Seeking Inclusive Global Governance for Human Germline Genome Editing: Our Common Future

Priya Ayyappaswamy
Faculty of Law
McGill University, Montreal

April 2025

A thesis submitted to McGill University in partial fulfilment of the requirements of the degree of Master of Laws, General Law.

Table of Contents

Abstract **3**

Résumé **4**

Acknowledgements **5**

Abbreviations **6**

Part 1 ..... **7**

Introduction **7**

Chapter I: Navigating the Ripple Effect: Ethical Concerns about HGGE's Impact on State, Society and Other Stakeholders **16**

1. Efficiency in Delivering HGGE Interventions *16*

2. The Prospect of Administering HGGE as an ART *18*

3. The Obligation of States *23*

3.1 ARTs Are "Disrupting" Traditional Understandings of Science, Family, and Reproduction 24

3.2 Methods of Governance and Implementation Raise Unique Concerns 28

3.3 The Effects of HGGE Regulatory Approaches on the Scientific Community and Researchers 33

4. Current Regulatory Approaches *34*

Part 2 ..... **37**

Chapter 2: Identifying Approaches to Govern HGGE: International Human Rights Law **37**

1. Current Governance of HGGE Urgently Needs Revisiting *37*

2. Turning to International Human Rights Law for ranl Clarity *39*

2.1 Is HGGE Permissible Under International Human Rights Law? 40

2.2 How Do Approaches Recognizing Intergenerational Rights Affect the Governance of HGGE? 47

2.3 Does IHRL Provide Insight into HGGE Best Practices and Ethical Guidance? 54

3. Limitations of Employing IHRL as the Sole Approach to Governing HGGE *59*

Chapter 3: Suggesting Inclusive Global Governance for HGGE **61**

1. An Alternative Approach to Govern HGGE *61*

1.1 Suggesting Inclusive Global Governance for Optimal Governance of HGGE 63

1.2 Recommendations for Optimal and Inclusive Governance of HGGE 66

1.3 Limitations to Establishing Optimal & Inclusive International Oversight for HGGE 76

2. The Path Forward *78*

Conclusion **80**

Bibliography **82**

Abstract

Several bioethics reports consider Human Germline Genome Editing (HGGE) an assisted human reproduction technique (ART) because it intends to treat genetic conditions by introducing targeted changes in the DNA of reproductive cells of human beings. Despite the potential benefit from its application as an ART, HGGE raises several bioethical-legal concerns that impede its implementation. Such concerns may include privacy, intergenerational risks, and possible genetic discrimination. These concerns have increased the research community's interest in governing HGGE through human rights law to ensure broad protections to human life. However, governing HGGE solely through human rights approaches is reported to have limitations as it can alienate stakeholders who may not agree with certain interpretations of fundamental human rights law regarding the administration of HGGE. This thesis argues that it is possible to protect a greater number of stakeholders (e.g., parents, children, states) through inclusive global governance of HGGE.

Keywords: *inclusive, governance, HGGE, human rights, intergenerational, privacy, genetic discrimination.*

Résumé

Plusieurs rapports de bioéthique considèrent l'édition du génome germinal humain (EGGH) comme une technique de procréation médicalement assistée (PMA) parce qu'elle vise à traiter des maladies génétiques en introduisant des modifications ciblées dans l'ADN des cellules reproductrices des êtres humains. Malgré les avantages potentiels de son application en tant que technique de procréation assistée, l'édition du génome germinal humain soulève plusieurs problèmes bioéthico-juridiques qui entravent sa mise en œuvre. Ces préoccupations peuvent porter sur la protection de la vie privée, les risques intergénérationnels et une éventuelle discrimination génétique. Ces préoccupations ont accru l'intérêt de régir le EGGH par le biais de la législation sur les droits de la personne afin de garantir une protection étendue de la vie humaine. Cependant, le fait de régir le EGGH uniquement par le biais de ces approches des droits de la personne est considéré comme ayant des limites car il peut aliéner certaines parties prenantes qui peuvent ne pas être d'accord avec ses approches de la gestion du EGGH. Cette thèse soutient qu'il est possible de protéger un plus grand nombre de parties prenantes (par exemple, les parents, les enfants, les États) par le biais d'une gouvernance inclusive du EGGH.

Keywords: *gouvernance inclusive, HGGE, droits de la personne, intergénérationnel, vie privée, discrimination génétique.*

Acknowledgements

Writing this thesis has been a challenging endeavour. I am immensely grateful for the support of my parents, sibling, peers, and supervisor, who helped me reach the finish line.

I would like to extend my heartfelt thanks to my mentors and colleagues at the Centre of Genomics & Policy for their support, encouragement, and guidance throughout this project. I am indebted to Prof. Bartha Knoppers, Prof. Yann Joly, and Prof. Man Zawati for providing me with unforgettable research opportunities.

I am grateful to my supervisor, Prof. Lara Khoury, for her unwavering support and help in improving my writing and finding my voice.

I would like to thank the Faculty of Law for their assistance.

Abbreviations

ART – Assisted Human Reproductive Technique

ACDC – American Centre for Disease Control

ACHR – American Convention of Human Rights

CHD – Common Heritage of Mankind Doctrine

CRC – Convention on the Rights of the Child

EAC – World Health Organization's (WHO) Expert Advisory Committee on Developing Global Standards for the Governance and Oversight of Human Genome Editing

ECHR – European Convention of Human Rights

ECtHR – European Court of Human Rights

HGGE – Human Germline Genome Editing

IACtHR – Inter-American Court of Human Rights

ICESCR – International Covenant of Economic Social and Cultural Rights

IHRL – International Human Rights Law

IVF – In Vitro Fertilization

MRT – Mitochondrial Donation Technique

PGD – Pre-implantation Genetic Diagnosis

UDBHR - Universal Declaration on Bioethics and Human Rights

UDHBHR – Universal Declaration on Human Genome and Human Rights

UDHC – Universal Declaration of Human Cloning

UDHR - Universal Declaration of Human Rights

UNESCO – United Nations Educational, Scientific, and Cultural Organization

WHO – World Health Organization

Part 1

Introduction

Human Germline Genome Editing (HGGE) refers to all possible interventions that alter the DNA contained within human reproductive cells, such as eggs, sperm, or embryos.[1] Such interventions have created an opportunity to possibly treat genetic conditions caused by specific gene mutations, and they may also allow parents to choose preferred human traits that are associated with the presence of specific gene sequences.[2] Unlike somatic genome editing interventions, which can treat genetic conditions in a single generation, HGGE introduces genetic changes to human reproductive cells that can be passed down to future generations.[3] The heritable nature of the changes brought by this technology carries ethical, legal, and social implications that may affect privacy and intergenerational rights, and cause concerns of possible genetic discrimination for the unborn child and future generations.[4] Because of these potential implications, bioethicists, lawyers, scientists, and other stakeholders have begun to consider more optimal ways of governing such interventions.[5]

Despite such pressing concerns, scientists continue to research and invest in genome editing because it can treat genetic conditions permanently.[6] This ability to modify genes gives HGGE the potential to eliminate genetic diseases in patients and communities that are adversely affected by heritable genetic conditions.[7] Through further research on HGGE interventions, scientists attempt to develop a better understanding of genetic diseases and human fertility in order to treat such disadvantaged communities.[8] However, potentially administering heritable interventions such as

---

[1] Tetsuya Ishii & Ińgo de Miguel Beriain, "Safety of Germline Genome Editing for Genetically Related 'Future' Children as Perceived by Parents" (2019) 2:6 The CRISPR Journal 370 at 370-371.
[2] *Ibid* at 370.
[3] Ishii & Beriain, *supra* note 1, at 370, 373; See e.g. Bryan Cwik, "Intergenerational Monitoring in Clinical Trials of Germline Gene Editing" (2020) 46:3 J Med Ethics 183 at 183, 185.
[4] Cwik, *ibid* at 183, 185.
[5] See e.g. Mara Almeida & Robert Ranisch, "Beyond Safety: Mapping the Ethical Debate on Heritable Genome Editing Interventions" (2022) 9:139 Humanities and Social Sciences Communications 1 at 2-4.
[6] See e.g. Paul A. Martin & Ilke Turkmendag, "Thinking the Unthinkable: How Did Germline Genome Editing Become Ethically Acceptable" (2021) 40:4 New Genetics & Society 384 at 391-392.
[7] Erika Kleiderman & Ian Norris Kellner Stedman, "Human Germline Genome Editing is Illegal in Canada, but it could be Desirable for Some Members of the Rare Disease Community" (2020) 11:2 J Community Genet 129 at 135.
[8] Kleiderman & Stedman, *ibid;* See e.g. Christopher Gyngell, "Gene Editing and the Health of Future Generations" (2017) 110:7 Journal of the Royal Society of Medicine 276 at 276-278.

HGGE on human embryos (to treat sickle cell disease, e.g.) in clinical trials to human beings will require addressing certain bioethical-legal concerns.[9]

The primary concern regarding HGGE has been its safe application on human beings because any off-target or unintended mutation to genes is passed down to future generations along with the desired genetic changes.[10] "The human genome has an estimated "3 x 10^9 base pairs of DNA" that are "99.6%" similar in all humans, with the remaining "0.4%" contributing to any genetic variation among all human beings.[11] Such genetic variations enable human diversity, but some genetic variations are also known to cause rare diseases and cancer and may also lead to an increased susceptibility of certain adult on-set diseases like diabetes or heart disease.[12] Therefore, any "off-target" mutation caused by HGGE interventions can have unknown or possibly disastrous implications for individuals and their progeny.[13] While scientists consider HGGE interventions a vital research avenue to be explored, the associated risks have discouraged them from experimenting on "human beings".[14]

Some bioethicists consider HGGE an assisted human reproduction technique (ART) similar to Mitochondrial Donation Technique.[15] Mitochondrial donation technique modifies the human egg by replacing the affected mitochondrial DNA with "healthy mitochondrial DNA" from a donor.[16] This technique creates three-parent babies because the egg, mitochondria, and sperm are

---

[9] See e.g. Dorota Krekova-Zajac, "Civil Liability Damages Related to Germline and Emrbyo Editing Against the Legal Admissibility of Gene Editing" (2020) 6: 30 Nature 1 at 1-6; Paola Frati et al., "Preimplantation and Prenatal Diagnosis, Wrongful Birth and Wrongful Life: A Global View of Bioethical and Legal Controversies" (2017) 23:3 Human Reproduction Update 338.

[10] Jennifer E. Chapman et al, "Approaches to Reduce CRISPR Cas-9 Off Target Effects for Safer Genome Editing" (2017) 22:1 The CRISPR Journal 7 at 9.

[11] "Base Pair" (17 August 2024), Online: National Human Genome Research Institute <https://www.genome.gov/genetics-glossary/Base-Pair#:~:text=Narration&text=One%20copy%20of%20the%20human,to%20300%20million%20base%20pairs>; "A New Gene Editing System Tackles Complex Diseases" (21 May 2024), Online: Science Daily < https://www.sciencedaily.com/releases/2024/05/240521124304.htm>.

[12] See e.g., Yukihide Momozawa & Keijiro Mizukami, "Unique Roles of Rare Variants in the Genetics of Complex Diseases in Humans" (2020) 66 Journal of Human Genetics 11 at 12, 14-16.

[13] See e.g. Dana Carroll, "Collateral Damage: Benchmarking Off-Target Effects in Genome Editing" (2019) 20:114 Genome Biology 1 at 1-3.

[14] Carroll, *ibid*; See e.g. Ekim Malmqvist, "Clinical Trials of Germline Gene Editing: The Exploitation Problem" (2021) 35:7 Bioethics 688 at 689-691.

[15] Ana Nordberg et al., "Regulating Germline Editing in Assisted Reproductive Technology: An EU Cross-disciplinary Perspective" (15 July 2018), Online: Human Germline Editing < DOI: 10.1111/bioe.12705>.

[16] "Mitochondrial Donation" (22 October 2014), Online (Pdf): House of Commons – UK< https://www.parliament.uk/globalassets/documents/commons-committees/science-technology/Mitochondrial-donation/MITCorrespondence.pdf>.

obtained from three individuals.[17] Mitochondrial donation, like HGGE, also modifies the DNA in the human egg by replacing the affected mitochondrial DNA with healthy DNA.[18] However, unlike HGGE, which is performed via technology like CRISPR Cas-9 that introduces precise breaks in the DNA of reproductive cells that modify the genetic material, Mitochondrial Donation involves only replacing mitochondrial DNA in the affected human egg with healthy mitochondrial DNA derived from a donor. In other words, the procedure does not intervene by editing the mitochondrial DNA contained within the human egg but instead just replaces it.[19] Mitochondrial Donation is considered an assisted human reproduction technique and is permitted in countries like the United Kingdom and Australia.[20] Despite this difference, since both technologies alter the human embryo, several bioethics reports suggest that HGGE should be governed similarly to technologies like Mitochondrial Donation Techniques.[21]

Assisted human reproductive technologies like Mitochondrial donation techniques and *in vitro* fertilisation (IVF) were clinically tried on human beings before laws or regulations were developed to govern such novel scientific advancements. The first IVF baby, Louise Brown, was born in 1978 before the United Kingdom could enact its Human Embryology and Fertilization Act in 1990.[22] Some scholars suggest the 1990 legislation in the United Kingdom was passed to effectively address, monitor, guide, and promote similar advancements in fertility treatments.[23] It is in September 2016 in Mexico that the world's first birth via the mitochondrial donation technique was carried out by Dr. John Zhang, a medical scientist from the New York–based New

---

[17] AS Reznichenko et al., "Mitochondrial Transfer: Implications for Assisted Reproductive Technologies" (2016) 11 Applied & Translational Genomics 40 at 41.
[18] Rosamund Scott & Stephen Wilkinson, "Germline Genetic Modification and Identity: The Mitochondrial and Nuclear Genomes" (2017) 37:4 Oxford Journal of Legal Studies 886.
[19] Scott & Wilkinson, *ibid.*
[20] Julian Koplin et al., "Ethical Implementation of Mitochondrial Donation in Australia" (2022) 62:6 Aust N Z J Obstet Gynaecol 921. See also. "Mitochondrial Donation Treatment", Online: Human Fertilisation and EmbryologyAuthority<https://www.hfea.gov.uk/treatments/embryo-testing-and-treatments-for-disease/mitochondrial-donation-treatment/#:~:text=The%20UK%20is%20the%20first,to%20be%20approved%20by%20us>.
[21] Nuffield Council on Bioethics, *Genome Editing and Human Reproduction: Social and Ethical Issues* (London, UK: Nuffield Council on Bioethics, 2018) at 65, 103. See also. International Commission on the Clinical Use of Human Germline Genome Editing, *Heritable Human Genome Editing* (Washington, DC: National Academies of Sciences, Engineering, and Medicine, 2020) at 151, 166.
[22] Katherine Dow, "'Now She's Just an Ordinary Baby': The Birth of IVF in the British Press" (2019) 53:2 Sociology 314.
[23] Ruth Deech, "The Legal Regulation of Infertility Treatment in Britain" in Sanford N. Katz et al, eds, *Cross Currents Family Law and Policy in the US and England* (London, UK: Oxford University Press, 2000) at 165-169. Amel Alghrani, "Regulation of Assisted Reproduction: Past, Present and Future" in *Regulating Assisted Reproductive Technologies: New Horizons*, Cambridge Bioethics and Law, ed (Cambridge: Cambridge University Press, 2018) at 19.

Hope Fertility Centre.[24] The birth of this boy took place in Mexico because this is where Dr. Zhang was legally permitted to conduct the procedure;[25] the United States had selectively prohibited genetic modifications on human embryos by restricting federal funding for research involving human embryos since 1996.[26] However, the United States has not explicitly criminalized such research.[27]

Likewise, the birth of the first germline-modified twins occurred in 2017 when a rogue scientist from China, He Jiankui, selectively modified the human embryos of Chinese twins named Lulu and Nana to make them genetically resistant to HIV-causing AIDS.[28] However, the results of his experimentation are still unclear and are mostly undisclosed to the public.[29] The 2003 Ethical Guiding Principles for Research on Embryonic Stem Cell issued by the Chinese Ministry of Science and Technology and the then Ministry of Health, still applicable in 2017, explicitly prohibited such research on *in vitro* embryos after the fourteenth day of development.[30] In this case, the germline modifications leading to the birth of the twins were banned and unethical but not explicitly criminalised when He Jiankui carried out his experimentation.[31] China addressed germline genome editing in 2020 by imposing civil liability on researchers violating ethical norms

[24] Jennifer Couzin-Frankel, "Unanswered Questions Surround Baby Born to Three Parents" (27 September 2016), Online: Science <https://www.science.org/content/article/unanswered-questions-surround-baby-born-three-parents>.
[25] *Ibid*.
[26] Section 508 (a) of the Dickey Wicker Amendment (1996) prohibits US federal funding for research that involves "creation and destruction of human embryos". See. Dickey-Wicker Amendment, Pub. L. No. 104-119, 110 Stat. 828 (1996). Available at <https://www.govinfo.gov/content/pkg/PLAW-104publ99/html/PLAW-104publ99.html>; See also. Kirstin R W Matthews & Daniel Morali, "Can We Do That Here? An Analysis of US Federal and State Policies Guiding Human Embryo and Embryoid Research" (2022) 9:1 J Law Biosci 1 at 6.
[27] Eli Y. Adashi & Glenn Cohen, "Selective Regrets: The 'Dickey Amendments' 20 Years Later" (25 November 2015), Online: JAMA Forum Archive <https://jamanetwork.com/channels/health-forum/fullarticle/2760581#:~:text=The%20%E2%80%9CDickey%2DWicker%E2%80%9D%20amendment,Balanced%20Budget%20Downpayment%20Act%2C%20I>.
[28] Vera Lucia Raposo, "The First Chinese Edited Babies: A Leap of Faith in Science" (2019) 23::3 JBRA Assist Reprod 197 at 197-199.
[29] Dennis Normile, "Researcher Who Created CRISPR Twins Defends His Work but Leaves Many Questions Unanswered" (28 November 2018), Online: Science < https://www.science.org/content/article/researcher-who-created-crispr-twins-defends-his-work-leaves-many-questions-unanswered>.
[30] *Ethical Guiding Principles for Research on Embryonic Stem Cell*. (2003) Ministry of Health. Esha Sarkar & Afreen Khan, "Erratic Journey of CRISPR Cas-9 in Oncology from Bench-Work to Successful-Clinical Therapy" (2021) 27 Cancer Treatment and Research Communications 2468 at 2476-2477.
[31] Shuang Liu, "Legal Reflections on the Case of Genome Edited Babies" (2020) 5:24 Global Health Research and Policy 1 at 1-3.

regarding gene editing.[32] Later, in 2021, it also criminalized clinical trials for HGGE to deter rogue actors like He Jiankui.[33]

Indeed, we can observe that scientific progress in other assisted reproduction technologies and HGGE interventions has been faster than the building of governance for such technologies.[34] In addition to the safety concerns around their clinical trials, HGGE interventions also raise ethical considerations regarding privacy, intergenerational risks, and possible genetic discrimination.[35] Still, research, discoveries, and progress in HGGE may greatly benefit individuals and society[36] because HGGE can potentially modify the human genome to treat genetic conditions by introducing desirable genetic changes.[37] Moreover, the human genome is the "common heritage of humanity" connecting all humans.[38] Therefore, any benefit from such discoveries and research on human genome editing can benefit all humans.[39] Thus, governing human genome editing will include balancing ethical considerations with its vast potential benefits.

To address the concerns arising from the potential implementation of HGGE, several scholars have championed using human rights approaches to govern the technology, especially when considering how to balance societal interests with scientific progress.[40] While it is possible to recognize the rights of stakeholders through human rights law, scholars have observed that this approach may be affected by conflicting interpretations of human rights.[41] These differing

---

[32] Dennis Normile, "In the wake of gene-edited baby scandal, China sets new ethics rules for human studies", (7 March 2023), Online: Science < https://www.science.org/content/article/wake-gene-edited-baby-scandal-china-sets-new-ethics-rules-human-studies>.
[33] Normile, *ibid.* See also. Criminal Law Amendment (2020). Standing Committee of the National People's Congress. <.http://www.npc.gov.cn/npc/c30834/202012/850abff47854495e9871997bf64803b6.shtml>.
[34] See e.g., Raposo, *supra* note 28.
[35] Rumiana Yotova, "Regulating Genome Editing Under International Human Rights Law" (2020) 69:3 International & Comparative Law Quarterly 653 at 659, 665.
[36] Colin Farrelly, "How Should We Theorize About Justice in the Genomic Era?" (2021) 40:1 Politics Life Sci <https://pubmed.ncbi.nlm.nih.gov/33949837/>.
[37] Ishii & Beriain, *supra* note 1 at 370.
[38] Faith N. Kabata & Donrich W. bo, "The Human Genome as the Common Heritage of Humanity" (2023) 14 Front. Genet. < https://www.frontiersin.org/articles/10.3389/fgene.2023.1282515/abstract>.
[39] Thomas Douglas & Katherine Devolder, "Gene Editing Identity & Benefit" (2021) 72:2 The Philosophical Quarterly 305.
[40] Yotova, *supra* note 35; Britta C. van Beers, "Rewriting the Human Genome, Rewriting Human Rights Law? Human Rights, Human Dignity, and Human Germline Modification in the CRISPR Era" Journal of Law and Biosciences 1.
[41] Where Yotova and Scott suggest IHRL can be used to regulate and even administer HGGE, Drabiak suggests that fundamental IHRL prohibits HGGE. Yotova, *supra* note 35; Katherine Drabiak, "The Nuffield Council's Green Light for Genome Editing Human Embryos Defies Fundamental Human Rights Law" (2020) 34:3 Wiley Bioethics 223 at 223-227. Scott J. Schweikart, "Global Regulation of Germline Genome Editing: Ethical Considerations and Application of International Human Rights Law" (2020) 43:3 Loy L.A. Int'Ll & Comp. L. Rev. 279.

interpretations may hamper building consensus about how HGGE should be optimally governed, given the multifaceted interests and risks involved.[42] Scholars suggest that participatory and inclusive governance approaches offer better avenues to govern HGGE because they not only account for human rights but also actively consider the perspectives of stakeholders whom HGGE will impact the most.[43]

In their report released in July 2021, the World Health Organization's (WHO) Expert Advisory Committee on Developing Global Standards for the Governance and Oversight of Human Genome Editing (EAC) also highlighted the need to develop international standards and increase the participation of stakeholders to govern HGGE more inclusively.[44] Scholars also consider that increasing stakeholder participation can enable a better representation of such individuals, and increased public engagement can help identify the "diverse views in a pluralistic society" to help shape policy.[45] Including such perspectives to guide policy, in turn, will help influence law-making and enable inclusivity in the governance of HGGE to mitigate the harms that can be caused to individuals due to the administration or withholding of ART procedures. This thesis thus examines how inclusive global governance approaches that are respectful of human rights can aid the international community and states in their implementation of HGGE so that all human beings—including the privileged and the disadvantaged, the dominant and the minority, and citizens of the global north and the global south —may benefit from progress in genomics.[46]

---

[42] *Ibid.* Giovanni Rubeis & Florian Steger, "Risks and Benefits of Germline Genome Editing: An Ethical Analysis" (2018) 10:2 Asian Bioeth Rev 133.

[43] Hanzhi Yu et al., "Towards inclusive governance of human genome editing" (2021) 118:47 PNAS 1 at 1-5. See also, Cynthia Selin, "Researching the future: scenarios to explore the future of human genome editing" (2023) 24:72 BMC Medical Ethics 1; Ma Danmeng et al., "WHO appoints panel to advise on gene editing governance" (20 February 2019), Online: Caixin Global <https://www.caixinglobal.com/2019-02-20/who-appoints-panel-to-advise-on-gene-editing-governance-101381785.html> Peter Mills, "Human Genome Editing and Moral Leadership: findings of the WHO Expert Advisory Committee" (14 July 2021), Online: Nuffield Council on Bioethics <https://www.nuffieldbioethics.org/blog/human-genome-editing-and-moral-leadership-findings-of-the-who-expert-advisory-committee>;

[44] World Health Organization, "WHO issues new recommendations on human genome editing for advancement of public health" (12 July 2021) Online: WHO News Release < https://www.who.int/news/item/12-07-2021-who-issues-new-recommendations-on-human-genome-editing-for-the-advancement-of-public-health>.

[45] Alessandro Blasimme, "Why Include the Public in Genome Editing Governance Deliberation?" (2019) 21:12 AMA J Ethics <doi: 10.1001/amajethics.2019.1065>; See also. Sheila Jasanoff & J Benjamin Hurlbut. "A Global Observatory for Gene Editing" (21 March 2018) Online: *Nature*, <https://www.nature.com/articles/d41586-018-03270-w>. See also. Tristan McCaughey, "A Need for Better Understanding is the Major Determinant for Public Perceptions of Human Gene Editing" (2019) 20:1 Human Gene Therapy 36; Sheila Jasanoff et al., "Democratic Governance of Human Germline Genome Editing" (2019) 2:5 The CRISPR Journal 266.

[46] Sarojini Nadimpally, "The Ethics, Equity, and Governance of Human Genome Editing Need Greater Consideration" (3 May 2023), Online: BMJ <doi:https://doi.org/10.1136/bmj.p996>.

Thesis Objective

The international community of scholars (e.g., scientists, bioethicists, philosophers, human rights scholars) through their publications assist states in clarifying the way they must approach regulating HGGE.[47] Such scholars are also involved with non-state actors such as specialized United Nations agencies (e.g., WHO, IBC), non-governmental organizations (e.g., Nuffield Council), and science academies (e.g., NASEM),[48] which release bioethics reports and ethics statements that intend to provide insight to all countries on approaches to govern HGGE more optimally. These stakeholders have made several recommendations on how states should approach governing HGGE.[49]

However, because of scholars' differing opinions on genetically modifying the human embryo, their recommendations on best practices to govern HGGE are not always in consensus.[50] This lack of consensus can impede society from HGGE-related benefits and even inadvertently contribute to potential misuse of the procedure.[51] The objective of this thesis is to identify an optimal approach to govern HGGE and thereby help foster greater consensus among scholars on approaches to govern HGGE.

We consider that the most optimal approach to govern HGGE to be one that can clarify to states their obligations. Of course, clarifying state obligations is crucial because state policy on HGGE can greatly affect the way the procedure is governed. Moreover, as highlighted above the international community of scholars is crucial in driving discussions on regulating HGGE and raising awareness on the urgency to develop international standards to govern the procedure.[52] Thus, greater consensus amongst these scholars can play an important role in clarifying to states their obligations to govern HGGE.[53]

---

[47] Yu et al, *supra* note 43.
[48] Yu et al, *supra* note 43.
[49] Yu et al, supra note 43.
[50] Almeida & Turkmendag, *supra* note 5; Yotova, *supra* note 35; Drabiak, *supra* note 41.
[51] Almeida & Turkmendag, *supra* note 5; Yotova, *supra* note 35; Drabiak, *supra* note 41.
[52] Yu et al, *supra* note 43.
[53] Yu et al, *supra* note 43.

The international community suggests that one way to clarify state obligations is to turn to International Human Rights Law (IHRL).[54] We thus consider whether IHRL can be used as the sole approach to govern HGGE. Increasingly, scholars have also come to rely on non-state actors to govern HGGE.[55] In this thesis we present our analysis of how IHRL and non-state actors can facilitate optimal governance of HGGE. We do this by interpreting IHRL and suggesting governance recommendations to optimise the ability of non-state actors to clarify state obligations and build consensus on best practices to govern HGGE.

Research Methodology

We conducted qualitative research to identify an optimal governance approach for HGGE. We primarily reviewed the literature on the governance of HGGE. We relied on primary legal sources including UN treaties, regional human rights treaties, state law, regulations, policy, and case law. We also considered journals, periodicals, treatises, bioethics reports, etc. as secondary sources of law. An extensive literature review on the topic governance of HGGE using platforms such as PubMed, BMJ, the Lancet, Jstor, Scopus, Web of Science, ScienceDirect, Hein Online helped identify key concepts, definitions, conflicting perspectives, key limitations in the governance of HGGE, and assess gaps in literature. We chose to review journals for analysing the background because they present information on the most recent advances in genome editing and the governance challenges states face including the ethical, legal, and social concerns the procedure raises. Furthermore, the journals we referred to were also authored by scholars whose contributions has been widely appreciated in several scholarly discourses on the topic: governance of HGGE.[56] This process enabled us to present our suggestions of approaches to govern HGGE more efficiently.

Thesis Outline

Part 1 of this thesis includes the introduction and Chapter 1. Chapter 1 will examine the potential of implementing HGGE and the concerns it raises. One needs to understand the concerns raised by a technology and its impact on different interest groups to consider avenues to govern it.

[54] Yotova, *supra* note 35; Schweikart, *supra* note 41.
[55] Yu et al, *supra* note 43; Jasanoff & Hurlburt, *supra* note 45; Jasanoff et al, *supra* note 45.
[56] See e.g., Jasanoff et al, *supra* note 45; Yotova, *supra* note 35; Drabiak, *surpa* note 41;

We also briefly state the importance of clarifying state's obligations to better protect stakeholders. We suggest that due to rapid scientific progress and the multifaceted concerns that arise from HGGE, it is imperative to consider approaches to govern the technology more optimally. **Part 2** consists of chapter 2 and chapter 3 and explores optimal approaches to governing HGGE. In chapter 2 we consider whether international human rights law, when employed as the sole approach to governing HGGE, can aid states in optimally addressing the regulatory concerns in governing HGGE. Because International Human Rights Law (IHRL) has certain limitations to governing HGGE optimally in chapter 3 we consider if *inclusive global governance* is a more optimal approach to govern HGGE.

Chapter I: Navigating the Ripple Effect: Ethical Concerns about HGGE's Impact on State, Society and Other Stakeholders

In this chapter we identify the concerns raised by the potential implementation of HGGE and how these concerns may affect the interests of stakeholders such as scientists, patients, parents, children, government, and the public. By doing so, we show that HGGE raises many difficult and context-specific questions about the state's obligations to protect these stakeholders' rights. Highlighting some aspects of how HGGE is presently governed, this chapter aims at demonstrating the importance of identifying mechanisms that may aid in adequately governing HGGE.

1. Efficiency in Delivering HGGE Interventions

The COVID-19 pandemic made several countries realize the importance of studying genetic variation to improve public health outcomes.[57] Indeed, one way the world is working to improve these outcomes is through the early diagnosis of genetic conditions, as this can increase opportunities to intervene and save lives.[58] Today, advanced genetic and genomic diagnostic technologies not only help predict disease and genetic conditions; they have also created opportunities to intervene by identifying individuals' genetic predispositions, allowing geneticists to predict whether a person carries genes that may adversely affect their health.[59] Once a genetic predisposition or condition has been identified, there are several ways to intervene, including through lifestyle changes, somatic genome editing or HGGE.

Among these interventions to improve health outcomes, genome editing procedures have been the object of greater regulatory scrutiny due to the safety and accessibility of these

[57] See e.g., Guiseppe Novelli et al., "COVID-19 One Year into the Pandemic: From Genetics and Genomics to Therapy, Vaccination, and Policy" (2021) 15:27 Human Genomics 1 at 9.
[58] Novelli, *ibid*. In new borns specifically, see e.g. Suma Elcy Varghese, "The Importance of Early Detection of Genetic Disease" (2021) 4:2 Dubai Med J 133.
[59] Wayne W. Grody, "The Transformation of medical genetics by clinical genomics: hubris meets humility" (2019) 21:9 Genetics in Medicine 1916 at 1921-1922. Dahui Qin, "Next-generation sequencing and its clinical application" (2019) 16:1 Cancer Biol Med 4.

procedures.[60] There are two types of genome editing procedures: first, somatic genome editing procedures, which are performed on adult and mature cells, and second, HGGE procedures, which are performed on reproductive cells.[61] Both procedures can be performed using various methods that deliver "gene editing tools" to target cells.[62]

Several tools allow to undertake somatic and germline genome editing interventions, but scientists have developed a preference for the Clustered Regularly Interspaced Short Palindrome Repeats (CRISPR Cas-9).[63] Discovered in 2012 by Jenifer Doudna and Emmanuel Charpentier, this technology provides scientists with a way to modify the human genome in a "faster", "cheaper", and "more precise" manner compared to "its predecessors" such as "zinc finger nucleases" (ZFNs) and "transcriptional activator-like-effector nucleases" (TALENS).[64] Due to the efficiency of CRISPR Cas-9, the research community has shown a considerable interest in human genome editing.[65] Research on genome editing has also produced results: in 2023 the United States and the United Kingdom approved CASGEVY, a somatic gene therapy that uses CRISPR to treat sickle cell disease (SCD).[66] This is considered a major milestone for genomics because it was the world's first CRISPR drug to be approved. [67]

---

[60] L.B. Moses, "Regulating in the face of sociotechnical change" in Scotford E. Brownsword, eds, *The Oxford Handbook of Law, Regulation, and Technology* (New York: Oxford University Press, 2016) 574-592. See also. Henry T. Greely, "Human Germline Genome Editing: An Assessment" (2019) 2:5 The CRISPR Journal 253; Kiran Munsuru et al., "What do We Really Think About Human Germline Genome Editing, and What Does it Mean for Medicine?" (2017) 10:5 Cardiovascular Genetics 1 at 1-3.

[61] Kelly E. Ormond et al., "Human Germline Genome Editing" (2017) 101:2 American Journal of Human Genetics 167 at 168-169.

[62] Hongyi Li et al., "Applications of Genome Editing Technology in the Targeted Therapy of Human Diseases: Mechanisms, Advances and Prospects" (2020) 5:1 Signal Transduction and Targeted Therapy 1 at 1-3.

[63] Li, ibid at 2-3. A.V. Bannikov, "CRISPR/Cas9, the King of Genome Editing Tools" (2017) 51 Molecular Biology 514 at 514, 523. Odatha W. Kotagama, "Era of genomic medicine: A narrative review on CRISPR technology as a potential therapeutic tool for human diseases" (2 October 2019), Online: BioMed international < doi:10.1155/2019/1369682>.

[64]Bannikov, *ibid.* Barry R. Furrow, "The CRISPR-Cas 9 Tool of Gene Editing: Cheaper, Faster, or Riskier?" (2017) 26:2 Annals of Health Law 33 at 35. Amy Maxmen, "Faster, better, cheaper: the rise of CRISPR in disease detection" (19 February 2019), Online < https://www.nature.com/articles/d41586-019-00601-3>.

[65] Tianxiang Li et al, "CRISPR/Cas9 therapeutics: Progress and Prospects" (2023) 8:36 Signal Transduction and Targeted Therapy 1 at 2; Kotagama, *supra* note 63.

[66] Carissa Wong, "UK first to approve CRISPR treatment for diseases: what you need to know" (16 November 2023) Online: Nature <https://www.nature.com/articles/d41586-023-03590-6>. Marissa Locke Rottinghaus, "FDA approves CRISPR-Cas 9 therapy for sickle cell disease" (8 December 2023), Online: ASBMB Today < https://www.asbmb.org/asbmb-today/science/120823/fda-approves-crispr-cas9-therapy-for-sickle-cell#:~:text=Officials%20at%20the%20U.S.%20Food,eligible%20for%20stem%20cell%20transplants>.

[67] Cormac Sheridan, "The world's first CRISPR therapy is approved: who will receive it?" (21 November 2023), Online: Nature Biotechnology < https://www.asbmb.org/asbmb-today/science/120823/fda-approves-crispr-cas9-therapy-for-sickle-cell#:~:text=Officials%20at%20the%20U.S.%20Food,eligible%20for%20stem%20cell%20transplants>.

Despite its comparative efficiency and success, CRISPR Cas-9 delivery can potentially cause off-target, epigenetic, and unintended mutations.[68] Therefore, scientists consider human genome editing interventions to be riskier than other medical interventions to improve health outcomes.[69] In addition, HGGE interventions are considered more critical than somatic genome editing procedures because they are delivered to reproductive cells and can affect multiple generations.[70] Because of uncertainties and risks surrounding these two genome editing procedures, it is important to examine the concerns raised by these technologies, particularly HGGE, and how these concerns affect stakeholders. First, we will present how germline interventions have become "ethically acceptable".[71]

2. The Prospect of Administering HGGE as an ART

Two influential bioethics reports from science academies and the Nuffield Council of Bioethics suggest "pathways" to "translate" applications of successful research using HGGE into human clinical trials.[72] In 2020, the International Commission on the Clinical Use of Germline Genome Editing published "Heritable Human Genome Editing," a joint initiative of the National Academies of Sciences and the Royal Society.[73] This report suggests "translational pathways" to implement HGGE once the procedure is deemed "safe" and there is a "legitimate need" for its use.[74] The 2018 report "Genome Editing and Human Reproduction," published by the Nuffield Council of Bioethics, also suggests potential scenarios in which HGGE could be administered to

[68] Martina Bauman, "CRISPR/Cas9 genome editing – new and ethical issues arising from a revolutionary technology" (2016) 10 NonoEthics 139 at 144, 149. Xiao-Hui Zhang et al., "Off-target Effects in CRISPR/Cas9-mediated Genome Engineering" (2015) 4 Cell Press 1. Walfer Doerfler, "Epigenetic Consequences of Genome Manipulation: Caveats for Human Germline Therapy and Genetically Modified Organisms" (2018) 11:3 Epigenomics 247.
[69] Furrow, *supra* note 64; Robert Ranisch, "Germline Genome Editing versus Preimplantation Genetic Diagnosis: Is There a Case in Favour of Germline Interventions?" (2020) 34:1 Wiley Bioethics 60. Jennifer Gumer, "The Dubious Benefits of Germline Editing" (2018) 4 Voices Bioeth, online: <https://journals.library.columbia.edu/index.php/bioethics/article/view/6003>.
[70] Ranisch, *ibid* at 62-63.
[71] Martin & Turkmendag, *supra* note 6.
[72] Nuffield Council on Bioethics, Genome Editing and Human Reproduction: Social and Ethical Issues (London: Nuffield Council on Bioethics, 2018). International Commission on the Clinical Use of Germline Genome Editing, Heritable Human Genome Editing (Washington, DC: National Academies Press, 2020).
[73] International Commission, *ibid* at 121-144. Calum MacKellar, "Why human germline genome editing is incompatible with equality in an inclusive society" (2021) 27:1 New Bioeth. 19 at 20.
[74] International Commission, *supra* note 72 at 121-144; Nuffield Council on Bioethics, *supra note* 72 at 23-27.

humans.[75] By considering the procedure's potential benefits (e.g., disease prevention, infertility treatment), both reports have supported the use of HGGE for reproductive purposes.[76]

Additionally, these reports have considered the possibility of performing HGGE as an Assisted Human Reproductive Technique (ART), a reproductive procedure that involves the handling of human reproductive material, such as eggs or embryos , to assist in pregnancy and childbearing.[77] ARTs such as *in vitro fertilization* (IVF) involve a procedure in which the egg and sperm are fertilized in vitro and the resulting embryo is implanted into a woman's uterus.[78] These procedures can help individuals who have difficulty conceiving naturally due to infertility, genetic conditions, or other underlying issues.[79]

However, the development of new ART technologies such as Preimplantation Genetic Diagnosis (PGD), MRT, and HGGE are changing this traditional understanding of ARTs by expanding its scope and purpose.[80] PGD refers to procedures that detect genetic abnormalities in the embryo prior to implantation to determine an embryo's viability for IVF procedures.[81] This procedure is used to increase the success of IVF and reduce the risk of miscarriage or late-stage selective termination.[82] Because PGD can detect the presence or absence of specific diseases or desired traits in the human embryos obtained from in vitro fertilisation, it allows for the early selection of the embryo, unlike traditional ARTs such as IVF.[83] MRT, on the other hand, requires detecting the presence of defective mitochondrial DNA in human embryos and replacing it with

---

[75] See e.g., Nuffield Council on Bioethics, *supra note* 72 at 60.
[76] Nuffield Council, *supra* note 72; International Commission, *supra* note 72.
[77] Center for Disease Control and Prevention, "What is Assisted Reproductive Technology?" (14 April 2022), Online: CDC <https://www.cdc.gov/art/whatis.html>; Nuffield Council, *supra* note 72; International Commission, *supra* note 72.
[78] Vitaly Kushnir et al, "The Future of IVF: The New Normal in Human Reproduction" (2022) 29 Reproductive Sciences 849; See also. "In Vitro Fertilization", Online: Mayo Clinic < https://www.mayoclinic.org/tests-procedures/in-vitro-fertilization/about/pac-20384716#:~:text=In%20vitro%20fertilization%2C%20also%20called,genetic%20problems%20to%20a%20child.>
[79] Kushnir, *ibid* at 849.
[80] Philip Ball, "Seven ways IVF changed the world – from Louise Brown to stem-cell research" (8 July 2018), Online: The Guardian < https://www.theguardian.com/society/2018/jul/08/ivf-in-vitro-fertilisation-louise-brown-born>.
[81] Harvey J. Stern, "Preimplantation Genetic Diagnosis: Prenatal Testing for Embryos Finally Achieving Its Potential" (2014) 3 J. Clin Med 280 at 280-282.
[82] Firuza Rajesh Parikh et al., "Preimplantation Genetic Testing: Its Evolution, Where Are We Today" (2018) 11: 4J Human Reprod Sci 306; Minghao Chen et al., "Can Comprehensive Chromosome Screening Technology Improve IVF/ICSI Outcomes? A Meta-Analysis" (2015) 15:10 Plos One Online < DOI: 10.1371/journal.pone.0140779>; Santiago Munné et al., "Preimplantation Genetic Diagnosis Significantly Reduces Pregnancy Loss in Infertile Couples: A Multicenter Study" (2006) 85:2 Fertil Steril Online: < DOI: 10.1016/j.fertnstert.2005.10.014>.
[83] Stern, *supra* note 81; Ranisch, *supra* note 69 at 63-66.

healthy mitochondrial DNA from a donor.[84] PGD can only select healthy embryos for implantation, but MRT can treat embryos carrying abnormal mitochondrial material *in vitro,* resulting in healthy pregnancies where the child is not affected by mitochondrial disease.[85]

Likewise, HGGE also requires modification of the DNA in the human embryo to improve the health and well-being of future generations by "eliminating" or "reducing" the risks of "inherited diseases" or "genetic conditions".[86] Scientists claim that HGGE can function similarly to PGD or MRT as it is able to prevent the inheritance of specific diseases and increase the success rate of IVF procedures.[87] It can do this by enabling the selection of "the most viable embryos for implantation" by genetically modifying and treating these embryos prior to implantation.[88] However, while PGD can help avoid the implantation of defective embryos and MRT can treat mitochondrial diseases, HGGE can help develop treatments for several untreatable genetic disorders and infertility.[89] In addition, because HGGE is able to modify individual genes associated with specific human traits, prospective parents may also be able to select and enhance the genetic traits with which their children will be born.[90] Therefore, HGGE presents unprecedented and diverse possibilities and applications unlike any other ART.

While such ARTs help to overcome barriers to natural conception and provide opportunities to have healthy children, they may also cause complications, in addition to the ethical concerns flowing from producing genetically enhanced children.[91] Such complications include: PGD may not provide conclusive results or may fail to detect certain genetic conditions in an embryo; IVF may not result in pregnancy, or it may cause unintended consequences such as multiple pregnancies or create health complications for the parents; and MRT, similar to HGGE, may

---

[84] Ranisch, *supra* note 69 at 64.
[85] Ranisch, *supra* note 69 at 63-64; Stern, *supra* note 81; See also Reznichenko, *supra* note 17.
[86] National Academies of Sciences, Engineering, and Medicine**.** *Human Genome Editing: Science, Ethics, and Governance* (Washington, DC: The National Academies Press, 2017).
[87] Ranisch, *supra* note 69 at 63-64; Ainsley J Newson & Anthony Wrigley, "Is Mitochondrial Donation Germline Gene Therapy? Classifications and Ethical Implications" (2017) 31:1 Bioethics 55 at 57-63.
[88]Newson & Wringley, *ibid* at 57-63*;* Ranisch, *supra* note 69.
[89] Ranisch, *supra* note 69; Newson & Wrigley, *supra* note 87;
[90] Ranisch, *supra* note 69; Newson & Wrigley, *supra* note 87;
[91] Giovanni Rubeis & Florian Steger, "Risks and Benefits of Human Germline Editing: An Ethical Analysis" (2018) 10 Asian Bioethics Review 133-141.

present unintended genetic mutations, mosaicisms, and other long-term effects.[92] For this reason, ARTs are generally presented as an option, not an imperative, to prospective parents by adequately informing them of the risks and benefits.[93] Due to these complications and uncertainties, governments internationally are committed to carefully regulating ARTs to administer the technology in a safe manner and to reconcile the new understandings of human reproduction that these technologies represent.[94]

Indeed, there are instances where ARTs have been implemented despite censure.[95] For example, when the IVF procedure was discovered in the early 1970s, states were unable to reconcile this new method of reproduction with existing definitions of human reproduction, which stated that conception and procreation were natural and simultaneous processes.[96] Yet IVF made it possible for queer or previously infertile individuals to have children, which necessitated a radical change to the traditional understanding of human reproduction.[97] Contemporaneous scholars thus considered technologies such as IVF "controversial" as it involved "the deliberate separation of reproduction from the act of human sexuality and from the human body."[98] In other words, IVF "challenge[d] deeply held moral, ethical, and religious values, [especially] those values that concern the family and [the] relationships among its members".[99] It was previously inconceivable that life could start in a "laboratory dish,"[100] but the successful birth of the first IVF

---

[92] "Study Finds Why Many IVF Embryos Fail to Develop" (19 July 2022), Online: Columbia Irving Medical Center <https://www.cuimc.columbia.edu/news/study-finds-why-many-ivf-embryos-fail-develop>; Nishtha Saxena et al., "Mitochondrial Donation: A Boon or Curse for the Treatment of Incurable Mitochondrial Diseases" (2018) 11: 1 J Hum Reprod Sci 3; Committee on Genetics, "Preimplantation Genetic Testing", (March 2020), Online:ACOG<https://www.acog.org/clinical/clinical-guidance/committeeopinion/articles/2020/03/preimplantation-genetic-testing>; Medical Advisory Secretariat, "In Vitro Fertilization and Multiple Pregnancies" (2006) 6:18 Ont Health Technol Assess Ser Online < https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3379537/>.

[93] Marta Kollthoff, "Assisted Reproduction and Pimum Non Nocere" (2007) 9:9 Vitual Mentor 605; Mehret Birru Talabi et al., "Redefining Primum *Non N*ocere to Include Reproductive Autonomy: A New Paradigm in Subspeciality Medicine" (2021) 2:1 Womens Health Rep Online < doi: 10.1089/whr.2021.0079>.

[94] See e.g., Chokri Kooli, "Review of Assisted Reproduction Technique Laws, and Regulations in Muslim Countries" (2020) 24:8 Middle East Fertility Society Journal 1. Walter G. Johnson & Diana M. Bowman, "Inherited Regulation for Advanced ARTs: Comparing Jurisdictions' Applications of Existing Governance Regimes to Emerging Reproductive Techniques" (2022) 9:1 Journal of Law and Biosciences 1 at 1-10. Olivia McDermott, "A Comparison of Assisted Human Reproduction (AHR) Regulation in Ireland with Other Developed Countries" (2022) 19:62 Reprod Health 1.

[95] See e.g., Institute of Medicine, *infra* note 96: von Wülfingen, *Infra* note 94.

[96] Institute of Medicine (US) Committee on Science, Engineering, and Public Policy, *Science and Babies: Private Decisions, Public Dilemmas*, (Washington, DC: National Academies Press, 1990) at ch 7.

[97] Ways to become a parent if you are LGBT+", Online: NHS < https://www.nhs.uk/pregnancy/having-a-baby-if-you-are-lgbt-plus/ways-to-become-a-parent-if-you-are-lgbt-plus/>.

[98] Institute of Medicine, *supra* note 96. See also, *supra* note 96.

[99] Institute of Medicine, *supra* note 96.

[100] Institute of Medicine, *supra* note 96.

baby, Louise Brown, precipitated an observable shift in discourse and the arguments made in favour of the procedure's use.[101] Today, IVF has been normalized to the extent that all countries allow the procedure to treat infertility despite the initial censure.[102]

Several states were initially reluctant to implement PGD as well because they understood PGD to allow embryo selection, a major ethical concern.[103] Today, however, laws targeting PGD are changing, and Germany, a state with highly restrictive ART laws, has begun to allow PGD for certain individuals who may have a higher likelihood of passing on a genetic defect to their offspring or experiencing a still birth or miscarriage.[104] In addition, many states have considered MRT to be highly controversial because of its risks and its ability to create children with genetic material from three individuals.[105] However, the United Kingdom, Australia, and Italy have legalized MRT, and the United Kingdom has reported the birth of children resulting from the procedure.[106] Scholars believe that such ARTs have been legalized in these states because they are technologically advanced enough to perform them safely, and they are also able to reconcile with the new definitions of procreation these technologies necessitate.[107] Considering how states have gradually accepted ARTs despite initial objections, several scholars suggest that in due time, HGGE, though currently presenting significant ethical concerns and uncertainties, will also be

---

[101] Institute of Medicine, *supra* note 96.
[102] Carlos Valerio et al, "IVF in Costa Rica" (2017) JBRA Assist Reprod 366 at 366-369.
[103] Margaret E.C. Ginoza & Rosario Isasi, "Regulating Preimplantation Genetic Testing Across the World: A Comparison of International Policy and Ethical Perspectives" (2020) 10:5 Cold Spring Harb Perspect Med Online <DOI: 10.1101/cshperspect.a036681>. Santiago Munné, "Status of Preimplantation Genetic Testing and Embryo Selection" (2018) 37:4 RBMO 393.
[104] Bettina Bock von Wülfingen, "Contested Change: How Germany Came to Allow PGD" (2016) 3 Reprod Biomed Soc 60.
[105] Robert Klitzman et al., "Controversies Concerning Mitochondrial Replacement Therapy" (2015) 103:2 Ferti Steril 344 at 344-346; See also. "Advisory on Legal Restrictions on the Use of Mitochondrial Replacement Techniques to Introduce Donor Mitochondria into Reproductive Cells Intended for Transfer into a Human Recipient" (16 March 2018), Online: FDA https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/advisory-legal-restrictions-use-mitochondrial-replacement-techniques-introduce-donor-mitochondria>; See also, S Mahomed, "Three to one – an ethico-legal outline of mitochondrial donation in South African context" (2023) 16:3 SAJBL 95 at 95-98.
[106] Jacqui Wise, "First baby born in the UK using mitochondrial donation therapy" (12 May 2023), Online: The BMJ < https://www.bmj.com/content/381/bmj.p1091.long>; Karinne Ludlow, "MRT in Australia" in Diana Bowman et al, eds, *Reproduction Reborn: How Science Ethics, and Law Share Mitochondrial Replacement Therapies* (New York: Oxford University Press, 2023); "Italy leads way for legislation Re Mito DNA Replacement" (27 February 2024), Online: < https://www.mitopatients.org/news/italy-leads-way-for-legislation-re-mito-dna-replacement>.
[107] *ibid.* See also, Marie A. Dziadek & Carolyn M. Sue, "Mitochondrial Donation: Is Australia Ready?" (2022) 16:3 Med J Aust. 118 at 118-121.

considered for legal implementation because of the unique benefits it presents to humanity and our collective future.[108]

3. The Obligation of States

Although they are riskier and present unique concerns, ARTs offer new possibilities for individuals to have children.[109] J G Schenker & V H Eisenberg suggest that states now not only have to guarantee reproductive rights and afford individuals access to ARTs, but they must also implement safeguards and address ethical concerns.[110] Furthermore, scholars highlight that a few domestic and regional courts have recognized the right to reproduce through ARTs as being a negative right, – where states should not restrict individuals' access to ART procedures.[111] States, however, have fewer obligations to ensure their equitable delivery; for example, they are not required to offer subsidized prices for ART procedures.[112] We argue, however, that states do have a greater responsibility to guarantee reproductive autonomy. Reproductive technology is advancing, and so must the human rights associated with ART access and implementation. For example, some argue that there should ideally be a state obligation to provide safe abortions and ensure equitable access to IVF procedures.[113] Yet there is a lack of clarity as to whether states are required to ensure equitable access to complex ARTs such as PGD, MRT, and HGGE.[114] Moreover, while there is excessive literature that demonstrates the concerns raised by these complex ARTs,

---

[108] Ludlow, *supra* note 106. See also, Alyssa Lane et al., "'Mitochondrial Replacement' Technologies and Human Germline Nuclear Modification" (2016) 38:8 Journal of Obstetrics and Gynaecology Canada 731.
[109] Ball, *supra* note 80.
[110] J G Schenker & V H Eisenberg, "Ethical issues relating to reproductive control and women's health" (1997) Int J 58:1 Gynaecol Obstet 167.
[111] See e.g., Kimberly Mutcherson, "Reproductive Rights without Resource" (2017) Hasting Center Report Online < https://onlinelibrary-wiley-com.proxy3.library.mcgill.ca/doi/10.1002/hast.790>; See also, Chantelle Washenfelder, Regulating a Revolution: The Extent of Reproductive Rights in Canada. (2003) 12:2 Health law review 44 at 44,43.
[112] R Trinchant, "Reproductive autonomy in Spain – reproduction as a negative right and the obligations of the state" (2023) 38:1 Human Reproduction 374 at 374-375; Georgina Antonia Hall, "Reproduction misconceived: why there is no right to reproduce and the implications for ART access" (2022) J Med Ethics Online < https://pubmed.ncbi.nlm.nih.gov/36347604/#:~:text=On%20one%20hand%2C%20there%20is,positive%20claim%2Dright%20to%20ART.>; Josephine Johnston & Rachel L. Zacharias, "The Future of Reproductive Autonomy" (2017) 47:3 Hasting Cent Rep 6.
[113] Johnston, *ibid*. Fernando Zegers Hothschild et al, "Human Rights to *In Vitro Fertilization*" 2014 18:1 JBRA Assist Reprod 27 at 27-31. "Q & A: Access to abortion is a human right" (24 June 2022), Online: Human Rights Watch < https://www.hrw.org/news/2022/06/24/qa-access-abortion-human-right>.
[114] Trinchant, note 101. See also. Mackay examines barriers to ARTS and how pharmacists can address them. While it is important to consider the approach stakeholders can take to increase equity in access, the Eshire Task Force on Ethics and Law examines equity of access to ARTs and states obligation such as "partial reimbursements" to voluntarily undertaken ART treatments. Amanda Mackay et al, "Inequity of Access: Scoping the Barriers to Assisted Reproductive Technologies" 11:1 (2023) Pharmacy 1. Eshire Task Force on Ethics and Law, "Equity of Access to Assisted Reproductive Technology" (2008) 23:4 Human Reproduction 772 at 772-774.

there is a paucity of literature clarifying the obligations of states to enable access or to even govern HGGE specifically. Thus, in this section, we consider the way ARTs may "disrupt" traditional understandings of science, family, and human reproduction, create unique societal concerns for current and future individuals, and affect research and scientific progress. We then argue that the unique possibilities and risks presented by this technology necessitate discussion on how these advances affect state obligations.

3.1 ARTs Are "Disrupting" Traditional Understandings of Science, Family, and Reproduction

Traditionally, reproductive laws (e.g., in countries such as the United Kingdom and Canada)recognize that genetically related individuals constitute a family.[115] In particular, they consider that families are "composed of two parents (heterosexual) living with genetically related children conceived within and gestated by the female partner".[116] This traditional definition of a family excludes genetically unrelated children and same-sex partners from being part of the traditional family unit.[117] Civil rights movements globally have fought to redefine the traditional family structure as something that includes adopted children and same-sex parents.[118] Today, the international community encourages the definition of nuclear families to ideally include single-parent families and families composed of heterosexual and same-sex couples, as well as genetically related and unrelated children.[119] Although several states (e.g., Canada and United Kingdom) have adopted this international standard, laws concerning families, adoption, and the ability of queer individuals to enter into civil unions are fragmented and vary according to federal, territorial, and/or provincial laws.[120]

---

[115] Griffiths, *Infra* note 59 at 197.
[116] Danielle Griffiths, "The "Re" Production of the Genetically Related Body in Law, Technology and Culture: Mitochondria Replacement Therapy" (2016) 24:196 Health Care Anal 196 at 197.
[117] Griffiths, *ibid* at 197.
[118] Elizabeth Burleson, "International Human Rights Law, Co-parent Adoption, and the Recognition of Gay and Lesbian Families" (2009) 55 Loy L. Rev 791; "Expanding Definitions of Family in Federal Laws" (26 May 2020), Online: CAP 20 < https://www.americanprogress.org/article/expanding-definitions-family-federal-laws/>.
[119] *Ibid.* Although we have not discussed surrogacy in our thesis Behjati Adrakani through the example of surrogacy shows how ARTs present opportunities for individuals to have children which can cause a change in the traditional definition of family. Zohreh Behjati Adrakani, "The Impact of Third-Party Reproduction on Family and Kinship" (2021) 22:1 J Reprod Infertil 3.
[120] P.R. Ghandhi, E. Macnamee, "The Family in UK Law and the International Covenant on Civil and Political Rights 1966" (1991) 5:2 International Journal of Law, Policy and the Family 104; Marg Buineman, "The Changing Definition of Family" (6 August 2019), Online: The Canadian Bar Association https://nationalmagazine.ca/en-ca/articles/law/in-depth/2019/the-changing-definition-of-family; Melissa Redmond & Beth Martin, "All in the (Definition of Family:

ARTs further disrupt such understandings of families by providing individuals with non-traditional ways of having children.[121] Procedures such as IVF allow individuals facing physical infertility, as well queer and other individuals facing social infertility, to have biological children.[122] Other ART procedures such as MRT and the use of donor gametes create children with varying degrees of relatedness to prospective parents constituting their family unit.[123] Cryopreservation, another ART, enables individuals to have biologically related children posthumously.[124] Because of the new possibilities these technologies present, they have not only disrupted traditional understandings of the nuclear family, but also created new obligations for prospective parents, physicians, healthcare professionals, and the state towards children born through ART procedures.[125]

HGGE in particular raises concerns about what the procedure could mean for prospective parents, future children, and society.[126] Somatic genome editing procedures are performed on the somatic cells of living persons who are capable of giving consent whereas HGGE procedures are performed on human embryos (or germ cells) on the request of their prospective parents.[127] Scholars debate whether HGGE should be employed to permanently eliminate heritable genetic conditions, despite the lack of consent from the unborn.[128] This is where the crux of several challenges in considering the potential implementation of HGGE arise.[129] Because the procedure is performed without the consent of the future person and carries considerable risks to that person, it presents a significant ethical-legal conundrum.[130]

Transnational Parent-Child Relationships, Rights to Family Life, and Canadian Immigration Law" (2021) 44:3 J Fam Issues 766.

[121]Ranisch, *supra* note 69.

[122]Ranisch, *supra* note 69; Anne-Kristin Kuhnt, "Families formed through assisted reproductive technology: Causes, experiences, and consequences in an international context" (2022) 14 Reprod Biomed Soc 289.

[123] Kuhnt, *ibid*; Reznichenko et al, *supra* note 17.

[124] Gary S. Nakhuda, "Posthumous Assisted Reproduction" (2010) 28:4 Semin Reprod Med 329.

[125] Valerie Gutmann, "Norms Reborn: Controversies and Challenges for the Future of Reproductive Technologies" (2022) 22:1 Hous. J. Health L. & Pol'y 1 at 1-6. See also. Vanessa Gruben, "Exploiting the Fiduciary Relationship: The Physician as Information Intermediary in Assisted Human Reproduction" (2009) 18:1 Health L Rev 29.

[126] See e.g. Tetsuya Ishii, "Assignment of Responsibility for Creating Persons Using Germline Genome Editing" (2021) 1:100006 Gene & Genome Editing 1 at 1-5.

[127] Ishii, *ibid;* Ranisch, *supra* note 69.

[128] Ishii, *supra* note 126. Erica C. Jonlin, "Informed Consent for Human Embryo Genome Editing" (2020) 14:4 Stem Cell Reports 530. See also. Andrew M. Joseph et al., "Ethical Perspectives of Therapeutic Human Genome Editing from Multiple and Diverse Viewpoints: A Scoping Review" (2022) 14:11 Cureus 1 at 2-4.

[129] Jonlin, *ibid*. Ishii, *supra* note 126;

[130] Ishii, *supra* note 126. See also, Yaojin Peng et al., "Responsible Governance of Human Germline Genome Editing in China" (2022) 107:1 Biology of Reproduction 261 at 263, 266.

Scholars observe that the element of consent is always lacking in ART procedures because they are administered as reproductive options to prospective parents, and it is impossible to obtain consent from an unborn individual.[131] They also note that children born from ART procedures would not have been brought into existence without the procedure having been performed.[132] Despite these justifications, HGGE has received greater regulatory scrutiny. For example, states such as the United Kingdom and Australia have implemented MRT and other ARTs but not HGGE, arguing that the genome editing of MRT does not to impact the identity of the future person the way the genome editing of HGGE can.[133] Yet we argue that this exceptionalization of HGGE must be contested as the literature demonstrates that its novel ability to permanently modify the human germline in fact matches the ability of MRT, as well as matching other ARTs ability to influence heredity and the identity of the future person to a certain extent.[134]

At the same time, the complications raised by HGGE and other ARTs must not be downplayed when obtaining informed consent from prospective parents.[135] Where extensive research has been conducted on the complications created by ARTs, the socio-psychological impact of these procedures on future children and families remains largely unexplored, especially issues such as whether parents undergoing an ART procedure have an obligation to monitor the health and well-being of their child born through ART assistance and inform the child at an appropriate age.[136] An additional complication is that these procedures can go wrong, and children or their parents can be dissatisfied with the results.[137] Such incidents of dissatisfaction are reported

---

[131] Jonlin, *supra* note 128; Joseph et al, *supra* note 128; Ishii, *supra* note 126.
[132] Jonlin, *supra* note 128. See also. Marcos Alonso & Julian Savulescu, "He Jiankui's gene-editing experiment and the non-identity problem" (2021) 35:6 Bioethics 563.
[133] Scott & Wilkinson, *supra* note 18 at 903; United Kingdom, House of Commons Library, *Mitochondrial Donation*, Standard Note: SN/SC/6833, (30 August 2014) at para 8, 16 at para 5.1.
[134] Marcy Darnovsky, "A slippery slope to human germline modification" (2013) 499 Nature 127. See also, Myrisha S. Lewis, "Is Germline Gene Editing Exceptional?" (2021) 51 Seton Hall Law Review 735 at 804-810.
[135] Ishii, *supra* note 126. Jonlin, *supra* note 128; See also, Naomi Cahn, "CRISPR Parents and Informed Consent" (2020) 23:1 SMU Science and Technology Law Review 1.
[136] We were unable to find articles that directly consider the sociopsychological impact of HGGE on parents and future children undergoing the procedure. Some articles investigated how ethical concerns and addressing them can shape governance of HGGE. Ishii, *supra* note 126. See also. Charis Thompson, "How should 'CRISPRed' Babies be Monitored Over Their Life Course to Promote Health Equity" (2019) 21:12 AMA J Ethics 1036; I Van Dijke et al., "Should germline editing be allowed? The effect of treatment characteristics on public acceptability" (2020) 36:2 Hum Reprod 465; Claire E. Wakefield, "The psychological impact of genetic information on children: a systematic review" (2016) 18 Genetics in Medicine 755.
[137] Navid Esfandiari & Carleigh Nesbit, "Catastrophic Human Error in Assisted Reproductive Technologies: A Systemic Review" (2020) 1:18 J Patient Saf 267.

to arise when the wrong or defective embryos are transferred and implanted, or the wrong sperm is used for insemination.[138] Studies also show that parents and children have not only reacted negatively to incidents of medical and human error in administering ARTs but also when the treatment does not give desired results (e.g., when an individual does not conceive despite repeated IVF cycles).[139] In these situations, either party (parents or child) can instigate liability claims against other stakeholders, suits mostly in the form of "wrong life" or "wrongful birth" actions against physicians and healthcare professionals administering ARTs.[140]

These exhibitions of dissatisfaction can have a significant impact on families who may be unable to accept the child born through ART procedures, therefore potentially also resulting in the child being unable to come to terms with their own existence.[141] If a wrongful life or wrongful birth suit is instigated against physicians or healthcare professionals, courts delineate the responsibilities of stakeholders, including physicians' duty to inform, which enables parents to make knowledgeable decisions about their choices and the process.[142] These claims also cover negligence in administering ART procedures.[143] In wrongful life cases, the individual born through an ART procedure can sue the physician for their inadequacy in performing their duties that resulted in adverse consequences.[144] In wrongful birth cases, the parents bring the claims to court on behalf of their children.[145] For ARTs and HGGE, this form of accountability of healthcare

---

[138] Esfandiari & Nesbit, *ibid*.
[139] CR Newton, "Motives for parenthood and response to failed in vitro fertilization: implications for counseling" (1992) 9:1 J Assist Reprod Genet 24; SMS Mathiesen et al, "Stress, distress and outcome of assisted reproductive technology (ART): a meta-analysis" (2011) 26:10 Human Reproduction 2763.
[140] Though parents can be dissatisfied with results of ART procedure they cannot initiate liability claims for their dissatisfaction occurring from standard medical practice. Frati et al., *Supra* note 9 at 338-357. Mary B. Sullivan, "Wrongful Birth and Wrongful Conception: A Parent's Need for a Cause of Action" (2000) 15:1 Journal of Law and Health 105.
[141] Studies like the one conducted by the UK Millennium Cohort assessing individuals where ARTs procedures performed have been successful show that the procedure did not have any adverse psychosocial effect on the offspring. We thus limit our argument to instances where ARTs do not result in the intended favourable outcome. *Ibid.* See also, Anna Barbuscia, "The psychosocial health of children born after medically assisted reproduction: Evidence from the UK Millennium Cohort" (2019) 7 Population Health 1. Sofia Yerken, "'Wrongful Birth' Claims and the Paradox of Parenting a Child with a Disability" (2018) 87 Fordam L. Rev. 583. See also. Janna Thompson, "What we risk as humans if we allow gene-edited babies: a philosopher's view" (18 February 2019), Online: The Conversation<https://theconversation.com/what-we-risk-as-humans-if-we-allow-gene-edited-babies-a-philosophers-view-110498#:~:text=What%20parents%20want,lead%20to%20denigration%20or%20rejection.>.
[142] Ishii, *supra* note 126. See e.g., A E James Jr., "The concepts of wrongful birth and wrongful life and their relation to medical imaging" (1989) 7:1 Health Matrix 54 at 54-57.
[143] James Jr., *ibid;* Jonlin, *supra* note 128.
[144] David Hirsch, "Rights and Responsibilities in Wrongful Birth/ Wrongful Life Cases" (2006) 29:2 UNSW Law Journal 233 at 233-238.
[145] Hirsch, *ibid.*

professionals is considered important because it can provide relief to individuals adversely affected by medical procedures such as ART.[146] It is evident that the administration of ART procedures also affect the people who administer them. Thus, when such novel reproductive procedures are implemented, to reduce incidence of dissatisfaction, harm, and liability, states must additionally delineate the duties of such professionals towards prospective parents and the unborn child.

3.2 Methods of Governance and Implementation Raise Unique Concerns

Scholars have also considered the risks that ART procedures present to future generations, and how permanently eliminating a genetic condition from an individuals' genetic lineage can be perceived as "inherently" discriminatory to "current members" of the society afflicted with such genetic conditions.[147] In addition, to modify the human germline, one needs to firstly modify a human embryo, which raises several "ethical" and "legal" concerns.[148] Religious groups in particular are opposed to such artificial manipulation of life.[149] However, scientists are discovering new possibilities to use CRISPR on human embryos to effectively treat hereditary heart conditions and other genetic conditions.[150] HGGE also holds the potential to relieve individuals of adverse genetic conditions even before they are born.[151] Because of potential benefits and risks HGGE presents, societies and individuals can deeply feel the consequences of state decisions, especially concerning the implementation of HGGE, in this section we also examine how states govern ARTs to show concerns current approaches raise and the effect these approaches may have on optimally implementing HGGE.[152]

---

[146] Chirstopher P Moutos & John Y Phelps, "Wrongful Birth and Wrongful Life Lawsuits in Obsterics and Gynecology" (21 May 2024), Online: American Journal of Obsterics and Gynecology <https://www.ajog.org/article/S0002-9378(24)00626-4/abstract>.

[147] MacKellar, *supra* note 73; Jodi Halpern et al., "Societal and Ethical Impacts of Germline Genome Editing: How Can We Secure Human Rights" (2019) 2:5 CRISPR J 293. Alix Lenia v. Hammerstein, "Is selecting better than modifying? An investigation of arguments against germline gene editing as compared to preimplantation genetic diagnosis" (2019) 20:83 BMC Medical Ethics 1.

[148] Halpern et al, *ibid*; Ishii, *supra* note 126;

[149] David Basinger, God and Human Genetic Engineering (London: Cambridge University Press, 2023).

[150] Gregory B. Lim, "Human Genome Editing in Heart Disease" (17 August 2017), Online: Nature < https://www.nature.com/articles/nrcardio.2017.128>. Hong Yi et al., "Applications of Genome Editing Technology in the Targeted Therapy of Human Diseases: Mechanisms, Advances and Prospects" (2020) 5:1 Signal Transduction and Targeted Therapy 1-23.

[151] Yi, *ibid;*

[152] Ishii, *supra* note 126; Jonlin, *supra* note 128; Halpern et al., *supra* note 147;

The concerns raised by HGGE can manifest differently and can be exacerbated depending on the approaches states may take to govern HGGE.[153] On the one hand, states that recognize the right to life of the unborn or recognize that human life begins from the moment of conception (such as Ecuador, El Salvador, Honduras), may prohibit HGGE despite its potential beneficial application.[154] States that do not similarly govern the embryo may take a more proactive approach in permitting HGGE. Therefore, equitable availability of HGGE is not just dependent on the availability of resources; it is also affected by state attitudes towards HGGE.[155] On the other hand, if HGGE is hypothetically applied indiscriminately, it can lead to potential eugenic practices.[156] Some scholars consider Iceland's practice of informing expectant mothers of a genetic test to screen for the likelihood of their child inheriting downs disease as a form of "'screening out' of particular groups of people and [leading to] the cultural acceptance of a 'new' [form of] eugenics".[157] Indeed, this practice almost led to the complete elimination of the occurrence of downs syndrome in Iceland.[158]

Scholars are therefore concerned about state attitudes towards genetic disorders and potential agendas to eliminate certain genetic conditions (e.g., Down's syndrome).[159] Based on the way they are offered and the conditions they target, ARTs and screening tests such as the one in Iceland can also negatively impact individuals suffering from these genetic conditions.[160] Studies report that individuals with debilitating conditions and even manageable genetic disorders oftentimes feel alienated.[161] These persons may feel "less than" if the technology that aims to eliminate their

---

[153] Vicki Xafis et al., "Germline Genome Modification through Novel Political, Ethical, and Social Lenses" (2021) 17:9 PLoS Genet 1.
[154] Gila Stopler, "Reproductive Rights" in Rainer Groter et al., eds, Max Planck Encyclopedia of Comparative Constitutional Law (London, Oxford University Press, 2017).
[155] Baylis et al's analysis of governance of HGGE in 96 states shows that some states are more reserved than others in administering HGGE. Francoise Baylis et al, "Human Germline and Heritable Genome Editing: The Global Policy Landscape" (2020) 3:5 The CRISPR Journal 365 at 372-374.
[156] Calum MacKellar, "Gene Editing and the New Eugenics" (2018) 25:1 Dignitas 3 at 3-9.
[157] Lucy Burke, "Hostile Environments? Down's Syndrome and Genetic Screening in Contemporary Culture" (2021) 47 Med Humanit 193 at 196-197.
[158] Anna Levy, "In Iceland, almost all diagnosed down syndrome pregnancies are aborted after prenatal testing. Some bioethics experts are concerned" (1 May 2024), Online: Australian Broadcasting Corporation < https://www.abc.net.au/news/2024-05-01/iceland-prenatal-testing-down-syndrome-ethics/103781058>.
[159] Burke, *supra* note 157. See also. Rosamund Scott, "The Appropriate Extent of Pre-Implantation Genetic Diagnosis: Health Professionals' and Scientists' View on the Requirement for a 'Significant' Risk of a Serious Genetic Condition" (2007) 15:3 Medical Law Review 320.
[160] Burke, *supra* note 157; Levy, *supra* note 158.
[161] Paolo Iovino et al., "A middle-range theory of social isolation in chronic illness" (2023) 20:6 Int J Environ Res Public Health 1; Eric Emerson, "Loneliness, social support, social isolation and well-being among working age adults with and without disability: Cross-sectional study" (2021) 14:1 Disabil Health J 1.

condition in future individuals is not introduced appropriately and delicately.[162] When scholars claim unequivocally that "life without a disability should be regarded as preferable to one with a disability" and consider this "an acceptable conclusion for everyone"[163] individuals with disabilities can become further alienated and vulnerable.[164] Due to such findings, and especially with recent strides in research where HGGE procedures are increasingly able to edit genes more precisely, scholars have sought to analyze the "perceptions" of the disabled community towards the technology in order to include them in conversations around HGGE that is very much relevant to them.[165]

Recounting her experience at the Third Human Genome Editing Summit held at the Francis Crick Institute in the early 2023, public health researcher and social scientist Sarojini Nadimpally, currently working with the non-profit SAMA, a resource group for women and health, shared that "scientific" and "technical" presentations on HGGE at the summit were silent on the "socio-political implications of categorizations such as 'disability,' 'disease,' and 'normalcy'".[166] Several scholars raise concerns over the lack of clear distinction between these categorizations.[167] We agree with Yotova that the understanding of "enhancement," "prevention," and "therapy," terms critical to the HGGE implementation, also remain undefined.[168] In her article, Rumaina Yotova states that the distinction between "diseases" and "serious diseases" can impact the "risk/benefit balance" for HGGE.[169] She also highlights how "deafness" can be considered a disease, but such classification is strongly opposed by the "deaf community".[170] Clarification of these concepts at the international level can help states implement HGGE optimally and in a manner that respects the rights of members belonging to such communities. Such discussion and categorization are critical because

---

[162] Mackellar, *supra* note 73. Yun Hwa Jung, "Impact of the acceptance of disability on self-esteem among adults with disabilities: a four-year follow-up study" (2022) 19:7 Int J Environ Res Public Health 1.
[163] Felicity Broadman, "Human Genome Editing and Identity Politics of Genetic Disability" (2020) 11:2 J Community Genet 125 at 125-127. See also, Iñigo de Miguel Beriain, "Gene editing and disabled people: a response to Felicity Broadman" (2020) 11:3 J Community Genet 241 at 241-243;
[164] Felicity Broadman, "Letter to the editor. Gene editing and disabled people: a response to Iñigo de Miguel Beriain (2020) 11:3 J Community Genet 245 at 245-247.
[165] Tom Shakespeare, "Gene Editing: Heed Disability Views" (25 November 2015), Online: Nature < https://www.nature.com/articles/527446a>; European Parliament, *European Parliamentary Research Service: The Impact of Rare Diseases on Patients and their Families* (2018), available at https://www.europarl.europa.eu/RegData/etudes/IDAN/2018/603218/EPRS_IDA(2018)603218_EN.pdf.
[166] Yotova, *supra* note 35; Nadimpally, *supra* note 46.
[167] Yotova, *supra* note 35 at 662.
[168] Yotova, *supra* note 35 at 662.
[169] Yotova, *supra* note 35 at 662.
[170] Yotova, *supra* note 35 at 662-663.

individuals classified as afflicted by genetic diseases become eligible for treatment, and individuals who are classified as afflicted by a disability may be offered other additional state support such as disability allowances, tax reliefs or pension plans.[171] Although these approaches vary from state to state, it is important that these classifications are considered in regulating HGGE.

Existing societal concerns about ARTs will also affect the implementation of HGGE.[172] When states such as India approach governing ARTs through a "scientific" lens, they "[fail] to tackle the social construct of infertility, which is still stigmatized".[173] Similarly, biased individuals may be reluctant to pursue ART procedures.[174] Therefore, states have an obligation to appropriately educate the public about the availability and benefits of such procedures to alleviate stigmatization and other underlying fears that can become barriers to accessing ARTs.[175] Thus, the state has additional obligations in implementing ARTs and that begins with educating individuals and ensuring that ARTs are administered in an ethical manner that respects societal values.

One example where laws regarding ARTs exist but there is mischief in its delivery is in India. State laws are in place to tackle issues such as sex determination, yet the state continues to face trouble with administering ART procedures such as PGD and IVF because of societal preferences for the male child.[176] Since India's adoption of the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act 1994, sex determination has been illegal in India.[177] Despite this restriction, ART clinics continue to provide services to determine sex through prenatal and preimplantation genetic diagnosis.[178] Furthermore, ART clinics in their advertisements declare that they recruit individuals from "higher status" or who are "fair skinned" to act as "donors" or

---

[171] See e.g., "Disability Inclusive Social Protection Across Europe and Central Asia" (28 June 2023), Online World Bank Group <https://www.worldbank.org/en/region/eca/brief/disability-inclusive-social-protection-across-europe-and-central-asia>.
[172] Almeida & Ranisch, *supra* note 5; Halpern et al., *supra* note 147.
[173] Nadimpally, *supra* note 46.
[174] See e.g., Basinger, *supra* note 149; Nadimpally, *supra* note 46.
[175] Mackay et al, *supra* note 114; See also. The Ethics Committee of the American Society for Reproductive Medicine, "Disparities in access to effective treatment for infertility in the United States: an Ethics Committee Opinion" (2021) 116:1 Fertility and Sterility 54.
[176] Nadimpally, *supra* note 46; Vitaly A. Kushnir et al, "Preimplantation sex selection *via* in vitro fertilization: time for a reappraisal" (2023) 4:3 F S Rep 241 at 241-243.
[177] Sheila Tabaie, "Stopping female feticide in India: the failure and unintended consequence of ultrasound restriction" (2017) 7:1 J Glob Health 1 at 1-3; The Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994, Act No 57 of 1994 (India), Ministry of Health and Family Welfare.
[178] Tabaie, *ibid.*

"surrogates," which propagates existing social biases.[179] Despite the existence of laws preventing discrimination and sex selection, these practices continue.[180] Therefore, ART clinics need to function in a more ethical manner and regulators must closely examine their obligations to protect individuals from such practices.

Despite these concerns, the potential for ARTs to improve lives—by, for example, eliminating hereditary genetic conditions—must not be ignored. However, ART procedures are not accessible to all members of society because of state laws and the manner in which these procedures are administered.[181] The economically challenged, minorities, and members of the queer community in particular report that it is difficult for them to access ART procedures.[182] These individuals may lack access due to a number of factors that may include state funding and their eligibility under law to access ARTs.[183] Moreover, ART procedures are not funded by all states, and states may also not provide financial assistance to individuals undergoing ART treatment.[184] In addition, several states are yet to recognize the rights of queer individuals to form civil unions or use ART treatment to have families.[185] Thus, these factors also impact the equitable availability of ART treatments and affect individuals' rights to private and family life. The state has an obligation to guarantee this right.

Moreover, in spite of the potential of these societal concerns to impact the implementation of ARTs, HGGE procedures remain a possibility, which raise concerns over the way a "genetically

---

[179] Nadimpally*, supra* note 46.
[180]Nadimpally*, supra* note 46; Tabaie, *supra* note 177; Alison W. Manhoff, "Banned and Enforced: The Immediate Answer to a Problem Without an Immediate Solution" (2005) 38:3 VJTL 889 at 890-919.
[181] MM Peterson, "Assisted Reproductive Technologies and Equity of Access Issues" (2005) 31 J Med Ethics 280 at 280-285.
[182] Nicole Rank, "Barriers to Access to Assisted Reproductive Technologies by Lesbian Women: The Search for Parity within the Healthcare System" (2010) 10 Hous J Health L & Pol'Y 115; Abirami Kirubarajan et al, "Cultural Competence in Fertility Care for Lesbian, Gay, Bisexual, Transgender, and Queer People: A Systematic Review of Patients and Provider Perspectives" (2021) 115:5 Fertility and Sterility 1294; Katie Harris et al., "Socio-economic disparities in access to assisted reproductive technologies in Australia" (2016) 33:5 Reproductive BioMedicine 575.
[183] Christopher N. Herndon, "Need for expanding insurance coverage for fertilization in the United States" (2019) 112:1 Reflections 37 at 37-38. Gerald O'Nolan et al., "Should the Governments Fund Assisted Reproductive Technologies?" (2019) 24:1 BMJ-Evidence Based Medicine Online:<https://doi.org/10.1136/bmjebm-2019-EBMLive.15>.
[184] O'Nolan, *ibid.*
[185] See e.g., Pedro Brandão, "European Policies on Same-Sex Relationships, Adoption and Assisted Reproduction" (2022) 11:8 International Journal of Reproduction Contraception Obstetrics and Gynecology 2306 at 2306-2313.

modified child" will belong and adapt within the traditional family and societal construct.[186] Indeed, scholars are concerned with whether being born genetically altered is a cause of potential discrimination and thus may also affect the ability of individuals born through genome editing procedures to access health and other services (e.g., insurance, employment).[187] We argue that the law must ensure that these genetically modified children are treated in the same way that naturally conceived children and children born through other ART procedures are treated in society. We suggest that state obligations towards such children will include not only ensuring their privacy and well-being, but also implementing measures to protect them from discrimination. We are also aware of the possibility that individuals afflicted with genetic conditions that could have been remedied through HGGE may express discontent; such individuals with treatable genetic conditions may experience disappointment if states do not provide adequate avenues for their treatment.[188] Thus, states have an obligation to these individuals as well.

3.3 The Effects of HGGE Regulatory Approaches on the Scientific Community and Researchers

States such as the United Kingdom and Belgium permit germline genome editing on human embryos for research purposes, but several states disincentivize scientists from conducting this research by denying them funding and their ability to patent their research findings, and even by imposing criminal sanctions on researchers interested in administering the procedure on human embryos.[189] The scientific community is concerned about the potential knowledge gap between

---

[186] Scholars like Mackellar and Halpern are concerned about the discrimination disabled people may face with the introduction of HGGE. We consider it prudent to also examine the ethical and legal consequences the gene edited offspring may come to face. Mackellar, *supra* note 73; Halpern et al., *supra* note 147. "Gene Therapy and Genetic Engineering", Online: Centre for Health Ethics < https://medicine.missouri.edu/centers-institutes-labs/health-ethics/faq/gene-therapy>.

[187] Carolyn Riley Chapman, "Genetic Discrimination: Emerging Ethical Challenges in the Context of Advancing Technology" (2020) 7:1 J Law Biosci 1; Béatrice Godard, "Genetic information and testing in insurance and employment: technical, social and ethical issues" (2004) 11 European Journal of Human Genetics 123.

[188] Jon Rueda Etxebarria, "The global governance of genetic enhancement technologies: Justification, Proposals, and Challenges" (2024) International Journal of Theoretical and Practical Reason 55 at 62. Jantina de Vries & Francois Baylis, "Equity and access need to at the forefront of innovation in human genome editing" (12 July 2021), Online: The Conversation <https://theconversation.com/equity-and-access-need-to-be-at-the-forefront-of-innovation-in-human-genome-editing-161794#:~:text=Germline%20human%20genome%20editing%20involves,its%20impact%20on%20future%20generations>.

[189] Fabbri discusses how human embryos are governed internationally. This provides insights about the way states regulate embryo research which directly also corresponds to research on HGGE. Morris Fabbri et al., "Modeling policy development: examining national governance of stem cell-based embryo models" (2023) 18:2 Regen Med 155 at 156, 161-162; See also. Baylis et al, *supra* note 155 at 367.

states that incentivize such research and those that disincentivize it, for as this thesis has made clear, this research can tremendously benefit communities suffering from these treatable genetic conditions.[190] Bioethicists and human rights scholars agree that although implementing HGGE raises several novel ethical and legal concerns, these concerns must not be the sole reason the realization of its benefits through HGGE is halted.[191] They urge states who restrict research to re-examine the laws governing HGGE.[192]

4. Current Regulatory Approaches

Present laws that govern ARTs, including those that impact accessibility and standards of care, differ based on jurisdiction.[193] These laws are important to consider because HGGE will likely be governed as an ART. We noted that most states prohibit HGGE trials on human beings. Although HGGE for reproductive purposes is prohibited in all countries, some states (Canada and Australia) regulate HGGE through criminal sanctions, whereas other states (India) govern the technology through soft law approaches such as ethical guidelines.[194] As this chapter has made clear, scholars suggest that states should not impose criminal bans on "disruptive" technologies with tremendous potential benefits such as HGGE.[195] These bans can disincentivize research, and scholars are concerned that ethical guidelines without binding effect are not optimal methods to govern potential scientific advancements arising from such technology. Thus, where strict regulations can stifle research and scientific progress, laxer governance of the technology can lead to ethical violations, and even research and medical tourism. Because of this, scholars are seeking

---

[190] Bartha Maria Knoppers et al., "Human gene editing: revisiting Canadian policy" (2017) 2:3 NPJ Regen Med 1 at 1-2; Claire Maldarelli, "Scientists Support Research on Gene Editing", 4 December 2015, Online: Popular Science < https://www.popsci.com/scientists-support-research-on-gene-editing-human-embryos/>.
[191] Knoppers et al, *ibid*; Yotova, *supra* note 35; Van Beers, *supra* note 40; Baylis et al., *supra* note 155 at 367;
[192] "Germline gene-editing needs rules" (13 March 2019), Online: Nature Editorial <https://www.nature.com/articles/d41586-019-00788-5>. See also. Knoppers et al., *supra* note 190.
[193] McDermott, *supra* note 94; Baylis et al*, supra* note 155 at 367; Timothy E. Murphy, "Access & Equity: International Standards and Assisted Reproductive Technologies" (2007) 14:1 Reproductive Biomedicine Online < https://doi.org/10.1016/S1472-6483(10)60719-5>. Aurélie Mahalatchimy & Emmanuelle Rial-Sebbag, "Deciphering the Fragmentation of the Human Genome Editing Regulatory Landscape" (2022) 3 Frontiers in Political Science 1.
[194] Andrea Boggio et al., "The regulation of human germline genome modification at the national level: a call for comprehensive legal reform" (2021) 43:3 Loyola of Los Angeles International and Comparative Law Review 201; Murali Krishna Chimata & Gyanesh Bharti, "Regulation of genome edited technologies in India" (2019) Transgenic Res 175; Baylis et al, *supra* note 155 at 367; Knoppers et al., *supra* note 190 at 1-2.
[195] Yotova, *supra* note 35; Etxebarria, *supra* note 188; John M. Conley, "A New Approach to Regulating Human Genome Editing" (2020) 22:2 NCJ Law Technol 107; Kevin Richard Smith, "Germline Genome Editing of Human IVF Embryos Should not be Subject to Overly Stringent Restrictions" (2024) 41 Journal of Assisted Reproduction and Genetics 1733.

alternative avenues to ideally govern HGGE in an ethical manner, one respectful of human rights.[196]

The governance and implementation of ARTs is also impacted by state obligation towards embryos and foetuses. Such obligations may arise from granting "personhood" to the embryo or from offering other forms of protection to the "unborn child",[197] as states that view the human embryo as a person will likely be more reluctant to implement novel ARTs.[198] Thus, although it is not the only factor affecting the implementation of HGGE, the legal status of the human embryo affects how the state understands its obligation to the unborn child.[199] One way to overcome limitations posed by the legal status of the embryo is to instead analyze the benefits the technology grants to members of the society afflicted with such genetic conditions by offering them avenues for treatment.[200]

Indeed, a better regulatory approach to govern these procedures would be to periodically examine the benefit and risks they present to humanity.[201] Although modifying the genome may be incomprehensible today, when mechanisms are eventually developed to administer the technology in a more efficient manner with minimal risks, states may begin to view HGGE as a positive, progressive treatment.[202] As this chapter demonstrates, this change in perception will affect multiple stakeholders, which will also create new obligations for the state to guarantee these stakeholders' rights.[203] It is impossible to identify the numerous ways states may perform their obligations, but our objective was to establish that "disruptive" ARTs such as HGGE should prompt states to identify and reconsider the following: the duty of healthcare professionals to monitor and inform prospective parents and future children about these procedures; and the way they guarantee human rights and other protections to stakeholders, which includes considering a broader and inclusive definition of family, and reconsidering the right to private and family life,

---

[196] See e.g., Conley, *ibid.* Bauman, *supra* note 68, at 141;
[197] Siegel, *infra* note 333; John Janez Miklavcic & Paul Flaman, "Personhood Status of the Human Zygote, Embryo, Fetus" (2017) 84:2 Linacre 130; Asim Kurjak et al., "Facts and Doubts on the Beginning of Human Life – Scientific, Legal, Philosophical, and Religious Controversies" (2023) 51:1 J. Perinat. Med. 39.
[198] Anna E. Melo, "Playing god in the 21st century: how the push for human embryonic germline gene editing sidelines individual and generational autonomy" (2023) 32 Cath U J L & Tech 77.
[199] *Ibid,* Siegel*, infra* note 333.
[200] Nuffield Council on Bioethics, *supra* note 72. International Commission, *supra* note 72.
[201] Nuffield Council on Bioethics, *supra* note 72. International Commission, *supra* note 72.
[202] Martin & Turkmendag, *supra* note 6.
[203] See e.g. Jessica Almqvist, "A human rights approach to risk: the case of human germline editing" (2021) Loy L A Int'L & Comp L Rev 185; Yotova, *infra* note 224.

equality, and rights against discrimination. We acknowledge that there may be other stakeholders who can also be affected by HGGE, and that there are other concerns to consider. Our views are not exhaustive. In **Part 2**, we will examine the ways in which HGGE can be more optimally governed.

Part 2

International Human Rights Law does not adequately clarify the obligations of States

Chapter 2: Identifying Approaches to Govern HGGE: International Human Rights Law

If states are to optimally govern HGGE, they will be required to address diverse and context-specific ethical, legal, and social issues. This chapter will discuss how HGGE is currently regulated and highlight the importance of creating greater clarity regarding the procedure's oversight. We observed that one way HGGE can be more optimally governed is by ascertaining the obligations of states and guaranteeing the rights of stakeholders. There is consensus among scholars that international human rights law (IHRL) is the most optimal approach to govern HGGE and guarantee the rights of stakeholders as it clearly defines state obligations.[204] We agree that IHRL has the potential to offer more clarity to states as to their obligations to govern HGGE. However, we argue that IHLR cannot be used as the sole approach to govern disruptive reproductive procedures such as HGGE.

1. Current Governance of HGGE Urgently Needs Revisiting

As explained in chapter 1, the law and regulatory approaches currently governing HGGE are fragmented. At present, sates regulate HGGE through hard law or soft law approaches.[205] For instance, some states have chosen to outright ban HGGE, while others conditionally permit it—for example, by allowing research on human embryos under strict state supervision.[206] Instead of legislating on the topic, some states have chosen to issue non-binding guidelines and recommendations to regulate the technology.[207] However, a few states have neither implemented hard law nor adopted soft law approaches, leaving HGGE unregulated in their jurisdictions. [208]

---

[204] Yotova, *supra* note 35 at 667, 672; Van Beers, *supra* note 40; Schweikart, 41 at 285; Yotova, *infra* note, 224.
[205] Baylis et al, *supra* note 155 at 367; Mahalatchimy & Rial-Sebbag, *supra* note 193 at 5-10; Fabbri, *supra* note 189 at 156, 161-162.
[206] Baylis et al, *supra* note 155 at 367; Mahalatchimy & Rial-Sebbag, *supra* note 193 at 5-10; Fabbri, *supra* note 189 at 156, 161-162.
[207] Baylis et al, *supra* note 155 at 367; Mahalatchimy & Rial-Sebbag, *supra* note 193 at 5-10; Fabbri, *supra* note 189 at 156, 161-162.
[208] Baylis et al, *supra* note 155 at 367; Mahalatchimy & Rial-Sebbag, *supra* note 193 at 5-10; Fabbri, *supra* note 189 at 156, 161-162.

This regulatory environment creates a two-fold problem. Firstly, there is a general lack of clarity about whether certain applications of HGGE are permitted. Our research shows that it is unclear whether HGGE on human embryos will be generally permitted or whether only certain therapeutic applications of the procedure will be permitted, such as for research and clinical trials while more controversial applications will be restricted.[209] Indeed, HGGE is distinct from traditional ARTs that have single applications. The sole use of IVF, for example, is to treat infertility, whereas PGD can be used to select healthy embryos and prevent the birth of a child afflicted with genetic disorder.[210] HGGE, on the other hand, has varied applications; it can be developed to prevent, treat, and enhance embryos through genetic modifications.[211] Secondly, vague and unclear regulation of HGGE can increase chances of its potential misuse or illegal application.

Furthermore, policy is affected by differences in moral perspectives among both the public and scientists about modifying the human embryo.[212] These differences can arise from varied social, economic, and political backgrounds.[213] The media also plays a significant role in informing the public about the procedure, and it has a significant effect on the way the public perceives HGGE.[214] Scholars are thus identifying approaches where individuals can be appropriately informed about the benefits and risks of the procedure and be led to form their own opinions.[215] In this process, scholars are also looking for an internationally agreed stance to guide these perspectives.[216] But there is currently neither an agreed upon direction in law nor in literature on HGGE.[217] Such lack of clarity in governing HGGE threatens to stall scientific progress.

---

[209] Baylis et al, *supra* note 155 at 367; Mahalatchimy & Rial-Sebbag, *supra* note 193 at 5-10; Fabbri, *supra* note 189 at 156, 161-162;
[210] Stern, *supra* note 81 at 280-282; Ranisch, *supra* note 69 at 60-64.
[211] Ishii & Beriain, *supra* note 1 at 370.
[212] See e.g., Cary Funk & Meg Hefferon, "Public View of Gene Editing for Babies Depend on How It Would Be Used" (26 July 2018), Online: PEW Research < https://www.pewresearch.org/science/2018/07/26/public-views-of-gene-editing-for-babies-depend-on-how-it-would-be-used/>. Alexander Muacevic & John R Adler, "Ethical Perspectives of Therapeutic Human Genome Editing from Multiple and Diverse Viewpoints: A Scoping Review" (2022) 14:11 Cureus 1. See also. Ana S. Iltis et al., "Ethical, Legal, Regulatory and Policy Issues Concerning Embryoids: A Systematic Review of Literature" (2023) 14:209 Stem Cell Research and Therapy 1.
[213] *Ibid.*
[214] Sarah Gurev, "CRISPR in Popular Media: Sensationalism of Germline Editing in Human Embryos" (2017) 10:2 Intersect 1. See also. Catherine Happer and Greg Philo, "The Role of the Media in the Construction of Public Belief and 'Social Change'" (2013) 1:1 Journal of Social and Political Psychology 321.
[215] Almeida & Ranisch, *supra* note 5; See also. Terry Kaan et al., "Germline Genome Editing: Moratorium, Hard Law, or an Informed Adaptive Consensus?" (2021) 17:9 PLOS Genetics 1.
[216] *Ibid.*
[217] Baylis et al, *supra* note 155 at 367; Mahalatchimy & Rial-Sebbag, *supra* note 193 at 5-10; Fabbri, *supra* note 189 at 156, 161-162; Kaan et al., *supra* note 215.

Indeed, there is an urgent need for a greater understanding of the technology and to develop optimal approaches to govern it especially since it is inevitable that some states will continue to explore its potential. The Committee of Social Affairs, Health and Sustainable Development of the Parliamentary Council of Europe, for example, has recognized that despite Europe's current restrictions, it is impossible "to stop genome-edited children from being born elsewhere."[218] This inevitability will lead to a development of the technology, and thus necessitate states to reconsider their regulatory approaches given the significant benefits of the procedure. Indeed, this situation can potentially arise in countries like Israel, where, as observed by Boggio et al, "the power to authorize clinical trials under exceptional circumstances is given to the Minister of Health, who can [then] adopt a regulation greenlighting experimenting germline engineering on humans."[219]

If the administration of HGGE on human beings is anticipated to be inevitable at least somewhere globally, we suggest that it is imperative that HGGE be more optimally and clearly governed through regulatory approaches that clarify whether: (1) it is ethical to implement HGGE in a particular situation and (2) which applications of HGGE must be permitted to be administered on human beings. Indeed, in addition to understanding the permissibility of HGGE interventions, implementing HGGE may require re-evaluating state obligations and stakeholder responsibilities, as mentioned in Chapter 1. This process must start with understanding the ethics of applying certain applications of HGGE on human beings. Only then will it be possible to consider states' obligations to ensuring equity and access of the procedure to diverse populations. We put forth that the current fragmented governance of HGGE globally needs to be addressed and updated to prevent potential misuse of the procedure and protect our collective future.

2. Turning to International Human Rights Law for Legal Clarity

[218] Committee of Social Affairs, Health and Sustainable Development, "The Use of New Genetic Technologies in Human Beings" (24 May 2017), Online: PACE < https://assembly.coe.int/nw/xml/XRef/Xref-XML2HTML-en.asp?fileid=23730&lang=en>.
[219] Andrea Boggio et al., "The Human Right to Science and the Regulation of Human Germline Genome Editing" (2019) 2:3 The CRISPR Journal Online <https://doi.org/10.1089/crispr.2018.0053>; Andrea Boggio et al., "Towards a Human Rights Framework for the Regulation of Human Genome Modification" in Andrea Boggio et al, eds, *Human Germline Modification and the Right to Science* (Cambridge: Cambridge University Press, 2020).

Scholars are actively seeking approaches that may create greater legal clarity informing regulators of the requirements in governing HGGE.[220] Gary E. Marchant, for example, suggested that international governance of HGGE can help "harmonize regulatory requirements" and prevent potential misuse of the procedure.[221] Rumiana Yotova and other human rights scholars are of the opinion that such governance is possible by turning to IHRL.[222] IHRL, they claim, can create enforceable obligations on states, clear responsibilities of healthcare professionals and geneticists, provide best practices for ethical and equitable administration, and therefore aid in achieving consensus and greater legal clarity.[223] Even the Nuffield Council Report authored by Yotova in 2017 suggests that IHRL "is binding on all states without the need of a treaty obligation".[224] Scholars claim IHRL is additionally promising for the ways it includes intergenerational rights, helping to ensure the safety of current and future generations.[225] This section considers whether these claims are valid and applicable to real-world situations. Specifically, we consider whether IHRL can build consensus by clarifying its stance on: (a) the permissibility of HGGE; (b) intergenerational rights; and (c) best practices and ethical guidance for HGGE. We ultimately argue that there are significant limitations to IHLR-based approaches, and that any approach to governing HGGE needs to go beyond this single law framework.

2.1 Is HGGE Permissible Under International Human Rights Law?

We propose to examine two legal questions that need to be better understood to govern HGGE more optimally, and we aim to answer them using IHRL as a framework: (1) whether it is legal to genetically modify the human embryo for reproductive purposes; and (2) whether it is legal to change the genetic characteristics of future offspring. These questions are important. For instance, in Canada, section 5 (1) (f) of the Assisted Human Reproduction Act (2004) expressly prohibits any individual from "knowingly [altering] the genome of a cell of a human being or *in vitro* embryo such that the alteration is capable of being transmitted to descendants."[226] Likewise,

---

[220] See e.g., Yotova, *supra* note 35; Kaan et al., *supra* note 215.
[221] Gary E. Marchant, "Global Governance of Human Germline Genome Editing: What are the Rules?" (2021) 22 Annual Review of Genomics and Human Genetics 385 at 393.
[222] Yotova, supra note 35 at 667, 672; Van Beers, *supra* note 40; Schweikart, *supra* note 41 at 285;
[223] Yotova, supra note 35 at 667, 672; Van Beers, *supra* note 40; Schweikart, *supra* note 41 at 285;
[224] Rumiana Yotova**,** *The Regulation of Genome Editing and Human Reproduction Under International Law, EU Law and Comparative Law* (Nuffield Council on Bioethics, 2017) 5.
[225] Yotova, supra note 35 at 667, 672; Van Beers, *supra* note 40; Schweikart, *supra* note 41 at 285;
[226] *Assisted Human Reproduction Act*, SC 2004, c 2, s 5(1)(f).

in Europe, the EU Regulation 536/2014 on Clinical Trials of Medicinal Products for Human Use also prohibits "gene therapy trials [] which result in modifications to the subject's germline genetic identity."[227] While these laws clearly state that the genetic modifications that HGGE procedures offer are in fact illegal, the important question is whether these laws need to be updated. We turn to IHRL to seek sound answers to these questions and arrive at the best governance approach when states consider updating their regulations on HGGE.

There is no binding international treaty that specifically addresses the governance of HGGE. However, two legal instruments specifically address the permissibility of HGGE: the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Oviedo Convention, 1997) and the Universal Declaration on the Human Genome and Human Rights (UDHGHR, 1997).[228] Before we explain the approach taken by these legal instruments, we would like to provide some context regarding the enforceability of these international instruments on states. The Oviedo Convention is binding on the twenty-nine countries that have ratified it and the UDHGHR is a soft law approach that aims to protect human beings from the ethical consequences and risks arising from developments in human genome research that hold the potential to jeopardize human life and dignity[229]. Given that the Oviedo Convention, managed by the Council of Europe, is regional in its application, there is no binding *international* treaty on HGGE.[230] Going forward, we will discuss provisions from the Oviedo Convention and the UDHGHR that address administering HGGE on human beings.

Scholars consider that Article 13 of the Oviedo Convention and Article 1 of the UDHGHR favour the prohibition of HGGE on humans.[231] Article 13 declares that the human genome can be modified only for "preventive, diagnostic, or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants."[232] As per this provision, all states

---

[227] *Regulation (EU) No 536/2014 of the European Parliament and of the Council on Clinical Trials of Medicinal Products for Human Use*, [2014] OJ L 158/1, art 3(1)(d).
[228] *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine* (Oviedo Convention, 1997), ETS 164, art 13; *Universal Declaration on the Human Genome and Human Rights,* UNESCO, 29th Sess, UN Doc SHS-97/WS-4 (1997), art 1. [UDHGHR]
[229] *Ibid.* See also. International Bioethics Committee**,** *Report of the International Bioethics Committee of UNESCO: The Human Genome and Human Rights* (UNESCO, 1997).
[230] Oviedo Convention, *supra* note 228. See also. Roberto Andorno, "The Oviedo Convention: A European Legal Framework at the Intersection of Human Rights and Health Law" (2005) 2:4 Journal of International Biotechnology Law 133.
[231] Yotova, *supra* note 35 at 669, 657; van Beers, *supra* note 40 at 11; Drabiak, *supra* note 41.
[232] Oviedo Convention, *supra* note 228.

that have ratified the Oviedo Convention are categorically prohibited from engaging in gene editing trials that can lead to human enhancements or affect future generations.[233] Unlike the Oviedo Convention, the UDHGHR does not expressly prohibit gene editing procedures, but Article 1 declares that the human genome is the "common heritage of humanity."[234] Because the human genome belongs to all human beings, it must be protected and not subjected to heritable interventions such as HGGE.[235] A similar reasoning was also adopted by the explanatory report to the Oviedo Convention to justify its restrictive approach: it claims that any potential "misuse of HGGE 'may endanger not only the individual but also the species itself.'"[236] Indeed, these human rights instruments do not support the administration of HGGE on human beings.

Human rights scholars consider that these reservations are not absolute as they do not completely impede the potential administration of the procedure on all humans everywhere.[237] States that have not ratified the Oviedo Convention may still implement HGGE, and the concept of "common heritage" can be interpreted to enabling access to HGGE to all human beings, especially individuals suffering from adverse genetic conditions and/or those unable to have children through other means.[238] In line with this interpretation, we suggest that an evolutive interpretation of IHRL may support the potential successful implementation of the procedure.[239]

In contrast to the restrictive scholarly interpretations of IHRL outlined above, we now wish to provide examples of case law that supports the administration of reproductive technologies such as IVF and HGGE. In the past, states have been directed by regional human rights courts to legalize IVF so that infertile individuals may realize their right to private and family life.[240] In other words,

---

[233] Oviedo Convention, *supra* note 228; Yotova, *supra* note 35.
[234] UDHGHR, *supra* note 228.
[235] See e.g., Parliamentary Assembly of the Council of Europe, *Recommendation 934 on Genetic Engineering*, Doc No 4920 (1982), Online: Council of Europe<http://assembly.coe.int/nw/xml/XRef/Xref-XML2HTML-en.asp?filexml:id=14968&xml:lang=en>.
Council for Responsible Genetics, *Genetic Bill of Rights* (2000), Online: Council for Responsible Genetics <http://www.councilforresponsiblegenetics.org/projects/CurrentProject.aspx?projectId=5>.
[236] Van Beers, *supra* note 40 at 12.
[237] Yotova, *supra* note 35. See also. Andrea Boggio & Rumiana Yotova, "Gene editing of human embryos is not contrary to human rights law: A reply to Drabiak" (2021) 35:9 Bioethics 956.
[238] Kabata & Thaldar, *supra* note 38.
[239] See e.g., Martin Hevia, "From Recognition to Regulation: Access to In Vitro Fertilization and the American Convention on Human Rights" (2013) 25:3 Florida Journal of International Law 453.
[240] Hevis, *ibid.* See also. Merel M. Spaander, "The European Court of Human Rights and the Emergence of Human Germline Genome Editing" (2022) European Journal of Health Law 458.

courts have permitted the administration of IVF once the technology was developed.[241] We suggest that HGGE may similarly be permitted once its technology is further developed. Therefore, the case law concerning IVF may allow us to anticipate how courts may treat HGGE technology in the future.

Our first example is the Murillo Case, which demonstrates the Inter-American Court of Human Rights (IACtHR)'s approach regarding IVF administration in Costa Rica.[242] In 2000, the Supreme Court of Costa Rica declared that IVF was unconstitutional through an interpretation of the right-to-life provision found at Article 4 of the American Convention on Human Rights (ACHR, 1978). The ACHR is a regional human rights treaty binding on the 24 countries that are signatories to the convention.[243] Article 4 of the ACHR states that "every person has the right to have his life respected. This right shall be protected by law, and in general, from the moment of conception."[244] For the IACtHR, the ACHR therefore protects the human embryo "from the moment of conception," and the IVF procedure holds the potential to "jeopardize the life and dignity" of the unborn child.[245]

The dissenting opinion, however, recognized that IVF "is not incompatible with the right to life or human dignity; on the contrary, it constitutes a scientific instrument and technique created to assist humanity, given that infertility […] must be regarded as a genuine disease."[246] The dissent also recognized that "assisted reproduction techniques […] are offered as a way to exercise the legitimate right to human reproduction which, even though it is not expressly recognized in [the] Constitution, is derived from the right of freedom and to self-determination, the right to privacy and family life, and the freedom to found a family."[247] We see similarities here with the arguments supporting the administration of HGGE and those that consider that its administration will endanger human life.

---

[241] See e.g., *Murillo et al. v. Costa Rica* (2012), Inter-Am Ct HR (Ser C) No 257 [Murillo]; *Dickson v. United Kingdom*, [GC], No. 44362/04, [2007] V ECHR 99 [Dickson]; Costa & Pavan v. Italy, No. 54270/10, [2012] II ECHR 703 [Costa & Pavan].
[242] Silvia Serrano Guzmán, "The Transformative Impact of the Artavia Murillo Case on In Vitro Fertilization" in Armin von Bogdandy et al., eds, *The Impact of the Inter-American Human Rights System: Transformations on the Ground* (New York: Oxford University Press, 2024).
[243] *American Convention on Human Rights*, "Pact of San José, Costa Rica," 22 November 1969, 1144 UNTS 123 [ACHR].
[244] ACHR*, ibid*, art 4.
[245] Murillo, *supra* note 241, at 24-25 paras 74, 75.
[246] Murillo, *supra* note 241, at 25-26 para 77.
[247] Murillo, *supra* note 241, at 26 para 77.

Later in 2011, the validity of Costa Rica's restrictions upon its citizens' ability to access IVF was questioned before the IACtHR.[248] In 2012, the IACtHR decided that Costa Rica's ban violated an individual's "right to private and family life and personal liberty and integrity" (Art. 8).[249] To guarantee this right, the court had to consider whether permitting IVF and ensuring individuals' their right to procreate violated the right-to-life provision of the ACHR (Art. 4), which, as mentioned above, indicates that the right to life begins at conception.[250] Does life indeed begin at conception, as enshrined under the ACHR?

Interestingly, in this case, the court chose to answer a different question: how did IVF change traditional understandings of human reproduction, and how does such change lead to new interpretations of Article 4 of the ACHR? The court claimed that "prior to IVF, the possibility of fertilization occurring outside a woman's body was not contemplated scientifically."[251] Thus, the interpretation of "conception" under Article 4 changed by the court recognizing that "some time may elapse between the fusion of the egg and the spermatozoid and implantation."[252] IVF necessitated a redefinition of "conception" for an additional reason: "the scientific evidence agrees in making a difference between two complementary and essential moments of embryonic development: fertilization and implantation."[253] The court highlighted this distinction, emphasizing that it is only after the completion of both cycles "that conception can be understood to have occurred."[254] The court justified its approach by claiming that "an embryo has no chance of survival if implantation does not occur."[255]

The reinterpretation of the term "conception" changed how IVF was regulated in Costa Rica. By recognizing that an IVF embryo is not a living person until implantation, the IACtHR was able to hold that Costa Rica's ban on IVF infringed on an individual's right to private and family life.[256]

---

[248] Murillo, *supra* note 241, at 4 para 1.
[249] ACHR, *supra* note 243, art 8.
[250] ACHR, *supra* note 243, art 4.
[251] Murillo, *supra* note 241, at 53 para 179.
[252] Murillo, *supra* note 241, at 53 para 179.
[253] Murillo, *supra* note 241, at 57 para 186.
[254] Murillo, *supra* note 241, at 57 para 186.
[255] Murillo, *supra* note 241, at 57 para 187.
[256] Valerio et al., *supra* note 102, at 366.

This case not only ensured the legality of IVF in Costa Rica but also throughout the 24 countries under the jurisdiction of the court.

The Murillo Case therefore shows how the interpretation of a regional human rights treaty can influence how individual states govern advances in reproductive technologies.[257] We suggest that as science progresses, courts will interpret human rights instruments to keep up with these scientific advances Today, HGGE challenges traditional legal and scientific understandings by presenting the possibility to modify embryos to cure genetic conditions.[258] Prior to HGGE, there was no need to consider the permissibility of modifying the human embryo under human rights law except in the case of MRT, another ART.[259] We thus agree with scholars who predict that interpretations of human rights and human rights instruments may eventually become more receptive to HGGE because of the potential benefits the technology presents.[260]

The IACtHR's approach to permitting IVF procedures in Costa Rica demonstrates a greater respect towards an individual's private and family life and choice to have a genetically related child.[261] We now turn our focus to European Court of Human rights (ECtHR) to compare its approach to that taken by the IACtHR. Of the several decisions made by the ECtHR regarding these rights, we choose to discuss two judgments that demonstrate that this court also supports an individual's right to private and family life and their choice to have genetically related children.[262] The two judgments we will be discussing are Dickson *v.* United Kingdom (2007) and Costa & Pavan *v.* Italy (2012).[263]

Although states tend to have a greater margin of appreciation over ethically controversial reproductive procedures, the ECtHR has still chosen to limit this margin in instances where it infringes upon an individual's right to a private and family life.[264] For instance, in Dickson, the United Kingdom had denied inmates "access to artificial insemination" to have biological children. The ECtHR considered that this practice amounted to setting a limitation on a prisoner's right to a

[257] Guzmán, *supra* note 242.
[258] Ishii & Beriain, *supra* note 1 at 370.
[259] Reznichenko et al, *supra* note 17.
[260] Kabata & Thaldar, *supra* notes 38; Boggio & Yotova, *supra* note 223; Spaander, *supra* note 240.
[261] Hevia, *supra* note 239; Guzmán, *supra* note 242.
[262] Dickson, *supra* note 241; Costa & Pava, *supra* note 241.
[263] Dickson, *supra* note 241; Costa & Pava, *supra* note 241.
[264] Spaander, *supra* note 240.

private and family life[265] forcing states to recognize these rights of inmates.[266] Similarly, in Costa & Pavan, the court recognized that Italy had infringed upon an individual's right to private and family life by denying them an opportunity to carry a healthy child through PGD and IVF.[267] In this case, the court noted that Italy permitted abortions of deformed foetuses or foetuses carrying a genetic condition, but still denied its citizens use of ARTs that could help prevent abortions by helping parents carry healthy children.[268] The ECtHR limited the margin of appreciation of Italy to decide its citizens' reproductive futures and recognized the rights of parents "to bring a child into this world who is not affected by the illness that they carry."[269]

Despite restrictive approaches taken by states to enable access to ARTs, the above mentioned decisions of the ECtHR and IACtHR evidence a trend towards greater recognition of reproductive rights, which can in turn enable better access to reproductive technologies. Recognizing this in his 2022 article, Spaander mentions that the right to access ARTs for therapeutic purposes is primarily protected under Article 8, the right to a private and family life provision of the ECHR.[270] Specifically, he considers that the scope of this right increases with advances in ARTs.[271] Considering the approach taken by the court, he rightly states, "the increasing focus on personal autonomy with regard to assisted procreation accentuates the 'empowering' dimension of human dignity."[272] Spaander thus suggests that the greater personal autonomy guaranteed by regional courts can perhaps encourage states to consider HGGE more favourably and one day even permit parents to change the unfavourable genetic characteristics of their offspring.[273]

However, some scholars consider that human rights treaties or approaches employed by regional courts in governing other ARTs do not necessarily favours the administration of HGGE to humans.[274] For instance, Drabiak, claims that the Nuffield Council's stance regarding HGGE is

---

[265] Dickson, *supra* note 241, at para 62.
[266] Spaander, *supra* note 240 at 468.
[267] Costa & Pavan, *supra* note 241.
[268] Stefano Biondi, "Access to medical-assisted reproduction and pgd in Italian law: a deadly blow to an illiberal statute? Commentary to the European Court on Human Rights's decision Costa and Pavan v. Italy) (2013) 21:3 Med Law Rev 474.
[269] Kjell Asplund, "Use of in vitro fertilization – ethical issues" (2020) 125:2 Ups J Med Sci 192 at 195.
[270] Spaander, *supra* note 240.
[271] Spaander, *supra* note 240, at 466.
[272] Spaander, *supra* note 240, at 471.
[273] Spaander, *supra* note 240.
[274] Drabiak, supra note 41; Boggio & Yotova, *supra* note 236.

against fundamental human rights law.[275] Recall from Chapter 1 that the Nuffield Council regards HGGE as an "ethically acceptable" procedure that can be administered on humans provided "the risks of adverse outcomes have been assessed and the procedure appears reasonably safe."[276] Drabiak argues that the human embryo should be regarded as a living person, and therefore genetically modifying them without their consent is equivalent to "failing to recognize the status of the embryo or foetus as a juridical person."[277] She concludes that such failure to recognize the embryo as a legal person "harms human dignity because it denies any rights absolutely and renders the embryo or foetus vulnerable."[278] Following Drabiak, should the human embryo be protected as a "juridical person" against unnatural procedures such as HGGE?[279] If so, can this right outweigh parental decision-making and the states' responsibility to guarantee greater reproductive autonomy?

2.2 How Do Approaches Recognizing Intergenerational Rights Affect the Governance of HGGE?

To answer whether future generations have a right to an unmanipulated genome, some scholars consider whether it is recognized under the broad category of rights of the future person or intergenerational rights.[280] We consider some provisions from international instruments to understand their stance on germline modifications. We already discussed how the Oviedo Convention took a negative stance on administering HGGE to humans and the UDHGHR found the human genome to be the "common heritage" of mankind and regarded HGGE modifications in a similar light. Other international instruments we examined also take a protective stance towards modifying the human genome considering the effect that the procedure can have on future generations. For instance, Article 6 of the United Nations Declaration on the Responsibilities of Present Generations Towards Future Generations states that "scientific and technological progress should not in any way compromise the preservation of the human and other species."[281] Additionally, Article 16 of the Universal Declaration on Bioethics and Human Rights (UDBHR,

[275] Drabiak, supra note 41, at 224.
[276] Nuffield Council, *supra* note 72.
[277] Drabiak, *supra* note 41, at 226.
[278] Drabiak, *supra* note 41, at 226.
[279] Drabiak, *supra* note 41, at 226.
[280] Nadia Primc, "Do we have a right to an unmanipulated genome? The human genome as the common heritage of mankind" (2020) 34:1 Bioethics 41; Drabiak, *supra* note 41.
[281] *Declaration on the Responsibilities of Present Generations Towards Future Generations*, UNESCO, 29th Sess, UN Doc 29 C/Resolution 44 (1997).

2005) states that "the impact of life sciences on future generations, including on their genetic constitution, should be given due regard."[282] These international instruments clearly adopt a precautionary tone towards modifying the human genome. Several scholars also approach governing HGGE from the perspective of protecting the foetus or unborn child from non-consensual germline modifications.[283]

During the framing of the UDHGHR in 1996, the International Bioethics Committee (IBC) argued that the human genome should join space, the moon, and the deep-sea bed, among others, as the common heritage of humanity, and the UDHGHR affirmed this status.[284] The common heritage doctrine (CHD) protects these shared resources from commercialization or commodification.[285] Ossorio outlines the "integral elements" of the CHD as follows: "(1) no single entity can have sovereignty over, or unilaterally appropriate, the resource or territory in question; (2) all countries will share in a management authority of some sort, which will manage the resource or territory for the 'benefit of all humanity'; (3) benefits from the exploitation of the territory or the resource will be actively shared among nations; and (4) the area will be used only for peaceful purposes."[286]

Kabata and Thaldar consider that this common heritage status is a result of developments such as the Human Genome Project that mapped the human genome, which gave way to greater scientific progress and increased the potential of appropriation and exploitation of information about the human genome by a few privileged stakeholders.[287] Scholars argue that because the human genome belongs to all human beings, everyone should benefit similarly from advances in genomics; the human genome, in other words, does not belong to one person and nor can its benefits be limited to a specific country or group of people.[288] These scholars suggest that the same reasoning applies to the context of HGGE , i.e., individuals should be able to enjoy advances in genomics such as HGGE. The problem here is that the same doctrine can also be interpreted as an

[282] *Universal Declaration on Bioethics and Human Rights*, UNESCO, 33rd Sess, UN Doc SHS/EST/05/CONF.204/3 REV.2 (2005). [UDBHR]
[283] Drabiak, supra note 41; See also. Liu, *supra* note 31.
[284] Kabata & Thaldar, *supra* note 38, at 2.
[285] Kabata & Thaldar, *supra* note 38, at 2.
[286] Pilar N. Ossorio, "The Human Genome as Common Heritage: Common Sense or Legal Nonsense?" (2007) 25:3 J Law Med Ethics 425 at 427.
[287] Kabata & Thaldar, *supra* note 38, at 2.
[288] Kabata & Thaldar, *supra* note 38.

approach that favours the preservation of the human genome for future generations—which is to say an unedited human genome.[289] This interpretation favours a protective attitude towards HGGE. Because of these differing interpretations, we consider it crucial that there be greater clarity at the international level on how states should interpret what the common heritage status means for the research and administration of HGGE.

Primc specifically considers whether "future generations [should] be granted a genuine right to inherit a genome unaltered by technical means."[290] She examines two justifications typically given to facilitate such a right and considers their implications. First is the argument that claims the genome should not be subjected to editing because of safety concerns. She considers this argument insufficient to prevent states from implementing HGGE if such concerns have been addressed adequately, noting that "one does not need the concept of [common heritage of humanity] to defend the right of prospective newborn babies not to be harmed of biomedical interventions."[291] Second, she considers the argument that a "'naturally' evolved genome" [292] is crucial to "our humanness and common human nature."[293] Primc claims that although this argument merits further discussion, merely altering a defective gene to prevent severe genetic diseases will not change the genetic constitution of a human being.[294] Individuals who have undergone HGGE procedures will still belong to the "human family."[295] She thus considers that the human genome's common heritage of humanity status cannot be used as an argument to prevent HGGE from being implemented, especially if the procedure "is restricted to the prevention of severe diseases and [is] made equitably accessible to the whole of humanity."[296] As we can see, despite the objections and protective approaches observed in scholarship, there is still a possibility that IHRL can be interpreted to support the administration of HGGE.

Here we find it appropriate to highlight the assertions put forth by Boggio and Yotova arguing against Drabiak's claim that fundamental human rights law does not support making

[289] Primc, *supra* note 280.
[290] Primc, *supra* note 280, at 44.
[291] Primc, *supra* note 280, at 44.
[292] Primc, *supra* note 280.
[293] Primc, *supra* note 280, at 44.
[294] Primc, *supra* note 280, at 46.
[295] Primc, *supra* note 280.
[296] Primc, *supra* note 280, at 44.

heritable genetic modifications to the human embryo.[297] Drabiak asserts that international instruments such as the "Oviedo Convention[298], the EU Charter on Fundamental Rights[299], the Genocide Convention[300], [the EU Directive on the Protection of Biotechnology][301], and the EU Regulation of Clinical Trials specifically[302] [prohibit] modifications to the human genome and [recognize] a right to genetic integrity."[303] In response, Boggio and Yotova claim that by relying on these human rights instruments because they address germline editing, Drabiak has limited herself to considering regional treaties that do not adequately address HGGE and potential scientific progress.[304] The Oviedo Convention's prohibition on HGGE is binding on the 29 EU member states that have ratified it, but the convention does "not [represent] the legal consensus with the region, let alone a global one."[305] They also claim that except for the Genocide Convention, all other legal instruments that Drabiak relies upon are more regional in their scope of applicability.[306] They dismiss Drabiak's claim that the UN Genocide Convention prohibits germline modifications to preserve the integrity of the human genome because the convention was adopted in 1948—before the human genome was discovered.[307] They thus claim that the instruments that Drabiak uses to argue that human germline modifications are against fundamental human right law are insufficient, which nullifies her argument.

To refute Drabiak's claim, Boggio and Yotova interpret specific provisions from legal instruments of a more universal character to support HGGE.[308] Moreover, they suggest that the right to health and to benefit from scientific progress guaranteed under the International Bill of Human Rights can be interpreted as favouring the equitable availability of HGGE.[309] Furthermore, the "legal standard invoked by Drabiak as a basis for prohibiting HGGE," such as "the rights and

---

[297] Drabiak, *supra* note 41; Boggio & Yotova, *supra* note 237.
[298] Oviedo Convention, *supra* note 228.
[299] *Charter of Fundamental Rights of the European Union (2012),* 2012/C 326/02 at Art 3, prohibits "eugenic practices, in particular those aiming at the selection of persons".
[300] *Convention on the Prevention and Punishment of the Crime of Genocide* (Genocide Convention, 1948), 9 December 1948, 78 U.N.T.S. 277 (entered into force 12 January 1951). Yotova, *supra* note 224 at 13-14.
[301] *Directive 98/44/EC of the European Parliament and of the Council on the Legal Protection of Biotechnological Inventions* (1998), OJ L 213/13, p. 13–21
[302] *Regulation (EU) No 536/2014*, *supra* note 214.
[303] Drabiak, *supra* note 41, at 226.
[304] Boggio & Yotova, *supra* note 237, at 957.
[305] Boggio & Yotova, *supra* note 237, at 958.
[306] Boggio & Yotova, *supra* note 237, at 958.
[307] Boggio & Yotova, *supra* note 237, at 958.
[308] Boggio & Yotova, *supra* note 237, at 957.
[309] Boggio & Yotova, *supra* note 237, at 961.

integrity of the future child," is a legal standard that is in fact "unknown in international law."[310] Instead, Boggio and Yotova consider the International Covenant on Civil and Political Rights (ICCPR, 1976)[311], the International Covenant on Economic Social and Cultural Rights (ICESCR, 1976)[312], the Universal Declaration of Human Rights (UDHR, 1948)[313], which together form the International Bill of Human Rights, and the UDHGHR.[314] They argue that Drabiak cannot claim that HGGE is against fundamental human rights law without considering these international instruments because they "represent the international community's consensus as a whole with respect to human rights standards."[315]

Indeed, as Boggio and Yotova highlight, the ICCPR is binding on the 173 states that have ratified it, and the ICESCR is binding on the 171 states that have ratified it, making these legal instruments more "universal" than the regional ones relied upon by Drabiak.[316] They argue that the "right to life" (Art. 6, ICCPR), "the right to health" (Art. 12, ICESCR), and "the right to enjoy the benefits of scientific progress" (Art. 15, ICESCR) can be interpreted in favour of HGGE.[317] First, they present that the right to life of the unborn child is not absolute. Second, they argue that HGGE is borne out of scientific progress and therefore should be equitably available to enable individuals to reach their "highest achievable standards of health."[318] Lastly, Boggio and Yotova find the UDHGHR adopted by 184 member states is also in favour of HGGE as it claims that the human genome "evolves by its nature and is subject to constant mutations."[319] Citing these universal approaches, they present that HGGE is not against IHRL and suggest that individuals must benefit from HGGE.[320]

---

[310] Boggio & Yotova, *supra* note 237, at 961.
[311] *International Covenant on Civil and Political Rights***,** GA Res 2200A (XXI), UN GAOR, 21st Sess, Supp No 16, UN Doc A/6316 (1966), 999 UNTS 171 (entered into force 23 March 1976). [ICCPR]
[312] *International Covenant on Economic, Social and Cultural Rights,* GA Res 2200A (XXI), UN GAOR, 21st Sess, Supp No 16, UN Doc A/6316 (1966), 993 UNTS 3 (entered into force 3 January 1976). [ICESCR]
[313] *Universal Declaration of Human Rights***,** GA Res 217A (III), UN GAOR, 3rd Sess, Supp No 13, UN Doc A/810 (1948).
[314] Boggio & Yotova, *supra* note 237, at 960.
[315] Boggio & Yotova, *supra* note 237, at 957.
[316] Boggio & Yotova, *supra* note 237, at 957.
[317] Boggio & Yotova, *supra* note 237, at 957.
[318] Boggio & Yotova, *supra* note 237, at 957.
[319] Boggio & Yotova, *supra* note 237, at 957.
[320] Boggio & Yotova, *supra* note 237, at 957.

States envisaging permitting HGGE must consider legally permitting scientists to modify the human germline; in many cases, this will require states to legalize genetically modifying the human embryo.[321] Several scholars therefore consider that the implementation of HGGE will be impacted by the laws governing human embryos, which are considered relatively reflective of the ethical and moral stance states take towards human embryos.[322] For instance, Germany has a positive obligation to protect human embryos, which has resulted in the prohibition of research on human embryos.[323] The United Kingdom, on the other hand, does not provide any specific status to the human embryo and therefore was one of the first countries to permit HGGE trials on human embryos as early as 2016.[324] Canada, despite not providing any special status to the human embryo, has not clarified its stance.[325]

In light of this fragmented approach to human embryo protection, scholars turn to human rights treaties and other regional and domestic courts for greater legal clarity.[326] The ECtHR's approach was determined by first answering whether the unborn child has a right to life, a question answered during Vo *v.* France, where the court had to consider the liability of a physician for unintentionally killing the unborn child.[327] Here the court also had to answer whether the unborn child was recognized a living person under Article 2, the right to life provision of the ECHR.[328] The court found that an "unborn child is not regarded as a 'person' directly protected by Article 2 of the Convention and that if the unborn do have a 'right to life,' it is implicitly limited by the mother's rights and interests."[329] It further clarified that "it may be regarded as common ground between states that the embryo/foetus belongs to the human race."[330] "The potentiality of that being

[321] Baylis et al, *supra* note 155.
[322] Baylis et al, *supra* note 155. See also. Takis Vidalis, "Genome Editing in Human Gametes and Embryos: The Legal Dimension in Europe" (2023) 12:1 Biotech 1; Rosario Isasi et al., "Mending the Gap: Ethically Sensitive Cells and the Evolution of European Stem Cell Policy" (2022) 17:8 Regen Med. 581 at 581-595.
[323] Sven Pompe et al., "Stem-cell research: the state of the art" (2005) 6:4 EMBO Rep 297. See also. Keren Goldberger, "The Clone Wars: The Right to Embryonic Gene Editing Under German Law" (2019) 45:1 Brooklyn Journal of International Law 404 at 424.
[324] Robin Lovell-Badge, "The regulation of human embryo and stem-cell research in the United Kingdom" (2008) 9:12 Nat Rev Mol Cell Bio 998. See also. G Bahadur, "The moral status of the embryo: the human embryo in the UK Human Fertilisation and Embryology (Research Purpose) Regulation 2001 debate" (2003) 7:1 Reproductive Biomedicine Online < https://www.sciencedirect.com/science/article/abs/pii/S1472648310617221>.
[325] Knoppers et al., *supra* note 190. See also. Bartha M. Knoppers et al., "The Human Embryo: Ethical and Legal Aspects" (2009) 550 Methods Mol Biol 281.
[326] Yotova, *supra* note 35; Van Beers, *supra* note 40; Drabiak, *supra* note 41.
[327] *Vo v. France* [GC], No. 53924/00, [2004] VIII ECHR 65 [Vo].
[328] Trees A.M. Te Braake "Does the fetus have a right to life? The case of Vo v. France" (2004) 11:4 European Journal of Health Law 381.
[329] Vo, *supra* note 327, at para 80.
[330] Vo, *supra* note 327, at para 84.

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."[331] The ECtHR provides a helpful framework: it is imperative to consider how states balance the interests of the human embryo, arising from its potential to develop into a human being, with the interests of the mother and other individuals who may be impacted by the way states recognize and protect the foetus.[332]

Indeed, two German Constitutional Court decisions about abortion also address the importance of balancing the interests of the current generation with that of the unborn child.[333] To do so, the court had to consider the state's duty to protect the right of the mother to make reproductive decisions as well as the state's duty to protect the future child from harm.[334] The first German Constitutional Court decision highlighted the state's positive obligation to protect the unborn child and found criminalizing abortions to be one way the state can perform this obligation.[335] However, this decision was critiqued by several human rights scholars because it undermined women's right to make their reproductive choices.[336] The second court decision, however, considered that the "states obligation to protect life is not so absolute that it even takes priority, without exception, over every other legal value."[337] The court claimed that the state may still protect the unborn child by offering counselling to pregnant women without the threat of criminal punishments.[338] Still, the court noted that the state must work to "preserve and revive the public's general awareness of the unborn's right to protection."[339] Despite this decision, today Germany does permit PGD on a case-by-case basis.[340] This nuanced example demonstrates how

[331] Vo, *supra* note 327, at para 84.
[332] Rhonda Copelon et al., "Human Rights Begin at Birth: International Law and the Claim of Fetal Rights" (2005) 13:26 Reproductive Health Matters 120.
[333] Vanessa MacDonnell & Jula Hughes, "The German Abortion Decisions and the Protective Function in German and Canadian Constitutional Law" (2013) 50:4 Osgoode Hall Law Journal 999.
[334] MacDonnell & Hughes, *ibid,* at 1001.
[335] MacDonnell & Hughes, *supra* note 333 at 1001; Schwangerschaftsabbruch I, (1975) 39 BVerfGE 1 (Fed Const Ct) (Germany) [First Abortion decision].
[336] Reva Siegel, 'Constitutionalization of Abortion', in Michel Rosenfeld and András Sajó, *Oxford Handbook of Comparative Constitutional Law* (Oxford, Oxford University Press, 2012); Albin Eser, "Reform of German Abortion Law: First Experiences" (1986) 34:2 Am J Comp L 369.
[337] MacDonnell & Hughes, *supra* note 333*;* Schwangerschaftsabbruch II, (1993) 88 BverfGE 203 (Fed Const Ct) (Germany) [Second Abortion decision] at para 153.
[338] MacDonnell & Hughes, *supra note* 333 at 1017.
[339] Schwangerschaftsabbruch II, *supra* note 337, headnote, at 10; MacDonnell & Hughes, *supra* note 333.
[340] Bartha M. Knoppers & Priya Ayyappaswamy, "International Comparative Perspectives on Human Embryo Research" (Unpublished, 2022); Hilary Bowman-Smart et al, "Non-invasive prenatal testing in Germany: a unique ethical and policy landscape" (2023) 31:5 Eur J Hum Genet 562.

novel ART procedures may be permitted even in states with protective laws in place for human embryos;[341] indeed, perhaps Germany may also one day come to favour HGGE.

Some scholars find favouring of HGGE in the International Bill of Human Rights.[342] They suggest that the bill's guaranteed right to benefit from scientific progress and the right to achieve the highest standards of health can be interpreted as favouring the procedure in cases where it resolves chronic and heritable genetic conditions.[343] Furthermore, scholars find the lack of explicit prohibition on HGGE when textually interpreting the UDHGHR, despite the IBC's stance being more favourable to prohibiting HGGE to mean that the UDHGHR does not prohibit HGGE.[344] Boggio and Yotova also support this assertion.[345] Considering that there is no explicit international ban on HGGE, apart from the Oviedo Convention prohibiting germline modifications on the 29 states that have ratified it, scholars conclude that states may implement HGGE.[346] In this scenario—where HGGE is not prohibited under IHRL—it is thus important to consider whether IHRL also offers some ethical guidance on best practices to administering HGGE.

2.3 Does IHRL Provide Insight into HGGE Best Practices and Ethical Guidance?

Fundamental human rights law does not bar HGGE, and states are not barred under general international law if they choose to administer it. Some scholars are thus concerned about differing interpretation of IHRL regarding the administration of the procedure.[347] We thus now consider whether such interpretations can affect governing HGGE more optimally and whether regional courts provide better insight regarding best practices.

Yotova and other scholars regard the provisions contained within the following international legal instruments to consider HGGE best practices: the Universal Declaration of Human Rights

---

[341] Knoppers & Ayyappaswany, *ibid.*
[342] Yotova, *supra* note 35; Van Beers, *supra* note 40; Yotova, *supra* note 224; Boggio & Yotova, *supra* note 237.
[343]Yotova, *supra* note 35; Van Beers, *supra* note 40; Yotova, *supra* note 224; Boggio & Yotova, *supra* note 237.
[344] The IBC in its 2015 report recommended a moratorium for HGGE. International Bioethics Committee (IBC), *Report of the IBC on Updating Its Reflection on the Human Genome and Human Rights* (UNESCO, 2015) at para 118-121. Boggio & Yotova, *supra* note 223, at 958.
[345] Boggio & Yotova, *supra* note 237, at 958.
[346] Boggio & Yotova, *supra* note 237.
[347] Yotova, *supra* note 35; Van Beers, *supra* note 40; Drabiak, *supra* note 41; Spaander, *supra* note, 240.

(UDHR, 1948)[348], the Universal Declaration on Bioethics and Human Rights (UDBHR, 2005)[349], the Convention on the Rights of the Child (CRC, 1989), the UDHGHR (1997)[350], and the International Covenant on Economic Social and Cultural Rights (ICESCR, 1976)[351]. The legal approaches suggested by these instruments include guaranteeing the right to life, the right to health, the right to benefit from scientific progress, human dignity, and the rights against discrimination, among others.

For instance, the UDHR states that "all human beings are born free and equal in dignity" and that "everyone has the right to life, liberty, and the security of person" (Article 1 and 3).[352] States have a positive obligation to ensure that they regard all human beings similarly without discrimination and guarantee their right to live freely and securely. Some scholars state that apart from protecting human life, states also have an obligation to ensure that individuals can "share in scientific advancements and its benefits," mentioned at Article 27 of the UDHR, and "enjoy the benefits of scientific progress and its applications" mentioned at Article 15 of the ICESCR.[353] However, states also have the duty to act with due diligence and prevent harm.[354] Article 3 (2) of the UDBHR recognizes the importance of safety of the individual over science or society.[355]As we can observe, IHRL requires that states guarantee their citizens human rights.

The UDBHR also states that that the benefits to research participants arising from science must be increased and that the risks to participants should be reduced (Article 4).[356] This declaration explicitly highlights the need to consider the risks to future generations and insists that the uniqueness of their genetic constitutions should be given proper consideration, as should risks associated with life sciences and technology (Article 16 & 20), articles that can be directly applicable to states as they consider how to administer HGGE.[357] The UDHGHR, on the other hand, suggests that diagnostic and therapeutic interventions on the human genome must be carried

[348] UDHR, *supra* note 313.
[349] UDBHR, *supra* note 282.
[350] *Convention on the Rights of the Child,* GA Res. 44/25, UN GAOR, 44th Sess., Supp. No. 49, UN Doc. A/44/49 (1989), 1577 UNTS 3 (entered into force 2 September 1990) 167. [CRC]
[351] ICESCR, *supra* note 312.
[352] UDHR, *supra* note 313.
[353] ICESCR, *supra* note 312; UDHR, *supra* note 313. See also. *Boggio* et al (2019), *supra* note 219.
[354] *Boggio* et al (2019), supra note 219.
[355] UDBHR, *supra* note 282.
[356] UDBHR, *supra* note 282.
[357] UDBHR, *supra* note 282.

out after careful study (Article 5 (a)), and that interventions on the human genome must only be performed if they relieve suffering (Article 12 (b)).[358] Some scholars use this article to argue that HGGE should only be performed as a treatment, not as an enhancement.[359]

To protect the diversity of the human genome, Article 2 of the UDHGHR recognizes that human dignity "makes it imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity."[360] The CRC recognizes "the right of the child to the enjoyment of the highest attainable standards of health and to facilities for the treatment of illness and rehabilitation of health" (Article 24).[361] Herein lies the difficulty of interpretation: the CRC's provision can be understood to appreciate scientific discoveries such as HGGE from which all human beings, especially children can enjoy the "highest attainable standards of health,"[362] whereas the UDHGHR encourages a more responsible and prudent approach towards benefiting from research and scientific progress.[363]

This nuance, we suggest, is important. These international instruments create the obligation of states to govern HGGE with diligence while still appreciating individuals' right to benefit from scientific progress. However, interpretations may indeed vary widely, and IHRL does not provide the answers to specific questions that may arise in governing HGGE, such as when a particular application of HGGE does not necessarily affect human dignity or when the procedure can be administered to improve the future child's health outcomes. In these cases, when states seek guidance regarding an ethical or scientific question for which there is no international legal or moral consensus, the decision-making is deferred to states. This is evident in the ECtHR case law examples: although human rights courts are more favourable to ARTs when it comes realizing reproductive rights, the ECtHR still deferred to states when presented with complex ethical and legal questions.[364]

---

[358] UDHGHR, *supra* note 228.
[359] Van Beers, *supra* note 40 at 24; Schweikart, *supra* note 41 at 291.
[360] UDHGHR, *supra* note 228.
[361] CRC, *supra* note 350.
[362] CRC, *supra* note 350.
[363] UDHGHR, *supra* note 228.
[364] Spaander, *supra* note 240.

In Parrillo *v*. Italy, as an example, Ms. Adelina Parrillo claimed that section 13 of the Italian Law no. 40/2004 prohibited her right to donate embryos for research purposes.[365] The ECtHR recognized that this situation did not interfere with her "right to respect for her private life" guaranteed under Article 8 of the ECHR because "the government has not overstepped the wide margin of appreciation enjoyed by them in the present case and that the ban in question was 'necessary in a democratic society.'"[366] Similarly, in A B C *v.* Ireland, the court considered whether it was "legitimate for a state to consider the unborn to be a person and to aim to protect that life."[367] Here, the ECtHR found that "the question of when the right to life begins is within the states' margin of appreciation because there was no European consensus on the scientific and legal definition of the beginning of life so that it was impossible to answer the question whether the unborn was a person to be protected for the purpose of Article 2."[368] In each decision, the ECtHR deferred to the states because of the lack of European consensus on the topic.

Similarly, in Evans *v.* United Kingdom, the ECtHR examined whether a British law that required both genetic parents' consent to implant IVF embryos violated Ms. Evan's right to private and family life.[369] The ECtHR considered whether the rights of the mother were greater than the rights of the father, should he refuse implantation of the embryo to which both contributed their reproductive material.[370] Here the court answered that the right of one genetic parent who wishes to have the child cannot be greater than the right of the genetic parent who refuses implantation.[371] Indeed, the court stated that, "regard must be had to the fair balance which has to be struck between competing interests [of the genetic parents]; and in both contexts, the state enjoys a certain margin of appreciation."[372] Such jurisprudence suggests a trend where "there is no clear common ground amongst member states [and] the margin of appreciation afforded to the respondent state must be a wide one."[373]

---

[365] *Parrillo v. Italy* [GC], No. 46470/11, [2015] V ECHR 95 [Parrillo]; Jessica Giles & Simon Lee, "Parrillo v. Italy: Is there life in the European Court of Human Rights" (2016) 5:1 Oxford Journal of Law and Religion 162.
[366] Parrillo, *ibid*, at para 3 & 197.
[367] *A.B.C. v Ireland* [GC], No. 25579/05, [2010] ECHR 2032 at para 222 [ABC].
[368] ABC, *ibid*, at para 185.
[369] *Evans v. United Kingdom* (2007), No. 6339/05, [2007] ECHR 264 [Evans]. Caroline Morris, "Evans v. United Kingdom: Paradigms of Parenting" (2007) 70:6 The Modern Law Review 992.
[370] Evans, *ibid*.
[371] Morris, *supra* note 369.
[372] Evans, *supra* note 369, at para 75.
[373] Evans, *supra* note 369, at para 81.

Despite the fact that governing ethical and legal concerns is done through national lawmaking processes, one may argue that the CESR's General Comment no. 14 on the Right to the Highest Attainable Standard of Health (Art. 12, ICESCR) places an obligation on states to ensure that stakeholders—such as "health professionals, families, local communities, intergovernmental and non-governmental organizations, civil society organizations," etc.[374]—are enabled to perform their duties appropriately and have "responsibilities regarding the realization of the right to health."[375] It also places upon states an obligation to provide "international assistance, especially economical and technical,"[376] to "developing countries to fulfill their core [human rights] and other obligations."[377] These obligations can be considered foundational to equitable and ethical governance of HGGE; however, the lack of specificity about how states may prescribe duties to stakeholders such as healthcare professionals is concerning.[378] Also, states can only come to rely on such non-binding directives regarding their obligations if there is consensus that administering HGGE is crucial to improve health outcomes, which in turn creates a right to access the procedure. Here again we encounter the critical limitations of IHRL.

The right to health and the right to benefit from scientific progress as outlined by IHRL create obligations on states to create national laws and guidelines that can guarantee these rights in their territory. However, the lack of ethical and moral consensus on research that permanently modifies human embryos is affecting states' ability to do this.[379] For instance, some scholars cite CESR's General Comment no. 17, which places an obligation on states to "safeguard the freedom of research" (Art. 15, ICESCR), as evidence that states are obligated to permit their scientists to conduct HGGE research.[380] Indeed, bioethics reports, and the international community of scholars are advocating for states to permit scientists to conduct research on HGGE and thereby realize the right to science.[381] Despite this directive and strong recommendation from the international research community, states such as Canada that have ratified the ICESCR are yet to permit HGGE

[374] ICESCR, supra note, 312; UN Committee on Economic, Social and Cultural Rights, General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art 12 of the Covenant) (11 August 2000) UN Doc E/C.12/2000/4; Zahara Nampewo et al., "Respecting, Protecting, and Fulfilling the Human Right to Health" (2022) 21:36 International Journal for Equity in Health Online < https://doi.org/10.1186/s12939-022-01634-3>.
[375] Nampewo, *ibid*.
[376] Nampewo, *supra* note 374.
[377] Nampewo, *supra* note 374.
[378] Nampewo, *supra* note 374.
[379] Iltis primarily discusses the ethical and moral concerns in governing embryoids but since HGGE also raises similar ethical concerns to this reference. Iltis, *supra* note 199 at 9.
[380]Boggio & Yotova, *supra* note 237; Yotova, *supra* note 35; *Boggio* et al (2019), *supra* note 219.
[381]Boggio et al., *supra* note 219; Bioethics Reports [Nuffield Council & International Commission] *supra* note 72.

research in their territory.[382] We thus suggest that IHRL currently provides too wide a margin of appreciation to states, which contributes to the fragmentary lack of global consensus and the stalled progress of humanity's potential benefit from HGGE.

The main limitation of this chapter is that it demonstrates *our* perspective in answering questions *we* have selected. Because governing HGGE requires us to observe its scientific progress in a regulatory environment strife with lack of ethical, moral consensus on key approaches to govern the technology, these answers could indeed be answered differently by another scholar. Likewise, states can also interpret IHRL in a different manner and either take a positive or protective approach towards governing the procedure. One can even argue that such differences in interpretation of IHRL—as observed in the difference between Drabiak's and Boggio and Yotova's arguments—demonstrates that as of now it will be short-sighted to use IHRL as the sole approach to govern HGGE.[383]

3. Limitations of Employing IHRL as the Sole Approach to Governing HGGE

This chapter has considered human rights treaties, their scholarly interpretations, and regional human rights decisions to answer our questions about the proper governance of HGGE. IHRL does not dispel the ambiguity states face in answering quite basic questions, such as whether HGGE can be administered on human beings, whether specific applications of HGGE should be permitted, and the obligations of states. IHRL provides insight to some approaches of governance, but it leaves questions on the ethical and equitable administration open to state interpretation and therefore does not solve the problem of creating greater clarity or consensus. Thus, IHRL alone cannot provide states with the answers needed to safely and lawfully govern HGGE.

IHRL is useful in its creation of the state's obligation to provide its citizens with the benefit of scientific progress, yet scholars consider it difficult to argue for its use in the implementation of HGGE because of the critical lack of consensus globally.[384] If IHRL provides a wide margin of appreciation when it comes to answering unique legal questions for which there is no international

[382] Medina Abdelkader, "Towards an equity-driven regulatory framework for germline editing: Considerations for amending the Assisted Human Reproduction Act" (3 August 2021), Online: The Canadian Bar Association < https://www.cba.org/Sections/Health-Law/Resources/Resources/2021/HealthEssayWinner2021>.
[383] Drabiak, *supra* note 41; Boggio & Yotova, *supra* note 237.
[384] Yotova, *supra note* 35; Schweikart, *supra* note 41.

consensus, it also means that if IHRL is adopted as the sole approach to governing HGGE, states will have a greater margin of appreciation in governing the procedure.[385] In other words, IHRL cannot be used as the sole governing approach to HGGE because it fails to build consensus—one of the primary issues at stake—especially concerning whether specific applications of HGGE should be permitted to improve human health. Remember that the Oviedo Convention imposes a prohibition on HGGE, and some scholars use this prohibition to state that fundamental international human right law prohibitions HGGE, while other scholars find that general international law does not necessitate such a prohibition.[386] Such differences in scholarly interpretations of IHRL can deter certain states from the potential revolutionary benefits of HGGE. IHRL thus has significant limitations as the sole approach to governance.

Such ambiguity can also affect stakeholders because there are different ethical, moral, religious sentiments attached to administering the procedure on human beings. Some scholars thus argue that broad consultations with stakeholders who attach certain beliefs to modifying the human germline are required to determine the right path forward.[387] Indeed, bioethicists are considering governance approaches that broadly include the positive and negative sentiments of several stakeholders.[388] Supporting this recommendation, some scholars claim that increasing public knowledge about the procedure can help dispel misconceptions and thereby facilitate governing HGGE more optimally.[389] Even the WHO has confirmed that it will consult with diverse stakeholders to govern HGGE more optimally.[390] Following this movement, Chapter 3 considers "inclusive global governance" as one possible approach to optimal HGGE governance.

---

[385] Spaander, *supra* note 240.
[386] Drabiak, *supra* note 41; Boggio & Yotova, *supra* note 237.
[387] See e.g., Yu et al., *supra* note 43; Jasanoff et al, *supra* note 45.
[388] Ana S. Iltis et al., "Public & Stakeholder Engagement in Developing Human Heritable Genome Editing Policies: What Does it Mean and What Should it Mean" (2021) 3 Frontiers in Political Science, online: <https://www.frontiersin.org/articles/10.3389/fpos.2021.730869>; John P. Nelson et al., "Towards Anticipatory Governance of Human Genome Editing: A Critical Review of Scholarly Governance Discourse" (2021) 8:3 J Responsible Innov 382.
[389] *Ibid.*
[390] WHO Report, *infra* note 423.

Inclusive Global Governance May Facilitate Optimal Governance of HGGE and Encourage and Clarify the Obligations of States

Chapter 3: Suggesting Inclusive Global Governance for HGGE

Our discussion of global governance asks the question of whether states' human rights obligations under IHRL oblige them to either administer HGGE ethically or prohibit it altogether. As discussed in chapter 2, several prominent human rights scholars have interpreted fundamental human rights law to answer this question. However, their opinions and interpretations of IHRL differ. This has led to a general lack of consensus in scholarly understanding of states' obligations under human rights law to govern HGGE.[391] Moreover, in cases where there is no international consensus regarding the governance of specific ethical and legal issues, human rights scholars suggest that states have a wide margin of appreciation to govern them. Similarly, there is no international consensus on best practices to govern the ethical and legal issues concerning HGGE, therefore states will also have considerable leeway in the manner they administer HGGE Thus, governing HGGE through IHRL is not optimal as it does not adequately clarify to states the way they need to address specific ethical and legal issues caused due to advances in HGGE. Therefore, in this chapter, we have sought an alternative approach to building consensus and governing HGGE more optimally.

1. An Alternative Approach to Govern HGGE

In this section, we consider other alternative international approaches to govern HGGE more optimally. We suggest that an optimal governance approach must be able to clarify best practices to states and to keep up with the ongoing advances in genome editing. Scholars have suggested different approaches such as governing the technology by interpreting existing human rights treaties[392], engaging in scientific self-governance[393], and initiating inclusive global governance[394]. We have already explained that although international human rights treaties apply similarly to all

[391] Yotova, *supra* note 35; van Beers, *supra* note 40; Drabiak, *supra* note 41.
[392] Yotova, *supra* note 35; van Beers, *supra* note 40; Drabiak, *supra* note 41.
[393] Liam W Harris, "Recognizing and Legitimizing the Transnational Scientific Governance of Human Gene Editing" (2018) 11:2 McGill JL & Health 87.
[394] Yu et al., *supra* note 43.

states and offer the highest human rights protections, they do not adequately clarify to states best practices to govern HGGE.[395] Instead, in this section we consider whether the alternate transnational governance approaches for HGGE such as scientific self-governance or inclusive global governance can provide better clarification of best practices to govern HGGE.

A straightforward solution to establish best practices for HGGE would be to deliberate with the scientists engaged in genome editing and confirm best practices for HGGE based on their insight. Such deliberation can help develop professional standards and clarify to states best practices to administer the technology. However, prominent voices in HGGE governance such Sheila Jasanoff, Benjamin Hurlburt, and Krishanu Saha in their 2019 article have expressed that in addition to deliberation among scientists, the inclusion of other perspectives in HGGE governance deliberations is crucial to govern the technology more optimally.[396] We support their suggestion to include other non-state actors such as bioethicists, lawyers, professional organizations, intergovernmental agencies, and states in the governance of HGGE.[397] Going forward, we will explain why we consider it crucial to involve diverse actors in HGGE governance.

We support the call for inclusion of a wider network of non-state actors in the governance of HGGE.[398] The reason is, scientists due to their lack of expertise may potentially overlook certain ethical, social, or legal aspects critical to HGGE governance which could have been obvious to an ethicist or a lawyer.[399] In addition, there is fear among the international scholarly community that in the quest for scientific progress scientists may adopt unethical practices and overlook the health risks it poses to patients.[400] For instance, take the international precedent where, despite certain scientists being aware of Chinese physicist He Jiankui's intention to genetically modify the human embryo to cure AIDs, they were unable to stop him from engaging in his illegal scientific pursuit.[401] Scholars specifically note how, despite the initial scientific scorn, he was able to relentlessly pursue his research and unethically create the world's first gene-edited children.[402]

---

[395] Yotova, *supra* note 35; van Beers, *supra* note 40; Drabiak, *supra* note 41.
[396] Jasanoff et al, *supra* note 45.
[397] Jasanoff et al, *supra* note 45.
[398] Yu et al., *supra* note 43; Jasanoff et al, *supra* note 45.
[399] Jasanoff et al, *supra* note 45.
[400] Jasanoff et al, *supra* note 45; R Jean Cadigan et al., "Scientists' Views on Scientific Self-Governance for Human Genome Editing Research" (2022) 33 Hum Gene Ther 1157.
[402] *ibid;* Jasanoff et al, *supra* note 45
[402] *ibid;* Jasanoff et al, *supra* note 45

This international precedent does not build confidence among the international community to solely rely on the scientists to govern HGGE.

Instead of relying solely on scientists to govern HGGE, scholars are now recommending the creation of deliberative platforms and encouraging greater engagement of the international community, public, and under-represented groups to guide future regulation for HGGE.[403] These scholars recommend that the deliberation and inclusion of diverse stakeholders in the international governance of HGGE can increase stakeholder engagement and help identify approaches to govern HGGE more optimally.[404] Apart from protecting patients from unethical genome editing practices, these scholars also want patients to benefit equitably from the technology.[405] Scholars consider that such optimal governance where individuals are not only protected but may also benefit from HGGE can be enabled by an inclusive international governance approach that encourages the participation of diverse stakeholders and promotes best practices to govern the technology.[406] We suggest that optimal governance of HGGE is possible through such inclusive global governance. But what is inclusive global governance and what does inclusive global governance for HGGE entail?

1.1 Suggesting Inclusive Global Governance for Optimal Governance of HGGE

Before discussing what inclusive global governance of HGGE is and what it entails, we will explain the concept of global governance. Global governance is a broad topic of which inclusive global governance is an application. Thakur & Van Langenhove define global governance as "the complex of institutions, mechanisms, relationships, and processes between and among states, non-state actors, markets, citizens, and organizations that [articulate collective interests on the global plane, establish rights and obligations, and mediate differences]".[407] Simply put, global governance presents the opportunity to bring several stakeholders (e.g., civil society organizations, states, and bioethicists, among others) together to assist states in their governance of issues that affect the

[403] Timothy Legrand & Diane Stone, "Science Diplomacy and Transnational Governance" (2018) 13 Br Poliy 392; Yu et al., *supra* note 43; Jasanoff et al, *supra* note 45.
[404] Legrand & Stone, *ibid*; Yu et al., *supra* note 43; Jasanoff et al, *supra* note 45.
[405] Legrand & Stone, *supra* note 403; Yu et al., *supra* note 43;
[406] Legrand & Stone, *supra* note 403; Yu et al., *supra* note 43; Jasanoff et al, *supra* note 45.
[407] Ramesh Thakur & Luk Van Langenhove, "Enhancing Global Governance Through Regional Integration" (2006) 12:3 Global Governance 233 at 233.

collective future of all human beings.[408] This includes, for instance, assisting states in addressing regulatory concerns on the permissibility of research and clinical trials of HGGE.

While Thakur and Van Langenhove's definition emphasizes global governance as a collaborative and inclusive process, it is important to acknowledge that traditional approaches to global governance (e.g., treaty making process) often remain state-centric, prioritizing the interests and authority of individual states over broader inclusivity.[409] In the context of HGGE, a state-centric model can be particularly disadvantageous as it can fail to build consensus on approaches to regulating HGGE because of the differences in states' social, legal, moral, and political interests. For example, states with different laws and moral stances on editing human embryos may refrain from ratifying an international treaty that does not cater to their interests.[410] Moreover, traditional models of global governance often emphasize the interests of developed nations while overlooking those of underrepresented or less influential states.[411] Thus, a state-centric approach can potentially inhibit building international consensus on approaches to regulating HGGE, exacerbate existing inequities, and undermine the legitimacy of international governance of HGGE.[412]

We suggest that it is possible to overcome the challenges (e.g., inequitable representation of stakeholders) presented by traditional, state-centric global governance approaches by modelling international governance to be more inclusive of diverse states and non-state actors. This dynamic solution of adapting international governance to accommodate a greater diversity of states and non-state actors is called inclusive global governance.[413] A 2021 synthesis paper released by Chatham House, a British thinktank renowned for its efforts to help "people, societies, and governments to understand and adapt to change", supports this definition.[414] This report recognizes inclusive global governance as a flexible and adaptive governance approach that entails

[408] Thakur & Van Langenhove, *ibid* at 233.
[409] Thakur & Van Langenhove, *supra* note 407 at 233.
[410] Marchant, *supra* note 221.
[411] Jinseop Jang et al., "Global Governance: Present and Future" (2016) 2 Palgrave Communications 1 at 2-4; Jasanoff et al, *supra* note 45.
[412] Jang, *ibid*; Yu et al., *supra* note 43; Chatham House, Synthesis Report, *infra* note 413.
[413] Chatham House, "Reflections on Building a More Inclusive Global Governance" (15 April 2021), online: Chatham House <https://www.chathamhouse.org/2021/04/reflections-building-more-inclusive-global-governance> [Chatham House, Synthesis Report].
[414] *Ibid.*

incorporating the perspectives of both states and non-state actors in governing issues of global importance, such as the regulation of HGGE.[415]

According to the Chatham House synthesis paper, inclusive global governance can be initiated by introducing specific measures that may increase the representation of non-state actors and enable equitable participation of state actors to address issues of global concern such as HGGE regulation.[416] We believe that this equitable and inclusive process can reduce emphasis on state interests, help the international community understand state and non-state concerns, and create an environment more conducive towards building international consensus.

Moreover, compared to traditional state-centric governance approaches, we suggest that inclusive global governance can foster greater collaboration between states and non-state actors, offer diverse interdisciplinary insight, and facilitate consensus on approaches to govern HGGE.[417] We suggest that this approach can potentially mitigate the adversarial tendency of state centric models which prioritize national sovereignty over collective decision-making.[418] Thus, while the overarching goal of both inclusive governance and traditional global governance is to address international regulatory concerns, inclusive global governance has greater potential to achieve broader international consensus and provide more nuanced solutions to govern HGGE.[419] We thus suggest that the international community must favour introducing governance measures to encourage inclusive governance for HGGE.

Despite the regulatory advantages of inclusive governance, there is a notable lack of literature on how such an approach can be initiated for HGGE. This gap may deter the international community from implementing and benefiting from inclusive governance. Based on our literature review, we suggest that it is possible to initiate inclusive governance for HGGE by: (1) establishing an international working group; (2) creating a diverse and inclusive global platform for dialogue; (3) fostering public engagement; (4) initiating international oversight mechanisms to monitor governance of HGGE; and thereby (5) developing international standards and (6) harmonizing

[415] Chatham House, Synthesis Report, *supra* note 413.
[416] Chatham House, Synthesis Report, *supra* note 413.
[417] Jasanoff et al, *supra* note 45; Yu et al., *supra* note 43; Legrand & Stone, *supra* note 403; Jang, *supra* note 411.
[418] Jasanoff et al, *supra* note 45; Yu et al., *supra* note 43; Legrand & Stone, *supra* note 403; Jang, *supra* note 411.
[419] Jasanoff et al, *supra* note 45; Yu et al., *supra* note 43; Chatham House, Synthesis Report, *supra* note 413.

regulatory practices. We suggest that introducing these measures can reduce opportunities for misuse and increase the potential of stakeholders to benefit from HGGE.

In addition to our recommendations, there are several other ways in which inclusive global governance for HGGE can be developed. While our recommendations offer some insight on the pressing need for an inclusive international governance mechanism, they are not exhaustive; optimal approaches to govern HGGE will likely evolve alongside scientific progress and regulatory demands. Moreover, our recommendations are informed by bioethics reports, journal articles, and policy statements. This governance approach presents certain limitations. For instance, non-state actors may not necessarily agree with our recommendations nor adopt them to govern HGGE. Nonetheless, we strongly believe it is essential to present the following governance strategies because we consider current governance practices insufficient to regulate HGGE optimally.

1.2 Recommendations for Optimal and Inclusive Governance of HGGE

We emphasise that, alongside the inclusion of diverse stakeholders, an optimal regulatory approach must also prioritize building international consensus on approaches to regulate HGGE. The current fragmentary regulation of the procedure stems from the absence of such consensus.[420] However, this fragmentation is not due to inaction by non-state actors. Scholars have observed that despite the issuance of over "60 statements, declarations, and codes of practice" since 2015, consensus on best practices and approaches to govern HGGE remains elusive.[421] This lack of consensus not only perpetuates regulatory fragmentation but also heightens the risk of misuse of the technology. We therefore suggest that it is crucial to implement international oversight mechanisms that can foster inclusive governance and reconcile differing perspectives. Going forward we will recommend some initiatives that can help govern HGGE more optimally.

(1) <u>creating an international working group to oversee the governance of HGGE</u>

We propose that international consensus on HGGE governance is more likely to emerge through a collaborative and inclusive process than through the unilateral efforts of various non-

[420] Yu et al., *supra* note 43.
[421] Yu et al., *supra* note 43.

state actors. Instead of releasing fragmented, individual recommendations, non-state actors could instead contribute to an international initiative that develops and disseminates governance recommendations. Such a collaborative approach would not only enable broad awareness of HGGE-related challenges and collective efforts to address them, but also facilitate coherent and consistent recommendations on best practices. Furthermore, it would enhance understanding and adoption of these practices among diverse stakeholders. One practical step towards this goal could be the establishment of an international working group dedicated to overseeing HGGE governance.

A working group refers to a specialized multidisciplinary team or committee that is established with a mandate to address the ethical concerns and develop best practices for HGGE.[422] Our suggestion to create a working group is inspired by the recommendations of the WHO's expert advisory committee on developing global standards for governance and oversight of HGGE (EAC).[423] The EAC suggested creating an interagency working group — a collaborative initiative between the WHO and the UN — to lead dialogue on HGGE.[424] To optimize such dialogue, we propose that this working group prioritize inclusive governance by actively engaging diverse stakeholders.[425] Furthermore, the working group could enhance its impact by publishing reports and frameworks to support the development of international standards for HGGE. In this regard, we strongly endorse the EAC's recommendation for intergovernmental organizations, namely the WHO, to spearhead this initiative, as their prior experience in addressing health concerns and their established networks with states and non-state actors can facilitate the working group's ambitions in initiating inclusive governance for HGGE.[426] By leveraging these strengths, we suggest that intergovernmental organizations can contribute to addressing governance challenges more holistically.

One practical example of a non-state actor creating international working groups to engage in collaborative work to develop governance standards is the Global Alliance for Genomics and

---

[422] See e.g., Global Alliance for Genomics and Health, "Regulatory and Ethics Workstream" Online: GA4GH < https://www.ga4gh.org/work_stream/regulatory-ethics/>.
[423] The WHO Report consists of: WHO Expert Advisory Committee, A Framework for Governance (Geneva, World Health Organization, 2021); WHO Expert Advisory Committee, Recommendations (Geneva, World Health Organization, 2021); WHO Expert Advisory Committee, Position Paper (Geneva, World Health Organization, 2021); WHO Expert Advisory Committee, Recommendations, at x; Danmeng et al, *supra* note 44.
[424] WHO Expert Advisory Committee, Recommendations, *ibid*, at x, 18; Glenn Cohen et al., "Handle with care: The WHO Report on Human Genome Editing" (2022) 52:2 Hastings Cent Rep 10; Mills, *supra* note 44.
[425] WHO Expert Advisory Committee, Recommendations, supra note 423 at x, 18.
[426] WHO Expert Advisory Committee, Recommendations, supra note 423 at 18.

Health (GA4GH). This organization is a non-state actor renowned for building international standards and harmonizing approaches for genomic data sharing.[427] The GA4GH's initiatives, such as its *Framework for Responsible Sharing of Genomic and Health-Related Data,* developed by the Regulatory and Ethics Working Group collaboratively with international research institutions, has helped standardize data-sharing practices and facilitate responsible cross-border genomic data sharing.[428] Many international research institutions and state-led research programs have adopted the GA4GH's standards to store and share genomic data.[429] Such success in developing international standards for data sharing are contributions of the GA4GH's regulatory working group and committees engaged in identifying governance challenges in genomic data sharing and developing regulatory tools to address those challenges.[430] Similarly, we envision that a working group dedicated to HGGE governance could harmonize regulatory practices and foster ethical, transparent, and equitable oversight of HGGE on a global scale.

Inspired by the EAC's recommendations and the work of the GA4GH, we urge the international community to consider establishing an international working group for HGGE. Creating a working group will include creating initiatives for the working group to undertake. We have identified a few undertakings the working group can implement to initiate inclusive governance, monitor the governance of HGGE, and propose regulatory reform.

(2) Creating a diverse and inclusive global platform for discussion on optimal governance of HGGE

Increasingly, there is consensus among scholars that there is an urgent need for dialogue amongst diverse non-state actors as well as states on addressing ethical concerns and identifying best practices to govern HGGE.[431] Again, instead of several non-state actors initiating different measures to undertake such dialogue, we suggest that it is possible to develop greater consensus if the international community adopts the EAC's recommendation for the working group/the WHO

[427] Heidi L. Rehm et al., "GA4GH: International Policies and Standards for Data Sharing Across Genomic Research and Healthcare" (2021) 1:2 Cell Genomics Online < https://doi.org/10.1016/j.xgen.2021.100029>.
[428] Lilian L Siu et al., "Facilitating a Culture of Responsible and Effective Sharing of Cancer Genome Data" (2016) 22:4 Nat Med 464.
[429] Siu, *ibid;* Rehm, *supra* note 427.
[430] Siu, *ibid;* Rehm, *supra* note 427.
[431] See e.g., Yu et al., *supra* note 43; Jasanoff et al, *Supra* note 45.

to lead international dialogue on HGGE.[432] While this recommendation is commendable the EAC has not clarified how the working group can initiate constructive dialogue on HGGE.[433] We suggest that the working group can initiate dialogue on HGGE by creating an international forum or an international platform that can lead such discussion. Going forward, we will discuss key aspects of establishing an international forum/global platform for discussion and the advantages such a forum presents to the international community.

An international forum refers to a physical or virtual or hybrid platform established to initiate dialogue (through periodic meetings/consultations) with diverse stakeholders to address challenges in governing HGGE.[434] To establish such a forum, the working group could begin by convening preliminary consultations with key stakeholders, including state representatives, scientific organizations, bioethicists, legal experts, patient advocacy groups, and civil society organizations. These consultations would help define the forum's objectives, governance structure, and operational mechanisms.

Once established, the working group could oversee the forum's early operations and ensure that they align with its goals of fostering inclusive dialogue and promoting best practices for HGGE governance. The forum could prioritize equitable participation, particularly the representation of under-represented groups and stakeholders from developing countries, by providing funding or other support to facilitate their involvement in meetings. Additionally, the working group could guide the forum in setting its agenda, focusing on critical issues such as establishing safety and efficacy standards, addressing ethical and human rights concerns, and enabling equitable access to genome editing technologies.

There are several benefits to establishing such an international forum for discussion. The main advantage we seek to highlight is that by bringing together diverse stakeholders, the forum facilitates inclusive dialogue and promotes collaboration among different state representatives, scientific organizations, bioethicists, legal experts, patient advocacy groups, and civil society

---

[432] WHO Expert Advisory Committee, Position Paper, supra note at 4; WHO Expert Advisory Committee, Recommendations, *supra* note 423 at x, 18.
[433] WHO Expert Advisory Committee, Position Paper, supra note at 4; WHO Expert Advisory Committee, Recommendations, supra *note* 423 at 18.
[434] See e.g., Danmeng et al., *supra* note 44; Mills, *supra* note 44; "Brave New Dialogue" (28 February 2019), Online: Nature Genetics Editorial <https://www.nature.com/articles/s41588-019-0374-2>.

organizations. Such collaboration with diverse stakeholders has great potential to assist the working group/international community in addressing ethical and human rights concerns and developing best practices that guarantee stakeholders their rights and offer greater protection of human rights such as privacy and reproductive freedom. In addition, to using the forum to identify best practices, the working group can use the forum to engage with diverse stakeholders to increase awareness amongst the international community of the working group's stance on key issues.

(3) Fostering Public Engagement

Several non-state actors highlight the importance of fostering public engagement, as it can provide the international community with critical insights on how laypersons perceive HGGE.[435] Such insight can help policymakers identify public concerns and assess the potential risks of implementing specific policies.[436] Furthermore, it can guide the development of strategies to foster public trust and acceptance. While such public engagement has been traditionally employed as a tool to influence and guide domestic policy decisions, it is increasingly recognized by non-state actors as a valuable mechanism to foster inclusive international governance.[437] We thus suggest engaging with the public can help the working group and international forum strategize responses to address the concerns of non-expert stakeholders.

There are various methods non-state actors can use to initiate public engagement, such as deliberative polling, citizen juries, consensus conferences, workshops, focus group meetings, and online surveys.[438] The working group and international forum can choose the most appropriate approach to gather public insights on HGGE governance. To better understand public views on the administration of HGGE, the international forum and working group should prioritize engagement with underrepresented groups, including those from the Global South, disability communities,

[435] John M. Conley et al., "The Promise and Reality of Public Engagement in the Governance of Germline Genome Editing Research" (2023) 23:7 Am J Bioeth 9; Yu et al., *supra* note 43; Nuffield Council, *supra* note 72; International Commission on the Clinical Use of Germline Genome Editing, *supra* note 72.
[436] Conley et al, *ibid*.
[437] Boy Vijlbrief, "Public Engagement with Human Germline Editing Requires Specification" (2023) 23:12 The American Journal of Bioethics 77; Yu et al., *supra* note 43; Herve Chneiweiss et al., "Fostering responsible research with genome editing technologies: a European perspective" (2017) 26 Transgenic Res 709; Nuffield Council, *supra* note 72; International Commission on the Clinical Use of Germline Genome Editing, *supra* note 72.
[438] See, Susanne B. Haga et al., "Promoting Public Awareness and Engagement in Genomic Sciences" (2013) 2:4 J Genet Couns 508.

individuals affected by genetic diseases, and other stakeholders most impacted by HGGE.[439] Special attention should be given to the participation of laypersons from the Global South, who have been historically underrepresented in genomic research and associated decision-making processes.[440] By involving these groups, the working group and international forum can gain more nuanced perspectives and address concerns that might otherwise be overlooked. However, the downside to employing public engagement is that it also highlights the differences in perspectives and opinions on optimal approaches to regulate HGGE.[441]

While employing diverse methods of public engagement can lead to fragmented opinions, the working group or international forum should not be discouraged by these differences. Regular engagement with the public is essential to monitor shifts in public perspectives, particularly as advances in HGGE continue. By tracking the views of affected communities, such as those with disabilities and genetic diseases, the working group can release policy recommendations that are relevant, adaptable, and more likely to resonate with the public. Ultimately, prioritizing the participation of vulnerable and underrepresented groups in global governance will support more inclusive, humanitarian, and effective governance of HGGE.

(4) initiating international oversight measures to monitor governance of HGGE

We suggest that implementing international oversight mechanisms to monitor and release updates on HGGE can help mitigate the impact of misinformation and enhance technological and regulatory awareness of the procedure. Implementing such oversight mechanisms is important because while numerous sources—such as reports, journals, and articles—publish information on HGGE, not all are reliable.[442] We are particularly concerned that non-state actors, including public

---

[439] Jang, *supra* note 411; Nason Maani et al., "Global Health Equity Requires Global Equity" (2023) 21:7 Health Equity 192.
[440] Jang, *supra* note 411; Rodrigo Pérez Ortega, "Genetic Databases Don't Fairly Capture Species Richness of Global South, New Data Shows" (18 October 2024), Online: Science <https://www-science-org.proxy3.library.mcgill.ca/content/article/countries-global-south-have-more-biodiversity-countries-north-databases-used-study>.
[441] Harris, *supra* note 393.
[442] Yoo Yung Lee, "Genome Editing or Genome Cutting? Communicating CRISPR in the British and German Press" (29 October 2020), Online <https://www.degruyter.com/document/doi/10.1515/gcla-2020-0004/html?lang=en#:~:text=Using%20a%20corpus%20of%20600,edit%20the%20DNA%2C%20replacing%20spelling>; Andrew Ikpomwosa Egbah & Stella Oziegbe Igene, "Legitimating Genome Editing: A Critical Discourse Analysis of Media Reportage" (January 2024), Online <

and underrepresented groups participating in international forums, may be influenced by unreliable information from entities such as the media or pharmaceutical companies, which may have profit-driven motives.[443] Reliance on misleading information risks undermining constructive dialogue on HGGE.[444] To address this issue, we suggest that the working group should establish oversight mechanisms to monitor and disseminate accurate updates on advances in HGGE and its international and domestic regulation.

We suggest that the working group can oversee HGGE more efficiently if it implements the following initiatives:

- If the working group establishes an international mechanism to update the international community on progress in HGGE, it can increase the international community's reliance on its updates. The working group can do this by networking with researchers, ethicists, and policymakers to publish annual reports summarising advancements, challenges, and ethical considerations regarding HGGE.

- The working group can track international and domestic regulation of HGGE and publish the practices of different states in governing HGGE. This can help the international community understand the regulatory practices of different countries and identify regulatory lacunae. A unique way to do this would be for the working group to create an international regulatory map showing regional as well as domestic regulatory practices for HGGE. The working group can also create an online bulletin to update the international community on any change in regulatory practices. To further increase awareness on regulatory practices, the working group can use the material on the map and bulletin to publish commentaries and articles in prominent journals on how states regulate HGGE.

In addition to our recommendations, the working group can also consider implementing oversight measures similar to those issued by the EAC for the WHO to undertake:

---

https://www.researchgate.net/publication/378469343_Legitimating_Genome_Editing_A_Critical_Discourse_Analysis_of_Media_Reportage>.

[443] *Ibid*.

[444] Lee, *supra* note 442.

- The EAC has urged the WHO to enhance its human genome editing registry, a one-of-a-kind "global registry" that lists information about clinical trials and experimentation of genome editing technologies on humans.[445] This registry is to also include information on HGGE once the procedure has been administered on humans.[446] As of now, the registry only includes information on trials that have been successfully performed.[447] The EAC has suggested this registry should be updated to also include information on "basic" and "pre-clinical trials".[448] Establishing such a registry to track advances in HGGE in real time can inform the international community of progress in HGGE.[449] Indeed, should non-state actors, in particular the WHO, heed the EAC's recommendation, it can increase transparency and help the international community track advances in genome editing technologies and HGGE.

- In addition to monitoring clinical trials, the EAC has suggested that in order to act promptly and prevent misuse of HGGE the international community must be able to track illegal and unsafe research and administration of HGGE on humans.[450] To do this, it has suggested establishing a whistleblowing mechanism for confidential reporting of potential misuse of HGGE to the WHO, so that it can act promptly and inform the appropriate regional and/or national regulatory authorities of the incident.[451] This suggestion of the EAC, if initiated, can help the international community and appropriate regulators deter scientists from engaging in illegal endeavours.[452]

We suggest that the working group should consider implementing these initiatives, as they can reduce the influence of incorrect information and increase reliance on the WHO/the working group for updates. Moreover, constant monitoring of regulatory practices and advances in HGGE as well as creating a whistleblowing mechanism for the procedure provide the working group with

[445] WHO Expert Advisory Committee, Recommendations, *supra* note 423 at 8.
[446] WHO Expert Advisory Committee, Recommendations, *supra* note 423 at 8.
[447] "WHO launches global registry on human genome editing" (29 August 2019), Online: WHO News < https://www.who.int/news/item/29-08-2019-who-launches-global-registry-on-human-genome-editing>.
[448] Jay Cohen, "WHO Panel Proposes New Global Registry for All CRISPR Human Experiments" (19 March 2019), Online: Science < https://www-science-org.proxy3.library.mcgill.ca/content/article/who-panel-proposes-new-global-registry-all-crispr-human-experiments>.
[449] WHO Expert Advisory Committee, Recommendations, *supra* note 423 at 8.
[450] WHO Expert Advisory Committee, Position Paper, *supra* note 423 at 4.
[451] WHO Expert Advisory Committee, Position Paper, *supra* note 423 at 4.
[452] WHO Expert Advisory Committee, Position Paper, *supra* note 423 at 4.

ample opportunity to identify regulatory lacunae. The working group can then discuss the issues identified in meetings or conferences initiated by the international forum with appropriate stakeholders and publish the feedback and governance recommendations received. Hence, we suggest that if such oversight measures to monitor HGGE are implemented they can improve the working group's efficiency and transparency.

(5) Developing international Standards to Guide the Regulation of HGGE

In earlier sections, we defined inclusive global governance and highlighted how the working group can encourage inclusive governance for HGGE. As stated earlier, the purpose of initiating such inclusive governance for HGGE is to gain insights and perspectives on HGGE governance, bridge differences, and thereby develop international standards for HGGE. Inspired by the EAC's suggestion for the WHO to create a working group and initiate dialogue for HGGE, we emphasized that, instead of different actors initiating dialogue on HGGE with different goals, greater consensus can be achieved through a specialized committee collaborating with other non-state actors to develop best practices that respect human rights.

Additionally, we suggested that the working group can create an international forum to engage with diverse stakeholders and assist releasing recommendations to govern HGGE. We further explained how a mechanism to monitor and update the international community on advances in HGGE can help inform discussions on HGGE governance and aid the working group in developing meaningful solutions to address the ethical and human rights concerns raised by HGGE. In the long run, we suggest that this approach can not only enable inclusive governance for HGGE but also help enhance human rights protections and develop consensus and international standards to guide regulation of HGGE.

(6) Harmonizing Regulatory Practices for HGGE

The objective of our suggestions is to foster consensus and assist the international community in developing standards for HGGE through inclusive dialogue, public engagement, and initiatives to monitor, update, and recommend optimal governance approaches. Once consensus on best practices is achieved, non-state actors can leverage formal and informal

governance mechanisms to enforce and further develop international standards.[453] For instance, non-state actors such as intergovernmental organizations (e.g., the WHO) can assist with implementing formal governance mechanisms such as binding international treaties that can prescribe bans, moratoriums, or technology-sharing practices to their signatories.[454] Science academies and international professional organizations can implement informal governance mechanisms, such as non-binding guidelines, to prescribe best practices.[455] Both formal and informal governance mechanisms can help harmonize regulatory practices, however, for these practices to be effectively implemented, states must first agree to them.[456] In other words, these practices do not automatically provide consensus, for states must show initiative to adopt them in the first place.[457] We suggest that non-state actors undertake certain measures to increase the appeal of formal and informal governance mechanisms to encourage global adherence to their recommended governance practices.

We also suggest one way non-state actors can foster global adherence to best practices in HGGE governance is by establishing collaborative research networks. These networks can provide scholarships and grants to researchers from countries that align their regulatory frameworks with international norms. Furthermore, scientists from countries with restrictive policies on HGGE research could be allowed to participate in ethical research abroad, which can expose them to collaborative opportunities and funding. Such exposure can turn researchers into advocates for reform; indeed, when they return to their home countries, they can promote the adoption of international standards to gain access to funding, advanced research facilities, and collaborative research. By linking participation in these networks to alignment with international norms, the international community can incentivize states to harmonize their regulatory approaches, paving the way for a more inclusive and ethically responsible approach to governing HGGE.

While collaborative research networks highlight how non-state actors can incentivise states to adopt non-binding guidelines, non-state actors can also introduce specific measures to incentivise states to ratify an international treaty and promote the uptake of international standards

[453] WHO Expert Advisory Committee, Position Paper, *supra* note 423, at 4; Thorben Sprink et al., "Genome Editing Around the Globe: An Update on Policies and Perceptions" (2022) 190:3 Plant Physiol 1579.
[454] Marchant, *supra* note 221; Sprink, *ibid*.
[455] Marchant, *supra* note 221; Kaan et al., *supra* note 215.
[456] Marchant, *supra* note 221; Kaan et al., *supra* note 215.
[457] Marchant, *supra* note 221; Sprink, 453.

through formal mechanisms. For instance, states may find binding international treaties outlining standards for the research and administration of HGGE, particularly those incorporating technology-sharing clauses, more favourable compared to treaties without benefit-sharing provisions. Human genetic data varies based on race, region, and other factors, and HGGE research results will also differ depending on these factors.[458] An international treaty with benefit sharing provisions presents an opportunity for states to adhere to similar practices and facilitate access to genomic and research data.[459] Thus, states can be persuaded by the international community to ratify the treaty so that there is an international mechanism to share information on HGGE for scientists to study how such differences and genomic variations impact research outcomes. Given the various approaches to drafting international treaties, we suggest that the working group or the WHO be tasked with collaborating with diverse stakeholders to draft the treaty and the technology-sharing clause. Signatories to such international treaties will have to enforce the treaties standards to govern HGGE and implement measures to enable the sharing of data, resources, or research on HGGE. Although moral perspectives on the administration of HGGE may still differ between states, we suggest that states seeking to better understand the human genome and equitably benefit from HGGE will be motivated to agree to such a treaty.

1.3 Limitations to Establishing Optimal & Inclusive International Oversight for HGGE

There are several concerns that could impede the initiation of inclusive global governance for HGGE. One significant challenge is the ambiguity surrounding the definition of inclusive global governance itself. As a relatively novel and evolving governance concept, this lack of clarity can hinder efforts to develop effective and inclusive oversight mechanisms for HGGE. However, since we have contextualized how inclusive global governance can be implemented for HGGE, our analysis will now focus specifically on the limitations of establishing international oversight based on our proposed recommendations.

---

[458] Guido Barbujani & Vincenza Colonna, "Human Genome Diversity: Frequently Asked Questions" (2010) 26:7 CellPress Trends in Genetics 285.

[459] Considering initiatives such as the 1000 Genomes Project operational and underway to study human genetic variation globally, developing international standards for genomic research and enabling adherence to such internationally recognized standards can enhance international research opportunities and facilitate genomic research. The 1000 Genomes Project Consortium, "A Global Reference for Human Genetic Variation" (30 September 2015), Online: Nature <https://www.nature.com/articles/nature15393>.

The working group tasked with initiating inclusive dialogue and oversight for HGGE governance may face several challenges. An unclear mandate can hinder its ability to facilitate meaningful discussions and propose actionable recommendations, while limited funding may restrict the scope and impact of its initiatives, such as monitoring HGGE, organizing consultations, and engaging diverse stakeholders.[460] Additionally, differing priorities among states and non-state actors can create conflicts, making it difficult to establish common goals or initiate oversight mechanisms. The dominance of scientifically advanced or economically powerful countries may further exacerbate these challenges by marginalizing the concerns of low and middle-income countries (LMICs) and underrepresented groups. These obstacles emphasize the need for clear objectives, sufficient resources, and deliberate measures to ensure balanced representation and equitable participation in the governance process.

Non-state actors may also encounter significant challenges in implementing formal and informal international oversight mechanisms for HGGE governance. As Marchant highlights, differences in state interests, ethical values, and regulatory frameworks can obstruct the implementation of international treaties that require ratification by states.[461] The effectiveness of time-bound moratoriums is similarly questionable, as they also rely on state acquiescence and may face resistance from states unwilling to forgo the potential benefits of HGGE.[462] Furthermore, once a moratorium is lifted, the international community would need to revisit and address unresolved governance concerns.[463] While informal mechanisms such as guidelines and bioethics reports can help harmonize international standards, their non-binding nature limits their ability to compel states to reform their regulatory approaches.[464] These challenges illustrate the complexities of fostering international oversight for HGGE.

We thus note that formal approaches (e.g., bans, moratoriums) can be difficult to implement on a topic with such conflicting views as governing HGGE. The other informal governance approaches (e.g., guidelines, frameworks, reports) that the WHO can publish must be voluntarily undertaken by states and research programs. Moreover, the other non-state actors may not

[460] Marchant, *supra* note 221; Kaan et al., *supra* note 215.
[461] Marchant, *supra* note 221.
[462] Marchant, *supra* note 221.
[463] Marchant, *supra* note 221.
[464] Kaan et al., *supra* note 215.

necessarily subscribe to WHO's HGGE governance approach. There is a possibility that reports and guidelines issued by non-state actors can be relied upon by policy makers and in courts, but these are secondary to formal international, regional, and domestic laws, are non-enforceable, and do not impose obligations on states. We have hope, however, that some informal standards (e.g., the 14 day rule established by the Warnock Committee) developed by the international community (which includes non-state actors) will become the norm.[465] This possibility should not be written off.

2. The Path Forward

We observe that science academies and non-state actors such as the WHO may face limitations in building international consensus about optimal HGGE governance, partly because states hold the power to regulate health concerns, which can dilute the impact of international non-state actors. We nonetheless hold that non-state actors like the WHO in particular can facilitate global governance due to their experience in managing global health issues. The WHO can help build consensus (among the international community and non-state actors) on ethical administration of HGGE, guiding national regulators, regional and national courts, human rights scholars, and policymakers in their decisions regarding the administration of HGGE; then, IHRL can be applied to build international human rights norms that can ensure that human rights are protected, and ethical standards are observed.

The search for optimal governance approaches do not uniquely concern HGGE. Two reproductive technologies similar to HGGE, reproductive cloning and MRT, also face similar governance challenges. The United Nations Declaration of Human Cloning (UNDHC, 2005) states that states need to prohibit all applications of reproductive cloning.[466] The UNDHC is a non-binding international instrument that was approved by the United Nations General Assembly.[467] Despite this approach promoted by the UNDHC, some states like the UK permit certain

[465] Guila Cavaliere, "A 14-day Limit for Bioethics: the Debate Over Human Embryo Research" (2017) 18:38 BMC Medical Ethics 1; See also. Sarah Chan, "How and Why to Replace the 14-Day Rule" (2018) 4:3 Curr Stem Cell Rep < doi: 10.1007/s40778-018-0135-7>.
[466] Adèle Langlois, "The global governance of human cloning: the case of UNESCO" (2017) 2:17019 Palgrave Communications - Nature Online < https://www.nature.com/articles/palcomms201719>.
[467] Langlois, *ibid*.

applications of reproductive cloning such as to extract stem cells.[468] Though controversial, MRT is administered in countries like Australia and the UK despite the absence of a unified international governance approach.[469] On the one hand, because UNDHC is recommending states to ban reproductive cloning, states that permit applications of reproductive cloning are unable to seek guidance for best practices. On the other hand, due to the fragmented international regulation of MRT, states are unable to equitably benefit from the technology. This is a bind familiar to those (e.g., bioethicists, human rights scholars) searching for optimal HGGE governance approaches.

We suggest that states may be able to govern such technologies better if they rely on multifaceted governance approaches. Non-state actors such as the WHO can promote international dialogue and help develop best practices and international oversight, and national regulators can use these approaches to tailor their national policy to govern HGGE. Once there is clear international oversight, consensus, and guidance, states may come to rely on purposive human rights approaches to govern the procedure. States can rely on such consensus to interpret human rights treaties a certain way and thus will be able to better appreciate IHRL in governing HGGE. Such application of governance approaches can also clarify to states their obligations to govern health concerns in a manner where individuals are protected and offered the highest standards of care. However, since international oversight as well as human rights approaches are still developing, we cannot point the ethical needle towards a certain type of approach the international community may take (e.g., banning HGGE, or promoting application of HGGE to treat certain conditions such as tuberculosis) or how such consensus may come about. We strongly predict, however, that the inclusive global governance made possible by non-state actors and IHRL will have a tremendous influence in shaping the regulatory landscape governing HGGE, as they do currently.

[468] Shaun D. Pattinson & Timothy Caulfield, "Variations & voids; the regulation of human cloning around the world" (2004) 5:9 BMC Med Ethics Online < https://www.ncbi.nlm.nih.gov/pmc/articles/PMC544897/>.
[469] Wise, *supra* note 106; Ludlow, *supra* note 106.

Conclusion

HGGE raises several ethical and legal concerns that affect a myriad of stakeholders, including scientists, patients, children, states, and institutions. Gaps in regulatory approaches, coupled with the ethical concerns surrounding the procedure, require that states and other stakeholders ensure that best practices are followed and that HGGE procedures are administered ethically and in a manner that shows respect for human rights. However, the absence of stakeholder consensus on optimal governance approaches has hindered the development of best practices for HGGE. Consequently, the international community is actively seeking a governance mechanism to develop international consensus on best practices to thereby harmonize regulatory practices for HGGE.

An optimal approach to govern HGGE lies in addressing the unique concerns raised by rapid scientific advancements through proper forums to ensure the procedure's safe and equitable implementation. This thesis first considered whether IHRL could govern HGGE optimally. We examined IHRL's ability to determine whether HGGE can be implemented, how it can protect intergenerational rights of stakeholders, and what guidance it offers on best practices and ethical administration of HGGE procedures. While IHRL emphasizes the rights of stakeholders such as parents, children, and scientists, and outlines states' obligations to guarantee these rights, the global lack of consensus about the interpretation of IHRL as a method of HGGE governance renders its ability to effectively govern the procedure rather ambiguous. Thus, at present, IHRL is not able to provide stakeholders with clear regulatory guidance of HGGE. This has led the international community to seek alternative approaches for governing HGGE.[470]

In Chapter 3, we discuss the challenges of using IHRL as the sole approach to regulate HGGE and propose inclusive global governance as an alternative. This chapter highlights the limitations of state-centric and fragmented regulatory approaches and advocates for the inclusion of diverse stakeholders—scientists, bioethicists, lawyers, intergovernmental organizations, and underrepresented groups—in governance discussions. We define inclusive global governance and explain how it can help engage with diverse stakeholders to develop meaningful solutions for HGGE. While there are several ways to initiate inclusive governance, we explained how

[470] Yotova, *supra* note 35; Marchant, *supra* note, 221.

intergovernmental organizations, such as, the WHO can create an international working group and international forum to monitor and update on progress in HGGE and lead inclusive dialogue. We suggest that such dialogue initiated by the international forum can aid the working group propose governance recommendations on HGGE that address ethical as well as human rights concerns. Additionally, we encourage different non-state actors to collaborate with the working group to facilitate dialogue on HGGE with the objective of developing best practices, instead of diverse non-state actors initiating individual efforts to facilitate dialogue for HGGE. Indeed, there is a greater possibility of developing consensus on best practices if diverse non-state actors defer to a single source.

Moreover, the governance of complex biotechnologies such as HGGE, mitochondrial replacement therapy (MRT), and human cloning is constantly evolving. The only way international oversight and national regulatory approaches can address these technologies optimally is by monitoring technological advances and developing laws, policies, and mechanisms to address emerging challenges in their governance. As the procedure advances, we suggest that inclusive global governance initiated by non-state actors, can complement IHRL and help guide regulatory change. Our recommendations focus on how non-state actors can monitor advances in HGGE, initiate inclusive governance and encourage consensus on best practices for HGGE. We suggest that such consensus can reduce differing interpretations of IHRL, standardise regulatory practices, and facilitate optimal governance of HGGE.

Our thesis is not exhaustive. In addition to our proposal on how non-state actors can help govern HGGE more inclusively there are other avenues and issues to consider. For instance, how might intellectual property, especially the patent system, be used to implement oversight? Future research may also consider the issues that cause stakeholders to benefit from HGGE inequitably, not just at the intra-national level but also at regional and international levels. We finally note that further research regarding optimal approaches to govern HGGE is still required.

Bibliography

Primary Sources: International Law

Convention on the Prevention and Punishment of the Crime of Genocide, 9 December 1948, 78 UNTS 277 (entered into force 12 January 1951).

Convention on the Rights of the Child, GA Res. 44/25, UN GAOR, 44th Sess., Supp. No. 49, UN Doc. A/44/49 (1989), 1577 UNTS 3 (entered into force 2 September 1990).

Declaration on the Responsibilities of Present Generations Towards Future Generations, UNESCO, 29th Sess, UN Doc 29 C/Resolution 44 (1997).

International Covenant on Civil and Political Rights, GA Res 2200A (XXI), UN GAOR, 21st Sess, Supp No 16, UN Doc A/6316 (1966), 999 UNTS 171 (entered into force 23 March 1976).

International Covenant on Economic, Social and Cultural Rights, GA Res 2200A (XXI), UN GAOR, 21st Sess, Supp No 16, UN Doc A/6316 (1966), 993 UNTS 3 (entered into force 3 January 1976).

United Nations Declaration on Human Cloning, GA Res 59/280, UN GAOR, 59th Sess, UN Doc A/RES/59/280 (2005).

Universal Declaration of Human Rights, GA Res 217A (III), UN GAOR, 3rd Sess, Supp No 13, UN Doc A/810 (1948).

Universal Declaration on Bioethics and Human Rights, UNESCO, 33rd Sess, UN Doc SHS/EST/05/CONF.204/3 Rev.2 (2005).

Universal Declaration on the Human Genome and Human Rights, UNESCO, 29th Sess, UN Doc SHS-97/WS-4 (1997).

Primary Sources: Regional Law

American Convention on Human Rights, "Pact of San José, Costa Rica," 22 November 1969, 1144 UNTS 123.

Charter of Fundamental Rights of the European Union (2012), 2012/C 326/02.

Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Oviedo Convention, 1997), ETS 164 (entered into force 1 December 1999).

Directive 98/44/EC of the European Parliament and of the Council on the Legal Protection of Biotechnological Inventions [1998] OJ L 213/13.

Regulation (EU) No 536/2014 of the European Parliament and of the Council on Clinical Trials of Medicinal Products for Human Use, [2014] OJ L 158/1.

Primary Sources: Legislation

*Assisted Human Reproduction Act***,** SC 2004, c 2.

Criminal Law Amendment (2020), Standing Committee of the National People's Congress (China),Online: <www.npc.gov.cn/npc/c30834/202012/850abff47854495e9871997bf64803b6.shtml>.

Dickey-Wicker Amendment (1996), Pub L No 104-119, 110 Stat 828 (US), Online: < www.govinfo.gov/content/pkg/PLAW-104publ99/html/PLAW-104publ99.html>.

The Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act (1994), Act No 57, Ministry of Health and Family Welfare (India).

Primary Sources: Case Law

A.B.C. v Ireland [GC], No 25579/05, [2010] ECHR 2032.

Costa & Pavan v Italy, No 54270/10, [2012] II ECHR 703.

Dickson v United Kingdom [GC], No 44362/04, [2007] V ECHR 99.

Murillo et al. v Costa Rica (2012), Inter-Am Ct HR (Ser C) No 257.

Parrillo v Italy [GC], No 46470/11, [2015] V ECHR 95.

Schwangerschaftsabbruch I, (1975) 39 BVerfGE 1 (Fed Const Ct) (Germany) [First Abortion decision].

Schwangerschaftsabbruch II, (1993) 88 BverfGE 203 (Fed Const Ct) (Germany) [Second Abortion decision].

Vo v France [GC], No. 53924/00, [2004] VIII ECHR 65.

Secondary Sources: Books/Reports

Abdelkader, Medina, "Towards an equity-driven regulatory framework for germline editing: Considerations for amending the Assisted Human Reproduction Act" (3 August 2021), Online: The Canadian Bar Association <https://www.cba.org/Sections/Health-Law/Resources/Resources/2021/HealthEssayWinner2021>.

Adashi, Eli Y. & Cohen, Glenn, "Disruptive Synergy: Melding of Human Genetics and Clinical Assisted Reproduction" (2020) 6:22 Cell Reports Medicine Online < https://doi.org/10.1016/j.xcrm.2020.100093>.

Alghrani, Amel, "Regulation of Assisted Reproduction: Past, Present and Future" in *Regulating Assisted Reproductive Technologies: New Horizons*, Cambridge Bioethics and Law, ed (Cambridge: Cambridge University Press, 2018).

Alonso, Marcos & Savulescu, Julian, "He Jiankui's gene-editing experiment and the non-identity problem" (2021) 35:6 Bioethics 563-573.

Bannikov, A.V., "CRISPR/Cas9, the King of Genome Editing Tools" (2017) 51 Molecular Biology 514-525.

Boggio, Andrea et al, eds, *Human Germline Modification and the Right to Science* (Cambridge: Cambridge University Press, 2020).

Boggio, Andrea & Yotova, Rumiana, "Gene editing of human embryos is not contrary to human rights law: A reply to Drabiak" (2021) 35:9 Bioethics 956-963.

Bowman, Diana et al, eds, *Reproduction Reborn: How Science Ethics, and Law Share Mitochondrial Replacement Therapies* (New York: Oxford University Press, 2023)

Brownsword, Scotford E., eds, *The Oxford Handbook of Law, Regulation, and Technology* (New York: Oxford University Press, 2016)

European Group on Ethics in Science and New Technologies. *Ethics of Genome Editing*. European Commission, 2021.

Groter, Rainer et al., eds, Max Planck Encyclopedia of Comparative Constitutional Law (London, Oxford University Press, 2017).

Haga, Susanne B. et al., "Promoting Public Awareness and Engagement in Genomic Sciences" (2013) 2:4 J Genet Couns 508-16.

Institute of Medicine (US) Committee on Science, Engineering, and Public Policy, *Science and Babies: Private Decisions, Public Dilemmas*, (Washington, DC: National Academies Press, 1990).

International Bioethics Committee**,** *Report of the International Bioethics Committee of UNESCO: The Human Genome and Human Rights* (UNESCO, 1997).

International Commission on the Clinical Use of Human Germline Genome Editing, *Heritable Human Genome Editing* (Washington, DC: National Academies of Sciences, Engineering, and Medicine, 2020).

Katz, Sanford N. et al, *Cross Currents Family Law and Policy in the US and England* (London, UK: Oxford University Press, 2000).

Levi-Faur, D. (ed.) The Oxford Handbook (New York: Oxford University Press, 2012).
National Academies of Sciences, Engineering, and Medicine**.** *Human Genome Editing: Science, Ethics, and Governance*. (Washington, DC: The National Academies Press, 2017).

Nuffield Council on Bioethics, *Genome Editing and Human Reproduction: Social and Ethical Issues* (London, UK: Nuffield Council on Bioethics, 2018).

Nuffield Council on Bioethics, *Genome Editing and Human Reproduction: Social and Ethical Issues - Short Guide* (London: Nuffield Council on Bioethics, 2018).

von Bogdandy, Armin et al., eds, *The Impact of the Inter-American Human Rights System: Transformations on the Ground* (New York: Oxford University Press, 2024).

Rosenfeld, Michel and Sajó,,András, *Oxford Handbook of Comparative Constitutional Law* (Oxford, Oxford University Press, 2012)

WHO Expert Advisory Committee, A Framework for Governance (Geneva, World Health Organization, 2021).

WHO Expert Advisory Committee, Position Paper (Geneva, World Health Organization, 2021).

WHO Expert Advisory Committee, Recommendations (Geneva, World Health Organization, 2021).

Yotova, Rumiana**,** *The Regulation of Genome Editing and Human Reproduction Under International Law, EU Law and Comparative Law* (Nuffield Council on Bioethics, 2017).

Secondary Sources: Journals

Almeida, Mara & Ranisch, Robert, "Beyond Safety: Mapping the Ethical Debate on Heritable Genome Editing Interventions" (2022) 9:139 Humanities and Social Sciences Communications 1-14.

Andorno, Roberto, "The Oviedo Convention: A European Legal Framework at the Intersection of Human Rights and Health Law" (2005) 2:4 Journal of International Biotechnology Law 133-143.

Asplund, Kjell, "Use of in vitro fertilization – ethical issues" (2020) 125:2 Ups J Med Sci 192-199.

Bahadur, G, "The moral status of the embryo: the human embryo in the UK Human Fertilisation and Embryology (Research Purpose)Regulation 2001 debate" (2003) 7:1 Reproductive Biomedicine Online < https://www.sciencedirect.com/science/article/abs/pii/S1472648310617221>.

Barbujani, Guido & Colonna, Vincenza, "Human Genome Diversity: Frequently Asked Questions" (2010) 26:7 CellPress Trends in Genetics 285-295.

Barbuscia, Anna, "The psychosocial health of children born after medically assisted reproduction: Evidence from the UK Millennium Cohort" (2019) 7 Population Health 1-11.

Bauman, Martina, "CRISPR/Cas9 genome editing – new and ethical issues arising from a revolutionary technology" (2016) 10 NonoEthics 139-159.

Baylis et al, Francoise, “Human Germline and Heritable Genome Editing: The Global Policy Landscape” (2020) 3:5 The CRISPR Journal 365-377.

Behjati Adrakani, Zohreh, “The Impact of Third-Party Reproduction on Family and Kinship” (2021) 22:1 J Reprod Infertil 3-15.

Beriain, Iñigo de Miguel, “Gene editing and disabled people: a response to Felicity Broadman” (2020) 11:3 J Community Genet 241-243

Biondi, Stefano, “Access to medical-assisted reproduction and pgd in Italian law: a deadly blow to an illiberal statute? Commentary to the European Court on Human Rights’s decision Costa and Pavan v. Italy) (2013) 21:3 Med Law Rev 474-486.

Blasimme, Alessandro, “Why Include the Public in Genome Editing Governance Deliberation?” (2019) 21:12 AMA J Ethics <doi: 10.1001/amajethics.2019.1065>.

Boggio, Andrea et al., “The Human Right to Science and the Regulation of Human Germline Genome Editing” (2019) 2:3 The CRISPR Journal Online <https://doi.org/10.1089/crispr.2018.0053>.

Boggio, Andrea et al., “The regulation of human germline genome modification at the national level: a call for comprehensive legal reform” (2021) 43:3 Loyola of Los Angeles International and Comparative Law Review 201-226

Boggio, Andrea & Yotova, Rumiana, “Gene Editing of Human Embryos is not contrary to human rights law : A reply to Drabiak” (2021) 35 Wiley Bioethics 956-963.

Bowman-Smart, Hilary et al, “Non-invasive prenatal testing in Germany: a unique ethical and policy landscape” (2023) 31:5 Eur J Hum Genet 562-567.

Brandão, Pedro, “European Policies on Same-Sex Relationships, Adoption and Assisted Reproduction” (2022) 11:8 International Journal of Reproduction Contraception Obstetrics and Gynecology 2306-2314.

Broadman, Felicity, “Human Genome Editing and Identity Politics of Genetic Disability” (2020) 11:2 J Community Genet 125-127.

Broadman, Felicity, “Letter to the editor. Gene editing and disabled people: a response to Iñigo de Miguel Beriain (2020) 11:3 J Community Genet 245-247.

Burke, Lucy, “Hostile Environments? Down’s Syndrome and Genetic Screening in Contemporary Culture” (2021) 47 Med Humanit 193-200.

Burleson, Elizabeth, “International Human Rights Law, Co-parent Adoption, and the Recognition of Gay and Lesbian Families” (2009) 55 Loy L. Rev 791-803.

Cadigan, Jean et al., “Scientists’ Views on Scientific Self-Governance for Human Genome Editing Research” (2022) 33 Hum Gene Ther 1157–1163.

Cahn, Naomi, “CRISPR Parents and Informed Consent” (2020) 23:1 SMU Science and Technology Law Review 1-30.

Carroll, Dana, “Collateral Damage: Benchmarking Off-Target Effects in Genome Editing” (2019) 20:114 Genome Biology 1-3.

Cavaliere, Guila, “A 14-day Limit for Bioethics: the Debate Over Human Embryo Research” (2017) 18:38 BMC Medical Ethics 1-12.

Chan, Sarah, “How and Why to Replace the 14-Day Rule” (2018) 4:3 Curr Stem Cell Rep < doi: 10.1007/s40778-018-0135-7>.

Chapman, Carolyn Riley, “Genetic Discrimination: Emerging Ethical Challenges in the Context of Advancing Technology” (2020) 7:1 J Law Biosci 1-23;

Chapman, Jennifer E. et al, “Approaches to Reduce CRISPR Cas-9 Off Target Effects for Safer Genome Editing” (2017) 22:1 The CRISPR Journal 7-13.

Chen, Minghao et al., “Can Comprehensive Chromosome Screening Technology Improve IVF/ICSI Outcomes? A Meta-Analysis” (2015) 15:10 Plos One Online < DOI: 10.1371/journal.pone.0140779>;

Chimata, Murali Krishna & Bharti, Gyanesh, “Regulation of genome edited technologies in India” (2019) Transgenic Res 175-181

Cohen, Glenn et al., “Handle with care: The WHO Report on Human Genome Editing” (2022) 52:2 Hastings Cent Rep 10-14.

Conley, John M., “A New Approach to Regulating Human Genome Editing” (2020) 22:2 NCJ Law Technol 107-141

Copelon, Rhonda et al., “Human Rights Begin at Birth: International Law and the Claim of Fetal Rights” (2005) 13:26 Reproductive Health Matters 120-129.

Cwik, Bryan, “Intergenerational Monitoring in Clinical Trials of Germline Gene Editing” (2020) 46:3 J Med Ethics 183-187.

Darnovsky, Marcy, “A slippery slope to human germline modification” (2013) 499 Nature 127.

Diamond, Rebecca et al., “The unexpected and unanticipated announcement of the “world’s first gene editing babies: breaching, repairing and strengthening scientific boundaries” (2022) 45:1 New Genetics & Society Online < https://www.tandfonline.com/doi/citedby/10.1080/14636778.2022.2155124?scroll=top&needAccess=true>.

Doerfler, Walfer, “Epigenetic Consequences of Genome Manipulation: Caveats for Human Germline Therapy and Genetically Modified Organisms” (2018) 11:3 Epigenomics 247-250.

Douglas, Thomas & Devolder, Katherine, “Gene Editing Identity & Benefit” (2021) 72:2 The Philosophical Quarterly 305-325.

Dow, Katherine, “’Now She’s Just an Ordinary Baby’: The Birth of IVF in the British Press” (2019) 53:2 Sociology 314-329.

Drabiak, Katherine, “The Nuffield Council’s Green Light for Genome Editing Human Embryos Defies Fundamental Human Rights Law” (2020) 34:3 Wiley Bioethics 223-227.

Dziadek, Marie A. & Sue, Carolyn M., “Mitochondrial Donation: Is Australia Ready?” (2022) 16:3 Med J Aust. 118-121.

Emerson, Eric, “Loneliness, social support, social isolation and well being among working age adults with and without disability: Cross-sectional study” (2021) 14:1 Disabil Health J 1-8.

Eser, Albin, “Reform of German Abortion Law: First Experiences” (1986) 34:2 Am J Comp L 369-383.

Esfandiari, Navid & Nesbit, Carleigh, “Catastrophic Human Error in Assisted Reproductive Technologies: A Systemic Review” (2020) 1:18 J Patient Saf 267-274.

Eshire Task Force on Ethics and Law, “Equity of Access to Assisted Reproductive Technology” (2008) 23:4 Human Reproduction 772-774.

Etxebarria, Jon Rueda, “The global governance of genetic enhancement technologies: Justification, Proposals, and Challenges” (2024) International Journal of Theoretical and Practical Reason 55-71.

Fabbri, Morris et al., “Modeling policy development: examining national governance of stem cell-based embryo models” (2023) 18:2 Regen Med 155-168.

Farrelly, Colin, “How Should We Theorize About Justice in the Genomic Era?” (2021) 40:1 Politics Life Sci Online <https://pubmed.ncbi.nlm.nih.gov/33949837/>.

Frati, Paola, et al., “Preimplantation and Prenatal Diagnosis, Wrongful Birth and Wrongful Life: A Global View of Bioethical and Legal Controversies” (2017) 23:3 Human Reproduction Update 338-357.

Furrow, Barry R., “The CRISPR-Cas 9 Tool of Gene Editing: Cheaper, Faster, or Riskier?” (2017) 26:2 Annals of Health Law 33-51.

Giles, Jessica & Lee, Simon, “Parrillo v. Italy: Is there life in the European Court of Human Rights” (2016) 5:1 Oxford Journal of Law and Religion 162-167.

Ginoza, Margaret E.C. & Isasi, Rosario, “Regulating Preimplantation Genetic Testing Across the World: A Comparison of International Policy and Ethical Perspectives” (2020) 10:5 Cold Spring Harb Perspect Med Online <DOI: 10.1101/cshperspect.a036681>.

Godard, Béatrice, “Genetic information and testing in insurance and employment: technical, social and ethical issues” (2004) 11 European Journal of Human Genetics 123-142.

Goldberger, Keren, “The Clone Wars: The Right to Embryonic Gene Editing Under German Law” (2019) 45:1 Brooklyn Journal of International Law 404-432.

Greely, Henry T., “Human Germline Genome Editing: An Assessment” (2019) 2:5 The CRISPR Journal 253-265.

Griffiths, Danielle, “The “Re” Production of the Genetically Related Body in Law, Technology and Culture: Mitochondria Replacement Therapy” (2016) 24:196 Health Care Anal 196-209.

Grody, Wayne W., “The Transformation of medical genetics by clinical genomics: hubris meets humility” (2019) 21:9 Genetics in Medicine 1916-1926.

Gruben, Vanessa, "Exploiting the Fiduciary Relationship: The Physician as Information Intermediary in Assisted Human Reproduction" (2009) 18:1 Health L Rev 29-36.

Gurev,Sarah, “CRISPR in Popular Media: Sensationalism of Germline Editing in Human Embryos” (2017) 10:2 Intersect 1-11.

Gutmann, Valerie, “Norms Reborn: Controversies and Challenges for the Future of Reproductive Technologies” (2022) 22:1 Hous. J. Health L. & Pol’y 1-6

Gyngell, Christopher, “Gene Editing and the Health of Future Generations” (2017) 110:7 Journal of the Royal Society of Medicine 276-279.

Halpern, Jodi et al., “Societal and Ethical Impacts of Germline Genome Editing: How Can We Secure Human Rights” (2019) 2:5 CRISPR J 293-298.

Hammerstein, Alix Lenia v., “Is selecting better than modifying? An investigation of arguments against germline gene editing as compared to preimplantation genetic diagnosis” (2019) 20:83 BMC Medical Ethics 1-13.

Happer, Catherine and Philo, Greg, “The Role of the Media in the Construction of Public Belief and ‘Social Change’” (2013) 1:1 Journal of Social and Political Psychology 321.

Harris, Katie et al., “Socio-economic disparities in access to assisted reproductive technologies in Australia” (2016) 33:5 Reproductive BioMedicine 575-584.

Herndon, Christopher N., “Need for expanding insurance coverage for fertilization in the United States” (2019) 112:1 Reflections 37-38.

Hevia, Martin, “From Recognition to Regulation: Access to In Vitro Fertilization and the American Convention on Human Rights” (2013) 25:3 Florida Journal of International Law 453.

Hirsch, David, “Rights and Responsibilities in Wrongful Birth/ Wrongful Life Cases” (2006) 29:2 UNSW Law Journal 233-238.

Iltis, Ana S. et al., “Ethical, Legal, Regulatory and Policy Issues Concerning Embryoids: A Systematic Review of Literature” (2023) 14:209 Stem Cell Research and Therapy 1-15.

Iltis, Ana S. et al., “Public & Stakeholder Engagement in Developing Human Heritable Genome Editing Policies: What Does it Mean and What Should it Mean” (2021) 3 Frontiers in Political Science, online: <https://www.frontiersin.org/articles/10.3389/fpos.2021.730869>;

Iovino, Paolo et al., “A middle-range theory of social isolation in chronic illness” (2023) 20:6 Int J Environ Res Public Health 1-12

Isasi, Rosario et al., “Mending the Gap: Ethically Sensitive Cells and the Evolution of European Stem Cell Policy” (2022) 17:8 Regen Med. 581-595.

Ishii, Tetsuya, “Assignment of Responsibility for Creating Persons Using Germline Genome Editing” (2021) 1:100006 Gene & Genome Editing 1-5.

Ishii, Tetsuya & Beriain, Ińgo de Miguel, “Safety of Germline Genome Editing for Genetically Related ‘Future’ Children as Perceived by Parents” (2019) 2:6 The CRISPR Journal 370-375.

James Jr., A E, “The concepts of wrongful birth and wrongful life and their relation to medical imaging” (1989) 7:1 Health Matrix 54-57.

Jang, Jinseop et al., “Global Governance: Present and Future” (2016) 2 Palgrave Communications 1-5.

Jasanoff, Sheila et al., “Democratic Governance of Human Germline Genome Editing” (2019) 2:5 The CRISPR Journal 266-271.

Jasanoff, Sheila & J Hurlbut, Benjamin, “A Global Observatory for Gene Editing.”(21 March 2018) Online: *Nature*, < https://www.nature.com/articles/d41586-018-03270-w>.

Johnson, Walter G. & Bowman, Diana M., “Inherited Regulation for Advanced ARTs: Comparing Jurisdictions’ Applications of Existing Governance Regimes to Emerging Reproductive Techniques” (2022) 9:1 Journal of Law and Biosciences 1-39.

Johnston, Josephine & Zacharias, Rachel L., “The Future of Reproductive Autonomy” (2017) 47:3 Hasting Cent Rep 6-11.

Jonlin, Erica C., “Informed Consent for Human Embryo Genome Editing” (2020) 14:4 Stem Cell Reports 530-537.

Joseph, Andrew M. et al., “Ethical Perspectives of Therapeutic Human Genome Editing from Multiple and Diverse Viewpoints: A Scoping Review” (2022) 14:11 Cureus 1-18.

Jung, Yun Hwa, “Impact of the acceptance of disability on self-esteem among adults with disabilities: a four-year follow-up study” (2022) 19:7 Int J Environ Res Public Health 1-11.

Kaan, Terry et al., “Germline Genome Editing: Moratorium, Hard Law, or an Informed Adaptive Consensus?” (2021) 17:9 PLOS Genetics 1.

Kabata, Faith N. & Thaldar, Donrich W., “The Human Genome as the Common Heritage of Humanity” (2023) 14 Front. Genet. < https://www.frontiersin.org/articles/10.3389/fgene.2023.1282515/abstract>.

Kirubarajan, Abirami et al, “Cultural Competence in Fertility Care for Lesbian, Gay, Bisexual, Transgender, and Queer People: A Systematic Review of Patients and Provider Perspectives” (2021) 115:5 Fertility and Sterility 1294-1301;

Kleiderman, Erika & Stedman, Ian Norris Kellner, “Human Germline Genome Editing is Illegal in Canada, but it could be Desirable for Some Members of the Rare Disease Community” (2020) 11:2 J Community Genet 129-138.

Klitzman, Robert et al., “Controversies Concerning Mitochondrial Replacement Therapy” (2015) 103:2 Ferti Steril 344-346.

Knoppers, Bartha M. et al., “The Human Embryo: Ethical and Legal Aspects” (2009) 550 Methods Mol Biol 281-305.

Knoppers, Bartha M. et al., “Human gene editing: revisiting Canadian policy” (2017) 2:3 NPJ Regen Med 1 at 1-2;

Knoppers, Bartha M. & Ayyappaswamy, Priya, “International Comparative Perspectives on Human Embryo Research” (Unpublished, 2022).

Kollthoff, Marta, “Assisted Reproduction and Pimum Non Nocere” (2007) 9:9 Vitual Mentor 605-610;

Koplin, Julian et al., “Ethical Implementation of Mitochondrial Donation in Australia” (2022) 62:6 Aust N Z J Obstet Gynaecol 921-924.

Kooli, Chokri, “Review of Assisted Reproduction Technique Laws, and Regulations in Muslim Countries” (2020) 24:8 Middle East Fertility Society Journal 1-15.

Krekova-Zajac, Dorota, “Civil Liability Damages Related to Germline and Emrbyo Editing Against the Legal Admissibility of Gene Editing” (2020) 6: 30 Nature 1-8.

Kuhnt, Anne-Kristin, “Families formed through assisted reproductive technology: Causes, experiences, and consequences in an international context” (2022) 14 Reprod Biomed Soc 289-296.

Kurjak, Asim et al., “Facts and Doubts on the Beginning of Human Life – Scientific, Legal, Philosophical, and Religious Controversies” (2023) 51:1 J. Perinat. Med. 39-50.

Kushnir, Vitaly A., “Preimplantation sex selection *via* in vitro fertilization: time for a reappraisal” (2023) 4:3 F S Rep 241-243.

Kushnir, Vitaly et al, “The Future of IVF: The New Normal in Human Reproduction” (2022) 29 Reproductive Sciences 849-856.

Lane, Alyssa et al., “’Mitochondrial Replacement’ Technologies and Human Germline Nuclear Modification” (2016) 38:8 Journal of Obstetrics and Gynaecology Canada 731-736.

Langlois, Adèle, “The global governance of human cloning: the case of UNESCO” (2017) 2:17019 Palgrave Communications - Nature Online < https://www.nature.com/articles/palcomms201719>.

Legrand, Timothy & Stone, Diane, “Science Diplomacy and Transnational Governance” (2018) 13 Br Poliy 392-408.

Lewis, Myrisha S., “Is Germline Gene Editing Exceptional?” (2021) 51 Seton Hall Law Review 735-813.

Li, Hongyi et al., “Applications of Genome Editing Technology in the Targeted Therapy of Human Diseases: Mechanisms, Advances and Prospects” (2020) 5:1 Signal Transduction and Targeted Therapy 1-23.

Li, Tianxiang et al, “CRISPR/Cas9 therapeutics: Progress and Prospects” (2023) 8:36 Siignal Transduction and Targeted Therapy 1-23.

Liu, Shuang, “Legal Reflections on the Case of Genome Edited Babies” (2020) 5:24 Global Health Research and Policy 1-3.

Lovell-Badge, Robin, “The regulation of human embryo and stem-cell research in the United Kingdom” (2008) 9:12 Nat Rev Mol Cell Bio 998-1003.

Maani, Nason et al., “Global Health Equity Requires Global Equity” (2023) 21:7 Health Equity 192-196.

MacDonnell, Vanessa & Hughes, Jula, “The German Abortion Decisions and the Protective Function in German and Canadian Constitutional Law” (2013) 50:4 Osgoode Hall Law Journal 999-1050.

Mackay, Amanda, “Inequity of Access: Scoping the Barriers to Assisted Reproductive Technologies” 11:1 (2023) Pharmacy 1-16.

MacKellar, Calum, “Gene Editing and the New Eugenics” (2018) 25:1 Dignitas 3-9.

MacKellar, Calum, “Why human germline genome editing is incompatible with equality in an inclusive society” (2021) 27:1 New Bioeth. 19-29.

Mahomed, S, “Three to one – an ethico-legal outline of mitochondrial donation in South African context” (2023) 16:3 SAJBL 95-98.

Mahalatchimy, Aurélie & Rial-Sebbag, Emmanuelle, “Deciphering the Fragmentation of the Human Genome Editing Regulatory Landscape” (2022) 3 Frontiers in Political Science 1-12

Malmqvist, Ekim, “Clinical Trials of Germline Gene Editing: The Exploitation Problem” (2021) 35:7 Bioethics 688-695.

Manhoff, Alison W., “Banned and Enforced: The Immediate Answer to a Problem Without an Immediate Solution” (2005) 38:3 VJTL 889-920.

Marchant, Gary E., “Global Governance of Human Germline Genome Editing: What are the Rules?” (2021) 22 Annual Review of Genomics and Human Genetics 385-405.

Martin, Paul A. & Turkmendag, Ilke, “Thinking the Unthinkable: How Did Germline Genome Editing Become Ethically Acceptable” (2021) 40:4 New Genetics & Society 384-405.

Mathiesen, SMS et al, “Stress, distress and outcome of assisted reproductive technology (ART): a meta-analysis” (2011) 26:10 Human Reproduction 2763-2776.

Matthews, Kirstin R W & Morali, Daniel, “Can We Do That Here? An Analysis of US Federal and State Policies Guiding Human Embryo and Embryoid Research” (2022) 9:1 J Law Biosci 1-24.

McCaughey, Tristan, “A Need for Better Understanding is the Major Determinant for Public Perceptions of Human Gene Editing” (2019) 20:1 Human Gene Therapy 36-43.

McDermott, Olivia, “A Comparison of Assisted Human Reproduction (AHR) Regulation in Ireland with Other Developed Countries” (2022) 19:62 Reprod Health 1-13.

McFadden, Brandon R et al., “US public opinion about the safety of gene editing in agriculture and medical fields and the amount of evidence needed to improve opinions” (2024) 12 Front. Bioeng. Biotechnol. Online < doi.org/10.3389/fbioe.2024.1340398>.

Medical Advisory Secretariat, “In Vitro Fertilization and Multiple Pregnancies” (2006) 6:18 Ont Health Technol Assess Ser Online < https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3379537/>.

Melo, Anna E., “Playing god in the 21st century: how the push for human embryonic germline gene editing sidelines individual and generational autonomy” (2023) 32 Cath U J L & Tech 77-107.

Miklavcic, John Janez & Flaman, Paul, “Personhood Status of the Human Zygote, Embryo, Fetus” (2017) 84:2 Linacre 130-144.

Momozawa, Yukihide & Mizukami, Keijiro, “Unique Roles of Rare Variants in the Genetics of Complex Diseases in Humans” (2020) 66 Journal of Human Genetics 11-23.

Morris, Caroline, “Evans v. United Kingdom: Paradigms of Parenting” (2007) 70:6 The Modern Law Review 992-1002.

Moutos, Chirstopher P & John Y Phelps, “Wrongful Birth and Wrongful Life Lawsuits in Obsterics and Gynecology” (21 May 2024), Online: American Journal of Obsterics and Gynecology <https://www.ajog.org/article/S0002-9378(24)00626-4/abstract>.

Muacevic, Alexander & Adler, John R, “Ethical Perspectives of Therapeutic Human Genome Editing from Multiple and Diverse Viewpoints: A Scoping Review” (2022) 14:11 Cureus 1-18.

Munné, Santiago et al., “Preimplantation Genetic Diagnosis Significantly Reduces Pregnancy Loss in Infertile Couples: A Multicenter Study” (2006) 85:2 Fertil Steril Online: < DOI: 10.1016/j.fertnstert.2005.10.014>.

Munné, Santiago, “Status of Preimplantation Genetic Testing and Embryo Selection” (2018) 37:4 RBMO 393-396.

Munsuru, Kiran et al., “What do We Really Think About Human Germline Genome Editing, and What Does it Mean for Medicine?” (2017) 10:5 Cardiovascular Genetics 1-3.

Murphy, Timothy E., “Access & Equity: International Standards and Assisted Reproductive Technologies” (2007) 14:1 Reproductive Biomedicine Online <https://doi.org/10.1016/S1472-6483(10)60719-5>.

Nadimpally, Sarojini, “The Ethics, Equity, and Governance of Human Genome Editing Need Greater Consideration” (3 May 2023), Online: BMJ <doi:https://doi.org/10.1136/bmj.p996>.

Nakhuda, Gary S., “Posthumous Assisted Reproduction” (2010) 28:4 Semin Reprod Med 329-335.

Nampewo, Zahara et al., “Respecting, Protecting, and Fulfilling the Human Right to Health” (2022) 21:36 International Journal for Equity in Health Online < https://doi.org/10.1186/s12939-022-01634-3>.

Nelson, John P. et al., “Towards Anticipatory Governance of Human Genome Editing: A Critical Review of Scholarly Governance Discourse” (2021) 8:3 J Responsible Innov 382-420.
Newson, Ainsley J & Wrigley, Anthony, “Is Mitochondrial Donation Germline Gene Therapy? Classifications and Ethical Implications” (2017) 31:1 Bioethics 55-67.

Newton, CR, “Motives for parenthood and response to failed in vitro fertilization: implications for counseling” (1992) 9:1 J Assist Reprod Genet 24-41.

Nordberg, Ana et al., “Regulating Germline Editing in Assisted Reproductive Technology: An EU Cross-disciplinary Perspective” (15 July 2018), Online: Human Germline Editing < DOI: 10.1111/bioe.12705>;

Norgren, Anders, “Designing Preclinical Studies in Germline Genome Editing: Scientific and Ethical Aspects” (2019) 16:4 J Bioeth Inq 559-570.

Novelli, Guiseppe et al., “COVID-19 One Year into the Pandemic: From Genetics and Genomics to Therapy, Vaccination, and Policy” (2021) 15:27 Human Genomics 1-13.

O’Nolan, Gerald et al., “Should the Governments Fund Assisted Reproductive Technologies?” (2019) 24:1 BMJ-Evidence Based Medicine Online:<https://doi.org/10.1136/bmjebm-2019-EBMLive.15>.

Ormond, Kelly E. et al., “Human Germline Genome Editing” (2017) 101:2 American Journal of Human Genetics 167-176.

Ossorio, Pilar N., “The Human Genome as Common Heritage: Common Sense or Legal Nonsense?” (2007) 25:3 J Law Med Ethics 425-439.

Parikh, Firuza Rajesh et al., “Preimplantation Genetic Testing: Its Evolution, Where Are We Today” (2018) 11: 306 J Human Reprod Sci 306-14.

Peng, Yaojin et al., “Responsible Governance of Human Germline Genome Editing in China” (2022) 107:1 Biology of Reproduction 261-268.

Peterson, MM, “Assisted Reproductive Technologies and Equity of Access Issues” (2005) 31 J Med Ethics 280-285.

Pompe, Sven et al., “Stem-cell research: the state of the art” (2005) 6:4 EMBO Rep 297-300.

Primc, Nadia, “Do we have a right to an unmanipulated genome? The human genome as the common heritage of mankind” (2020) 34:1 Bioethics 41-48.

Qin, Dahui, “Next-generation sequencing and its clinical application” (2019) 16:1 Cancer Biol Med 4-10.

Ranisch, Robert, “Germline Genome Editing versus Preimplantation Genetic Diagnosis: Is There a Case in Favour of Germline Interventions?” (2020) 34:1 Wiley Bioethics 60-69.

Rank, Nicole, “Barriers to Access to Assisted Reproductive Technologies by Lesbian Women: The Search for Parity within the Healthcare System” (2010) 10 Hous J Health L & Pol’Y 115-46;

Raposo, Vera Lucia, “The First Chinese Edited Babies: A Leap of Faith in Science” (2019) 23::3 JBRA Assist Reprod 197-199.

Rehm, Heidi L. et al., “GA4GH: International Policies and Standards for Data Sharing Across Genomic Research and Healthcare” (2021) 1:2 Cell Genomics Online < https://doi.org/10.1016/j.xgen.2021.100029>

Reznichenko, AS et al., “Mitochondrial Transfer: Implications for Assisted Reproductive Technologies” (2016) 11 Applied & Translational Genomics 40-47.

Rubeis, Giovanni & Steger, Florian, "Risks and Benefits of Germline Genome Editing: An Ethical Analysis" (2018) 10:2 Asian Bioeth Rev 133-141.

Sarkar, Esha & Khan, Afreen, "Erratic Journey of CRISPR Cas-9 in Oncology from Bench-Work to Successful-Clinical Therapy" (2021) 27 Cancer Treatment and Research Communications 2468-2942.

Saxena, Nishtha et al., "Mitochondrial Donation: A Boon or Curse for the Treatment of Incurable Mitochondrial Diseases" (2018) 11: 1 J Hum Reprod Sci 3-9.

Schenker, J G & Eisenberg, V H, "Ethical issues relating to reproductive control and women's health" (1997) Int J 58:1 Gynaecol Obstet 167-76.

Schweikart, Scott J., "Global Regulation of Germline Genome Editing: Ethical Considerations and Application of International Human Rights Law" (2020) 43:3 Loy L.A. Int'Ll & Comp. L. Rev. 279-296.

Scott, Rosamund & Wilkinson, Stepehn, "Germline Genetic Modification and Identity: the Mitochondrial and Nuclear Genomes" (2017) 37:4 Oxford Journal of Legal Studies 886-915.

Siu, Lilian L et al., "Facilitating a Culture of Responsible and Effective Sharing of Cancer Genome Data" (2016) 22:4 Nat Med 464-471.

Spaander, Merel M., "The European Court of Human Rights and the Emergence of Human Germline Genome Editing" (2022) European Journal of Health Law 458-483.

Stern, Harvey J., "Preimplantation Genetic Diagnosis: Prenatal Testing for Embryos Finally Achieving Its Potential" (2014) 3 J. Clin Med 280-309.

Thakur, Ramesh & Van Langenhove, Luk, "Enhancing Global Governance Through Regional Integration" (2006) 12:3 Global Governance 233-240.

Thompson, Charis, "How should 'CRISPRed' Babies be Monitored Over Their Life Course to Promote Health Equity" (2019) 21:12 AMA J Ethics 1036-1041.

The Ethics Committee of the American Society for Reproductive Medicine, "Disparities in access to effective treatment for infertility in the United States: an Ethics Committee Opinion" (2021) 116:1 Fertility and Sterility 54-63.

Trinchant, R, "Reproductive autonomy in Spain – reproduction as a negative right and the obligations of the state" (2023) 38:1 Human Reproduction 374-375.
Scott, Rosamund, "The Appropriate Extent of Pre-Implantation Genetic Diagnosis: Health Professionals' and Scientists' View on the Requirement for a 'Significant' Risk of a Serious Genetic Condition" (2007) 15:3 Medical Law Review 320-356.

Siu, Lilian L et al., "Facilitating a Culture of Responsible and Effective Sharing of Cancer Genome Data" (2016) 22:4 Nat Med 464.

Smith, Kevin Richard, “Germline Genome Editing of Human IVF Embryos Should not be Subject to Overly Stringent Restrictions” (2024) 41 Journal of Assisted Reproduction and Genetics 1733-1737

Sprink, Thorben et al., “Genome Editing Around the Globe: An Update on Policies and Perceptions” (2022) 190:3 Plant Physiol 1579.

Sullivan, Mary B., “Wrongful Birth and Wrongful Conception: A Parent’s Need for a Cause of Action” (2000) 15:1 Journal of Law and Health 105-120.

Sykora, Peter & Caplan, Arthur, “The Council of Europe should not reaffirm the ban on germline genome editing in humans” (2017) 18:11 EMBO Rep Online < doi: 10.15252/embr.201745246”;

Tabaie, Sheila, “Stopping female feticide in India: the failure and unintended consequence of ultrasound restriction” (2017) 7:1 J Glob Health 1-3.

Talabi, Mehret Birru et al., “Redefining Primum *Non N*ocere to Include Reproductive Autonomy: A New Paradigm in Subspeciality Medicine” (2021) 2:1 Womens Health Rep Online < doi: 10.1089/whr.2021.0079>.

Thakur, Ramesh & Van Langenhove, Luk, “Enhancing Global Governance Through Regional Integration” (2006) 12:3 Global Governance 233 at 233.

Thaldar, Donrich, “A deliberative public engagement study on heritable human genome editing among South Africans: Study results” (2021) 17:11 PLoS One Online < doi: 10.1371/journal.pone.0275372>.

Wakefield, Claire E., “The psychological impact of genetic information on children: a systematic review” (2016) 18 Genetics in Medicine 755-762.

Wang, Leifan et al., “Genome Editing and Human Rights: Implications of the UNGPs” (2022) 4:5 Biosafety and Health 386-391.

Valerio, Carlos et al., “IVF in Costa Rica” (2017) 21:4 JRBA Assist Reprod 366-369.

van Beers, Britta C., “Rewriting the Human Genome, Rewriting Human Rights Law? Human Rights, Human Dignity, and Human Germline Modification in the CRISPR Era” Journal of Law and Biosciences 1-36.

Van Dijke, I et al., “Should germline editing be allowed? The effect of treatment characteristics on public acceptability” (2020) 36:2 Hum Reprod 465-478.

Varghese, Suma Elcy, “The Importance of Early Detection of Genetic Disease” (2021) 4:2 Dubai Med J 133-141.

Vidalis,Takis, “Genome Editing in Human Gametes and Embryos: The Legal Dimension in Europe” (2023) 12:1 Biotech 1.

von Wülfingen, Bettina Bock, "Contested Change: How Germany Came to Allow PGD" (2016) 3 Reprod Biomed Soc 60-67.

Williamsm Kate & Johnson, Martin H., "Adapting the 14-day rule for embryo research to encompass evolving technologies" (2020) 10 Reprod Biomed Soc Online < doi: 10.1016/j.rbms.2019.12.002>.

Xafis, Vicki et al., "Germline Genome Modification through Novel Political, Ethical, and Social Lenses" (2021) 17:9 PLoS Genet 1-13.

Xue, Yang & Shang, Lijun, "Are we ready for the revision of the 14-day rule? Implications from Chinese Legislation Guiding Human Embryo and Embryoid Research" (2022) 10 Front Cell Dev Biol Online < 10.3389/fcell.2022.1016988>;

Yerken, Sofia, "'Wrongful Birth' Claims and the Paradox of Parenting a Child with a Disability" (2018) 87 Fordam L. Rev. 583-628.

Yotova, Rumiana, "Regulating Genome Editing Under International Human Rights Law" (2020) 69:3 International & Comparative Law Quarterly 653-684.

Yu, Hanzhi et al., "Towards inclusive governance of human genome editing" (2021) 118:47 PNAS 1-5. See also, Cynthia Selin, "Researching the future: scenarios to explore the future of human genome editing" (2023) 24:72 BMC Medical Ethics 1-12.

Zegers Hothschild, Fernando et al, "Human Rights to *In Vitro Fertilization*" 2014 18:1 JBRA Assist Reprod 27-31.

Zhang, Xiao-Hui et al., "Off-target Effects in CRISPR/Cas9-mediated Genome Engineering" (2015) 4 Cell Press 1-8.

Secondary Sources: Other

Adashi, Eli Y. & Cohen, Glenn, "Selective Regrets: The 'Dickey Amendments' 20 Years Later" (25 November 2015), Online: JAMA Forum Archive <https://jamanetwork.com/channels/health-forum/fullarticle/2760581#:~:text=The%20%E2%80%9CDickey%2DWicker%E2%80%9D%20amendment,Balanced%20Budget%20Downpayment%20Act%2C%20I>.

"Advisory on Legal Restrictions on the Use of Mitochondrial Replacement Techniques to Introduce Donor Mitochondria into Reproductive Cells Intended for Transfer into a Human Recipient" (16 March 2018), Online: FDA <https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/advisory-legal-restrictions-use-mitochondrial-replacement-techniques-introduce-donor-mitochondria>.

"A New Gene Editing System Tackles Complex Diseases" (21 May 2024), Online: Science Daily < https://www.sciencedaily.com/releases/2024/05/240521124304.htm>.

Ball, Philip, “Seven ways IVF changed the world – from Louise Brown to stem-cell research” (8 July 2018), Online: The Guardian < https://www.theguardian.com/society/2018/jul/08/ivf-in-vitro-fertilisation-louise-brown-born>.

“Base Pair” (17 August 2024), Online: National Human Genome Research Institute <https://www.genome.gov/genetics-glossary/Base-Pair#:~:text=Narration&text=One%20copy%20of%20the%20human,to%20300%20million%20base%20pairs>.

Baylis, Francois, “Stem-cell community drops the 14-day rule” (1 June 2021), Online: Dal New < https://www.dal.ca/news/2021/06/01/stem-cell-research-community-drops-14-day-limit-on-human-embryo-.html>.

Brave New Dialogue” (28 February 2019), Online: Nature Genetics Editorial <https://www.nature.com/articles/s41588-019-0374-2>.

Center for Disease Control and Prevention, "What is Assisted Reproductive Technology?" (14 April 2022), Online: CDC <https://www.cdc.gov/art/whatis.html>.

Committee on Genetics, “Preimplantation Genetic Testing”, (March 2020), Online:ACOG <https://www.acog.org/clinical/clinical-guidance/committeeopinion/articles/2020/03/preimplantation-genetic-testing>;

Committee of Social Affairs, Health and Sustainable Development, “The Use of New Genetic Technologies in Human Beings” (24 May 2017), Online: PACE < https://assembly.coe.int/nw/xml/XRef/Xref-XML2HTML-en.asp?fileid=23730&lang=en>.

Committee on the Elimination of Discrimination Against Women, *Concluding Observations of the Committee on the Elimination of Discrimination Against Women: Argentina*, UN CEDAWOR, 46th Sess, UN Doc CEDAW/C/ARG/CO/6 (2010).

Council for Responsible Genetics, *Genetic Bill of Rights* (2000), Online: Council for Responsible Genetics <http://www.councilforresponsiblegenetics.org/projects/CurrentProject.aspx?projectId=5>.

Couzin-Frankel, Jennifer, “Unanswered Questions Surround Baby Born to Three Parents” (27 September 2016), Online: Science <https://www.science.org/content/article/unanswered-questions-surround-baby-born-three-parents>.

Danmeng, Ma et al., “WHO appoints panel to advise on gene editing governance” (20 February 2019), Online: Caixin Global <https://www.caixinglobal.com/2019-02-20/who-appoints-panel-to-advise-on-gene-editing-governance-101381785.html>.

de Vries, Jantina & Baylis, Francois, “Equity and access need to at the forefront of innovation in human genome editing” (12 July 2021), Online: The Conversation < https://theconversation.com/equity-and-access-need-to-be-at-the-forefront-of-innovation-in-human-genome-editing-

161794#:~:text=Germline%20human%20genome%20editing%20involves,its%20impact%20on%20future%20generations>.

Díaz-Figueroa, Gabriel, "Shaping Science: The UK Citizens Jury on Human Genome Editing" (4 June 2024), Online: Innovative Genome Institute < https://innovativegenomics.org/news/uk-citizens-jury-human-genome-editing/>.

"Disability Inclusive Social Protection Across Europe and Central Asia" (28 June 2023), Online World Bank Group <https://www.worldbank.org/en/region/eca/brief/disability-inclusive-social-protection-across-europe-and-central-asia>.

Ethical Guiding Principles for Research on Embryonic Stem Cell. (2003) Ministry of Health.

European Academies Science Advisory Council. *About EASAC*. European Academies Science Advisory Council (Accessed 3 August 2024), Online: EASAC < https://easac.eu/about/>.

European Commission. *European Group on Ethics in Science and New Technologies*. (accessed August 3, 2024).<https://research-and-innovation.ec.europa.eu/strategy/support-policy-making/scientific-support-eu-policies/european-group-ethics_en#:~:text=European%20Group%20on%20Ethics%20in,of%20science%20and%20new%20technologies>.

European Medicines Agency. *About Us*. European Medicines Agency, (Accessed 3 August 2024), Online: EMA <https://www.ema.europa.eu/en/about-us>.

European Parliament, *European Parliamentary Research Service: The Impact of Rare Diseases on Patients and their Families* (2018), available at https://www.europarl.europa.eu/RegData/etudes/IDAN/2018/603218/EPRS_IDA(2018)603218_EN.pdf

Expanding Definitions of Family in Federal Laws" (26 May 2020), Online: CAP 20 < https://www.americanprogress.org/article/expanding-definitions-family-federal-laws/>.

Funk, Cary & Hefferon, Meg, "Public View of Gene Editing for Babies Depend on How It Would Be Used" (26 July 2018), Online: PEW Research < https://www.pewresearch.org/science/2018/07/26/public-views-of-gene-editing-for-babies-depend-on-how-it-would-be-used/>.

"Gene Therapy and Genetic Engineering", Online: Centre for Health Ethics < https://medicine.missouri.edu/centers-institutes-labs/health-ethics/faq/gene-therapy>.

"Germline gene-editing needs rules" (13 March 2019), Online: Nature Editorial <https://www.nature.com/articles/d41586-019-00788-5>.

"Germline Genome Editing Needs One Message" (21 November 2019), Online: Nature < https://www.nature.com/articles/d41586-019-03525-0>.

Global Alliance for Genomics and Health, “Regulatory and Ethics Workstream” Online: GA4GH < https://www.ga4gh.org/work_stream/regulatory-ethics/>.

Gumer, Jennifer, “The Dubious Benefits of Germline Editing” (2018) 4 Voices Bioeth, online: <https://journals.library.columbia.edu/index.php/bioethics/article/view/6003>.

Ikpomwosa Egbah, Andrew & Oziegbe Igene, Stella, “Legitimating Genome Editing: A Critical Discourse Analysis of Media Reportage” (January 2024), Online < https://www.researchgate.net/publication/378469343_Legitimating_Genome_Editing_A_Critical_Discourse_Analysis_of_Media_Reportage>.

“In Vitro Fertilization”, Online: Mayo Clinic <https://www.mayoclinic.org/tests-procedures/in-vitro-fertilization/about/pac-20384716#:~:text=In%20vitro%20fertilization%2C%20also%20called,genetic%20problems%20to%20a%20child.>.

“Italy leads way for legislation Re Mito DNA Replacement” (27 February 2024), Online: < https://www.mitopatients.org/news/italy-leads-way-for-legislation-re-mito-dna-replacement>.

Jasanoff, Sheila & Hurlbut, Benjamin, “A Global Observatory for Gene Editing.”(21 March 2018) Online: *Nature*, < https://www.nature.com/articles/d41586-018-03270-w>.

Kotagama, Odatha W., “Era of genomic medicine: A narrative review on CRISPR technology as a potential therapeutic tool for human diseases” (2 October 2019), Online: BioMed international < doi:10.1155/2019/1369682>.

Lee, Yoo Yung, “Genome Editing or Genome Cutting? Communicating CRISPR in the British and German Press” (29 October 2020), Online <https://www.degruyter.com/document/doi/10.1515/gcla-2020-0004/html?lang=en#:~:text=Using%20a%20corpus%20of%20600,edit%20the%20DNA%2C%20replacing%20spelling>;

Levy, Anna, “In Iceland, almost all diagnosed down syndrome pregnancies are aborted after prenatal testing. Some bioethics experts are concerned” (1 May 2024), Online: Australian Broadcasting Corporation < https://www.abc.net.au/news/2024-05-01/iceland-prenatal-testing-down-syndrome-ethics/103781058>.

Locke Rottinghaus, Marissa, “FDA approves CRISPR-Cas 9 therapy for sickle cell disease” (8 December 2023), Online: ASBMB Today < https://www.asbmb.org/asbmb-today/science/120823/fda-approves-crispr-cas9-therapy-for-sickle-cell#:~:text=Officials%20at%20the%20U.S.%20Food,eligible%20for%20stem%20cell%20transplants>.

Maldarelli, Claire, “Scientists Support Research on Gene Editing”, 4 December 2015, Online: Popular Science < https://www.popsci.com/scientists-support-research-on-gene-editing-human-embryos/>.

Maxmen, Amy, “Faster, better, cheaper: the rise of CRISPR in disease detection” (19 February 2019), Online < https://www.nature.com/articles/d41586-019-00601-3>.

Mills, Peter, “Human Genome Editing and Moral Leadership: findings of the WHO Expert Advisory Committee” (14 July 2021), Online: Nuffield Council on Bioethics <https://www.nuffieldbioethics.org/blog/human-genome-editing-and-moral-leadership-findings-of-the-who-expert-advisory-committee>

“Mitochondrial Donation Treatment”, Online: Human Fertilisation and Embryology Authority <https://www.hfea.gov.uk/treatments/embryo-testing-and-treatments-for-disease/mitochondrial-donation-treatment/#:~:text=The%20UK%20is%20the%20first,to%20be%20approved%20by%20us>.

“Mitochondrial Donation” (22 October 2014), Online: House of Commons – UK < https://www.parliament.uk/globalassets/documents/commons-committees/science-technology/Mitochondrial-donation/MITCorrespondence.pdf>.

Molteni, Megan, “World Health Organization advisers urge global effort to regulate genome editing” (12 July 2021), Online STAT News < https://www.statnews.com/2021/07/12/genome-editing-world-health-organization/>;

National Academy of Sciences, *"International Summit on Human Gene Editing" (2023),* online: National Academies <https://www.nationalacademies.org/our-work/international-summit-on-human-gene-editing#:~:text=The%20National%20Academy%20of%20Sciences,issues%20associated%20with%20these%20advances>.

National Academy of Sciences, *"The Second International Summit on Human Gene Editing" (2018),* online: National Academies https://www.nationalacademies.org/our-work/the-second-international-summit-on-human-gene-editing.

Normile, Dennis, “Researcher Who Created CRISPR Twins Defends His Work but Leaves Many Questions Unanswered” (28 November 2018), Online: Science < https://www.science.org/content/article/researcher-who-created-crispr-twins-defends-his-work-leaves-many-questions-unanswered>.

Normile, Dennis, “In the wake of gene-edited baby scandal, China sets new ethics rules for human studies”, (7 March 2023), Online: Science < https://www.science.org/content/article/wake-gene-edited-baby-scandal-china-sets-new-ethics-rules-human-studies>.

Organizing Committee, *"Third International Summit on Human Genome Editing" (6-8 March 2023),* online: The Royal Society <https://royalsociety.org/science-events-and-lectures/2023/03/2023-human-genome-editing-summit/>.

Ortega, Rodrigo Pérez, “Genetic Databases Don’t Fairly Capture Species Richness of Global South, New Data Shows” (18 October 2024), Online: Science <https://www-science-org.proxy3.library.mcgill.ca/content/article/countries-global-south-have-more-biodiversity-countries-north-databases-used-study>.

Parliamentary Assembly of the Council of Europe, *Recommendation 934 on Genetic Engineering*, Doc No 4920 (1982), Online: Council of Europe<http://assembly.coe.int/nw/xml/XRef/Xref-XML2HTML-en.asp?filexml:id=14968&xml:lang=en>.

"Q & A: Access to abortion is a human right" (24 June 2022), Online: Human Rights Watch < https://www.hrw.org/news/2022/06/24/qa-access-abortion-human-right>.

Shakespeare, Tom, "Gene Editing: Heed Disability Views" (25 November 2015), Online: Nature < https://www.nature.com/articles/527446a>;

Sheridan, Cormac, "The world's first CRISPR therapy is approved: who will receive it?" (21 November 2023), Online: Nature Biotechnology < https://www.asbmb.org/asbmb-today/science/120823/fda-approves-crispr-cas9-therapy-for-sickle-cell#:~:text=Officials%20at%20the%20U.S.%20Food,eligible%20for%20stem%20cell%20transplants>.

Study Finds Why Many IVF Embryos Fail to Develop" (19 July 2022), Online: Columbia Irving Medical Center <https://www.cuimc.columbia.edu/news/study-finds-why-many-ivf-embryos-fail-develop>.

The 1000 Genomes Project Consortium, "A Global Reference for Human Genetic Variation" (30 September 2015), Online: Nature <https://www.nature.com/articles/nature15393>.

Thompson, Janna, "What we risk as humans if we allow gene-edited babies: a philosopher's view" (18 February 2019), Online: The Conversation < https://theconversation.com/what-we-risk-as-humans-if-we-allow-gene-edited-babies-a-philosophers-view-110498#:~:text=What%20parents%20want,lead%20to%20denigration%20or%20rejection.>.

"UN adopts non-binding cloning ban" (10 March 2005), Online PET < https://www.progress.org.uk/un-adopts-non-binding-human-cloning-ban/>.

UN Committee on Economic, Social and Cultural Rights, General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art 12 of the Covenant) (11 August 2000) UN Doc E/C.12/2000/4.

United Kingdom, House of Commons Library**,** *Mitochondrial Donation*, Standard Note: SN/SC/6833, (30 August 2014).

Ways to become a parent if you are LGBT+", Online: NHS < https://www.nhs.uk/pregnancy/having-a-baby-if-you-are-lgbt-plus/ways-to-become-a-parent-if-you-are-lgbt-plus/>.

Wise, Jacqui, "First baby born in the UK using mitochondrial donation therapy" (12 May 2023), Online: The BMJ < https://www.bmj.com/content/381/bmj.p1091.long>

Wong, Carissa, "UK first to approve CRISPR treatment for diseases: what you need to know" (16 November 2023) Online: Nature <https://www.nature.com/articles/d41586-023-03590-6>.

World Health Organization, “WHO issues new recommendations on human genome editing for advancement of public health” (12 July 2021) Online: WHO News Release < https://www.who.int/news/item/12-07-2021-who-issues-new-recommendations-on-human-genome-editing-for-the-advancement-of-public-health>.