the benefits of scientific progress and its applications, including technology transfer and capacity-building.

c) Protection from abuse and adverse effects of science and its applications. Areas of contemporary controversy include, for example, stem cell research, nanotechnologies, nuclear energy, GMOs, climate change, generic seeds that can be reused, cloning, ethics of science and technology, new technologies in the working environment. The possibility of adverse effects of science in these and other regards requires that impact

[107] General Comment No. 17 (2005), E/C.12/GC/17, para. 35.

assessments should be seen as an integral part of the development of science.[108]

The Special Rapporteur in the Field of Cultural Rights stresses that:

> The right to science connotes, first of all, a right of access: scientific knowledge, information and advances must be made accessible to all…without discrimination of any kind as to race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status. Access must be to science as a whole, not only to specific scientific outcomes or applications…
>
> Another aspect is the right to have access to scientific applications and technologies. One core principle is that innovations essential for a life with dignity should be accessible to everyone, in particular marginalized populations. The potential implications of scientific advances likely to have a significant impact on human rights, such as electricity, information and communication technologies, nanotechnology and synthetic biology, need attention.
>
> States should ensure that the benefits of science are physically available and economically affordable on a non-discrimination basis.
>
> The need to promote everyone's access to science and its applications raises the issue of the sharing of benefits and the transfer of scientific knowledge and technologies.[109]

Based on these interpretations and on the practice of States on the implementation of the ICESCR in their domestic laws, it can be observed that the right to benefit from science includes the right to access scientific knowledge and information without discrimination, the freedom of scientific research, the protection from abuse of science, the adverse effects from its applications and its use in a way contrary to human rights. The less settled aspects of the right to benefit from science include the right to equitable (i.e. physically available and economically affordable) access to scientific applications and technologies, and the promotion of sharing of benefits and transfer of technologies between developed and underdeveloped States. This aspect of the right is very relevant to genome editing as once it becomes clinically available, the right would oblige States to ensure at the minimum equal if not equitable access to it, which could have significant financial implications. With respect to international cooperation in the field of genome editing, the weak wording of Article 15(4) ICESCR

[108] Venice Statement on the Right to Enjoy the Benefits of Scientific Progress and its Applications, UNESCO (2009), para. 13.
[109] 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' A/HRC/20/26 14 May 2012, paras 26-30, 66.

whereby States recognise the benefits from international scientific cooperation without actually committing to it suggests that there is no positive obligation to cooperate, let alone to transfer technology.

Some of the domestic cases on the right to benefit from science shed further light on its content. For example, the Inter-American Court on Human Rights decided a case against Costa Rica where couples challenged the blanket prohibition against IVF services, holding that:

> the right to private life and reproductive freedom is related to the right to have access to the medical technology necessary to exercise that right. The right to enjoy the benefits of scientific progress has been internationally recognized…Therefore, and in keeping with Article 29(b) of the American Convention, the scope of the rights to private life, reproductive autonomy and to found a family, derived from Articles 11(2) and 17(2) of the Convention, extends to the right of everyone to benefit from scientific progress and its applications. The right to have access to scientific progress in order to exercise reproductive autonomy and the possibility to found a family gives rise to the right to have access to the best health care services in assisted reproduction techniques, and, consequently, the prohibition of disproportionate and unnecessary restrictions, *de iure* or *de facto*, to exercise the reproductive decisions that correspond to each individual.[110]

Similarly, the Supreme Court of Venezuela held that the failure of the Venezuelan Institute for Social Security to ensure a regular and consistent supply of the drugs needed by HIV-positive persons constituted a violation of the right to enjoy the benefits of scientific progress.[111]

It can be observed that domestic and regional courts have shown willingness to enforce the right to benefit from science in practice, particularly the aspect requiring equitable access to medical products and technologies. Such an approach could have important implications for genome editing, allowing courts to enforce the obligation of States to allow equal access to it.

Another aspect of the right to benefit from science, which has significant implications for the research in genome editing is the freedom of research. Freedom of scientific research is universally protected as a human right. It is set out in Article 15(3) of the ICESCR, in Article 15 of the Oviedo Convention, in which provides for the freedom of scientific research in the fields of biology and medicine, subject to the protection of human rights and also in Article 13 of the EU Charter of Fundamental Rights. The freedom of scientific research is also affirmed in soft law instruments, including in

[110] *Artavia Murillo v Costa Rica* (2012) 165 ILR 1, 159, para. 150 (emphasis added).
[111] *López, Glenda y otros c. Instituto Venezolano de los Seguros Sociales (IVSS),* Sentencia No. 487, 2001.

Article 12(b) of the UNESCO Declaration on the Human Genome and in Article 2(b) of the Universal Declaration on Bioethics and Human Rights. It can now be said that the freedom of research is part of custom as a source of international law within the meaning of Article 38(1)(b) of the Statute of the International Court of Justice. As such, it is binding upon all States without the need of a treaty obligation. This means that the freedom to conduct research into genome editing is not only not prohibited but protected under international human rights law so long as it is not in violation of other human rights.

The UNESCO Declaration on Science and the Use of Scientific Knowledge notes that "scientific research is a major driving force in the field of human health and social care and that greater use of scientific knowledge would considerably improve human health".[112] It stresses, however, that "scientific research and the use of scientific knowledge should respect human rights and the dignity of human beings" and further that "that scientists with other major actors have a special responsibility for seeking to avert applications of science which are ethically wrong or have an adverse impact".[113]

The UNESCO Universal Declaration on the Human Genome and Human Rights notes in similar vein that "[t]he applications of research, including applications in biology, genetics and medicine, concerning the human genome, shall seek to offer relief from suffering and improve the health of individuals and humankind as a whole", mandating that:

> States should take appropriate steps to provide the framework for the free exercise of research on the human genome with due regard for the principles set out in this Declaration, in order to safeguard respect for human rights, fundamental freedoms and human dignity and to protect public health. They should seek to ensure that research results are not used for non-peaceful purposes. [114]

The UNESCO Declaration on Bioethics and Human Rights too stresses that in applying and advancing scientific knowledge and technologies, the benefit to affected individuals such as patients should be maximised and any possible harm ought to be minimised.[115] The Declaration notes the need to give due regard to the impact of life sciences on future generations[116] and emphasises the need of assessment and adequate management of the risk related to medicine, life sciences and associated technologies.[117] Furthermore, according to the Universal Declaration on the Human Genome and Human Rights:

[112] Declaration on Science and the Use of Scientific Knowledge, UNESCO, 1 July 1999, para. 12.
[113] Ibid, paras 19 and 21.
[114] UNESCO Universal Declaration on the Human Genome and Human Rights, 11 November 1998, Art. 12(2) and 15.
[115] UNESCO Universal Declaration on Bioethics and Human Rights, 19 October 2005, Art. 4 Benefit and Harm.
[116] Ibid, Art. 16 Protecting Future Generations.
[117] Ibid, Art. 20 Risk Assessment and Management.

> No research or research applications concerning the human genome, in particular in the fields of biology, genetics and medicine, should prevail over respect for the human rights, fundamental freedoms and human dignity of individuals or, where applicable, of groups of people.[118]

The Declaration stresses further that the applications of research in genetics and medicine concerning the human genome "shall seek to offer relief from suffering and improve the health of individuals and humankind as a whole."[119]

The Declaration on the Use of Scientific and Technological Progress in the Interests of Peace and for the Benefit of Mankind calls on States to "take measures to extend the benefits of science and technology to all strata of the population and to protect them, both socially and materially, from possible harmful effects of the misuse of scientific and technological developments".[120]

It can be concluded that while the freedom of scientific research is protected under international law, such research ought to be done in a manner respectful of human rights. Some soft law and regional instruments also require that such research is done only for therapeutic purposes. The implications of the freedom of scientific research for genome editing are that genome editing research ought to be allowed and protected so long as it is respectful of human rights. Blanket moratoria on scientific research in genome editing would not be in accordance with international law.

Other Relevant Rights

Non-Discrimination

There are a number of other human rights which also have some relevance to genome editing, be it less directly, which will be addressed in brief. One example is the prohibition against discrimination of any kind, including on the basis of genetic features as specified in Article 21(1) of the EU Charter of Fundamental Rights and Article 11 of the Oviedo Convention. A general prohibition against discrimination is contained in Article 2 of the ICESCR. It is a broadly formulated ban on "discrimination of any kind", which is followed by a non-exhaustive list concluding with the open-ended phrase "or other status". Therefore, Article 2 of the ICESCR can be interpreted as including genetic discrimination.

The prohibition against discrimination is an *erga omnes* obligation under international law, owed to the international community as a whole, which means that given the

[118] UNESCO Universal Declaration on the Human Genome and Human Rights, Article 10.
[119] Ibid, Article 12(b).
[120] Declaration on the Use of Scientific and Technological Progress in the Interests of Peace and for the Benefit of Mankind, GA Res, 3384 (XXX) of 10 November 1975, para. 6.

importance of the rights involved, all States have an interest in their protection.[121] The first cases of genetic discrimination have already been reported in China and the US. Accordingly, the real likelihood of discrimination based on genetic traits and the fundamental character of the international norms prohibiting all kinds of discrimination necessitate that in the context of genome editing, any permissive regulation should be accompanied by an express guarantee against genetic discrimination. One example of good practice in this regard is Canada with its recent Genetic Non-Discrimination Act, which "prohibits any person from requiring an individual to undergo a genetic test or disclose the results of a genetic test as a condition of providing goods or services to, entering into or continuing a contract or agreement with, or offering specific conditions in a contract or agreement with, the individual."[122]

Right to Family

Also relevant is the right to family, which is given "the widest possible protection and assistance" under Article 10 of the ICESCR, as well as in Article 23 of the ICCPR. According to General Comment No. 19 on Article 23 of the ICCPR, "[t]he right to found a family implies, in principle, the possibility to procreate".[123] Respect for family life is also protected under Article 7 of the EU Charter whose Commentary affirms that the right to found a family "provides for some aspects of reproductive choice including the use of new procreative technologies." [124] The Commentary notes the varying approaches of European States in this context with some guaranteeing access to infertility treatments and reproductive assistance by obliging public authorities to fund such services and others not. It can be concluded that the right to family includes a right to found a family, which is closely related to the reproductive health rights. As discussed above, this could have implications for the clinical application of genome editing by requiring States to provide support for couples who need but cannot afford it.

Rights of the Child

The special protection of the rights of the child accorded under the universally ratified UN Convention on the Rights of the Child (CRC) is also relevant to genome editing. The CRC recognizes the inherent right to life of every child and imposes an obligation on all States to "ensure to the maximum extent possible the survival and development of the child."[125] Furthermore, the Convention provides that:

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[121] *Barcelona Traction Light and Power Company Limited,* Second Phase, Judgment, ICJ Reports 1970, p. 3, paras 33-4.
[122] Genetic Non-Discrimination Act, Bill S-201 (2017) available at: https://openparliament.ca/bills/42-1/S-201/ .
[123] CCPR General Comment No. 19: Protection of the Family (1990), para. 5.
[124] EU Charter Commentary, p. 104.
[125] Convention on the Rights of the Child, 1577 UNTS 3, 3 November 1989, with 196 States Parties, Article 6.

> States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services.
>
> 2. States Parties shall pursue full implementation of this right and, in particular, shall take appropriate measures:
> (a) To diminish infant and child mortality;
> (b) To ensure the provision of necessary medical assistance and health care to all children with emphasis on the development of primary health care;
> (c) To combat disease and malnutrition, including within the framework of primary health care, through, inter alia, the application of readily available technology…
> …
> (f) To develop preventive health care…[126]

Accordingly, the protection of the rights of the child could be a strong argument in favour of the clinical implementation of genome editing technologies for the purposes of reducing child mortality, ensuring the survival and development of the child and achieving the highest attainable standard of child health. It can also incentivize the introduction of some forms of genome editing, i.e. for the most serious genetic diseases, as part of primary health care.

Rights of Persons with Disabilities

Last but not least, the protection of the rights of persons with disabilities should also be taken into account. The Convention on the Rights of Persons with Disabilities has as its purposes the respect for the "inherent dignity, individual autonomy including the freedom to make one's own choices", the "[r]espect for difference and acceptance of persons with disabilities as part of human diversity and humanity", as well as the "respect for the right of children with disabilities to preserve their identities." [127] It is conceivable that an ethical argument could be made that genome editing could undermine the inherent dignity and identity of persons with disability, as well as their acceptance as part of human diversity and humanity. Legally speaking, however, the rights of persons with disabilities, like other human rights, are protected only after birth, which puts germline editing outside of their temporal scope of protection.

[126] Ibid, Art. 24.
[127] Convention on the Rights of Persons with Disabilities, 2006, Art. 3 General Principles.

International human rights obligations of the UK and mechanisms for their oversight and enforcement

It should be noted that the UK is a State Party to the ICESCR, ICCPR, the UN Charter, the ECHR, the International Convention on the Elimination of All Forms of Racial Discrimination, the Convention on the Discrimination of All Forms Against Women, the Convention on the Rights of the Child, the Convention on the Rights of Persons with Disabilities, the Genocide Convention, as well as the EU Charter of Fundamental Rights by virtue of its membership of the European Union. It should be noted in this context that once a State has signed a treaty, it is bound to comply with it[128] and has a positive obligation under international law to modify its legislation in order to ensure the fulfillment of its undertakings.[129] This means that if the UK chooses to regulate the research and/or clinical application of genome editing, it would have to make sure that any such regulation complies with its international law obligations. In this context, it is also relevant that the UK is a member of UNESCO, the WHO, the Council of Europe and at the time of the writing of this report, of the EU.

With respect to oversight, most human rights treaties establish treaty-monitoring bodies, such as the Committee on Economic, Social and Cultural Rights under the ICESCR, the Committee on the Rights of the Child under the CRC and the Committee on Civil and Political Rights under the ICCPR. These bodies overview compliance with their respective treaties, they receive periodic reports from States Parties and have the power to issue non-binding recommendations to improve compliance. Notably, the UK is also a party to the Optional Protocol to the ICESCR, recognising the competence of the CESCR to receive and consider communications from individuals and from other States alleging its non-compliance with the ICESCR.

Some human rights treaties, including the ECHR and the EU Charter also have a court system which can establish violations and prescribe remedies. The competent courts under these treaties are the European Court of Human Rights and the Court of Justice of the EU, respectively. Last but not least, the UK has issued an optional clause declaration under Article 36(2) of the Statute of the International Court of Justice, which is the principal judicial organ of the United Nations, accepting as compulsory its jurisdiction over all disputes arising after 1987 on the condition of reciprocity.[130] The ICJ has broad competence to hear all legal disputes concerning a question of international law, the interpretation of a treaty, the existence of any fact which would constitute a breach of an international obligation and to determine the nature or extent

[128] Vienna Convention on the Law of Treaties, 1155 UNTS 331, Article 26 Pacta Sunt Servanda.
[129] *Exchange of Greek and Turkish Populations*, Advisory Opinion, PCIJ, Ser. B, No. 10, 21 February 1925, 20.
[130] UK Declaration of 22 February 2017 available at: http://www.icj-cij.org/jurisdiction/index.php?p1=5&p2=1&p3=3&code=GB .

of reparation. Accordingly, the Court would be competent to hear cases arising out of genome editing brought by or against the UK.

Conclusion

Based on the human rights obligations of the UK under international law, it can be concluded that both the research and the clinical application of human genome editing ought to be regulated in a manner that guarantees their accordance with human rights law, including the principles of human dignity, equality and non-discrimination. Furthermore, international law would prohibit genome editing for certain purposes, including eugenics, discriminatory or military purposes. One open question is whether genome editing can be done for non-therapeutic purposes. Such use goes against many non-binding soft law instruments, as well as the Oviedo Convention, to which the UK is not a party.

Genome editing as a hazardous activity not prohibited under international law

Another regime of international law, which would apply to genome editing are the set of rules on preventing transboundary harm from hazardous activities not prohibited under international law. This area of international law comprises a number of principles of environmental law, understood broadly as including human health. It is codified and developed in the International Law Commission's (ILC) Draft Articles on Prevention of Transboundary Harm from Hazardous Activities.[131] The focus of the Draft Articles is the duty to prevent in the context of authorization and regulation of hazardous activities posing a significant risk of transboundary harm.[132]

The preventive principle/no-harm principle

The preventive principle is set out in Principle 2 of the Rio Declaration on Environment and Development, affirming the responsibility of States to ensure that activities within their jurisdiction or control do not cause harm to other States.[133] It is based on the Roman maxim *sic utere tuo ut alienum non laedas,* meaning that one should use their own resources in a manner not injurious to others.[134] The International Court of Justice affirmed that the principle is now part of the corpus of international law in its opinion on the *Legality of the Threat or Use of Nuclear Weapons.*[135]The applicability of the

[131] 2001 *Yearbook of the International Law Commission* II:2.
[132] Ibid, p. 148.
[133] Report of the United Nations Conference on Environment and Development, 1992, resolution 1, annex 1. See also Principle 21 of the Stockholm Declaration.
[134] See in general J Brunnee, 'Sic Utere Tuo Ut Alienum Non Laedas' (2010) Max Planck Encyclopaedia of International Law, online edition.
[135] ICJ Reports 1996, p. 226, para. 29.

preventive principle to biotechnology and biodiversity is confirmed in UN Agenda 21.[136]

The obligations of States under the preventive principle are codified in Article 3 of the ILC Draft Articles:

> The State of origin shall take all appropriate measures to prevent significant transboundary harm or at any event to minimize the risk thereof.

The key terms are defined in Article 2 as follows:

> (a) "risk of causing significant transboundary harm" includes risks taking the form of a high probability of causing significant transboundary harm and a low probability of causing disastrous transboundary harm;
>
> (b) "harm" means harm caused to persons, property or the environment;
>
> (c) "transboundary harm" means harm caused in the territory of or in other places under the jurisdiction or control of a State other than the State of origin, whether or not the States concerned share a common border;
>
> (d) "State of origin" means the State in the territory or otherwise under the jurisdiction or control of which the activities referred to in article 1 are planned or are carried out;

Given the current state of science and technology, genome editing would most likely qualify as a risky activity whose effects would cross State borders. Accordingly, States on whose territory genome editing takes place, should act in accordance with the preventive principle and take all appropriate measures to prevent harm and minimize risk.

It should be noted in this context that the obligation of the State of origin is one of due diligence, i.e. an obligation of conduct rather than of result. According to the ILC, due diligence is the degree of care expected of a good Government, manifested in reasonable efforts by the State to inform itself of the factual and legal components relating foreseeably to a contemplated activity and taking appropriate measures to address them.[137] The duty of due diligence is proportionate to the degree of hazard involved and requires a State to keep abreast of technological changes and scientific developments.[138]

Notably, the International Tribunal for the Law of the Sea clarified that:

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[136] Agenda 21, United Nations Conference on Environment and Development, 1992, para. 15.3.
[137] ILC Draft Articles on Transboundary Harm with Commentaries, p 154.
[138] Ibid, pp 153-55.

> The content of "due diligence" obligations may not easily be described in precise terms. Among the factors that make such a description difficult is the fact that "due diligence" is a variable concept. It may change over time as measures considered sufficiently diligent at a certain moment may become not diligent enough in light, for instance, of new scientific or technological knowledge.[139]

The principles of prevention and due diligence was applied by the International Court of Justice (ICJ) in the context of the obligation to prevent transboundary harm in the *Pulp Mills* case holding that*:*

> the principle of prevention, as a customary rule, has its origin in the due diligence that is required of a State in its territory…A State is thus obliged to use all means at its disposal in order to avoid activities which take place in its territory, or in any area under its jurisdiction, causing significant damage to the environment of another State.[140]

Later, in the case of *Certain Activities in the Border Area*, the ICJ clarified further that the principle of due diligence has general applicability not only to industrial, but to any proposed activities which may have a significant transboundary impact.[141]

The applicability of the no-harm principle to economic, social and cultural rights, including the right to health was recognised by the Maastricht Principles on Extraterritorial Obligations of States in the Area of Economic, Social and Cultural Rights affirming that "all States have the obligation to refrain from conduct which nullifies or impairs the enjoyment and exercise of economic, social and cultural rights of persons outside their territory."[142] According to the Maastricht Principles, the no harm principle also applies to the acts of non-State actors over which the State exercises jurisdiction.[143] The obligations of States in this context are to "take necessary measures to ensure that non-State actors…such as private individuals and organisations and transnational corporations and other business enterprises, do not nullify or impair the enjoyment of economic, social and cultural rights."[144] If such violations by non-State actors do take place, the State ought "to hold them to account for any such abuses, and to ensure effective remedy for those affected."[145]

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[139] *Responsibilities and Obligations of States with respect to Activities in the Area,* Advisory Opinion, 1 February 2011, ITLOS Reports 2011, p. 10, para. 117.
[140] *Pulp Mills on the River Uruguay* (Argentina v Uruguay), ICJ Reports 2010 (I), pp 55-6, para. 101.
[141] *Certain Activities Carried Out by Nicaragua in the Border Area (Costa Rica v Nicaragua),* ICJ Reports 2015, para. 104.
[142] Maastricht Principles on Extraterritorial Obligations of States in the Area of Economic, Social and Cultural Rights, 5 March 2012, Principle 20 Direct Interference and Principle 21 Indirect Interference.
[143] Ibid, Principles 24 and 25.
[144] Ibid, Principle 24.
[145] Ibid, Principle 27.

With respect to genome editing, the preventive principle and the requirement of due diligence would entail a high degree of care, including understanding of the factual, scientific and technological background before it is implemented for clinical application. The introduction of genome editing would also require stringent regulation of the private sector so as to ensure that the high standard of care is applied across all providers.

The principle of impact assessment

The principle of impact assessment prior to undertaking a hazardous activity is closely related to the duty of prevention and the due diligence obligation. As noted by the ICJ in the *Certain Activities in the Border Area* case:

> To fulfill its obligation to exercise due diligence in preventing significant transboundary environmental harm, a State must, before embarking on an activity having the potential adversely to affect the environment of another State, ascertain if there is a risk of significant transboundary harm, which would trigger the requirement to carry out an environmental impact assessment…If the environmental impact assessment confirms that there is a risk of significant transboundary harm, the State planning to undertake the activity is required, in conformity with its due diligence obligation, to notify and consult in good faith the potentially affected State, where that is necessary to determine the appropriate measures to mitigate the risk.[146]

The principle of impact assessment is codified in Article 7 of the ILC Draft Articles on Prevention of Transboundary Harm, in Principle 17 of the Rio Declaration, in Agenda 21 and in the EPSOO Convention on Environmental Impact Assessment in a Transboundary Context, to which the UK is a party. The essence of the principle is set out in Article 7 of the ILC Draft, providing that:

> Any decision in respect of the authorization of an activity within the scope of the present articles shall, in particular, be based on an assessment of the possible transboundary harm caused by that activity, including any environmental impact assessment.

According to the ILC Commentary to this provision, an impact assessment should contain an evaluation of the possible transboundary impact of an activity, including its effects on persons. The principle of impact assessment forms part of international law and has been applied by the ICJ in the *Pulp Mills* and the *Certain Activities in the Border Area* cases. Indeed, in *Pulp Mills,* the Court concluded that:

[146] *Certain Activities Carried Out by Nicaragua in the Border Area (Costa Rica v Nicaragua),* ICJ Reports 2015, para. 104.

> it may now be considered a requirement under general international law to undertake an environmental impact assessment where there is a risk that the proposed industrial activity may have a significant adverse impact in a transboundary context, in particular, on a shared resource.[147]

Agenda 21 stressed the "need for further development of internationally agreed principles on risk assessment and management of all aspects of biotechnology".[148]

Notably, Article 20 of the Universal Declaration on Bioethics and Human Rights on Risk Assessment and Management provides that:

> Appropriate assessment and adequate management of risk related to medicine, life sciences and associated technologies should be promoted.

It can be concluded that the principle of impact assessment would require a State to carry out an assessment of the risks related to genome editing, including its possible effects on human health and human rights, before permitting its clinical application.

[147] *Pulp Mills on the River Uruguay,* para. 204.
[148] Agenda 21, para. 16.29.

The precautionary approach

The precautionary approach has a somewhat unclear status under international law. It is set out in Principle 15 of the non-binding Rio Declaration, providing that:

> Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

While it has not yet been applied by the ICJ, the Court did mention the principle in passing in the *Pulp Mills* case, noting that " a precautionary approach may be relevant in the interpretation and application of the provisions of the Statute."[149] Interestingly, the International Tribunal for the Law of the Sea somewhat progressively affirmed the customary status of the precautionary in its advisory opinion on the Responsibilities and Obligations of States Sponsoring Persons and Entities with Respect to Activities in the Area, holding that:

> the precautionary approach is also an integral part of the general obligation of due diligence of sponsoring States, which is applicable even outside the scope of the Regulations. The due diligence obligation of the sponsoring States requires them to take all appropriate measures to prevent damage that might result from the activities of contractors that they sponsor. This obligation applies in situations where scientific evidence concerning the scope and potential negative impact of the activity in question is insufficient but where there are plausible indications of potential risks. A sponsoring State would not meet its obligation of due diligence if it disregarded those risks. Such disregard would amount to a failure to comply with the precautionary approach.[150]

Notably, the precautionary principle forms part of EU law codified in Article 191(2) of the Treaty on the Functioning of the European Union (TFEU). The Court of Justice of the EU (CJEU) has recognised that the precautionary principle applies to the protection of health in the context of the mad cow crisis, upholding France's embargo against the import of beef from the UK.[151] The principle is also incorporated in the EU regulation of genetically modified organisms.[152] If applied to genome editing, the precautionary approach would entail the adoption of all appropriate measures to prevent harm even in the face of uncertainty as to the risk involved.

[149] *Pulp Mills on the River Uruguay,* para. 164.
[150] *Responsibilities and Obligations of States with respect to Activities in the Area,* Advisory Opinion, para. 131.
[151] Case C-180/96, *United Kingdom v Commission*, ECJ, 5 May 1998, p. 2265.
[152] Directive 2001/18/EC, 12 March 2001, on the deliberate release into the environment of genetically modified organisms, OJ L 106.

The principle of inter-generational equity

The principle of intergenerational equity is also a recent development with uncertain status under international law. It calls on States to take into account the rights of future generations when undertaking activities which may affect them. It is referred to in the Preamble of the Oviedo Convention affirming "that progress in biology and medicine should be used for the benefit of present and future generations".[153] The principle is also set out in numerous soft law instruments, such as the UN Declaration on the Rights of Future Generations, which states that "[t]he present generations have the responsibility of ensuring that the needs and interests of present and future generations are fully safeguarded."[154] Similar provisions can be found in the UNESCO Declaration on Science and the Use of Scientific Knowledge.[155] Interestingly, the Declaration has a specific provision on the human genome stating that "[t]he human genome, in full respect of the dignity of the human person and human rights, must be protected" and that "[s]cientific and technological progress should not in any way impair or compromise the preservation of the human species".[156]

Article 16 of the Universal Declaration on Bioethics and Human Rights provides in similar vein that States ought to give due regard to "[t]he impact of life sciences on future generations, including on their genetic constitution".[157]

If applied to genome editing, the principle of inter-generational equity would require States to take into account the rights of future generations, including at the minimum the preservation of the human species in its diversity, when regulating genome editing.

Genome editing under EU law

In addition to the EU Charter of Fundamental Rights, discussed above, the most significant aspects of EU law in relation to genome editing are set out in the EU Regulation on Clinical Trials of Medicinal Products for Clinical Use (the 'Clinical Trials Regulation').[158]

It should be noted that the EU does not have exclusive competence to harmonise rules in the area of public health, which is a shared competence with the Member States. According to Article 6(a) TFEU, in the area of protection of human health, the EU has the competence "to carry out actions to support, coordinate or supplement the actions of the Member States." The EU has adopted approximation measures under Article

[153] Oviedo Convention, Preamble, para. 1.
[154] UNESCO Declaration on the Responsibilities of the Present Towards Future Generations, Art. 1.
[155] (1999), para. 39.
[156] Ibid, Art. 6.
[157] Universal Declaration on Bioethics and Human Rights, Article 16.
[158] Regulation (EU) No. 536/2014 of the European Parliament and the Council on clinical trials on medicinal products for human use (EU Clinical Trials Regulation).

114 TFEU that have as their object the establishment and functioning of the internal market. Such measures can pursue public health objectives provided they genuinely contribute to improving the functioning of the internal market by eliminating existing or likely obstacles to free movement or appreciable distortions of competition.[159]

It is therefore no surprise that the EU Clinical Trials Regulation was adopted on the basis of Article 114 TFEU and Article 168(4)(c), the latter being a special derogation from Article 6(a) TFEU giving the EU competence to adopt "measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives" without prejudice to the competence of Member State to maintain or introduce more stringent protective measures. Given the legal basis for its adoption and its focus on clinical trials, it can be observed that the EU Clinical Trials Regulation has a limited scope of application. This is confirmed by its Article 1, which states that the Regulation applies "to all clinical trials conducted in the Union". The term "clinical trial" is defined in Article 2 of the Regulation, providing that:

> 'Clinical trial' means a clinical study which fulfils any of the following conditions:
>
> (a) the assignment of the subject to a particular therapeutic strategy is decided in advance and does not fall within normal clinical practice of the Member State concerned;
>
> (b) the decision to prescribe the investigational medicinal products is taken together with the decision to include the subject in the clinical study; or
>
> (c) diagnostic or monitoring procedures in addition to normal clinical practice are applied to the subjects.

The Clinical Trials regulation refers to Article 1 of Directive 2001/83/EC on the Community code relating to medicinal products for human use for the definition of medicinal product, which provides that a medicinal product is:

> Any substance or combination of substances presented for treating or preventing disease in human beings.
>
> Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product.[160]

[159] Case C-376/98 *Germany v Parliament and Council* [2000] ECR I-8423.
[160] Directive 2001/83/EC on the Community code relating to medicinal products for human use, Article 1(2).

Accordingly, the Clinical Trials Regulation would apply to genome editing only where it is used in the context of clinical trials on medicinal products for human use as defined in the Community code relating to medicinal products. It should be noted that the definition of medicinal product in EU law is broad and genome editing trials might fall under the scope of the EU Clinical Trials Regulation if the technique used in the process consists of the administration of substances.

Notably, Article 90 of the Clinical Trials Regulation setting out specific requirements for special groups of medicinal products provides that:

> No gene therapy clinical trials may be carried out which result in modifications to the subject's germ line genetic identity.

Regrettably, the Regulation does not provide definitions of what “gene therapy” or “germ line genetic identity” are, nor is there any case law shedding light on these terms under the Regulation or under its predecessor, the Clinical Trials Directive,[161] which contained the same provision. So the question remains open for interpretation and for clarification in future practice. Based on the ordinary meaning of the provision and its systemic place in the Clinical Trials Regulation, it could be inferred that it prohibits gene therapy clinical trials of medicinal products involving any germline editing. However, the broad wording of the provision might suggest that it was intended to prohibit all gene therapy clinical trials involving germline editing, irrespective of whether they relate to medicinal products. It is doubtful whether such a broad prohibition would fall within the competence of the EU under Article 6(a) and 168(4)(c) TFEU. It is also not entirely clear what is the relationship between ‘gene therapy clinical trials’ and genome editing and whether the former definition necessarily includes all forms of the latter process.

Also relevant in the context of genome editing is the EU Directive on the legal protection of biotechnological inventions (EU Biotech Directive).[162] It should be noted that unlike regulations, which are directly applicable and effective in their entirety in the domestic laws of the Member States, directives need to be implemented and are only binding with respect to the result that they aim to achieve, leaving some scope of discretion to the national legislature.

In its Preamble, the Biotech Directive recalls that:

> patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person;
> whereas it is important to assert the principle that the human body, at any stage in its formation or development, including germ cells, and the simple discovery

[161] EU Clinical Trials Directive 2001/20/EC, Article 90.
[162] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.

> of one of its elements or one of its products, including the sequence or partial sequence of a human gene, cannot be patented; whereas these principles are in line with the criteria of patentability proper to patent law, whereby a mere discovery cannot be patented;[163]

Notably, the Preamble also asserts that:

> Whereas there is a consensus within the Community that interventions in the human germ line and the cloning of human beings offends 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;[164]

While preambles are not legally binding they form an important part of the context in which legal acts are interpreted, including in the determination of the object and purpose of these acts.[165] In its operative part, the Biotech Directive provides:

> Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.
>
> On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:
> …
> (b) processes for modifying the germ line genetic identity of human beings;
>
> (c) uses of human embryos for industrial or commercial purposes;[166]

Accordingly, EU law prohibits the patenting of processes for germline editing that would modify the genetic identity of human beings. It is not clear whether "human beings" are to be understood as a collective with a genetic identity or narrowly, as the genetic identity of any given human being.

One case of the CJEU that sheds some light on the burden of proof that lies upon Member States invoking *ordre public* or morality to justify a derogation from a directive is *Commission of the European Communities v Poland.*[167] Poland relied on public morality, including ethics and religion to resist implementing certain provisions of

[163] Ibid, Preamble, para. 16.
[164] Ibid, Preamble, para. 40.
[165] Article 31(2) of the Vienna Convention on the Law of Treaties.
[166] Biotech Directive, Art. 6(1) and (2).
[167] Case C-165/08 *Commission of the European Communities v Poland*, Judgment of 16 July 2009.

Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms. The CJEU rejected Poland's justifications, reasoning:

> As regards, more specifically, the justification based on the protection of public morality relied on by the Republic of Poland in the present case, it must be held, first, that the relevant evidentiary burden is not discharged by statements as general as those put forward by that Member State …consisting in references to fears regarding the environment and public health and to the strong opposition to GMOs manifested by the Polish people, or even to the fact that the administrative regional assemblies adopted resolutions declaring that the administrative regions are to be kept free of genetically modified cultures and GMOs…
>
> The Republic of Poland essentially referred to a sort of general presumption according to which it can come as no surprise that such provisions were adopted in the present case. First, the Republic of Poland relies on the fact that it is well known that Polish society attaches great importance to Christian and Roman Catholic values. Secondly, it states that the political parties with a majority in the Polish Parliament at the time when the contested national provisions were adopted specifically called for adherence to such values. In those circumstances, according to that Member State, it is reasonable to take the view that the Members of Parliament, who do not, as a general rule, have scientific training, are more likely to be influenced by the religious or ethical ideas which inspire their political actions, rather than by other considerations, in particular, those linked to the complex scientific assessments relating to the protection of the environment or of human health.
>
> However, such considerations are not sufficient to establish that the adoption of the contested national provisions was in fact inspired by the ethical and religious considerations… It emerges, in particular, from Article 4(4) of Directive 2002/53 that any refusal to include a variety in the national catalogue solely because it is genetically modified is justified only if there has been a failure to take all appropriate measures to prevent adverse effects on human health and the environment, which – as the Commission rightly submitted – cannot, in particular, be the case where a variety has been authorised under Directive 2001/18.[168]

It can be concluded that where a Member State purports to derogate from a EU directive on the basis of public morality, it bears a particularly high burden of proof which is not discharged by mere references to the prevailing religious or ethical views of its population or administrative organs.

[168] Ibid, paras 54, 58 and 59.

Overall, EU law does not contain an outright or general prohibition of genome editing, not least because the EU does not have exclusive competences in the area of public health in order to adopt one. However, EU law does place certain limitations on the patentability of genome editing processes that would result in "modifying the germ line genetic identity of human beings", however, without defining the meaning of this expression. Furthermore, EU law prohibits gene therapy clinical trials of medicinal products which would "result in modifications to the subject's germ line genetic identity." Notably, EU law does not seem to prohibit the products themselves or their use.

III. GENOME EDITING IN SELECTED DOMESTIC JURISDICTIONS

This section provides a general overview of relevant legislative provisions, ethical and medical guidelines and case law in selected jurisdictions.

USA

While the USA does not prohibit genome editing as such, it imposes limits on funding for research involving embryos in general and genome editing of embryos in particular. US law prohibits State funding of research in which human embryos are "destroyed, discarded or knowingly subjected to risk of injury or death greater than that allowed for research of fetuses in utero".[169] Accordingly, the question of whether research involving genome editing could be funded by the USA would involve an evaluation as to whether or not it would amount to knowingly subjecting the embryo to risk of injury or death greater than that allowed for research in utero.

Notably, the US Food & Drug Administration (FDA) has the authority under the Public Health Service Act and the Federal Food, Cosmetic and Drug Act to regulate products and drugs involving genome editing, including human genome editing on the federal level. On 19 January 2017, the FDA issued draft revised Guidance for Industry (GFI) #187 on the "Regulation of Intentionally Altered Genomic DNA in Animals", coupled with a call for public input on human and animal foods derived from plants produced using genome editing.[170] It is expected that the FDA will also regulate human genome editing within the scope of its competence.

The White House Office of Science and Technology Policy (OTSP) is also working on modernising the federal regulatory system for biotechnological products, including a regulatory oversight of genome editing and its applications. In 2016 the OTSP issued a National Strategy for Modernizing the Regulatory System for Biotechnological Products, noting that the FDA intends to clarify its policy for the regulation of products

[169] Omnibus Appropriations Act, 2009 (Dickey-Wicker Amendment, 1996), Sec. 509(a).
[170] Available at: https://www.fda.gov/food/ingredientspackaginglabeling/geplants/ucm537109.htm .

derived from genome editing techniques.[171] The 2017 OTSP Update to the Coordinated Framework for the Regulation of Biotechnology summarises the public responses to its 2015 Request for Information consultation, noting relevant recommendations to include genome editing in the definition of 'genetic engineering', as well as that it is critical for the NAS study to be completed and for agencies to formulate policies on genome editing after the risks of these technologies, if any, are identified.[172] There were also comments expressing strong concern about the prospect of genome editing for human reproduction, and recommending that the Coordinated Framework call on agencies to refrain from any human germline modification.[173] The National Academy of Sciences (NAS) and the National Academy of Medicine (NAM), however, issued recommendations on human genome editing in February 2017, calling somewhat more progressively for using the existing regulatory infrastructure and processes to evaluate future basic laboratory research on genome editing and somatic gene therapy involving genome editing.[174] The NAS and NAM recommended further that the authorities should evaluate the safety and efficacy of somatic genome editing "in the context of the risks and benefits of intended use, recognizing that off-target events may vary with the platform technology, cell type, target genomic location, and other factors."[175] With respect to germline editing, it was suggested that "Ongoing reassessment of both health and societal benefits and risks, with broad ongoing participation and input by the public, should precede consideration of any clinical trials of heritable germline genome editing."[176] It was stressed that clinical trials of somatic or germline editing should not be authorized for any purposes other than treatment or prevention of disease and disability.[177]

Also relevant to genome editing in clinical genetics are the statement of the American College of Medical Genetics and Genomics, American College of Medical Genetics and Genomics (ACMG) (January 2017) and the National Institutes for Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (2016) whose Appendix M defines germline editing as: Germ line alteration involves a specific attempt to introduce genetic changes into the germ (reproductive) cells of an individual, with the aim of changing the set of genes passed on to the individual's offspring. Notably, the 2016 NIH Guidelines provide that:

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[171] National Strategy for Modernizing the Regulatory System for Biotechnological Products, p. 17, available at: https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GEPlants/UCM537320.pdf .

[172] OTSP Update available at: https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GEPlants/UCM537311.pdf , p. 62.

[173] Ibid, p. 65.

[174] National Academy of Sciences and National Academy of Medicine, 'Human Genome Editing: Science, Ethics and Governance' (2017), Recommendations 3-1 and 4-1.

[175] Ibid, Recommendation 4-3.

[176] Ibid, Recommendation 7-2.

[177] Ibid, Recommendation 6-1. For the US broad approach to defining a 'disease' see *Katskee v Blue Cross/Blue Shield* 515 N.W.2d 645 (1994), holding that it is a condition encompassing "any abnormal condition of the body or its components of such a degree that in its natural progression would be expected to be problematic; a deviation from the healthy or normal state affecting the functions or tissues of the body; an inherent defect of the body; or a morbid physical or mental state which deviates from or interrupts the normal structure or function of any part, organ, or system of the body and which is manifested by a characteristic set of symptoms and signs".

> The NIH will not at present entertain proposals for germ line alterations but will consider proposals involving somatic cell gene transfer. The purpose of somatic cell gene transfer is to treat an individual patient, e.g., by inserting a properly functioning gene into the subject's somatic cells. Germ line alteration involves a specific attempt to introduce genetic changes into the germ (reproductive) cells of an individual, with the aim of changing the set of genes passed on to the individual's offspring.
>
> The NIH continues to explore the issues raised by the potential of *in utero* gene transfer clinical research. However, the NIH concludes that, at present, it is premature to undertake any *in utero* gene transfer clinical trial. Significant additional preclinical and clinical studies addressing vector transduction efficacy, biodistribution, and toxicity are required before a human *in utero* gene transfer protocol can proceed. In addition, a more thorough understanding of the development of human organ systems, such as the immune and nervous systems, is needed to better define the potential efficacy and risks of human *in utero* gene transfer. Prerequisites for considering any specific human *in utero* gene transfer procedure include an understanding of the pathophysiology of the candidate disease and a demonstrable advantage to the *in utero* approach. Once the above criteria are met, the NIH would be willing to consider well rationalized human *in utero* gene transfer clinical trials.[178]

It remains to be seen what approach will the US regulator choose to follow with respect to human genome editing. One interesting example of a regulatory approach on the level of States is the California Health and Safety Code, which prohibits “transferring the nucleus from a human cell from whatever source into a human or nonhuman egg cell”.[179]

The US Supreme Court made a judgment in 2013 regarding the patentability of genes but leaving open the question as to the patentability of methods of modifying them, which may have important implications for the patentability of methods of genome editing, if not for the edited genomes themselves. The Court held that:

> A naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but cDNA is patent eligible because it is not naturally occurring… Myriad did not create or alter either the genetic information encoded in the BCRA1 and BCRA2 genes or the genetic structure of the DNA… This case, it is important to note, does not involve method claims, patents on new applications of knowledge about the BRCA1 and BRCA2

[178] NIH, Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, April 2016, p. 100.
[179] California Health and Safety Code, Sec. 24185-24187.

> genes, or the patentability of DNA in which the order of the naturally occurring nucleotides has been altered.[180]

In general, it is useful to bear in mind that the USA is a common law jurisdiction. The reception of international law in the US legal order is governed by the Constitution, which provides that:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.[181]

This provision is further elaborated in the Third Restatement of the Foreign Relations of the US, setting out that:

> (1) International law and international agreements of the United States are law of the United States and supreme over the law of the several States.
>
> (2) Cases arising under international law or international agreements of the United States are within the Judicial Power of the United States and, subject to Constitutional and statutory limitations and requirements of justiciability, are within the jurisdiction of the federal courts.
>
> (3) Courts in the United States are bound to give effect to international law and to international agreements of the United States, except that a "non-self-executing" agreement will not be given effect as law in the absence of necessary implementation.
>
> 4) An international agreement of the United States is "non-self-executing"
> (a) if the agreement manifests an intention that it shall not become effective as domestic law without the enactment of implementing legislation,
> (b) if the Senate in giving consent to a treaty, or Congress by resolution, requires implementing legislation, or
> (c) if implementing legislation is constitutionally required.[182]

In this context, it should be recalled that from the human rights treaties discussed, the USA has ratified the ICCPR, the International Convention on the Elimination of All Forms of Racial Discrimination, the Convention Against Torture and the Genocide Convention. The US has signed but not ratified the ICESCR and the Convention on

[180] *Association for Molecular Pathology v United States Patent and Trademark Office,* United States Supreme Court, No. 12–398, 13 June 2013.
[181] USA Constitution, Art. 6(2).
[182] Third Restatement of the Foreign Relations Law of the US, s. 111.

the Rights of the Child and the Convention on the Rights of Persons with Disabilities, which means that it is not bound by the entirety of the treaties but it is obliged not to defeat their objects and purpose.[183]

The status of customary international law, while not addressed directly in the Constitution, is that of federal law – it is treated like equivalent to the common law and is thus supreme over State law.[184]

Russia

Russia's Civil Code was modified in 2014 to prohibit the patentability of the methods of modifying the genetic integrity of the human germline.[185] The Russian Citizens' Health Protection Law gives the right to a woman who is undergoing IVF to be informed of the results of the medical genetic examination.[186]

The act most pertinent to genome editing is Order No. 107 of the Ministry of Health on the Uses of Reproductive Technologies: prohibitions and limitations. It provides that women with a history (including close relatives) of congenital and chromosomal diseases, as well as those suffering from primary amenorrhea, should undergo genetic and chromosomal tests.[187] Women with hereditary sex-related diseases, such as hemophilia, Duchenne muscular dystrophy, X-linked ichthyosis, Charkot-Marie neural amyotrophy and others, have to undergo mandatory preimplantation genetic diagnostics (PGD).[188] PGD is also recommended for children with high risk of hereditary diseases.[189] Genetic diseases are listed as one of the indicators for using donor oocytes for IVF, along with absence of oocytes, radio or chemo therapy.[190] Donors of oocytes themselves have to undergo medical and genetic testing.[191] The Order does not address directly the question of genome editing.

Russia's Federal Law No. 86 of 5 July 1996 (as amended 4 July 2016) on State Regulation in the Area of Genetic Engineering Activity excludes from its scope of application the manner of genetically engineering humans, their tissues and cells, except for genetic diagnostics and gene therapies. Article 2 of the Act defines genetic engineering as the methods and technologies, including technologies for achieving recombinant RNA and DNA, for isolating genes from the organism, manipulating genes and introducing them in other organisms. Gene therapy is defined as genetic engineering (biotechnological) and medical methods for modifying the genetic

[183] Article 18 Vienna Convention on the Law of Treaties.
[184] Third Restatement, s. 111, Comment (d).
[185] Russian Civil Code, Article 1349(4) paras. 2 and 3 as modified by Federal Law No. 35-FZ, 12.03.2014.
[186] Russian Citizens' Health Protection Law No. 5487-I, 22 July 1993 (as amended 2009), Art. 35(4).
[187] Order of the Ministry of Health No. 107, 30 August 2012 on the Uses of Reproductive Technologies: prohibitions and limitations, s. 14.
[188] Ibid, s. 22(c).
[189] Ibid, s. 39.
[190] Ibid, s. 55 (a).
[191] Ibid, s. 54.

composition of somatic cells for therapeutic purposes and genetic diagnostics are defined as methods for identifying genetic mutations.

Also relevant is Russia's Federal Law No. 180 of 23 June 2016 on Biomedical Products, whose Article 3(4) prohibits the creation of human embryos for the purposes of producing biomedical cell products. Article 3(5) prohibits the use of biomedical cell products derived from interrupting the development of human embryos or fetuses.

Russia is a civil law jurisdiction. According to Article 15(4) of the Russian Constitution of 1993:

> The generally recognized norms of international law and international treaties and agreements of the Russian Federation shall be a part of its legal system. If an international treaty or agreement of the Russian Federation establishes other rules than those envisaged by law, the rules of the international agreement shall be applied.

The effect of this provision is that treaties signed by the Russian Federation, as well as norms of customary international law and general principles of law have priority over domestic laws but are subject to the Constitution. In this context, it should be recalled that Russia is a party to the ICCPR, ICESCR, the Convention on the Elimination of All Forms of Racial Discrimination, the Convention Against Torture, the Convention on the Rights of the Child, the Convention on the Rights of Persons with Disabilities and the ECHR. Russia has neither signed nor ratified the Oviedo Convention.

Israel

The Israeli Law on the Prohibition of Genetic Intervention establishes that "certain kinds of genetic intervention shall not be performed on human beings in view of the moral, legal, social and scientific aspects of the prohibited forms of intervention and their implications for human dignity, and in order to assess public policy regarding those kinds of intervention in view of those aspects, considering also freedom of scientific research for the advancement of medicine."[192] The Law prohibits in particular "[u]sing reproductive cells that have undergone a permanent intentional genetic modification (Germ Line Gene Therapy) in order to cause the creation of a person."[193] The sanctions for violating this prohibition are criminal, involving up to four years of imprisonment.[194] However, the Minister has the power to give permission for otherwise prohibited genetic interventions "if he is of the opinion that human dignity will not be

[192] Prohibition of Genetic Intervention (Human Cloning and Genetic Manipulation of Reproductive Cells) Law 5759-1999, Art. 1.
[193] Ibid, art. 3(2).
[194] Ibid, Art. 6(2).

prejudiced, upon the recommendation of the advisory committee and upon such conditions as he may prescribe".[195]

Also relevant is the judicial recognition of the right to parenthood under Israeli law. In the case of *Moshe v Board for Approval of Embryo Carrying Agreements under the Embryo Carrying Agreements Law,* the Israeli Supreme Court held that:

> The right to family life is a sub right that derives from the constitutional right to human dignity. The right to parenthood is a granddaughter right to the right to family life and it encompasses various methods for fertility, reproduction and birth… The right to parenthood was recognized as a right with "negative" and "positive" aspects. The negative aspect concerns protecting the individual from external intervention in the right and its exercise. The positive aspect goes to the state's duty to assist the individual in exercising the right...[196]

Israel's legal system is largely based on the common law. According to the Israeli Supreme Court, customary international law is part of the law of the land.[197] Treaties signed and ratified by Israel do not automatically become part of its law but require implementation through a separate act of Parliament.[198]

India

India is a common law legal system. Its international treaty obligations do not automatically become part of domestic law but need a separate act of Parliament to give them effect and make them justiciable in domestic courts.[199] Customary international law, however, is treated by courts as part of domestic courts and enforceable by courts. The Indian Supreme Court held that "[i]t is almost accepted proposition of law that the rules of Customary International Law which are not contrary to the municipal law shall be deemed to have been incorporated in the domestic law and shall be followed by the Courts of Law."[200]

Legislation

On the level of legislation, the most relevant act to genome editing is the Pre-Conception and Pre-Natal Diagnostic Techniques Act 1994 (as amended 2002). Its aim is to impose an absolute prohibition on sex selection before and after conception,[201] as well as to regulate pre-natal diagnostic techniques, which are

[195] Ibid, Art/ 5(a).
[196] *Moshe v Board for Approval of Embryo Carrying Agreements under the Embryo Carrying Agreements Law (Approval of the Agreement and the Status of the Child) 5756-1996* HCJ 5771/12.
[197] *Stampfer* v. *Attorney General* 10 PD 4 (1956), pp. 14-15.
[198] Civil Appeal 65/67 *Kurtz & Letushinsky* v. *Kirschen*, 21(2) PD 20 (1967); 47 ILR 212.
[199] Art. 51 (c) and 253 of the Indian Constitution. See also *Jolly Jeorge v Bank of Cochin,* AIR 1980 SC 470.
[200] *Vellore Citizens Welfare Forum v. Union of India and Others,* AIR 1996 SC 2715.
[201] S. 3A, Pre-Conception and Pre-Natal Diagnostic Techniques Act 1994 (as amended 2002).

allowed in strictly defined cases. The Act sets out important legal definitions, which could inform any future genome editing regulation, including those of:

> (ba) ”conceptus” means any product of conception at any stage of development from fertilization until birth including extra embryonic membranes as well as the embryo or foetus;
>
> (bb) “embryo” means a developing human organism after fertilization till the end of eight weeks (fifty-six days);
>
> (bc) “foetus” means a human organism during the period of its development beginning on the fifty- seventh day following fertilization or creation (excluding any time in which its development has been suspended) and ending at the birth;
> …
> (i) “pre-natal diagnostic procedures” means all gynaecological or obstetrical or medical procedures such as ultrasonography, foetoscopy, taking or removing samples of amniotic fluid, chorionic villi, blood or any other tissue or fluid of a man, or of a woman for being sent to a Genetic Laboratory or Genetic Clinic for conducting any type of analysis or pre-natal diagnostic tests for selection of sex before or after conception;
>
> (k) “pre-natal diagnostic test” means ultrasonography or any test or analysis of amniotic fluid, chorionic villi, blood or any tissue or fluid of a pregnant woman or conceptus conducted to detect genetic or metabolic disorders or chromosomal abnormalities or congenital anomalies or haemoglobinopathies or sex-linked diseases;
> …
> (o) “sex selection” includes any procedure, technique, test or administration or prescription or provision of anything for the purpose of ensuring or increasing the probability that an embryo will be of a particular sex; [202]

Pre-natal diagnostic techniques can be conducted only for the purposes of detecting the listed abnormalities, namely: chromosomal abnormalities; genetic metabolic diseases; haemoglobinopathies; sex-linked genetic diseases; congenital anomalies; as well as any other abnormalities or diseases as may be specified by the Central Supervisory Board.[203] The Act also provides that pre-natal diagnostic techniques can be used if “the pregnant woman or her spouse has a family history of mental retardation or physical deformities such as, spasticity or any other genetic disease”.[204]

[202] Ibid, s.2.
[203] Ibid, s.4(2).
[204] Ibid, s. 4(3).

Non-binding Guidelines

India has two sets of non-binding guidelines issued by the Council of Medical Research, which address genome editing directly. First, the Ethical Guidelines for Biomedical Research on Human Subjects[205] whose Chapter VI sets out specific principles for human genetics and genomics research, stressing that:

> Genetic manipulations have consequences for the future, some of which are unknown. Hence, greater care towards potential dangers is necessary.
>
> There is greater likelihood of situations cropping up where there is conflict of interest between an individual, and that of family and society at large. Careful guidelines need to be evolved by peers in the profession to tackle such situations. The professional societies should actively participate in these activities.[206]

The Ethical Guidelines define alleviating human suffering as the goal of human genetic research, specifying that:

> > Somatic cell gene therapy is the only method that may be permissible for the purpose of preventing or treating a serious disease when it is the only therapeutic option. It should be restricted to alleviation of life threatening or seriously disabling genetic disease in individual patients and should not be permitted to change normal human traits. However, rapid advance in science necessitates periodic review of guidelines in this area. This includes evaluation of safety and efficacy of DNA vaccines and transgenic foods as well…
> >
> > Safety should be ensured especially because of the possibility of unpredicted consequences of gene insertion. All gene therapy trials should have the provision for long term surveillance. Informed consent must be taken especially regarding uncertainties about outcome. Children could be candidates for therapy, if the therapy is meant for a childhood disorder.[207]

The competent bodies regulating such trials are the National Bioethics Committee under Department of Biotechnology (DBT) and the local IEC and Central Ethical Committee (CEC) of the ICMR.

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[205] Available at: http://www.icmr.nic.in/ethical_guidelines.pdf .
[206] Ibid, s. iv and v.
[207] Ibid, s.(i).

The guidelines ban germ line therapy "under the present state of knowledge",[208] as well as attempting gene therapy with the aim of enhancement of genetic characteristics (so called designer babies) because:

> we possess insufficient information at present to understand the effects of attempts to alter/enhance the genetic machinery of humans. Also, the influence of environmental interaction on the expression of genetic characters is poorly understood. It is not safe or ethical for parents to give, for example, growth hormone to their normal offspring in order to produce very large football or basketball players. Similarly it would be unethical to use genetic engineering for improvement of intelligence, memory etc. even if specific gene/genes are identified in future. [209]

Last but not least, the Guidelines also prohibit eugenic genetic engineering "for selection against personality, character, formation of body organs, fertility, intelligence and physical, mental and emotional characteristics".[210]

The Annex to the Guidelines sets out the following definitions:

Genetic material/genome: Genetic material refers to DNA or any other material carrying hereditary information in each cell of an organism. It consists of unique, single copies of genes, which make up approximately 10% of the DNA. The total informational content of an individual is known as 'genome'.

Chromosome: The thread-like DNA in a cell is divided into several separate lengths. Each length forms a structure called a chromosome. There are two copies of each chromosome in every cell. Human cells contain 23 pairs of chromosomes.

Gene: A gene is a length of DNA that contains the information needed to make one polypeptide. For example, the beta globin gene contains the information needed to make the beta globin polypeptide found in hemoglobin of red blood cells. More than one gene may be involved in making one protein, and more than one polypeptide may be formed from one gene as a result of alternate splicing.

Genetic Engineering : It is the process of creating new DNA such as by cutting and patching (recombinant DNA technology). Several other technologies such as site directed mutagenesis, vector mediated integration or deletion of DNA etc. have evolved and are continuing to evolve.

The second set of relevant guidelines are the 2017 Draft National Guidelines for Stem Cell Research which are also non-binding. Their preamble notes the "challenges

[208] Ibid, s.(ii).
[209] Ibid, s.(iii).
[210] Ibid, s. (iv).

related to the contentious human germ-line engineering”. [211] Interestingly, the Guidelines preview that in cases where cell lines undergo genetic manipulation and have the potential for commercilaisation, the IP rights of the biological material will not vest with the donor but that “effort should be made if any benefit can be passed on to the donor/community wherever possible.”[212]

The Guidelines establish two bodies for overseeing stem cell research and clinical trials, namely, the National Apex Committee for Stem Cell Research and Therapy to set out guidelines and regulate at the national level, as well as the Institutional Committee for Stem Cell Research, which approves and monitors stem cell research at the institutional level.[213]

The Guidelines categorise research into permissible, restricted and prohibited based on the ethical and safety concerns, necessitating additional review and monitoring. Genome editing of stem cells, germ-line stem cells or gamete and human embryos is restricted to in vitro studies and requires review by the IC-SCR, IEC, IBSC and the RCGM.[214] There is a prohibition on the culturing of genome modified human embryos beyond 14 days of fertilization or the formation of primitive streak, whichever occurs earlier.[215] Notably, research related to human germ line gene therapy is a prohibited area of research together with the use of genome modified human embryos, germ-line stem cells or gametes for developmental propagation and research involving implantation of human embryos after in vitro manipulation into humans or primates.[216]

Japan

Japan’s regulation of genome editing is contained in the non-binding 2002 Guidelines on Gene Therapy Clinical Research. The Guidelines define "gene therapy" as “administering a cell into which a gene or genes have been introduced into a human body for the purpose of treating a disease”. [217] The gene therapy clinical research has to meet a number of requirements, including the targeting of serious genetic disorder, cancer, acquired immune deficiency syndrome and other life-threatening diseases or disorders that significantly impair the function of the body. [218] Furthermore, the therapeutic effect of the clinical research ought to significantly outweigh other currently possible methods and it ought to be sufficiently certain that the benefit obtained by gene therapy clinical research for subjects will exceed the disadvantage. [219] The overall requirement for clinical research of gene therapy is for it to be effective and

[211] Draft National Guidelines for Stem Cell Research, Indian Council for Medical Research and Department for Biotechnology (July 2017), Preamble, p.1.
[212] Ibid, s. 5.1.1.4.
[213] Ibid, s. 6.
[214] Ibid, s. 9.2.8.
[215] Ibid, s. 9.2.8.3.
[216] Ibid, s. 9.3.
[217] Japan Guidelines on Gene Therapy Clinical Research 2002 (as amended 2008), s. 2(1).
[218] Ibid, s. 3(1).
[219] Ibid, s. 3(2) and (3).

safe "based on sufficient scientific knowledge".[220] The Guidelines expressly prohibit germ line editing:

> Gene therapy clinical research aimed at, or that may cause, genetic modification of human germ cells or embryos (that is, a cell or a group of cells which, as it is, has a possibility of growing into one individual by going through the process of occurrence in the womb of a human being or an animal, before the formation of the placenta is started…) should not be performed.[221]

There are official reports that the Council for Science, Technology and Innovation at the Prime Minister's Office is considering revising the Japanese policy set out in the draft Comprehensive Strategy on Science, Technology and Innovation, as well as adopting regulations on embryo research in order to adequately address the challenges posed by genome editing.[222] According to these reports, the Government is considering restricting human embryo modification through genome editing to basic research and prohibiting the implantation of edited embryos.[223]

The Japanese legal system is a civil law one. According to Article 98(2) of the Constitution, treaties ratified by Japan "shall be observed faithfully". They become part of domestic law hierarchically superior to statutes and regulations but inferior to the Constitution.[224] Japan is a party to the ICESCR, the Convention Against Torture, the Convention on the Elimination of All Forms of Racial Discrimination, the Convention on the Rights of the Child and the Convention on the Rights of Persons with Disabilities.

Germany

The key German act with implications for genome editing is the 1990 Embryo Protection Act. Section 1 of the Act which lists the improper uses of reproduction technologies includes the artificial fertilisation of an egg "for any purpose other than bringing about a pregnancy in the woman from whom the egg cell was collected." The Act also prohibits sex selection except "to protect the child from Duchenne muscular dystrophy or a similarly serious sex-linked hereditary disease".[225] Pre-implantation diagnostics are limited to cases involving "a high risk of a serious genetic disease" or "to identify an abnormality that would be highly likely to lead to still-birth or miscarriage".[226] The most important provision is section 5 of the Act on Artificial alteration of human reproductive cells, stating that:

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[220] Ibid, s. 4.
[221] Ibid, s.6.
[222] See e.g, http://japan.kantei.go.jp/97_abe/actions/201605/13article1.html .
[223] http://www.freedomofresearch.org/article/2017-05-01-050000/japan-plans-revise-policy-doing-research-human-embryos .
[224] T Webster, 'International Human Rights Law in Japan: The View at Thirty'(2010) Case Western Reserve University Faculty Publications Paper No. 579, 245.
[225] S. 3, Embryo Protection Act 1990 (Gesetz zum Schutz von Embryonen (Embryonenschutzgesetz - ESchG).
[226] Ibid, s. 3a.

(1) Whoever artificially alters the genetic information of a human germ line cell will be punished by up to 5 years' imprisonment or a fine.

(2) Anyone who uses a human gamete with artificially altered genetic information for fertilisation will also be punished.

(3) Attempt is also punishable.

(4) Subsection (1) is inapplicable to:

1. any artificial alteration of genetic information of a gamete located outside the body, if it will not be used for fertilisation.
2. any artificial alteration of genetic information of such an endogenous reproductive cell, which has been taken from a foetus, a person or a deceased person, if it is excluded that

a) it will be transferred to an embryo, foetus or person, or
b) a gamete will develop from it;

Case law

The German Supreme Court had the occasion to interpret section 3(a) of the Embryo Protection Act in a case concerning the criminal prosecution of a gynaecologist who carried out extracorporeal fertilisation in order to do pre-implantation diagnostics and procure a pregnancy only with a healthy embryo. The Supreme Court acquitted the doctor, reasoning:

> With the exclusion of PID, a high risk would be borne – as here – that a non-viable or seriously ill child would be born… The Senate's interpretation does not allow for an "unlimited selection based on genetic characteristics". The element on which a decision has to be made is the volition to conduct an examination of serious genetic defects in order to reduce the mentioned serious risks in course of the [PID]. This purpose does not constitute an alternative intention sufficient for criminal liability…Whether…the same would be true for the intention to diagnose an embryo's genetic predispositions in relation to a disease which would only manifests after the attaining of the age of 18, this is a matter the senate does not have to reach a decision on. This of course does not change the fact that an unequivocal legal regulation would be desirable.[227]

Germany's legal system follows the civil law traditions. According to the German Basic Law, "[t]he general rules of public international law shall be an integral part of federal

[227] *5 StR 386/09 - wegen Verstoßes gegen das Embryonenschutzgesetz* (Bundesgerichtshof, 6 July 2010), paras 26 and 29.

law. They shall take precedence over the laws and shall directly create rights and duties for the inhabitants of the federal territory."[228] Germany is a party to the ICESCR, the Convention Against Torture, the Genocide Convention, the Convention on the Elimination of All Forms of Racial Discrimination, the Convention on the Rights of the Child, the Convention on the Rights of Persons with Disabilities and the European Convention on Human Rights. Germany is also a Member State of the European Union and thus bound by its Founding Treaties and secondary legislation.

Mexico

Mexico's 1997 General Law on Health regulates the use of assisted reproduction technologies and the human genome. While it recognises the right of every person to infertility treatment and assisted reproduction, it prohibits the fertilization of human eggs for any purposes other than procreation.[229] This has been interpreted as prohibiting the use of embryos for research, including genome editing.[230]

The General Law on Health contains important definitions of the human genome as "the genetic material that characterises the human species and that contains all the genetic information of the individual, considered as the basis for the fundamental biological unity of human beings and their diversity."[231] It also declares the human genome and the knowledge in this area to be the heritage of humanity, while affirming that the individual genome of each human belongs to them.[232] Interestingly, the Law prohibits discrimination based on genetic characteristics[233] and sets out the right of every person to decide whether to be informed of the results of their genetic examination.[234] The Law emphasises the principle that scientific research and technological development relating to the human genome ought to be aimed at the protection of health and give primacy to the respect for human rights, freedoms and the dignity of the individual.[235] Last but not least, the Ministry for Health is vested with the competence to control the research and developments related to the human genome in order to preserve the public interest and morals.[236]

On the level of state, the Mexico Criminal Code contains two provisions criminalising genetic interventions. Article 154 imposes up to six years of imprisonment, disqualification or suspension from public office or profession for those who manipulate human genes in a manner that modifies the genotype for purposes other than the elimination or suppression of serious diseases or conditions. Notably, the

[228] Art. 25, German Basic Law (Grundgesetz).
[229] Art. 7, General Law on Health 1997.
[230] http://www.df.gob.mx/leyes/normatividad.html?materia=1&apartado=16&disp=394 .
[231] Art. 103 Bis, General Law on Health.
[232] Ibid, Art. 103 Bis 1.
[233] Ibid, Art. 103 Bis 2.
[234] Ibid, Art. 103 Bis 4.
[235] Ibid, Art. 103 Bis 5.
[236] Ibid, Art. 103 Bis 6.

provision also prohibits the performance of genetic modification for illicit purposes.[237] Interestingly, the Criminal Act also previews civil law consequences of a birth of a child as a result of the prohibited acts being the reparation for damages, including the payment of manintenance for the mother and the child.[238] The Federal Criminal Code, however, does not criminalise genetic manipulation of humans.

Mexico's legal system is of the civil law type. According to Article 1 of the Mexican Constitution "all persons shall enjoy the human rights recognized by the Constitution and international treaties to which Mexico is party, as well as the guarantees for their protection, the exercise of which cannot be restricted or suspended, except in the cases and under the conditions established by this Constitution." The case law of the Mexican Supreme Court confirms that international human rights treaties to which Mexico is a party have the same rank as the rights under the Constitution, whereas other treaties are in the same position as federal laws.[239]

Australia

Australia's Prohibition of Human Cloning for Reproduction Act 2002 defines the heritable alterations to the genome as a criminal offence:

> (1) A person commits an offence if:
> (a) the person alters the genome of a human cell in such a way that the alteration is heritable by descendants of the human whose cell was altered; and
> (b) in altering the genome, the person intended the alteration to be heritable by descendants of the human whose cell was altered.
> Maximum penalty: Imprisonment for 15 years.[240]

The Act also criminalises the importing, exporting or placing a prohibited embryo defined as:

> (a) a human embryo created by a process other than the fertilisation of a human egg by human sperm; or
> (c) a human embryo that contains genetic material provided by more than 2 persons; or
> (d) a human embryo that has been developing outside the body of a woman for a period of more than 14 days, excluding any period when development is suspended; or

[237] Art. 154 (3) Código Penal para el Distrito Federal (available at: https://www.juridicas.unam.mx/legislacion/ordenamiento-entidad/458-codigo-penal-para-el-distrito-federal#74669).
[238] Ibid, Art. 155.
[239] C M Cerna, 'Status of Human Rights Treaties in Mexican Domestic Law' (2016) 20:4 ASIL Insights available at: https://www.asil.org/insights/volume/20/issue/4/status-human-rights-treaties-mexican-domestic-law#_edn1 .
[240] Art. 15, Prohibition of Human Cloning for Reproduction Act 2002 (as amended 2008).

(e) a human embryo created using precursor cells taken from a human embryo or a human fetus; or
(f) a human embryo that contains a human cell (within the meaning of section 15) whose genome has been altered in such a way that the alteration is heritable by human descendants of the human whose cell was altered; or
(h) a chimeric embryo or a hybrid embryo.[241]

Australia adheres to the traditions of the common law. While international treaties need to be implemented in domestic law through an act of Parliament, customary law is a source of the common law.[242] Australia is a party to the Genocide Convention, the International Convention on the Elimination of All Forms of Racial Discrimination, the Convention Against Torture, the Convention on the Rights of the Child, the Convention on the Rights of Persons with Disabilities. It has signed but not ratified the ICESCR.

France

The French Civil Code prohibits the violation of the integrity of the human specie and any eugenic practice aimed at the selection of persons.[243] It also prohibits the modification of genetic traits with the purpose of modifying the germ line, creating an exception from the prohibition for research aimed at the prevention or treatment of genetic diseases.[244]

The Bioethics Law stipulates that the methods of modifying the genetic identity of humans are not patentable.[245]The Criminal Code defines eugenic and reproductive cloning as crimes against humanity, setting out that the implementation of an eugenic practice for the organization of the selection of persons is punishable by thirty years imprisonment and a fine of EUR 7,500,000.[246]

On the level of non-binding guidelines, the National Academy of Medicine recommended maintaining the current legislation prohibiting all manipulation of the genome resulting in changes to the genome of offspring and the development of research using technologies for targeted genome editing, including work on germline cells and human embryos, so long as the edited embryos are not transferred to the uterus under the current state of knowledge and legislation.[247]

France is a civil law system. According to Article 55 of the Constitution treaties ratified by the State become part of French law and override conflicting legislation. France is

[241] Ibid, Art. 20 (emphasis added).
[242] *Chow Hung Ching v The King,* (1949) 77 CLR 449.
[243] Art. 16-4 Code civil (1804) (as amended March 2017).
[244] Ibid.
[245] Loi No. 2011-814 du 7 juillet 2011 relative à la bioéthique, Art. 611-18.
[246] Art. 214-1, Code Penal (as amended April 2017).
[247] Genetic editing of human germline cells and embryos, Académie Nationale de médecine (April 2016), Recommendations.

a Member State of the European Union and a party to the Genocide Convention, the Convention Against Torture, the Convention on the Elimination of All Forms of Racial Discrimination, the ICESCR, the Convention on the Rights of the Child, the Convention on the Rights of Persons with Disabilities and the European Convention on Human Rights.