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DISSERTATION

The place of human dignity within the field of genomic research in
relation to the law of bioethics

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Abstract

The object of this dissertation is to ascertain the conceivability, usefulness, and potential impact of using human dignity as a unifying theory to address emerging issues within contemporary bioethics in consideration of revolutionary gene-editing practices applicable to human beings that may directly challenge the definition of what it means to be human.

To this end, we will examine the relevance, scope and limitations of the concept of human dignity under recent developments in the technology of gene-editing, and more specifically germline editing, the practice of editing the genes of human embryos in order to create genetically modified people able to pass on these modifications to future generations.

These technological advances call for a review and revision of international regulations in the law of bioethics. The subject is explored in particular in relation to the first experimental case of babies born from gene-edited embryos, by applying human dignity as an ethical tool to assess possible legal implications. This assessment will be conducted through a study of recent literature on the subject of human dignity, bioethics law and genomic manipulation as it pertains to the case, as well as the reports of expert committees and relevant case law, an analysis of the existing legal and regulatory context for gene-editing, which relies heavily on human rights principles, as well as a doctrinal analysis of the current understandings surrounding these subjects.

We will showcase a range of theoretical understandings of human dignity, the current progression of its use as a basis for bioethics regulations, institutions, and its application to practices, demonstrating both its potential as the "Theory of Everything" in bioethics that is supported by Charles Foster, but also the severe limitations that require urgent deliberation and international consensus on how to leverage the use of human dignity as an ethical standard.

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Introduction

Until a few years ago, manipulation of the human genome was technically at a halt. The technology to read and compile our genetic code or DNA existed, but attempts to edit it remained outside of our reach, and scientific experimentation was focused on the cellular level instead, within the promising field of stem cell research. However, the discovery of CRISPR-cas9, a gene-editing method derived from the natural process used by bacteria to target specific segments of DNA, has made gene-editing fast, accurate, and incredibly accessible.¹ It opens up the possibility to cure diseases and harmful genetic conditions and even to prevent them from developing in the first place. Beyond the numerous medical applications, however, the ability to alter the genetic make-up of an individual raises profound ethical concerns, and thus legal ones as well, not only as to the acceptability and potential risks accompanying the human experimentations necessary to develop these techniques but also regarding the social and moral ramifications of their implementation. In addition, gene editing can be used to alter sperm or egg cells, also called germline cells, and embryo cells, both of which are the source of genetic material for all other cells in the organism. As such, germline gene editing is able to pass on modifications to future generations and carries the potential for repercussions on the evolution of the species as a whole.²

Unfortunately, there is currently no unified regime of regulation for research around this subject. The rapid pace of these evolutions in biotechnology and their consequences makes it pressing and crucial to scrutinise the theoretical tools at the disposal of legal systems in order to reevaluate their efficacy and applicability. In addition, responding to ethical issues raised calls for a well-developed overarching global theory that can, in turn, serve as the backbone to an international regulatory system. The current regime relevant to these emergent biotechnologies revolves around international declarations of principles and intent, and specialised legislation at the territorial level on technology-specific implementations. Such international instruments, and by extension national regulations, rely heavily on mentions of the principle of human

¹ 'What are genome editing and CRISPR-Cas9?' (10 October 2017)

<https://ghr.nlm.nih.gov/primer/genomicresearch/genomeediting> accessed 27 August 2019.

² Ormond KE and others, 'Human Germline Genome Editing' (2017) *Am J Hum Genet* 101(2) 167-176.

dignity, derived from the international human rights law framework. This modern conception of dignity emerged from the ashes of the Second World War to signify a strong belief in the equal inherent worth of every individual, though its roots reveal a more varied patchwork of interpretations.³ It has gained traction in contemporary ethics, the study of how moral standards are defined in society, and subsequent human rights instruments that use it as a universal rationale for a supranational system of rights. The inherent dignity of every human being serves as the basis from which equality, the sanctity of life, essential freedoms, and fundamental rights, are derived in human rights doctrine. As such, the area of bioethics, which draws from both ethics and human rights perspectives, has seen the concomitant adoption of human dignity as a conceptual tool. At the intersection of philosophy, law, social sciences and the life sciences, it is the branch of applied ethics that considers both ethical and legal issues arising from studying the interactions of living beings, and especially human beings, and their environment, notably in biology and medicine.⁴ Bioethics is precisely the domain where the consequences and governance of biotechnologies are given due consideration. There, the notion of dignity has been widely deployed in related international documents to serve both as a moral standard of the absolute value of a human being and as an alternative legal standard to personal autonomy. Human dignity is a philosophical concept that has become a "universal ethical and legal principle,"⁵ and is foundational in the exploration of personhood, identity, the value of human worth, and the nature of humanity. However, it suffers from a range of issues that render it open to contestation, from uncertainty as to its theoretical basis to ambiguity around its meaning or inconsistency in its deployment. In effect, dignity has been used to both empower, and constrain genomic research, begging the question as to its suitability as a bioethical tool. Human dignity remains a controversial notion and its value as a moral or legal standard, whether in human rights or bioethics, has been debated by academics and researchers alike. This enduring and nebulous ambivalence indicates the additional need for an in-depth analysis of its scope and import, which we will conduct while exploring genomic manipulation, and especially germline gene-editing, as current points of contention in bioethics and the law.

³ Jeff Malpas and Norelle Lickiss (eds.), *Perspectives on Human Dignity: A Conversation*, Springer 2017.

⁴ Roberto Andorno, 'Human dignity and human rights as a common ground for a global bioethics' (2009) 34 *Journal of Medicine and Philosophy* 223.

⁵ Roberto Andorno, 'Human Dignity' in Henk ten Have, *Encyclopedia of Global Bioethics*, Springer 2015.

This research proposes to identify the extent to which human dignity is, and has been used as a legal tool in a global bioethics framework, its limitations in that regard, and interactions with changes in societies or shifts of its meaning, as well as their legal repercussions. The subject will be approached through the issue of genomic exploration and modification, in order to determine the extent to which human dignity is able to contend with the legal implications of these expanding ethical boundaries. In order to address these issues, this project will first attempt to circumscribe the notion of human dignity in a legal context, including the current conceptions surrounding it, in particular through the work of Charles Foster, and its limitations. This will be undertaken chiefly by doctrinal analysis of recent literature on the subject of human dignity, bioethics law, and genomic manipulation, as well as the reports of expert committees and relevant case law. Subsequently, we will examine recent evolutions in the legal doctrine around the bioethics law on genomic manipulation and its relation to the critical concept of human dignity extended to consent. Lastly, the dissertation will attempt to catalogue some of the different modifications undergone by legal systems and expert opinions through a comparative analysis of different jurisdictional frameworks.

I. Human dignity as the defining principle of bioethics and its application to genome editing technologies

What is the importance of human dignity in the international normative framework of bioethics? What is the purpose of human dignity in the law of bioethics and does its ubiquity throughout multiple interpretations weaken the concept as a legal tool?

a. The role of dignity in the international framework pertaining to human genome editing

Human dignity has both been defined as “the shaping principle” of international bioethics⁶ and a “mere slogan”, “a useless concept in medical ethics” that “can be eliminated without loss of content”.⁷ Regardless of its perceived flaws, the prominence of dignity in the bioethics discourse is undeniable. From the Declaration of Helsinki on the protection of human participants in experimentation⁸ to the Universal Declaration on the Human Genome setting out guidance for a legal framework around genetic research⁹ and the Convention on Human Rights and Biomedicine¹⁰, dignity is cited as a principle, and perhaps even a right, to be upheld and protected against abuse. Moreover, multiple international organisms rely on its language. The international regulatory framework on human genome editing falls within the oversight of biomedical practice and research regulations, which are also informed by human rights principles and conventions. This creates a primary, strong connection between bioethics laws and the reliance on human dignity as a concept through its role within human rights. The presence necessitates a careful examination in order to reveal the role dignity plays as well as its shortcomings within this legal context, and especially in relation to the issues brought about by the specificities of gene editing on human subjects. In addition, the rights-based framework surrounding dignity further fuels the debate on its status as a right or principle itself. We will necessarily attempt, if not to clarify, to explore these facets of dignity and expose its purpose in bioethics through its application to the regulation of gene editing practices on

⁶ Nöelle Lenoir and Bertrand Mathieu, *Les normes internationales de la bioéthique*, Presses Universitaires de France 1998.

⁷ Ruth Macklin, ‘Dignity Is a Useless Concept’ (2003) 327 BMJ 1419-1420.

⁸ World Medical Association Declaration of Helsinki 1964.

⁹ UN Educational, Scientific and Cultural Organisation (UNESCO), Universal Declaration on the Human Genome and Human Rights 1997.

¹⁰ Oviedo, Convention on Human Rights and Biomedicine, 4 April 1997.

human beings.

i. Human dignity in relation to international human rights law

Human dignity plays a prominent role in many legal systems and regulatory instruments that call upon human rights principles, such as those concerning human experimentation and research on human gene editing. This is in major part due to the fact that it is inextricably linked to the protection of human rights, both due to the desire to safeguard the rights of patients and researchers alike, and to an insistence on the respect for human dignity.¹¹ It is the founding concept upon which the modern human rights system is built, one derived from the international instruments at the source of international human rights law. The 1948 Universal Declaration of Human Rights has claimed that its “recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world.” In conjunction with the The Vienna Declaration of 1993’s statement that “all human rights derive from the dignity and worth inherent in the human person,”¹² and both the International Covenant on Civil and Political Rights (ICCPR)¹³ and International Covenant on Economic, Social and Cultural Rights (ICESCR)¹⁴ setting out in their preambles that the rights contained within “derive from the inherent dignity of the human person,” this positions dignity as a universal source of rights. Seen otherwise, human rights would be those rights necessary to protect human dignity. From its legal framework to its schools of thought and derived approaches, the cornerstone of human rights thinking is the notion that there is a fundamental element within the characteristics of human beings that is inherently worthy of respect, and that each human being is equally possessed of it in such a way that the existence of every human being is equally valuable and worthy of respect. In turn, this status ought to be protected by the guarantee of essential rights equally granted to each individual. That is the foundational understanding of human dignity, one that seems to emerge from the documents establishing the basis for the human rights framework, the framework that many

¹¹ Roger Brownsword, ‘Human dignity from a legal perspective’ in Marcus Düwell and others (eds), *The Cambridge Handbook of Human Dignity*, CUP 2014.

¹² The Vienna Declaration on Human Rights 1993.

¹³ UN General Assembly, International Covenant on Civil and Political Rights, 16 December 1966.

¹⁴ UN General Assembly, International Covenant on Economic, Social and Cultural Rights, 16 December 1966.

bioethics instruments have been attached to. However, two things should be noted before further analysis. The first is the lack of clear definition not only of the meaning of dignity in those texts but also of "the relationship between human rights and human dignity."¹⁵ The second is that, as Donnelly noted, "dignity carries more independent weight in bioethics contexts than in standard international human rights contexts".¹⁶

ii. Human dignity in relation to international bioethics law

The Declaration of Helsinki, adopted in 1964, sets out as its first basic principle for all medical research that "it is the duty of the physician in medical research to protect the life, health, privacy, and dignity of the human subject."¹⁷ This early mention of "dignity" places it amongst other recognised human rights, the right to life,¹⁸ to health,¹⁹ to privacy²⁰. It imposes a duty, one that is moral if not yet legal, an obligation to protect it. The first legally binding international instrument on biomedicine, the Council of Europe's Oviedo Convention, is fully titled as the 'Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine', with the stated aim "to preserve human dignity, rights and freedoms, through a series of principles and prohibitions against the misuse of biological and medical advances."²¹ Its opening article indeed sets the convention's object and purpose as the necessity for its parties to give effect in their internal law to its provisions in order to "protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine."²² The obligation here to protect the dignity of all human beings is placed on the same level as the protection of their identity, their integrity, and their fundamental rights and freedoms. The reasoning behind this purpose is given in the preamble, which states that the Parties have resolved "to take such measures as are

¹⁵ David Beylveled and Roger Brownsword, *Human Dignity in Bioethics and Biolaw* (OUP 2001).

¹⁶ Jack Donnelly, 'Human Dignity and Human Rights' (2009).

¹⁷ World Medical Association Declaration of Helsinki 1964, section B para 10.

¹⁸ Universal Declaration on Human Rights (UDHR) 1948, art 3.

¹⁹ International Covenant on Economic, Social and Cultural Rights 1966, art 12.

²⁰ International Covenant on Civil and Political Rights 1966, art 17.

²¹ Council of Europe Treaty Series - No. 164, Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine 1997, summary.

²² Council of Europe Treaty Series - No. 164 (n 21), art 1.

necessary to safeguard human dignity (...)" due to the joint conviction of "the need to respect the human being both as an individual and as a member of the human species" and a recognition of "the importance of ensuring the dignity of the human being", while being "conscious that the misuse of biology and medicine may lead to acts endangering human dignity".²³

Unfortunately, a clearer definition of what exactly "dignity" represents is not forthcoming, although this preamble emphasises both its importance and the need to defend it against the threat posed by misuse in biomedicine. The text goes on to outline which processes are prohibited and how to conduct good practice, notably with article 13 restricting gene editing practices while prohibiting germline gene editing.²⁴ The Additional Protocol of 2005 concerning Biomedical Research also underlines in its Preamble that "biomedical research that is contrary to human dignity and human rights should never be carried out",²⁵ requiring amongst other measures that scientific research be independently examined by an ethics committee, whose purpose would be to ensure "the ethical acceptability of the research project" with a view explicitly to the protection of "the dignity, rights, safety and well-being of research participants."²⁶ This does not, again, clarify the boundaries of "dignity", but it seems to indicate its use as a standard. Beyond its status as the foundational concept of human rights, human dignity is recognised as a normative principle of bioethics.²⁷ Other such additional protocols to the Oviedo Convention have been released, but we will particularly reference the one on the prohibition of cloning human beings,²⁸ which declares that "the instrumentalisation of human beings through the deliberate creation of genetically identical humans is contrary to human dignity and thus constitutes a misuse of biology and medicine."²⁹

The Universal Declaration on the Human Genome and Human Rights (UDHGHR),³⁰ issued by the

²³ Council of Europe Treaty Series - No. 164 (n 21), preamble.

²⁴ Council of Europe Treaty Series - No. 164 (n 21), art 13.

²⁵ Council of Europe Treaty Series - No. 195, Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research 1995.

²⁶ Council of Europe Treaty Series - No. 195 (n 25), art 9.

²⁷ Jack Donnelly (n 16).

²⁸ Council of Europe Treaty Series - No. 168, Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings 1998.

²⁹ Council of Europe Treaty Series - No. 168 (n 28), preamble.

³⁰ United Nations Educational, Scientific and Cultural Organization, Universal Declaration on the Human Genome and Human Rights, 1997.

United Nations Educational, Scientific and Cultural Organization (UNESCO) a few months after the Oviedo Convention's signature, mentions "dignity" fifteen times total, of which three are in its preamble, going so far as to name its first heading "Human dignity and the human genome".³¹ This declaration can be considered as of yet the primary source of international obligations on human gene editing as it was adopted by the United Nations General Assembly Resolution on December 1998.³² In contrast, the Oviedo Convention remains a regional instrument although it boasts thirty-five signatories and twenty-nine ratifications.³³ Dignity in the UDHGHR is sometimes but not always referenced in conjunction with human rights and fundamental freedoms, and the UNESCO is bound to respect the original UDHR and Human Right Covenants. This reinforces trend in international instruments relating to human genome editing to use the notion of human dignity as the rationale for the standards they set. This is done either through the establishment of the protection of dignity as the purpose for their existence or applying it as the ethical principle from which they derive their normative or prescriptive standards, and sometimes both. Before addressing individually the content of this instrument, it is important to note its effect in international law and for national legislation. The UDHGHR, while not legally binding, nevertheless remains soft law in international law. Essentially, its articles are not merely ethical standards and acquire legal value.³⁴

The first of these articles states that "the human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity."³⁵ It paints human dignity, beyond the purview of the individual, as a unifying characteristic of the human species in parallel to its distinctive genomic code, which lends weight to the idea of dignity as a universal value. Article 2 declares that "everyone has a right to respect for their dignity and for their rights regardless of their genetic characteristics" and this very dignity "makes it imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity."³⁶ Together, these first articles set out the relationship between human dignity and the human genome, with the latter serving as a vessel for the former. The articles 6, 10 and 15 reference in one breath "human rights, fundamental freedoms and human dignity."³⁷ Article 11 prohibits "practices which are contrary to human dignity".³⁸ The instrument also emphasises the obligation for States to take measures "regarding the fundamental issues relating to the defence of human dignity which may be raised by research in biology, in genetics and in medicine, and its applications."³⁹ Article 24 sets out the statutory powers of the UNESCO's International Bioethics Committee.⁴⁰ It specifically makes mention of giving advice "in particular regarding the identification of practices that could be contrary to

³¹ Council of Europe Treaty Series - No. 168 (n 28), section 1.

³² United Nations Human Rights, Universal Declaration on the Human Genome and Human Rights 1998

³³ Council of Europe Treaty Series - No. 164 (n 21), signatures.

³⁴ Roberto Andorno (n 4).

³⁵ UNESCO (n 30), art 1.

³⁶ UNESCO (n 30), art 2.

³⁷ UNESCO (n 30), art 6, 10.

³⁸ UNESCO (n 30), art 11.

³⁹ UNESCO (n 30), art 21

⁴⁰ UNESCO, 'International Bioethics Committee (IBC)' <https://en.unesco.org/themes/ethics-science-and-technology/ibc> accessed 25 November 2019.

human dignity, such as germ-line interventions."⁴¹ This specific prohibition will be explored in a later section, while we will discuss international bodies pertaining to bioethics briefly in the next part of this section.

In 2005, UNESCO adopted the Universal Declaration on Bioethics and Human Rights.⁴² It reaffirms the emphasis of the UDHR on human dignity as a key principle as well as the reliance of bioethics on human rights. The discourse around human dignity does not significantly differ from the preceding instruments upon which it builds. Nevertheless, two particular formulations are noteworthy: the declaration aims to promote human dignity "by ensuring respect for the life of human beings"⁴³ and "the fundamental equality of all human beings in dignity and rights is to be respected so that they are treated justly and equitably."⁴⁴ Common threads can be noted on the role assigned to human dignity in these conventions. For example, the UN Commission on Human Rights Resolution 2003/69 of 25 April 2003 entitled "Human rights and bioethics",⁴⁵ which strongly insists on the need to ensure the protection of human rights in this field and makes a recurring appeal to the "dignity of the human being" continues to present human dignity as an articulation of human rights and bioethics. However, it is also clear that there are several possible interpretations to its purpose and its place in relationship to gene-editing and human rights. Human dignity is consistently present in the preamble of the instruments we have examined, firmly establishing it as a foundational principle. This lends significant weight to the idea that "dignity is both the foundation and the ultimate aim of human rights systems,"⁴⁶ systems into which the international bioethics conventions seek to insert themselves. However, there are also significant differences in the way that dignity is incorporated into the body of these instruments.

Human dignity is, turn by turn, presented as a value, a right or a component of the content of specific rights, a status that gives rise to rights and duties, and a principle serving as a standard for action. It is treated as a source of right, in the aspect of a foundational principle that we have described above, but also as the purpose of human rights. The latter represents the idea that human rights exist to protect dignity, and they are present because of this in the domain of bioethics where it is particularly threatened. Human dignity also stands as a benchmark when considering the article on the integrity of persons. Yet, while its purpose may vary, it purportedly serves another function as a placeholder value. "Where there are tensions between different fields of international law, or emerging practices in international law, human dignity is an important tool for focusing on the normative forces at work, in particular the significance of the individual as transcending the boundaries of state authority and as justifying state authority. It is fair to say that at this level human dignity is of enormous symbolic importance though human dignity is not, in itself, an enforceable norm of international law (the exception

⁴¹ UNESCO (n 30), art 24.

⁴² Universal Declaration on Bioethics and Human Rights. (2005). Records of the General Conference, 33rd session Paris, 3-21 October 2005, adopted 19 October.

⁴³ UNESCO (n 30), art 2c.

⁴⁴ UNESCO (n 30), art 10.

⁴⁵ 'Commission on Human Rights Resolution 2003/69: Human Rights and Bioethics' (2003)

⁴⁶ Catherine Dupre, 'Unlocking Human Dignity: Towards a Theory for the 21st Century' in *European Human Rights Law Review* Issue 2, OUP 2009.

to this is in international humanitarian law's Common Article 3, a prohibition on "outrages upon personal dignity")."⁴⁷ While there have been attempts to establish an international consensus on scientific research and national legislation, such as the International Summit on Human Genome Editing, held in December 2015, the current lack of such consensus requires the significance of human dignity to draw collective understandings on the bioethics of genome editing together.

iii. International organisations and interpretations of dignity

There are a number of international organisms, both institutions and associations, which have an impact on the international bioethical scene, notably through reports, published guidelines and advocacy. The leading institution is the UNESCO'S International Bioethics Committee, a body of 36 independent experts appointed on matters of evolutions in the life sciences, their research and application. Their aim, as described above, is to ensure the respect of human dignity and fundamental freedoms and rights. It is joined in this endeavour by another UN institution for medical health, the World Health Organization (WHO), created in 1948. This institution promotes the right to health as the highest standard of living and also provides a service for ethical guidance and whistleblowing in the form of the Office of Compliance, Risk Management and Ethics.⁴⁸ The World Health Organisation (WHO) Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing has published a paper on the Ethics of Human Genome Edition.⁴⁹ In addition, the Global Health Ethics Unit examines ethical issues that arise in the course of the organization's functioning as well as facilitating a support network for states attempting to address ethical issues on their national territory, ranging "from public health surveillance to developments in genomics, and from research with human beings to fair access to health services."⁵⁰ Critically, the unit publishes reports on these issues to raise awareness although it has yet to have one commissioned on gene editing.⁵¹ The Monash Bioethics Centre was established by Professor Peter Singer in 1980 as Australia's first research centre devoted to bioethics and seeks to address ethical questions that arise due to progress in the biological sciences.

The various statements of the ethics committee of the Human Genome Organisation (HUGO),⁵² which emphasise the need to "adhere to international norms of human rights" and to accept and uphold "human dignity and freedom".⁵³ Founded in 1988, it is an international organisation of scientists involved in human genetics, much like the the Human Genome Project (HGP), which is also a global collaborative scientific endeavour with the goal of mapping and sequencing the entire chain of human DNA and genes.

⁴⁷ Stephen Riley and Gerhard Bos, 'Human Dignity' (2016) <https://www.iep.utm.edu/hum-dign/> accessed 18 August 2019.

⁴⁸ <https://www.who.int/about/ethics/> accessed 2 November 2019.

⁴⁹ Guilia Cavaliere, 'The Ethics of Human Genome Editing' (2019).

⁵⁰ <https://www.who.int/health-topics/ethics> accessed 2 November 2019.

⁵¹ <https://www.who.int/ethics/publications/year/en/> accessed 2 November.

⁵² Human Genome Organisation's (HUGO) Ethics Committee. Statements. in Roberto Andorno *Global bioethics at UNESCO: in defence of the Universal Declaration on Bioethics and Human Rights*, 2007.

⁵³ HUGO (n 48).

Several associations are equally active in the field, the Association of Responsible Research and Innovation in Genome Editing (ARRIGE), the Genome Writers Guild (GWG) and the Japanese Society for Genome Editing (JSGE). They have published joint statements on the use of genome editing techniques in human embryos leading to live births.⁵⁴ The ARRIGE has likewise made a statement on the He Jiankui incident, an unsanctioned experiment on living human beings.⁵⁵ It is clear that there is a number of active international actors seeking to regulate and provide guidance on the bioethics of genome editing, and that they refer as well prominently to human dignity in their efforts.

b. The human rights framework relating to genome editing

The legal presence of human dignity is most often found in relation to human rights, as a source from which they derive their meaning – the preservation, protection, of the sanctity of human dignity. This stands as a replacement and reminder in its vague outline, of the natural rights origin of modern human rights and their substantial source in the necessity of a higher design. Indeed, "human rights, from the UDHR to the present, has been motivated by the desire to safeguard "human dignity" generally. Bioethics [...], although directed at enhancing the availability and quality of healthcare, often both draws and impacts on "human dignity."⁵⁶ The relation between human rights and human dignity, as we have seen above, is a complex one.⁵⁷ It can be found in almost every instance of documentation that has been explored here and yet this overabundance only causes it to become more difficult to clarify. Further obscuring the issue, there are a great many instances where the bioethics framework is positioned in relation to human rights, in such a way that both strengthens the importance of dignity as a legal concept while further diluting its precise role and purpose. Conjointly, there have been both critiques and defences of the reliance of bioethical standards on a human rights framework.

⁵⁴ARRIGE, 'Common statement between the Association for Responsible Research and Innovation in Genome Editing (ARRIGE), the Genome Writers Guild (GWG) and the Japanese Society for Genome Editing (JSGE)' http://arrige.org/Common_statement_Arrige_GWG_JSGE.pdf accessed 3 December 2019.

⁵⁵ ARRIGE, 'Statement from ARRIGE Steering Committee on the possible first gene-edited babies' http://arrige.org/ARRIGE_statement_geneeditedbabies.pdf accessed 4 December 2019.

⁵⁶ Shawn H.E. Harmon, 'The Significance of UNESCO's Universal Declaration on the Human Genome & Human Rights' (2005).

⁵⁷ Jeremy Waldron, 'Is Dignity the Foundation of Human Rights?' (2013) Public Law Research Paper No. 12-73.

i. The significance of the human rights framework for bioethics regulation

Roberto Andorno, writing in defence of the Universal Declaration on Bioethics and Human Rights, quotes an aphorism by Secretary General Dag Hammarskjöld on the UN's aspiration to merely prevent hell, not reach paradise.⁵⁸ He draws the parallel towards the UNESCO's work on bioethics, one that is flawed and yet plays an irreplaceable role in current frameworks. According to Andorno, human dignity relies on human rights to provide an effective legal framework through which to enforce claims to rights and thus ensure the protection of dignity in its role as a normative standard of bioethics.⁵⁹ It is true that the aim to safeguard areas that touch on human rights principles, such as integrity, privacy, health or equality, makes it natural to refer to an already existing framework on which to build up. Adding the prominence of references to human dignity, it appears equally evident that the human rights framework is a necessity, as without it dignity would risk becoming merely "an ethical concept with no regulatory force in international law"⁶⁰ Nevertheless, the human rights framework builds upon existing issues of lack of global governance and enforcement in the international legal system, compounding them with an unclear basis that is contested by adherents of cultural relativism. It is often used as a policy tool instead of the supranational legal standard of minimum protection that it should represent, emancipated from national systems of norms that may be insufficient. It is still undetermined, however, if it is the correct system for maximum legal effectiveness in bioethics. In fact, "the notion of human dignity is beginning to be seen as the last barrier against the alteration of some basic features of the human species that might result from practices such as reproductive cloning or germ-line interventions. It should be noted that resorting to human rights is insufficient to cope with these new challenges because human rights only belong to existing individuals, not to humanity as such."⁶¹ Paradoxically, some have also "feared that, insofar as human dignity is assumed in various legal contexts to override the interests of an individual human, its adoption could endanger the commitment to human rights. If human dignity is a concept with an under-determined content but which could trump human rights, it could be a kind of Trojan horse in relation to human rights regimes."⁶² As such, there remains a tension in the positioning of the individual in the center of a human rights framework that may not correspond to the framing required for a regulatory bioethics system in practice.

ii. Human rights relevant to genome editing

⁵⁸ Roberto Andorno, 'Global bioethics at UNESCO: in defence of the Universal Declaration on Bioethics and Human Rights' (2006) 33 J Med Ethics.

⁵⁹ Roberto Andorno (n 4), 234.

⁶⁰ Nicoleta-Ramona Predescu, 'Human Dignity - A Right Or a Principle of Human Rights', (2018) CONF. INT'L DR. 137.

⁶¹ Roberto Andorno, 'Human dignity and human rights as a common ground for a global bioethics (2009) Journal of Medicine and Philosophy page 223.

⁶² Marcus Düwell and others (eds), 'The Cambridge Handbook of Human Dignity' CUP 2014.

A report for the UK's Nuffield Council of Bioethics on genome editing regulations reveals sets out a number of human rights that have implications for genome editing, the first of which is human dignity.⁶³ There is for some a right to the respect of dignity.⁶⁴ In addition, the right to health, which includes reproductive health, to integrity, as well as to enjoy the benefits from scientific progress and the freedom of scientific research⁶⁵ are all relevant to the bioethics of genome editing. A more controversial right is the right to genetic identity, one that once again makes a connection between human dignity and the issue of identity.⁶⁶

In essence, it appears clear that the human rights framework presents both advantages and disadvantages. It functions for bioethics somewhat like Churchill's affirmation on democracy, as the worst form of government, except for all the others that have been tried so far. In conclusion, human dignity can be considered as being present through two main channels in bioethics. Firstly, an international human rights law notion, one ambiguous and multi-faceted in its interpretation but nonetheless part of a rights-based framework, whether as its foundation, as a defining source of rights, as a standard of achievement or as a fundamental value, sometimes used to define the boundaries of the individual sphere that needs protections or sometimes used to define the limits of where an individual or collective should not encroach.⁶⁷ Secondly, a bioethics principle on the same level as autonomy, benevolence, non-maleficence and justice, all of which will be explained more in-depth later on. It is in this context a coordinate principle to other, equally useful tools for determining normative and prescriptive standards of biomedicine.

⁶³ Rumiana Yotova, 'The Regulation of Genome Editing and Human Reproduction Under International Law, EU Law and Comparative Law' (2017) Report for the Nuffield Council of Bioethics.

⁶⁴ Deryck Beylveid and Roger Brownsword, *Human Dignity in Bioethics and Biolaw* (2001) page 12.

⁶⁵ UDHR, article 15.

⁶⁶ Raposo, 'Gene Editing: The Mystic Threat to Human Dignity' (2019).

⁶⁷ Roger Brownsword, 'Human dignity from a legal perspective' in M. Düwell, J. Braarvig, R. Brownsword, & D. Mieth (eds.), *The Cambridge Handbook of Human Dignity: Interdisciplinary Perspectives* (pp. 1-22) CUP 2014.

II. Human dignity as a regulatory tool in the bioethics of genome editing practices

What are the ethical issues raised by research, technology and actual germline editing? How does human dignity intervene at each of these steps as a tool for regulation and how is this influenced by its different interpretations?

a. Acceptability to society: understandings of dignity

i. Ethical issues and the law: the importance of regulating human genome editing

Towards the end of 2018, the birth of two non-identical twins was announced as the result of a scientific experiment. Nana and Lulu, as they are referred to, are the first known genetically-engineered human babies. They are the product of new gene-editing technology and unsanctioned experimentation on human beings, in what has been termed a "monstrous", "irresponsible" and "deeply ethically problematic" undertaking.⁶⁸ In 2017, Chinese scientist He Jiankui set out to experiment on the genes of otherwise healthy embryos from infertile couples with one HIV-positive parent, using the technology of CRISPR-cas 9. His aim was to produce individuals that would be HIV-resistant at birth through germline editing. This aim, from what information is available, does not seem to have been met with success. However, the multiple points of failures surrounding this controversial experiment make it uniquely suited for an analysis of the issues raised in consideration of research on gene editing, during the course of its experimentation, and on its consequences. It is our particular interest to underline not only the need for regulation, but the role played by existing regulations and ethical guidelines at each step of this process. In the search for the role played by human dignity in the bioethics of gene editing, we aim to show precisely how it is used in its instrumental capacity in regulation. We will first focus on human dignity as the core underlying notion behind current guiding principles in medical and scientific research pertaining to the human body and its genetic identity. While human dignity is but one principle of biomedical ethics, it serves as a basis for human rights principles, bringing it within the arsenal of legal tools employed in agreements over the regulation of gene editing technologies. In addition, it is widely employed in the discourse of bioethics for reasons which we will also explore.

In 2002, the American President's Council on Bioethics published a report on Human Cloning and Human Dignity.⁶⁹ Within this report was an analysis of the ethical, moral and social stakes behind human experimentation, including the use of embryos in scientific research. The Council argued

⁶⁸ Julian Savulescu (26 November 2018) <http://blog.practicaethics.ox.ac.uk/2018/11/press-statement-monstrous-gene-editing-experiment/> accessed 13 October 2019; Sarah Chang, 'Claims over human genome editing: scientific irresponsibility at its worst' (28 November 2018)

<https://blogs.bmj.com/medical-ethics/2018/11/28/claims-over-human-genome-editing-scientific-irresponsibility-at-its-worst/> accessed 13 October 2019.

⁶⁹ The President's Council on Bioethics, 'Human Cloning and Human Dignity: An Ethical Inquiry' (2002).

that the foreseeable consequences of allowing such research – after underlining safety risks, issues of consent, patient exploitation, risk distribution, for instance—would result in the objectification and dehumanisation of human worth. Boundaries, stated the report, should be drawn to protect the inviolable nature of human persons, or what has been termed their human dignity. The report emphasised that the necessity to protect against human rights violation as well as the risk of encroachment upon the moral value of human life, essential to the fabric of society, outweighed the potential benefits brought about by medical progress. The Council concluded on a complete ban on the birth of children produced by experimentation and a majority was in favour of a ban on using embryos for research.⁷⁰ In 2016, the Nuffield Council on Bioethics, the leading UK advisory body on bioethics, produced a report establishing that heritable genome editing, another name for germline editing, which translates to making changes to the human genome that would pass down to future generations, could be considered ethically acceptable under specific circumstances.⁷¹ In 2018, the first two genetically engineered babies were born from He Jiankui's experiment. A third baby may be expected for 2019,⁷² while Japan has only just legalised experimentations on chimeras, modifying human embryos with animal genes.⁷³ On the other hand, condemnations ran high when He Jiankui's operation was publicised, both nationally and internationally,⁷⁴ and numerous calls towards international consensus on tighter regulations as well as a rise in the examination of ethical positions regarding gene editing on humans are being witnessed.

It is perhaps again not surprising that human dignity is so widely invoked in this context, as it is in line with the aim to ensure that scientific development, from research to application, proceeds not only in respect with human rights but also in consideration with ethical principles.⁷⁵ Ethics is the process by which choices and their consequences are examined in terms of rights or wrongs, and their acceptability judged consistent with recognised moral values. It serves as a necessary referee in the world of scientific research and experimentation, and is even more crucial when the technologies called upon are closely enmeshed with the essential characteristics that make up a human being. Put succinctly:

"Ethics is the study of what we ought to do; science is the study of how the world works. Ethics is essential to scientific research in defining the concepts we use (such as the concept of 'medical need'), deciding which questions are worth addressing, and what we may do to sentient beings in research."⁷⁶

The sphere of bioethics, which applies to scientific research concerned with the relationships

⁷⁰ The President's Council on Bioethics (n 65), 227.

⁷¹ Nuffield Bioethics Council, 'Genome Editing: an ethical review' (2016).

⁷² G. Owen Schaefer, 'Rogue science strikes again: The case of the first gene-edited babies' (2018) <https://theconversation.com/rogue-science-strikes-again-the-case-of-the-first-gene-edited-babies-107684> accessed 10 June 2019.

⁷³ Kento Fukui, 'Japan allows gene editing for research only' (5 December 2018) <https://asia.nikkei.com/Business/Science/Japan-allows-gene-editing-for-research-only> accessed 17 October 2019.

⁷⁴ Henry T Greely, 'CRISPR'd babies: human germline genome editing in the 'He Jiankui affair'' (2019) *Journal of Law and the Biosciences*, Volume 6, Issue 1, pages 111–183; Jing-Bao Nie 'He Jiankui's Genetic Misadventure, Part 2: How Different Are Chinese and Western Bioethics?' (13 December 2018) <https://www.thehastingscenter.org/jiankuis-genetic-misadventure-part-2-different-chinese-western-bioethics/> accessed 1 December 2019.

⁷⁵ Deryck Beyleveld and Roger Brownsword, 'Human Dignity, Human Rights, and Human Genetics' (1998)

61 *The Modern Law Review* Human Genetics and the Law: Regulating a Revolution 661-680.

⁷⁶ Julian Savulescu and Peter Singer, 'An ethical pathway for gene editing' (2019) 33 *Bioethics* 221–222.

between living organisms and their environments — essentially fields that are related to and derived from biology — deals "more specifically with the philosophical, social and legal issues arising in medicine and the life sciences."⁷⁷ Although the term can be interpreted narrowly to only refer to ethical issues within the life sciences, it has been used here with the broader interpretation that "bioethics may also be understood as including the legal aspects of biomedical issues," as defended by academic Roberto Andorno.⁷⁸ Bioethics is both a study of the standards around biotechnologies and of the legal regulations in place to enforce them, and as such it includes both legal and ethical standards and norms. It is within this sphere that human dignity has seen a surge in popularity as a human standard to gauge practices.⁷⁹

b. Human dignity in the law of bioethics: human right principle or ethical principle? (I?)

i. Understandings of dignity: the stakes of a clear consensus

"Today, the widespread contemporary use of human dignity both in law and in ethics is under the spotlight, particularly in the areas of law and medical ethics. The underlying consensus about what human dignity means or requires is increasingly in question. [...] The way in which in our pluralist society we develop and hold on to a shared understanding of such a key concept can have an immense influence on the quality of moral and social developments of people, and in particular on the practical development of law."⁸⁰ The higher level the concept, and the more it is used not only in itself but to delineate other boundaries, the more crucial it becomes to define it clearly in order to ascertain a common, workable understanding. Unfortunately, it is equally true that "the more important the concept, the less likely it is that we can expect to be able to define it in a clear and unambiguous fashion."⁸¹ Human dignity is a prime example in the domain of biotechnologies, and especially the controversial corner of human genetics where morally and socially complex issues are raised. Ultimately, the usefulness of the notion as a regulatory tool is an ongoing inquiry and one that should be kept so to gauge its adaptation to current issues. However, regardless of the difficulties brought by the ubiquitous use of the concept with its multiplicity of definitions, we hope to demonstrate that there is a need for an international consensus around what constitutes the essential characteristics of a human being in such a way that enabling its flourishing presents inherent worth while curtailing it is of negative value.

An ethical approach to human dignity differs from a legal one as it looks at the linguistic and philosophical roots of the concept rather than its interpretation through legal texts and jurisprudence. From

⁷⁷ Ruth Felicity Chadwick, 'Bioethics' (Encyclopaedia Britannica 2018)

<https://www.britannica.com/topic/bioethics> accessed 27 July 2019

⁷⁸ Roberto Andorno, 'Human dignity and human rights as a common ground for a global bioethics' (2009) 34 *Journal of Medicine and Philosophy* 223.

⁷⁹ Deryck Beyleveld and Roger Brownsword, *Human Dignity in Bioethics and Biolaw*, OUP 2012.

⁸⁰ Vincent Nichols in Christopher McCrudden (ed), *Understanding Human Dignity*, OUP 2014.

⁸¹ Jeff Malpas and Norelle Lickiss (eds.) (no 3).

Jack Donnelly's linguistic analysis of the word and its origin, dignity can be considered a "worth that demands respect", while the "claim of human dignity is that simply being human makes one worthy or deserving of respect". In relationship to human rights, the concept of dignity is used to describe the duties and rights afforded by this respect to the individual, and thus they become "one particular mechanism—a particular set of practices—for realising a certain class of conceptions of human dignity."⁸² Dignity has undergone a process of evolution from its origin as a philosophical notion to its current form as a prominent ethical and legal principle. Indeed, there are "major paradigms of dignity that have contributed over the centuries to shape the modern idea that every individual has inherent worth"⁸³ and become the source of rights derived from this established worth, with the ambition of serving as a universal moral standard.

The main issue being that such universal appeal has reduced the clarity of how human dignity is defined to the risk of becoming a meaningless and amorphous concept, and as such reducing its impact and utility. There are a great many interpretations of what it stands for, what its purpose is and how it achieves it, although there is some overlap. This is further complicated by the fact that scientific development aims to progress in line with a joint respect for ethical principles and for human rights, both of which may call upon the notion of dignity in different ways, from a broader perspective of values to a rights-based approach. The nuances of this notion through its historical developments and applications and its use in the discourse of bioethics nevertheless show that, while philosophically diverse, its roots have converged towards a unified construct that can stand as a cornerstone of ethical and legal theory.⁸⁴

The philosophical conception of an essence that captures the status and value of the quintessential experience of existence as a human being, human dignity has existed since the Ancient Greeks and perhaps beyond, as a social and civic value throughout Christian interpretations in the Middle relying on religion and leading to the establishment of natural law.⁸⁵ It is seen as the defining characteristic of human beings. When described in this manner, its relationship with the human genome, the scientific expression of the essence that characterises a being as belonging to the human species, becomes evident. Human dignity is the moral corollary to the scientific expression present through the human genome and above that a principle that has been imbued with legal weight. It is then a fitting tool to serve as an ethical standard to manipulations of the genome, which become manipulations of the physical vessel of one's dignity.

⁸² Jack Donnelly (n 16).

⁸³ Roberto Andorno (n 5).

⁸⁴ F. Daniel Davis, 'Human Dignity and Respect for Persons' in Edmund D. Pellegrino (ed), *Human Dignity and Bioethics* (2009) 19.

⁸⁵ Marcus Düwell and others (eds), *The Cambridge Handbook of Human Dignity*, CUP 2014.

ii. The maximisation of human dignity: a theory of bioethics in the context of genome editing

Throughout his book on Human Dignity in Bioethics and Law, Charles Foster defends the thesis that dignity is the “bioethical Theory of Everything.”⁸⁶ While bioethics are guided, in addition to the role played by human rights, by a set of diverse principles collated to cover a variety of scenarios, Foster contends that there are inadmissible gaps between these principles, which cannot function in a unified theory of bioethics. He postulates that existing ethical principles discussed earlier, and especially autonomy as the central one in terms of ethical standard in the care of individuals, fail to provide adequate responses in edge cases. They presuppose the agency of the individual, a problematic premise when it comes to regulating the ethical status of unattached bodily components, such as genetic material, or individuals who may not legally and practically be capable of this agency, or individuals who are only considered individuals-in-waiting in the case of embryo cells for example, notwithstanding the continuing debate around personhood and its defining characteristics. The question is, then, how human dignity performs in those edge cases and whether it effectively outperforms other ethical principles to the point of surpassing them as the normative standard for bioethics. Charles Foster proposes a model that is surprising close to the moral framework deployed in utilitarianism, a consequentialist approach to normative ethics that seeks to maximise the overall good produced as the result of an action, where this good is ‘the greatest amount of good for the greatest number’.⁸⁷ In Foster’s proposal, one would consider instead whether a specific solution would maximise the amount of dignity in the world and evaluate as such between competing interests, while approaching human dignity as “objective human flourishing”.⁸⁸ When enhancing the amount of dignity in the world, he declares, one enhances the very characteristics of humanity. Human dignity is therefore not the defining characteristic of humanity in the sense that it is the distinctive element that distinguishes it, but in the sense that it is the element that measures its presence and existence, the marker of humanity understood as a self-realised state of being. Autonomy is then seen as a function or manifestation of human dignity. Some caveats must nevertheless be raised to this theory. If it is to be workable, dignity cannot be an amorphous, over-stretched notion spread between overlapping yet competing understandings that seek to make use of its symbolic importance to fill a legal or ethical gap. In addition, while human dignity would become a parent principle and possess primacy over other ethical principles, Foster concedes that “it is not very obviously superior to other principles in the realm of resource allocation and distributive justice generally.” Instead, “its superiority is most dramatically on display when the focus of the ethical inquiry is on the status of an individual human.”⁸⁹ Our exploration of this application of dignity as a regulatory tool will thus be conducted over the facts and consequences of such a case, the experiment led by He Jiankui.

⁸⁶ Charles Foster, *Human Dignity in Bioethics and Law*, Hart Publishing 2011,

⁸⁷ Jeremy Bentham, *An Introduction to the Principles of Morals and Legislation*, Clarendon Press 1907.

⁸⁸ Charles Foster (n 83), page 6.

⁸⁹ Charles Foster (n 83), page 20.

c. Ethical issues in biotechnology research & dignity

"[Human] genetics ... is beginning to create a new generation of acute and subtle dilemmas that will in the new millennium transform the ways in which we think of ourselves and of society. It is genetics, bringing both a new understanding of what we are and almost daily developing new ways of enabling us to influence what we are, that is creating a revolution in thought, and not least in ethics."⁹⁰ We will consider the ethical issues raised by research, technology, and specifically germline editing, as well as how human dignity relates to and can be effective at each step as a tool for regulation. In order to delve into the workability of human dignity as a regulatory tool, this analysis of these issues will be undertaken first through the

It is clear from an ethical perspective that scientific research proceeds from the position that human life is valuable and should be preserved. Biomedical ethics promote a series of principal to ensure that procedures, both in research and applied medicine, respect core principles to ensure the minimisation of harm to patients and society, and a form of 'due process' standard. The first of these is justice, seeking to establish fairness and equality in the distribution of risks and benefits in the provision not only of medical practices but also resources, for patients and also for researchers, doctors and throughout territories. Indeed, the idea of justice covers a large scope, from procedural and substantive fairness to equality of access, non-discrimination, and distributive allocation of resources according to the needs of society.⁹¹ The two next principles, benevolence and non-maleficence, should be considered together to "aim at producing net benefit over harm."⁹² They emerge from the Hippocratic oath to "do no harm", interpreted through benevolence as ensuring a net benefit while reducing harmful effects as much as possible. Medical procedures as well as the development of human altering technologies, from research to application, should proceed in such a way that they are not be harmful, not only to the patient but also to society, or at least must minimise the risk of harm. The last principle is that of autonomy, and the one most collated with human dignity insofar as one approach of dignity is through human agency, and the Kantian view that humans must be treated as autonomous agents that are an end in themselves and not merely means to something.⁹³ The most widespread manifestation of autonomy is consent or the necessity for participants to make fully-informed decisions free of coercion or coaxing. Human dignity would then be given the same substantive value as these principles and used to preserve the physical and spiritual (in terms of faith or belief) integrity of patients as well as

⁹⁰ John Harris, 'Introduction: The Scope and Importance of Bioethics' in John Harris (ed.), *Bioethics*, OUP 2001.

⁹¹ David Miller, 'Justice' (2017) <https://plato.stanford.edu/entries/justice/> (accessed 2 December 2019).

⁹² Raanan Gillon, 'Medical ethics: four principles plus attention to scope' (1994) *BMJ Clinical Research*; 'What are the Basic Principles of Medical Ethics'.

⁹³ Deryck Beylveled and Roger Brownsword, (no 65).

i. Interests of research participants (privacy, informed consent)

The interests of research participants are closely guarded through two mechanisms: their informed consent to safeguard their autonomy and the privacy of their data and information. In the latter, He Jiankui can be said to have taken measures to preserve the families' informations, going so far as to hide the names of the nurses and doctors having practiced the procedures on them. However, in terms of informed consent there is clearly an issue in his experiment. He Jiankui attempted to publish his experiment for accreditation, a publication that was refused ostensibly due to a faulty processing of consent forms. In addition, it appears that the parents may have been pressured due to two factors, invalidating their consent. He Jiankui recruited couples that were infertile and with one parent HIV positive. In China, HIV positivity imposes a social stigma and fertility procedures are often refused on those grounds. However, He Jiankui targeted a vulnerable patient group and additionally pressured them by promising access to fertility treatment. It is also unclear whether the parents clearly understood the nature of the experiment, as it was presented on the form under the terms "HIV vaccination." It is somewhat ludicrous to realise the amount of misuse present in the one case, a case with very real consequences for the families and especially children impacted.⁹⁴

Some of the issues in He Jiankui's experimental procedure and its consequences include a lack of ethical review and accountability, as there is absolutely no transparency on funding and the university denies having approved his research.⁹⁵ In addition, he has been accused of misrepresenting data as his team did not actually reproduce the mutation it sought to but created new ones.⁹⁶ The medical benefits of the experiment are dubious at best, as HIV is controlled through existing medication, meaning that there is no need to engage in experimental procedures on live babies. Sperm-washing, an already established method was used to prevent parental transmission of HIV, further ensuring that the immediate benefit seem remote.^{97,98}

d. Ethical issues in biotechnology application & dignity

⁹⁴ Joe Pinkstone, 'Disgraced Chinese scientist He Jiankui who controversially gene-edited embryos to be resistant to HIV 'may have created unintended mutations', never-seen-before extracts from his 'outrageous' research reveal' (3 December 2019) <https://www.dailymail.co.uk/sciencetech/article-7752141/Never-seen-extracts-outrageous-research-disgraced-scientist-Jiankui.html> accessed 3 December 2019; Antonio Regalado, 'China's CRISPR babies: Read exclusive excerpts from the unseen original research' (3 December 2019) <https://www.technologyreview.com/s/614764/chinas-crispr-babies-read-exclusive-excerpts-he-jiankui-paper/> accessed 3 December 2019.

⁹⁵ Henry T Greely, (no 72).

⁹⁶ Henry T Greely, (no 72).

⁹⁷ Agence France-Presse, 'China gene-edited baby experiment 'may have created unintended mutations'' (4 December 2019) <https://www.theguardian.com/science/2019/dec/04/china-gene-edited-baby-experiment-may-have-created-unintended-mutations> accessed 4 December 2019.

⁹⁸ Antonio Regalado, (no 97).

i. Social concerns (rights & legal protections of creatures, resource allocation)

The Oviedo convention particularly states under article 13 regarding interventions on the human genome that they "may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants."⁹⁹ It appears obvious that concerns having a potential impact on social order, the environment or present health risks must be properly assessed before being given the go ahead. In addition, germline editing poses issues of moral permissibility and social acceptability, two serious concerns that have a far-reaching impact at a global level in addition to a personal one on the lives of the affected individuals. It is clear that He Jiankui's malpractice has had an effect on the perceptions relating to the bioethics of gene editing, however there is some fear that it may be too late. It is certainly too late for the individuals who suffer the consequences of the experiment, as to whether it is too late to stop and regulate further experimentation on the subject, this remains to be seen.

⁹⁹ Oviedo Convention (no 10), art 13.

III. The future of human dignity in the changing landscape of gene editing practices and its impact on bioethics

Does human genome editing reinforce or violate human dignity? What are the immediate effects of the availability of gene editing technologies on human life and how are they compatible with a future that promotes the place of the individual in global networks?

a. The revolution of human genetics in the law

"Scientific and technological progress [permits] increasing control of our environment and ... our living conditions. In the fields of biology and genetics especially, progress is all the more staggering since man, for the first time, has the power to transform living matter in a programmed and selective manner. ... It is above all in the biomedical field that progress has been the most spectacular and provokes the most questions, especially since it involves living human beings."¹⁰⁰ The social and cultural change brought by the advent of the age of media and communication has been compounded with the rapid pace of evolution in sciences and technologies, and the effects of these, now in conjunction with the revolution brought about by gene editing, has necessitated a redefinition of our perception of the place of human beings in the world. As technologies progress, their perception and assimilation into common knowledge lead to social and cultural acceptance. It becomes necessary to take a look at the applicable laws and reflect such changes on the legal system, not only to keep the legislation relevant but also to protect against new abuses and address emerging issues or areas of uncertainty.¹⁰¹ In other words, "we are faced once again with the need to assess the socio-ethical and legal implications of intentional modification of the human germline, as the nearly unanimous condemnation of germ-line modification in the 1990s pre-empted the very debate that should have been taking place over the past 25

¹⁰⁰ N. Lenoir, 'Annual Report of the IBC' in UNESCO, *Proceedings of the Second Session of the IBC*, vol. I, 1995, pages 1-9, at 1.

¹⁰¹ R. Brownsword et al., "Human Genetics and the Law: Regulating a Revolution" in R. Brownsword et al. (eds.), *Law and Human Genetics: Regulating a Revolution* (Oxford: OUP, 1999) 1- 5, at 5.

years."¹⁰² Clear policies are necessary to draw an effective jurisdictional framework able to enforce current and future international, agreed-upon norms, something which is currently lacking. The examination of edge cases where it is more difficult to keep to a dogmatic prohibition of medical research due to pressing needs, such as disability or gene therapy applications to illnesses, may shed some light on the boundaries of such policies. As such, we will look at some of the emerging points of contention in the specific domain of human gene editing, which is only a subset of the more pressing concerns raised by new technologies but also the one with the potential to most directly impact human life from within. Using human dignity as a measuring rod for the ethical acceptability and usability of human gene editing practices, this section of the dissertation explores under which circumstances and in what context medical research and application become a necessity, as well as how to ensure the definition of a common framework for this context to be achieved.

b. Germline Editing: human dignity and medical research

The practice of heritable genome editing or germline editing is the one use of gene editing biotechnologies where prohibition raises the most "widespread global agreement that [it] should remain off-limits".¹⁰³ Some have nevertheless asserted that germline editing is the way forward,¹⁰⁴ despite concerns over the spectre of eugenics and the accompanying atrocities committed during the Second World War. Indeed, while this control afforded over the minutiae of human biological systems "has the potential to increase healthcare options," it also "prompts fears that attempts to control present health could injure future health" and "the capability to "design" the humans of the future, [also excites] anxiety over sex and genetic discrimination and the development of

¹⁰² Rosario Isasi and Bartha Maria Knoppers, 'Oversight of human inheritable genome modification' (2015) 33 *Nature Biotechnology*.

¹⁰³ Marcy Darnovsky, 'Genetically modifying future children isn't just wrong. It would harm all of us', (17 July 2018) <https://www.theguardian.com/commentisfree/2018/jul/17/genetically-modifying-future-children-embryos-nuffield-council-bioethics> accessed 20 July 2019.

¹⁰⁴ Heritable genome editing: action needed to secure responsible way forward" (17 July 2018)

<https://nuffieldbioethics.org/news/heritable-genome-editing-action-needed-secure-responsible> accessed 30 July 2019; Ruairi Mackenzie, 'Bioethics Council Rules Heritable Genome Editing "Ethically Acceptable" In Certain Circumstances' (18 July 2018)

<https://www.technologynetworks.com/genomics/news/bioethics-council-rules-heritable-genome-editing-ethically-acceptable-in-certain-circumstances-306404> accessed 8 August 2019.

heretofore unheard of liability claims."¹⁰⁵ An exploration of this boundary line drawn around gene editing is precisely the opportunity to understand what is at stake in terms of the fears and possibilities that arise from its potential applications. Human dignity has been proposed as the normative standard of human genome editing in bioethics. We ask two questions: is heritable gene editing, a practice that may touch on the very nature what it means to be human, the essential identity of not only an individual but the species as a whole, compatible with human dignity in the first place? Secondly, is there the possibility of an international consensus around this issue in terms of ethical principles that would be used to describe its regulation, in other words, is it possible to reach a consensus as to the basis of the ethical principles, for example, human dignity, that would be employed to regulate germline editing? This is no longer purely theoretical given the human consequences of He Jiankui's experiment.^{106 107108}

ii. Human dignity and the international consensus on its regulation

Xu Nianping, the Chinese vice-minister for science and technology, had announced following the backlash that He Jiankui's experiment was in violation of "China's relevant laws and regulations" and of "the ethical bottom line that the academic community adheres to", declaring it "shocking and unacceptable."¹⁰⁹ China is now poised to introduce new gene-editing regulations in reaction to the scandal around the experiment.¹¹⁰ "The draft regulations, issued by the National Health Commission on 26 February, state that gene editing in any type of cell that will end up in humans, including embryos, will need the commission's approval, as will other high-risk biomedical procedures." These new regulations notably introduce penalties, which were previously lacking, for their infringement. These penalties range from fines to grant blacklisting.¹¹¹

¹⁰⁵ Shawn H.E. Harmon, (no 56).

¹⁰⁶ Roberto Andorno, (n 4).

¹⁰⁷ Seppe Segers and Heidi Mertes, 'Does human genome editing reinforce or violate human dignity?' (2019) 00 Bioethics 1–8.

¹⁰⁸ Peter Sykora & Arthur Caplan, 'Germline gene therapy is compatible with human dignity' (2017) 18 EMBO.

¹⁰⁹ Lily Kuo, 'Work on gene-edited babies blatant violation of the law, says China' (29 November 2018) <https://www.theguardian.com/science/2018/nov/29/work-on-gene-edited-babies-blattant-violation-of-the-law-says-china> accessed 3 November 2019.

¹¹⁰ David Cyranoski, 'China set to introduce gene-editing regulation following CRISPR-baby furore' (20 May 2019) <https://www.nature.com/articles/d41586-019-01580-1> accessed 8 December 2019.

¹¹¹ David Cyranoski, 'China to tighten rules on gene editing in humans' (6 March 2019) <https://www.nature.com/articles/d41586-019-00773-y> accessed 8 December 2019.

Several Chinese scientists have reacted, often advocating for stricter and clearer regulations and hailing the incident as a wake-up call to the dangers of a lack of consequences and transparency in the context of the potential issues and uncertainty surrounding new biotechnologies. Such an article states that: "These characteristics of emerging biotechnologies [such as bias in data, uncertain outcomes due to complex and interdependent factors and potential risk to future generations] illustrate why a proactionary approach is inappropriate. Instead, we have to take an approach called *lun li xian xing* (ethically thinking ahead of action). Before we launch any project that uses these emerging biotechnologies, we have to develop tentative regulations based on comprehensive inquiry and rigorous ethical discussion." In addition, the authors add that "cultural differences are not a justifiable reason to reject international guidelines and refuse to participate in international efforts to develop shared regulations on the innovations, R&D, and applications of biotechnologies."¹¹² Indeed, one of the most commonly raised arguments regarding human rights, and the universality of human dignity is that of cultural relativism. This is the notion that social or moral values are culturally determined, and that cultural diversity presupposes the impossibility of the universality of one such value. In addition, attempts to press this universality are seen as supporting "the hegemony of the dominant global powers."¹¹³ The same arguments have been used against the workability of international bioethics regulations, especially given assumptions of "a scientific ethical divide between China and [the] West".¹¹⁴ In 2015, Members of the Chinese National Medical Ethical Committee had declared in the press that "ethics are a question of culture, and that is about tradition, especially where it touches on human life," adding that "inside China, there are people who are opposed to international standards, citing cultural differences."¹¹⁵

c. Gene Therapy: human dignity and medical application

The Human Genome Project has made predictions on the integration of gene

¹¹² Zhai, Xiaomei, Ruipeng Lei, and Renzong Qiu, 'Lessons From the He Jiankui Incident' (2019) *Issues in Science and Technology* 35.

¹¹³ Michael Freeman, 'Universality, Diversity and Difference' in *Human Rights* (Polity Press, 2017) 120.

¹¹⁴ Didi Kirsten Tatlow, 'A Scientific Ethical Divide Between China and West' (2015).

¹¹⁵ Didi Kirsten Tatlow, (no 115).

therapy into ordinary life and its legal impact on courts.¹¹⁶ The issues projected, new categories of medical litigation, new social differentiation and areas of discrimination also present unforeseen control over one's life and health. The report paints a very different world in an attempt to face necessary debates and awareness around ethical, moral and social quandaries that may seem distant but are growing increasingly closer as biotechnological progress continues. There are, as we have discussed, compelling arguments in favour of integrating gene editing into the medical tool set available to deal with disability, illness and genetic diseases. Gene therapy is considered particularly promising in the field of research against cancer, able to provide the ability to experiment around the genetic characteristics of cancer cells and deeper insights into their manipulation.¹¹⁷ Existing human rights, such as the right to health, may compel the continuation of such research. The International Covenant on Economic, Social and Cultural Rights (ICESCR) recognises the right to the highest standard of physical and mental health. It asserts that its parties have an obligation to take steps to improve hygiene, prevent diseases, assure medical service and reduce infant mortality in order to achieve the full realisation of this right.¹¹⁸ It is inevitable that a discussion on the integration of gene editing in medical practices requires the need for a re-examination of human enhancement, which touches on the controversial subject of eugenics, in light of now decades of setting up an elaborate system built around a value of human dignity that stands against the commodification of human individuals and their characteristics.

Existing bioethics principles seek to minimise risks of harm by regulating experimental research in terms of net benefit. "In deciding whether a risk is reasonable, it is important to evaluate not only the probability of achieving a benefit, but also the extent of the benefit in question. A greater expected benefit is worth greater risk than a smaller expected benefit."¹¹⁹ The prohibition of eugenics set out in the Rome Statute of the International Criminal Court declares this practice part of the crimes against

¹¹⁶ Maxwell J. Mehlman, 'The Human Genome Project and the Courts: Gene Therapy and Beyond' (1997) 268 Faculty Publications

https://scholarlycommons.law.case.edu/cgi/viewcontent.cgi?article=1267&context=faculty_publications

tions

¹¹⁷ Tianzuo Zhan and others, 'CRISPR/Cas9 for cancer research and therapy' (2019) 55 Seminars in Cancer Biology; 'Gene Editing Tool Fights Cancer in Early Study' (2019)

<https://www.webmd.com/cancer/news/20191107/gene-editing-tool-fights-cancer-in-early-study>

¹¹⁸ ICESCR, article 12

¹¹⁹ Julian Savulescu and Peter Singer, 'An ethical pathway for gene editing' (2019) 33 Bioethics 221–222

humanity.¹²⁰ The EU Charter of Fundamental Rights also reinforces this prohibition in its article on the right of a person to integrity.¹²¹ This is clarified in the commentary on the Charter as pertaining specifically to the selection of persons in a widespread, deliberate operation such as situations of "campaigns for sterilisation, forced pregnancy, compulsory ethnic marriage" for ethnic cleansing purposes, such as what was performed during the Second World War.¹²²

Erik Parens, when attempting to elucidate a structure for the debate on human enhancement, argues that its current uncertain state relies on several ethical frameworks of authenticity born from different understandings of authenticity's meaning.¹²³ He describes authenticity as being true to oneself, or the self-fulfilment of one's own flourishing. It is my opinion instead that the notion of authenticity is not the one in question, but a particular conception of agency that calls upon a moral claim to freedom of self-determination. This need to respect both individual and collective agency harkens back to the Kantian approach of dignity. It brings up a tension between questions of desirability and worth, a theme that is pregnant in the debate around the (pre)selection of desirable genetic characteristics. Erik Parens also notes, "Jonathan Glover observed that enhancement technologies force us to think anew about the oldest, most pressing, and most infuriatingly difficult of questions: What does human flourishing consist in?"¹²⁴ Indeed, this is an essential premise to enable us to assess whether these technologies, gene editing in our case, will promote or harm human flourishing. It is also the reason why I believe that the principle in play relates to the conception of human dignity as explored in this dissertation. Charles Foster, when describing dignity as the bioethical golden standard, contends that "human thriving is connected to human dignity".¹²⁵ Foster argues that flourishing is about being, and human dignity is about being human. As such, enhancement Michael Sandel criticises the dangers of new

¹²⁰ article 7(1)(g)

¹²¹ article 3.2(b)

¹²² EU Network of Independent Experts on Fundamental Rights, *Commentary of the Charter of Fundamental Rights of the European Union* (2006) 40

¹²³ Erik Parens, 'Toward a more fruitful debate about enhancement' in Saluvescu and Bostrom (eds), *Human Enhancement* (2009)

¹²⁴ Erik Parens (n1 23), 196.

¹²⁵ Charles Foster, *Human Dignity in Bioethics and Law* (Hart Publishing, 2011) 4

biotechnologies that give unforeseen control over the human biomechanics when applied to human enhancement, arguing that “they represent a kind of hyperagency.”¹²⁶ They promote “a drive to mastery” that is at risk of destroying “an appreciation of the gifted character of human powers and achievement.”¹²⁷

¹²⁶ Michael Sander, ‘The Case Against Perfection’ (2004) 293 *Atlantic Monthly* 51

¹²⁷ Michael Sander (n 126)

Conclusion

The premise of a discussion on human genome and bioethics is that of complex issues being raised, touching on the social and biological evolution of our species in a current situation where the effective application of regulatory measure is being outpaced by advances in biotechnologies. Ideas of genetic selection and discrimination, reproductive and human enhancement biotechnologies that facilitate eugenics, identity and the tension between individual value and socially assigned worth, arising from an environment where human gene-editing is a reality and its use readily available are no longer the purview of exploratory science fiction movies like *Gattaca*.¹²⁸ It is a premise where the international community aims to ensure that the sentence "your scientists were so preoccupied with whether or not they could, they didn't stop to think if they should"¹²⁹ is never uttered—with, as we have seen, varying degrees of success considering the fact that He Jiankui's unsanctioned experiment led to the birth of genetically engineered human babies, individuals who will be directly confronted to issues of genetic alteration in their personal lives. Amidst the attempts made to regulate these biotechnologies, their research, their experimentation and application, two issues have surfaced in particular. The need for a collective consensus on the values and standards used to evaluate and form the basis for a system of governance. The certainty that unless a consensus is reached, national control of biotechnologies that may affect the entire human species risks being insufficient.

Today's world has been revolutionised by the technologies we use, technologies which have led to a thinning of the shell provided by the State and the institution of Law between an individual's private sphere and the public, collective sphere. Legal questions of privacy, property and identity are being raised in a globalised data-driven world, and are now further blurring these boundaries. Human gene editing poses the same threat to our self-actualisation but at a biological level, one that may far outreach the impact of

¹²⁸ *Gattaca* (1997) <https://www.imdb.com/title/tt0119177/> accessed 8 December 2019

¹²⁹ *Jurassic Park* (1993) <https://www.imdb.com/title/tt0107290/> accessed 8 December 2019

social or economic concerns on the future of human beings given its potential for altering the very essence of our nature. In the end, this dissertation seeks to explore multiple questions raised by vast legal concepts in a changing world, concepts of identity, respect, and human worth embodied through one notion—human dignity. Concepts dwell in the world of ideas. They necessarily fail when applied to an imperfect external world. However, this failure is not necessarily a definitive failure if they still serve a purpose. The first question that emerges, then, is what purpose? In order to evaluate the concept itself, whether it fulfils its role, how it goes about it, if it is more efficient than another in reaching its end, one must know the goal that is sought. That is the first thorny question because as we have seen, there is no consensus on the precise role played by human dignity in the law. Instead, there is a consensus on its importance. Perhaps that is enough, and what is needed is this consensus that there is an significant value to be protected in humanity, one from which we can derive substantive rights. What remains and needs to be defined is then the actual content of these rights. The international community has rallied around guidelines and conventions, however these must be enforceable in order to serve as regulations.

The recourse to a human rights framework in bioethics has been explained by some out of a necessity to apply the language of rights to the normative standard that is dignity in order to functionally enforce claims of competing interests.¹³⁰ Nevertheless, several aspects of this implementation are troubling. The lack of a hierarchisation of rights does not provide a blueprint to assess conflicts of interests unfortunately frequent in biotechnologies, such as the right to health of an individual weighed against the human dignity of the species. Other ethical principles fail as well. For example, the problem of personhood raised by employing personal autonomy, that is, consent, to determine whether speculative practices should be applied when considering embryo cells that are not recognised as individuals. This is solved in part by using dignity, through the prism of a notion applicable not only to the individual but to the collective definition of humanity and also an idea of residual dignity available not only to the whole being in life but to body parts or corpses. Paradoxically, human dignity is also used to defend against the enhancement or treatment of the individual in the name of the collective good. Perhaps more interestingly than a mere extension of human rights into

¹³⁰ Roberto Andorno (n 4) 234

bioethics, a more effective pathway would adopt an independent bioethical framework relying on an overarching conception of dignity as the measuring standard of achievement, factoring the incorporation of human-rights based approaches as applied in development. Through the integration of a process that promotes and protects human right principles of universality and inalienability, indivisibility, interdependence and interrelatedness, accountability and the rule of law, participation and inclusion and finally equality and non-discrimination,¹³¹ the benefits of a human rights could be applied to bioethics without some of its drawbacks in a more flexible manner.

As we have seen in the present work, the ongoing debate over gene editing has not yet given us a comprehensive tool set for the arising issues, including a clear and unambiguous definition on the principle of human dignity applied to bioethics. However, as stated by Conti, "as increasingly accurate genome editing technology proliferates across national borders, a coherent and cohesive international stance on the issue is more urgently needed than ever. Time waits for no human right."¹³² Proof of this urgency has been amply demonstrated by the experience of He Jiankui's experiment. Thus despite a generally positive attitude towards science, humanity is gaining access to incredibly approachable¹³³ technologies that promote eugenism, originally articulated by Francis Galton as: "the science of improving stock, which is by no means confined to questions of judicious mating, but [includes] all influences that tend in however remote a degree to give to the more suitable races or strains of blood a better chance of prevailing speedily over the less suitable than they otherwise would have had."¹³⁴ A desire to perfect our lives has led to technological improvements that may ultimately, as a collective aggregate, propel our momentum on the path of hyper control to instrumentalising ourselves. That is precisely why a continued ethical questioning and awareness of our value as human beings is necessary, and why the notion of human

¹³¹ See further Jacob Kirkemann Boesen and Hans-Otto Sano, 'The Implications and Value Added of a Human Rights-Based Approach', in Bård A. Andreassen and Stephen P. Marks (eds), *Development as a Human Right – Legal, Political and Economic Dimensions* (Intersentia 2010) 57–63.

¹³² Adam Conti, 'Drawing the Line: Disability, Genetic Intervention and Bioethics' (2017) 6 *Laws* 19.

¹³³ Tim Schauenberg, 'Biohacking - genetic engineering from your garage' (2018) <https://www.dw.com/en/biohacking-genetic-engineering-from-your-garage/a-42030559> accessed 9 December 2019

¹³⁴ Dominique Aubert-Marson, 'Sir Francis Galton: the father of eugenics' (2009) 25 *Med Sci* 641–645.

dignity as the flourishing of humanity—both the species and the quality—is so crucial.