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The Legal Status of Personhood in the Wake of Genetic Editing

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Introduction

Policies and laws regarding human health require continual examination as technologies improve, and genetic editing technologies that have the ability to modify a person's DNA are unquestionably relevant to examine. The technologies most intriguing to investigate are those with the ability to directly edit the nuclear genes (segments of DNA within the nucleus of cells) through techniques such as CRISPR-Cas9 and Cpf1. This study intends to answer the questions of how should policy develop to accommodate for the improving medical technology of genetic editing and how could genetic editing technologies affect the legal status of personhood for the purposes of international human rights law?

Technological advancements require continual changes to laws and healthcare policies. As healthcare technologies increasingly improve, it is pertinent to consider the implications of genetic editing on our currently existing laws. Human Rights law already affords access to healthcare as a human right, and recently, new genetic editing techniques have entered as viable options for treating certain conditions. How will we regard the legal status of personhood with such technologies having the ability to edit a human's genetic material at the base level?

In my research, I use the examples of in vitro fertilization (IVF) on health law, specifically its varying interpretations of the legal status of personhood, as a scientific and legal precedent to genetic editing. In relating IVF to the CRISPR-Cas9 technique, an evaluative basis for analysis and future research emerges to advise as technologies continually improve. The second part describes both the ethical and legal considerations that need be considered as the genetic editing technology CRISPR-Cas9 evolves. CRISPR-Cas9 is used as the primary example of gene editing techniques because it is the current leading technique of genetic editing and is cheap, quick, and easy to use. The outcome of this research is the provision of a concise theory

as to how law and policy should develop to accommodate advances in the medical technology of genetic editing.

Currently genetic editing is a domestic matter, but it needs to be an international matter for a few reasons. One of the main issues in individual countries proceeding differently with the technology is in it creating divides in our understanding and improvement of CRISPR genome editing technologies. For example, China has begun with genetic editing trials and also completed a germline[1] genome editing trial on twins *in vitro*. The need for having a concerted effort for understanding and improving CRISPR technologies is to ensure both the integrity of the human species and contemplate the serious social, ethical, philosophical, and theological consequences of the technology, because 'such great consequences require deep reflection' (Collins & Wolinetz 2019). Another reason genetic editing needs to be an international matter is because of the off-target effects and risk of not knowing how genetic editing could affect humans. Scientists are calling for a global moratorium, or a prohibition, of such germline editing, until an international framework on the technique's use can be established in response to this case.[2] This relates to China's case of beginning clinical trials as well, because there have already been demonstatable issues directly related to their lack of regulation and oversight which led to losing track of their patients post trial.[3] Because of the aforementioned issues related to the accelerated rate of implementation of genetic editing technologies in China, this issue requires immediate international attention.

[1] Germline editing involves germline cells, or reproductive cells, which produce offspring.
[2] See https://www.the-scientist.com/news-opinion/scientists-push-for-a-moratorium-on-human-germline-editing-65593
[3] See https://www.wsj.com/articles/chinese-gene-editing-experiment-loses-track-of-patients-alarming-technologys-inventors-11545994801

Beyond the necessity for implementing international standards of law surrounding genetic modification, there is also the need for updating currently existing regulations. 'Most of currently existing regulation was created in a time when CRISPR-Cas9 was not even conceived and some of its clauses do not fit well with the state of the art technology' (De Miguel Beriain 670). Issues regarding the currently outdated or nonexistent regulations on genetic editing play into further questions of will genetic modifications seeking to modify the expression of a gene, associated with a concrete disease, be considered to be an alteration of the identity of a human being or not?

There are differing laws and policies on genetic editing that add to the need for the universal adoption of international conventions and declarations. For example, patents are territorially regulated, depending on where protection is sought. On patenting genes, Francesco Francioni provides information on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) which is an international legal agreement between all of the member national of the World Trade Organization. It states that 'any invention, whether products or processes, in all fields of technology, provided that they are new, provide an intensive step, and are capable of industrial application is patentable' [Art. 27(1)]... and allows for the exclusion for 'plants and animals other than microorganisms' [Art. 27(3)(b)] (22). This agreement introduces a loophole, in that states are allowed to classify genes as microorganisms grants patent protection to gene sequences. If there were to be some underlying benefit to lawmakers or those making the decision of classification, there is the possibility for corruption and falsely classifying genes or sequences in order to be patentable.

Throughout the rest of the paper, I will tie the concepts of international and human rights laws into debates on the legal status of personhood and genetic editing policy. To explain the connection, I will use legal and philosophical definitions of personhood along with the precedent case of *in vitro* fertilization to construct a policy recommendation on how to proceed with CRISPR medical technologies. I anticipate that *in vitro* fertilization will provide a useful legal precedent in which genetic editing policy may be founded upon. The discussion of personhood and its dissensus on definition and subsequent implementation will be integral to developing a theory on how to proceed with the emerging technology of genetic editing. Finally, I anticipate that China's current legislation will provide an insightful look into how national regulation will not be enough to ensure adequate oversight on genetic editing technologies, further supporting my proposition that international regulation and multiple levels of enforcement will be necessary for adequate coverage of regulation.

Genetic Editing

Genetic editing can be understood as the insertion, deletion, modification, or replacing of DNA segments in the genome of a living organism. Cribbs and Perera define gene editing as 'techniques for making precise and targeted manipulations of DNA sequences in living cells', which is much more effective and precise than previous gene therapy methods (626). They also define the acronym CRISPR as "Clustered Regularly Interspaced Palindromic Repeat" of RNA that acts as a guide for genome targeting and the CRISPR-Cas9 technique as

> using an RNA guide molecule to bind to complementary DNA sequences, which simultaneously recruits the endonuclease Cas9[4] to introduce double-stranded breaks in the target DNA […] the resulting double-stranded break is then repaired, allowing modification or removal of specific DNA bases (625-627).

[4] DNA cutting enzyme

Essentially, the CRISPR technique of gene editing can target sections of DNA to then modify in some way. The importance of this technique is in its ability to target and change sequences of DNA in an increasingly precise way. Whereas former techniques of gene therapy had low success rates, CRISPR technologies' success rates of cells targeted are up to ninety percent.[5]

Regardless of a high success rate in targeted cells, the technology does not have equal success in all cells. After CRISPR-Cas9 is put into cells, UC Berkeley postdoctoral fellow Chris Richardson said, "It goes and creates these breaks and you count on the cells to fix them."[6] In CRISPR-Cas9 or CRISPR-Cpf1, Cas9 and Cpf1 refer to the RNA-guided DNA endonuclease enzymes associated with the CRISPR locus. Essentially, they help the CRISPR system determine where to cleave DNA to then edit and repair.

The article also outlines the scientific and ethical issues that may influence the development of CRISPR technologies in a clinical setting-where the 'science and ethics of CRISPR-Cas9 are two co-dependent factors required for better applications and effective ways of treating diseases,' delivery systems' need for further development due to off-target effects, and the bans and restrictions associated with the technology at the time of writing (Cribbs and Perera 625-631).

Genetic editing has two applications, somatic and germline cell editing. Somatic cells are those which comprise body tissues other than what produces offspring, whereas germline cells, or reproductive cells, are those which produce offspring. 'Germline editing is highly contentious precisely because the resulting genetic changes could be inherited by the next generation, and the

[5] Read Uri David Akavia"s team study here: https://www.biorxiv.org/content/10.1101/248179v3
[6] See the article: https://phys.org/news/2018-07-dna-crispr-people-thought.html

technology therefore would cross a line many have viewed as ethically inviolable.' NASEM states:

> With the possibility of making heritable changes through the use of germline genome editing, it moves the conversation away from individual-level concerns and toward significantly more complex technical, social, and religious concerns regarding the appropriateness of this degree of intervention in nature and the potential effects of such changes on acceptance of children born with disabilities (7).

Because of the heightened possibility of a shift in how medical professionals will manage their legal and social obligations to their patients, 'policy in this area will require a careful balancing of cultural norms, the physical and emotional well-being of children, parental autonomy, and the ability of regulatory systems to prevent inappropriate or abusive applications' (7).

In the Journal of Clinical Research and Bioethics, Eduardo Rodriguez makes similar arguments to Cribbs and Perera regarding the ethical issues of the CRISPR-Cas9 technology. Both authors reference that a 'high frequency of off-target effects has been found in human cells,' due to the highly homologous nature of our DNA. Genetic editing is currently being attempted on non-viable human embryos, meaning that the embryos have been discarded regardless. Germline genetic editing would affect every cell in the resulting person and their future progeny could be affected by the editing.[7] This would allow for much greater consequences of any error or unanticipated effect than somatic cell editing. With germline editing, 'every cell in the resulting person and their future progeny could be affected by gene editing,' which would entail that 'any error or unanticipated effect would likely be much greater than somatic gene editing' (Merchant 27).

[7] Ideas expressed by G.E. Merchant (2016) follow with the legal risks and liability of human gene editing. In editing the germline cells, the DNA of every cell would change, rather than in the case of somatic editing in which only the cells targeted would be changed.

With the current possibilities[8] CRISPR technologies offer in genetic editing[9], there is an urgent need of both binding international convention and domestic level regulation (which would be according to international conventions and criteria). The need for such regulation is crucial to the positive progress of the improving medical technology. Similar to the draft final statement UNESCO provided in 2011 on Human Cloning and International Governance, the need for both developed and developing countries of binding regulations, regardless of divergent opinions, is pertinent to progress. Because of the unknown nature of where edits will take effect beyond the selected region, authors call for a halt on progress towards clinical trials and identify the dire need for a moratorium on germline editing since it would most definitely have unintended consequences in the DNA, ecological damage that would occur, and the legal ramifications due to lack of informed consent (Rodriguez 2; Cribbs and Perera 627,630). In October 2015, the International Bioethics Committee (IBC) under UNESCO also called for a moratorium on germline editing at its meeting on the human genome and human rights (UNESCO Report of the IBC).

Precedent cases of Preimplantation Genetic Diagnosis and In Vitro Fertilization

A precedent case to genetic editing that highlights a similar ethical dilemma is preimplantation genetic diagnosis for in vitro fertilization. 'Preimplantation genetic diagnosis (PGD) is used in conjunction with in vitro fertilization to guarantee the most terrible monogenetic diseases (such as Huntington's disease, cystic fibrosis (C.F.), Duchenne MD) would not be present in vitro created embryos' (De Miguel Beriain 669). In vitro fertilization is

[8] Possibilities of genetic editing include: correcting genetic errors that cause disease, eliminate the microbes that cause disease, enhancement, and heritable genome editing (germline editing) for prevention of heritable genetic disease, and treating diseases that affect multiple tissues.
[9] Cribbs and Perera note that "A major potential goal of developing CRISPR-Cas9 genome editing technology is its use in preventing or treating disease or disability" (628).

an assisted reproduction technique (ART), in which egg and sperm are combined outside of the body, in vitro, in a laboratory dish and then transferred back into the uterus for implantation. In many cases, multiple eggs are fertilized and then PGD is used prior to implantation to help identify genetic defects within embryos. Whereas PGD was the premier way of knowing if a monogenetic disease would be passed down to one's offspring, genetic editing could be used in determining and then correcting a disease or health affliction if present. While PGD is useful in most cases, there are a few cases in which selection of the unaffected embryos using the technique would not be possible, such as with autosomal recessive diseases such as C.F. and autosomal dominant diseases such as Huntington's disease. This is where genetic editing could prove more useful than PGD.

As there are differing opinions on whether PGD is ethical to use in choosing which embryos are void of the undesirable disease or affliction to be implanted, there are also opposing opinions in the ethics community between 'supporting gene editing at the beginning of human life on the basis of research freedom or the beneficence principle, and other bioethicists and scientific associations being totally against it due to the presumed violation of human dignity that it involves' (De Miguel Beriain 670). The latter argue that beginning of life gene editing would be a slippery slope that leads to consequences such as the risk of 'undesirable side effects in the individual or the whole of humankind', and even an 'intrusion into nature' (De Miguel Beriain 670-71). The former argue that the continual improvement of medical technologies should coincide with the continual advancement of techniques used to treat diseases and other medical ailments.

IVF has also been contested on similar ethical and moral grounds as PGD. Martin Hevia and Carlos Herrera Vacaflor identify there have been many cases where states have regulated IVF, citing the 'right to life' of the fetus is of most importance and therefore IVF is impermissible because it would involve a high probability of embryos being discarded in the process. Protection of the right to life is the case in Costa Rica, Argentina, Peru, and Ecuador (61). In Argentina's jurisprudence, it was originally held that an embryo or un-implanted pronucleate oocyte held personhood status and thus IVF was illegal, but the country has since amended their stance to allowing IVF 'only on the condition that un-implanted embryos be cryopreserved or donated' (64). 'In this way, the court reasoned the right to life and dignity of this life form is respected, and in some way, protected' (64).

This leads us to the question of how law is handled in South America. There are three routes of IVF jurisprudence taken: (1) absolutely banning IVF because it violates the right to life; (2) allowing access to IVF in certain cases because a total ban would violate the rights to privacy and family planning; and (3) allowing access to IVF because embryos do not have a right to life. The argument in favor of absolutely banning access to IVF is in favor of the state protecting and respecting the right to life, and this absolute right trumps any other right (Hevia and Herrera Vacaflor 56). As for the second route, Brazil is a perfect example of state regulation of IVF because a total ban would violate the rights to privacy. "All competent persons" are allowed access to IVF, which includes same-sex couples and unwed individuals, and Brazil prohibits the destruction of embryos through allowing for crypto-preservation and selection (Hevia and Herrera Vacaflor 59). It 'suggests that the right to life is not absolute and must be harmonized with the protection of other rights, such as a woman's right to privacy' (Hevia and Herrera

Vacafor 64). The issue with a total lack of regulation of IVF is that 'the practice is completely "de facto," leaving the ethical and practical challenges of IVF directly in the hands of doctors (Hevia and Herrera Vacafor 61). This is the case with Ecuador, as they do not regulate IVF at all.

With these examples in mind, let us now transition back to discussing the regulation of genetic editing. The regulation of genetic editing continues to be a domestic matter, since 'previous attempts to create international binding regulations have ended so far in pyrrhic victories' (De Miguel Beriain 671). Martin Hevia, Carlos Herrera Vacaflor and Iñigo De Miguel Beriain all show that when states have separate regulations, it creates divides in the understanding of both technologies and their implications. They also show through their research that, if left without international regulation, countries will create their own regulations or, worse, fail to regulate. The questions we must ask are: Do we want to maintain the status quo to allow individual countries to determine what they do, or is it significant enough with this new and unique technology that something else is warranted? Should we push for international regulation? I believe the answer is yes.

International regulation will aid in countries' policy creation following set standards for genetic editing. As mentioned in the Introduction, there is a dire need for updating currently existing regulations since 'most of currently existing regulation was created in a time when CRISPR-Cas9 was not even conceived and some of its clauses do not fit well with the state of the art technology' (De Miguel Beriain 670). An exemplary representative case is in EU regulation because it is scarce and imprecise by addressing eugenic practices but not genetic editing regulation[10], relates to intellectual property rights issues but does not ban genetic editing

[10] Article 3 of the EU Charter of Fundamental Rights

of the germline[11], and lack clarification on the sense and limits of how to preserve human 'genetic identity'.[12] These issues play into further dilemmas of international regulation because in IVF, there was a trend towards letting states handle it, so the natural policy outcome with genetic editing would follow suit in supporting state sovereignty and allowing states to govern themselves. But that cannot happen because this technology offers much more of a concern ethically, ecologically, and scientifically than previous technologies. Genetic editing cannot be left up to countries to create their own regulations or worse, fail to regulate, because it has raised more dilemmas for personhood than previous techniques or technologies such as IVF and PGD. The international community must take action to regulate genetic editing rather than letting individual countries decide policies and regulations for themselves, as has been done in past cases.

Currently genetic editing is a domestic matter, but it needs to be an international matter. The issue is in countries proceeding differently and thus creating divides in our understanding of CRISPR genome editing technologies. For example, China has begun with genetic editing trials and also completed a germline genome editing trial on twins in vitro. Key issues with China beginning clinical trials are directly related to their lack of regulation and oversight which led to losing track of their patients post trial.[13] [14]

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[11] EU Directive on Biotechnological Interventions (Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions)

[12] Article 9.6 of the EU Directive 2001/20/EC, EU Regulation No 536/2014 of the European Parliament and Council of 16 April 2014 on clinical trials on medicinal products for human use

[13] See for article:
https://www.wsj.com/articles/chinese-gene-editing-experiment-loses-track-of-patients-alarming-technologys-inventors-11545994801

[14]This situation is still occurring today and is also likely to affect the governance of human genome editing research, including the governance of clinical trials and potential clinical applications. [National Science Foundation of China (NSFC)]

The reason for China's lack of regulation and oversight is because China has varying and at times lenient enforcement in regards to regulatory standards set by the Chinese ministry of health and international standards. Because of this and the four autonomous municipal governments, it is "sometimes difficult for the national ministries to get accurate data about what is happening in remote regions, let alone govern them" (Warrell D. et al.; Nuffield Council on Bioethics 6). Because of the lack of regulation and oversight, a Chinese scientist has begun with genetic editing trials and also completed a germline genome editing trial on twins in vitro. As mentioned previously, the reasoning behind needing a concerted effort for understanding and improving CRISPR technologies is to ensure both the integrity of the human species and contemplate the serious social, ethical, philosophical, and theological consequences of the technology, because 'such great consequences require deep reflection' (Collins & Wolinetz 2019).

This example highlights a key point regarding genetic editing that requires immediate international attention, because of the current lack of regulation internationally, states are beginning to govern themselves. As stated in the beginning of this section, because there was a trend towards letting states handle IVF legislation, the natural policy outcome with genetic editing is beginning to follow suit in supporting state sovereignty and allowing states to govern themselves. This cannot be permitted to happen because this technology offers much more of a concern ethically, ecologically, and scientifically than previous technologies.[15] It isn't adequate for states to manage genetic editing technologies precisely because of China's case. Genetic editing cannot be left up to countries to create their own regulations or worse, fail to regulate,

[15] Reference page for explanation on the concerns related to genetic editing.

because it has raised more dilemmas for personhood than previous techniques or technologies such as IVF and PGD. The international community must take action to regulate genetic editing rather than letting individual countries decide policies and regulations for themselves, as has been done in past cases.

The issues previously mentioned play into the further question of will a genetic modification seeking to modify the expression of a gene associated with a concrete disease be considered to be an alteration of the identity of a human being or not? This will be discussed in the following sections on ‘Personhood’.

Legal Status of Personhood

It has become increasingly important to address the implications of emerging technologies on human rights. Bioengineering, specifically human genetic engineering, has been in development for almost 30 years. The Human Genome Project acted as a catalyst for increased research into genetics and gene therapy. Afterwards, questions of how to cure genetic diseases entered the research of scientists within the field. Gene therapy through viral vectors was first used in attempt to improve human health, but did not have high success rates due to many factors. Now, CRISPR-Cas9 gene editing has been created as a technology to directly 'cut, edit, and paste' new genes into the patient’s genome. The technology makes it easier to make alterations within the genome, and is much more accurate than previous forms of gene editing. It is more accurate because it allows for the introduction of genetic sequence changes precisely into the genome, effectively altering the composition of the genome for medical treatment of genetic diseases that were once incurable.

Since the conception of the term personhood, there has been a contestation of the meaning and the status it entails in philosophy and politics. There has been debate on what defines personhood in legal arguments because it can be defined in the biological concept of Homo-Sapien, the notion of a rational agent, and/or as the unity of consciousness. With each concept, the determination of rights shifts accordingly.

The concept of human can be understood in the Kantian sense of those with the "ability to reason," or in the Cartesian sense that thinking denotes some sense of humanity. It could even be understood in the contemporary sense that one's knowledge of oneself [16] maintains that they are human (Velleman 1989). The essentialist view of personhood in the Aristotelian-Thomistic view is rival to the Cartesian and Kantian views. In the essentialist view, to be a person is is to be the kind of thing that is human, where by its nature has the powers of personhood like reason, intrinsic self-awareness, reasoning, and one's desires. One need only possess these powers in potentia to be have personhood status. Perry points out that it matters 'who counts as human' when we are dealing with human rights. Aquinas posed that there are *natural laws*, or inherent goods, that are natural because they are 'naturally known by human beings and are founded on those desirable activities which perfect and fulfill human beings' (Boyle 113). His conception of natural human good was formative in the conception of morality as well as current politics, law, and human community (Boyle 113).

It is important to note that the foundation of human good posed by Aquinas, inherent in all humans, could also maintain that therein lies a common humanity, of humanness. The arguments posed in contemporary debate on human rights still follow questions of how does one

[16] Self-awareness

define self and determine self-knowledge (following the Descartian model), and who/what counts as human (following the Kantian model). Why is there a distinction to be made in these cases? Within the different conceptions of human-hood lie issues of distinction. The following arguments will be based on historical conceptions and contemporary examples of human-hood, human rights, and natural law, as well as introduce possible questions to be raised about the conception of human rights as new technologies emerge.

Nussbaum makes a compelling statement, following along with Aquinas' natural laws, that underlying good of humans are the 'features of humanness that lie beneath all local traditions and are there to be seen whether or not they are in fact recognized in local traditions' (Perry 69). These features of humanness 'constitute the measure of culture and the condition ensuring that 'man does not become the prisoner of any of his cultures.' [17] From Nussbaum's theory of human good, it follows that some of the issues with human rights are not that we cannot identify ways of life that are good/best for every human being, contrary to Rorty's claims, it is that those ways of life may not fit into some current systems.

Hellsten identifies that the 'idea of human rights had to be invented and grounded on various philosophical, theological, and political theories and are enforced by a number of international covenants and agreements as well as by national laws and regulations' (62). Following the Universal Declaration of Human Rights (UDHR) in 1948, it was established that "the promotion of universal respect for and observance of human rights and fundamental freedoms" is to be universally protected. In order to uphold human rights and personhood status of humans with emerging technologies, the same process of debate and theory testing,

[17] Quote by John Paul II in the article: *Are Human Rights Universal?*

enforcement of international covenants and agreements, and then the creation of national laws and regulations as Hellsten postulates must be done.

Moving on to the legal definition, in Black's Law Dictionary a 'person' is "a human being"... and only persons are "members of the human family" or "human beings" (Paulk 785). Because of this limiting definition and legal ambiguity and discord surrounding it, the status of the embryo is contested. The status of the embryo in the US being contested (ie: not being considered a person until birth) allows for legal ambiguity in the case of embryonic genetic editing and possibly germline editing. This could lead to future negative consequences if regulations, both national and international, are not applied and enforced.

Revision of the legal definition of personhood would aid in clarifying what rights the embryo has and does not have. This is especially pertinent to the prospect of beginning clinical trials with CRISPR technologies, and its implications on human embryo trials. What is both a need and a right, is the insurance of well-being through the ethical practice of medicine. Without having a universal legal definition of personhood, it allows for the possibility of differing interpretations of subsequent law as a result.

Due to the disensus on the definition of personhood, there will need to be further discussions to arrive at a consensus on a definition. There should be serious consideration on clarifying the definition of personhood since there are such radical disagreements between philosophers, bioethicists, and citizens over it. In utilizing the process outlined by Hellsten, the issue of ambiguous personhood and subsequent rights could be corrected.

Referencing the National Academy of Sciences and National Academy of Medicine's Report in February 2017, the extended criteria for ethical practice of genome editing is as follows:

> therapy should be used only for the treatment and prevention of disease and disability; should not be tried for enhancement at this time; do not extend without extensive public engagement and input; heritable [germline] genome editing needs more research before it might be ready to be tried; heritable [germline] genome editing must be approached cautiously and according to strict criteria with stringent oversight.

Does it require the consent of the unborn for parents to remove their likelihood of passing on a potentially fatal and or life-altering genetic condition to their offspring? The issue with this question remains in the relevance of autonomy in human rights, entailing that the subject is the best at deciding based on their interests. What if that person is/will be limited by a severe disability or underlying severe genetic defect that would affect their ability to reason or make decisions for themself? It would entail that unfortunately, they have a limited autonomy for decision-making due to their disability, unless there were a way to remove the arguably unnecessary struggle of their disability.

Respect for the presence, absence, or degree of autonomy of an individual are morally relevant characteristics to consider in the dilemma of editing the genetic makeup of that individual, especially when dealing with future questions regarding the ethics of germline genetic editing. When facing the ethical question of what to do when no prior preference or value can be traced, or cannot be gathered, it is the standard to 'rely on best-interests standards based on nonmaleficence and beneficence' (Childress 65). This is where CRISPR-Cas9 gene editing could have basis: to afford individuals a full life, void of harm or hurt, when other forms of medical treatment or medicine are not available. It is making the choice to necessarily protect

individuals whom have no other alternative to their disease - effectively following the nonmaleficence and beneficence principles of ethical medical practice.

Personhood in Legal Arguments

Other issues that arise from genetic editing are along questions of personhood. When we begin changing the sequencing of a person's DNA, we must consider the patented sequencing of DNA and how it might affect who we determine as a person versus property. We will also need to consider how many changes can be made before we create new species of humans, since in the case of germline editing since every cell in the resulting person and their future progeny could be affected by gene editing.[18] This possibility is mentioned for the sake of invoking intrigue in the discussion of germline editing, but will not be discussed further in this paper.

Article 1 of the Universal Declaration of Human Rights states "All human beings are *born* free and equal in dignity and rights," intentionally using "born" to exclude the fetus or any antenatal application of human rights and "clearly reject[ing] claims that human rights that human rights should attach from conception or any time before birth" (Copelon et al.). Similarly, the Convention on the Rights of the Child makes clear that it does not recognise the right to life until birth; "For the purposes of the present Convention, a child means every human being below the age of 18 years…" which, consistent with the Universal Declaration of Human Rights, refers only to born persons" (Copelon et al.). Furthermore, the reason for precluding recognition of fetal rights is because of the "breadth of women's human rights that would be at stake were overriding claims of fetal rights to be accepted" (Copelon et al.).

Performative Personhood

[18] Merchant, G.E.. "Legal Risks and Liabilities of Human Gene Editing." Scitech Lawyer. 2016. Vol 13(1) 26-29.

The dualist, understood as body-self dualism under the performative personhood view, is concerned with the inner observer, or "self *qua* subject" in which having self-conception presupposed the capacity for rationality, and as such, only human beings can have such self conceptions (Himma). Mary Anne Warren identifies five traits, or criteria, that are "most central" to personhood: 1) consciousness and the capacity to feel pain, 2) reasoning, 3) self-motivated activity, 4) the capacity to communicate, and 5) "the presence of self-concepts, and self-awareness, either individual or racial or both" (Vaughn 316). To be a person, 'one need not possess all these traits, but surely any being which satisfies *none* of (1)-(5) is certainly not a person', therefore since a fetus satisfies none and is therefore not yet a person and 'cannot coherently be said to have full moral rights' (Vaughn 317). Merely being a creature with human DNA is not sufficient for personhood in Warren's argument.

The difference between the performative view of personhood and the essentialist view is in their meanings. Whereas the performative view is concerned with self conception and a capacity for rationality in order to gain personhood, the essentialist view believes that there should be no differentiation between human and person. This key difference between the essentialist and performative views of personhood illustrates the dissensus on an encompassing definition of personhood. Although no encompassing definition of personhood will be provided in this paper, a consensus will need to be established on the definition of personhood and a subsequent analysis of its ramifications will need to be considered in the near future when dealing with policymaking on genetic editing.

Tying back to the issue of germline genetic editing, if the fetus is not a person it could leave room for the argument that since it is not yet a person, it has no rights as a person who

possesses any or all of the five traits Warren identified as being most central to personhood. In the instance that they have a lack of consent of the fetus and future generations, it must be considered the informed consent of the mother making the decision and future generations cannot be taken into account and therefore should not move into clinical trials on the basis of the lack of information surrounding the effects of germline editing on future generations, even if the fetus has no personhood status.

On the other hand, if Warren's argument that simply having human DNA does not constitute personhood were to be applied in a genetic editing scenario, there is potential for arguments that once edited to form non naturally occurring proteins in the human genome they would no longer have personhood status. Warren's argument that merely having human DNA is not sufficient for personhood also leaves room for issues of persons who do not meet the criteria she proposed, and could have negative consequences if applied in a dehumanizing effort.

This goes back to needing more rigorous regulation on germline editing since the Chinese researcher edited human embryos for a disease that had other options for treatment and prevention.

> International law provides a more complete answer to the embryonic personhood debate because it outlines rights that governments should protect and provide… and, in the case of governments that have signed and ratified human rights treaties, which rights governments are *obligated* to protect and provide (Paulk 785).

'If an embryo is a person, and therefore entitled to protection under human rights law, government allowance or regulation of IVF may be a violation of international human rights law', but if an embryo is not a person and not protected under human rights law, government regulation or denial of IVF or abortion would be supported (Paulk 786). Rights without access mean very little to a majority of the population,' so the key point to take away is that without the

international regulations and standards for genetic editing, the rights afforded to all persons in the Universal Declaration of Human Rights are null (Paulk 790). Similar to the issue of personhood, complications arise when there are differences of definition since the determination of rights shifts accordingly with each definition. This is why a reevaluation of definitions and laws surrounding personhood will be integral in moving forward with genetic editing regulation.

Although Warren's specification of personhood aids to discussions on abortion and reproductive rights, it also allows for research to begin on human embryos, as they lack the rights of born persons. However, there are differing opinions on whether the practice of doing scientific research for genetic editing on human embryos is ethical. In support of research, the argument holds that it is required to understand genetic editing technologies' effect on humans. Ethicists suggest human dignity is threatened by the application of genetic editing on human embryos and that there should be a line drawn due to the unintended consequences that could come with the technique.

Fetal personhood debates

Conflicts related to fetal personhood arise not over such fundamentals of development, but over the 'nonmoral facts such as the nature of the fetus and over the meaning and application of moral standards' (Vaughn 314). Because debates are based around the meaning and application of moral standards, it stands that the issue of abortion is a legal and moral issue due to the complex nature of rights of the mother and rights of the unborn, and also because of the many ways in which personhood has been argued to be defined.

Most anti-abortion arguments rely on the premise that the fetus is a human being, a person, however the U.S. Supreme Court noted in the landmark case of *Roe v. Wade* that the

constitution does not define 'person' and that "the word 'person' as used in the Fourteenth Amendment, does not include the unborn… the law has never maintained that the unborn are persons 'in the whole sense'" (Vaughn 313). So the case 'balanced the woman's right and state interests according to trimester of pregnancy', where only in the 'second trimester may the state limit-but not entirely prohibit-the woman's right by regulating abortion for the sake of her health' and 'after viability, the state may regulate and even ban abortion except for when it is necessary to preserve her life or health' (Vaughn 313).

However, Roe v. Wade was changed by Planned Parenthood v. Casey in significant ways. The latter case included a private right to define one's concept of meaning and existence, where the debate about personhood is privatized as a decision left to individual women. It also separated the line of viability from a specific time to allow for medical progress in the areas of embryonic and fetal research. Finally, it introduced the undue burden standard which established a legal restriction on "placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus." In short, Roe v. Wade and Planned Parenthood v. Casey were both integral decisions to governing this area of law.

International Law

In this section, I will discuss the definition of international law and relate it to the obligations states have in regard to international law. Then, I will identify shortcomings in international and patent law that lead to a lack of clarity when proceeding with new medical technologies like CRISPR-Cas9 and Cpf1. Later in my 'policy' section, I will provide suggestions for how to navigate forward in appropriating international law on the national plane in order to protect the human rights of those who utilize CRISPR technologies as medical treatment.

International law can be defined as “the rules and principles of general application dealing with the conduct of states and of international organizations and with their relations *inter se”*, meaning that the rules are principles are dealt with among states and international organizations themselves, “as well as with some of their relations with persons, whether natural or juridical” (American Law Inst., 1987). Insuch, “the rights and obligations which a state has on the international plane are superior to any rights or duties it may have under its national law, such as in treaties, accords, etc.." (Buergenthal & Murphey 7). Although states may have a superior obligation to that which is established on the international plane, ultimately states carry out their own interest in protection of their state sovereignty. The issue with this contradiction highlights the main issue with international conventions and declarations-states will need to ratify and support them in a national setting if they are to be upheld with any congruence with other states.

Isolationists hiding behind the guise of state sovereignty are missing part of the bigger picture: state regulation isn't sufficient. International regulation, especially in the interconnected and modern world we live in, is absolutely necessary. Isolationists use arguments of state sovereignty to refuse the international law necessary for emerging technologies such as CRISPR. Subsequently, there is a tension between state sovereignty and overarching international laws. Where state sovereignty is overly limited when it comes to emerging technologies as in the case of IVF regulation and China’s current genetic editing regulation lacking sufficient enforcement and oversight, international laws and regulations are not limited in that they have the ability to ensure the world is progressing in a joint effort. Especially with the improving genetic editing technologies, it is pertinent to ensure international regulation is supported and enforced.

Law and regulation is meant to enforce justice and prescribe duty or obligation, to protect those who may be affected. The issue of genetic editing is both philosophical and scientific, and the consequences of this technology becoming political would be catastrophic. In genetic editing becoming political, there is the issue of corruption of the scientific process by pushing clinical trials to begin with a technology that is not mature enough. Furthermore, if states refuse to agree upon a consensus for adhering to international laws created, there is the potential for ecological disequilibrium - related to common heritage and common concern - as a result of germline editing having a high possibility for off-target effects, and even its use in biological attacks.

The distinction between resources under national sovereignty and those beyond national jurisdiction, such as common heritage and common concern, are addressed in Francioni's work in highlighting that a 'majority of biogenetic material that has been commercially developed are placed under the regime of national sovereignty.' Because of this, Francioni states that the relationship between investors and source countries be appropriately regulated by the body of international law through the Convention on Biological Diversity[19], FAO Treaty, and the 2002 Bonn Guidelines[20] (22-23).

Francioni also brings up the issue of 'potential conflict with specific Human Rights, such as the right not to be discriminated against grounds of genetic traits, privacy, and the right not to know.'[21] Overall, this source was useful in providing an introduction to patenting and possible outcomes and conflicts related to commercial and national interests.

Between Francioni's work, the 2002 Bonn Guidelines, the Convention on Biological Diversity, and the World Trade Organization (WTO), there is conflict between their principles

[19] See https://www.cbd.int/doc/legal/cbd-en.pdf
[20] Cited in Appendix 1
[21] Reference GINA, Article 12 of the Universal Declaration of Human Rights, and Andorno, R.

and policy goals, especially as it relates to 'general principles of sovereignty over natural resources, and principles of freedom and common heritage of mankind.' This arises from the need to preserve freedom of research and the right of everyone to benefit from the advancements in science and technology, and its potential to collide with the fundamental concept of human dignity and the integrity of the human person.

Policy

In this section, I will establish a background of the current NASEM report on human genome editing and outline the current policies regarding human genome editing. Then, I will provide an analysis of potential policy prescriptions and their related implications to genome editing technology. Finally, my suggestions for how to navigate forward in appropriating international law on the national plane, in the form of policy implications, will be outlined.

The National Academy of Sciences, Engineering, and Medicine (NASEM) produced a report on the science, ethics, and governance of human genome editing in 2017. In their report, discussions pertaining to 'concern about whether the appropriate systems are in place to govern the technologies and whether societal values will be reflected in how genome editing is eventually applied in practice' are used to suggest that in order to promote transparency, confer legitimacy, and improve policy making, there must be emphasis on meaningful engagement with decision makers and stakeholders (4). Suggesting meaningful engagement with the public and private sectors is the first important step in identifying how to move forward on policy determinations. With emerging genetic editing technologies, consideration for the science behind the processes will further aid in producing policy.

Meaningful engagement in this context can be understood as "the engagement of people from all sectors of society in a debate about genetic modification" (Weisberg et al.). Weisberg et

al. state that it is "critical to understanding if there is broad support for relevant health policies and regulations", following the education of the public on such new technologies. Gauging the initial measure of people's attitudes 'toward the promise and perils of such research' after comprehensive education on CRISPR technologies allows for an accurate understanding of how to move forward with and improve upon subsequent policies. It also ties back in with the values associated with meaningful engagement such as transparency and sustained legitimacy. Following education and engagement with the public, meaningful engagement with decision makers and stakeholders furthers the connection society has with emerging genetic editing technologies. Once there is an encompassing understanding of the public and private attitudes on genetic editing technologies, along with the much needed understanding of the technology, its applications, and surrounding ethics, policy around the issue will become more accurate.

In 2017, the United Kingdom, China, and United States began allowing the modification of non-viable human embryos for scientific research. Also, there is a prohibition on the U.S. Food and Drug Administration's (FDA) use of federal funds to review 'research in which a human embryo is intentionally created or modified to include a heritable genetic modification.'[22] These precedents provide a basis for examining the legal and policy debates surrounding state decisions on the modification of human embryos. The removal of prohibitions on modifying non-viable embryos followed the NASEM Report in February 2017 that set a criteria for the ethical practice of genome editing - essentially limiting researcher's use of therapy for the outstanding circumstances for the treatment and prevention of disease and disability. This report

[22] Consolidated Appropriations Act of 2016, Public Law 114-113 (adopted December 18, 2015).

includes the ethical and moral arguments against the implementation of germline editing unless no other option is available and the condition is sufficiently severe to warrant its use.

NASEM's ten point criteria is a regulatory framework for clinical trials using heritable genome editing, where it only be permitted only if it follows the following criteria[23]:

- absence of reasonable alternatives;
- restriction to preventing a serious disease or condition;
- restriction to editing genes that have been convincingly demonstrated to cause or to strongly predispose to the disease or condition;
- restriction to converting such genes to versions that are prevalent in the population and are known to be associated with ordinary health with little or no evidence of adverse effects;
- availability of credible preclinical and/or clinical data on risks and potential health benefits of the procedures;
- ongoing, rigorous oversight during clinical trials of the effects of the procedure on the health and safety of the research participants;
- comprehensive plans for long-term, multigenerational follow-up that still respect personal autonomy;
- maximum transparency consistent with patient privacy;
- continued reassessment of both health and societal benefits and risks, with broad ongoing participation and input by the public; and
- reliable oversight mechanisms to prevent extension to uses other than preventing a serious disease or condition.

It follows that the trials would be limited to only the 'most compelling circumstances' of conditions in order to 'protect the research subjects and their descendents and to institute safeguards against inappropriate expansion into uses that are less compelling or well understood' (134).

As an example of the legislation and interpretation of positive laws surrounding the issue, South Korea created the BioAct, which serves as a basis for regulation of research on gene therapy and differentiation between (born) humans and embryos in regards to aforementioned research (Kim 2017). In the BioAct, gene therapy is defined as "1) Procedures altering genes in

[23] See criteria here: https://www.ncbi.nlm.nih.gov/books/NBK447260/

the human body and 2) procedures transferring genetic material or cells into which the genetic material has been introduced to the human body." Insuch, it is required that:

> all gene therapy research procedures are to meet the criteria 1 and 2 (in which a person must be facing a certain type of disease that threatens life or causes a severe disability and where no applicable therapy exists or gene therapy presents a greater chance of being more effective than other therapies, respectively) (BioAct §47(1) 2012).

NASEM's 2017 report follows the scientific and ethical issues outlined about the CRISPR-Cas9 technology. Referring back to Rodriguez, Merchant, and Cribbs and Perera, all authors reference the technology resulting in a 'high frequency of off-target effects has been found in human cells' due to the highly homologous nature of our DNA. Being that germline genetic editing would affect every cell in the resulting person and their future progeny, it has a higher possibility of error or unanticipated effect than somatic cell editing.[24] Because of the unknown nature of where edits would be made beyond the selected region, they call for a halt on progress towards clinical trials and identify the dire need for a moratorium on germline editing since it would most definitely have unintended consequences in the DNA, ecological damage that would occur, and the legal issue of lack of informed consent (Rodriguez 2; Cribbs and Perera 627,630).

The current ethical standing on germline editing involves the WHO, UNESCO, and the Declaration on the Human Genome and Human Rights all condemning the practice, but are still formulating guidelines on the matter as of 2017 (Cribbs and Perera 629). In December 2018, days after news surfaced of the germline edited babies being born in China, the WHO announced that it would assemble experts to set international guidelines for the use of CRISPR in germline

[24] Ideas expressed by G.E. Merchant (2016) follow with the legal risks and liability of human gene editing. In editing the germline cells, the DNA of every cell would change, rather than in the case of somatic editing in which only the cells targeted would be changed.

editing (Nebehay). However, the WHO is not a regulatory body and does not have the capability of enforcement, so the guidelines set by the WHO advisory board on genetic editing are 'intended to set research-backed international standards for member countries to each set their own national regulations about issues like research and medical treatment, and how to enforce them' (Eschner). The article, aptly titled "We need to police gene editing. The World Health Organization agrees," shared a quote from Kelly Ormond, a geneticist at Stanford University which states: Many who work on human genome editing "really feel like the biggest issue around this topic is nobody sets international law" (Eschner).

Referencing South Korea's BioAct legislature and South American IVF jurisprudence as a precedent, there are three logical policy prescriptions for regulating genetic editing that follow: a complete ban on genetic editing; regulated permission; or unregulated permission. Further categorization between somatic and germline genetic editing can then be made under each policy prescription (See Table 1). With a complete ban on all genetic editing, policymakers would follow an essentialist framework with the intention of ensuring human dignity is preserved. There are not many proponents of banning somatic genetic editing, so it will not be covered throughout the rest of the policy section. However, there are more proponents of banning germline genetic editing. Most scientists and bioethicists alike are pushing to enacting a moratorium on germline editing. This would mean a temporary ban on germline editing in order to further research and understanding to improve the technology before it is phased into clinical trials. Arthur Caplan, a professor of bioethics at New York University School of Medicine, 'advises a cautious approach to germline editing: [25]

[25] Smith, Dana G. "The Case for CRISPR Babies: Some families with genetic diseases are finding hope in the controversial technology." *Medium.* 23 Jan 2019.
https://medium.com/s/story/the-case-for-crispr-babies-4d4e0a6fbfdb

> "I'm for it," he says. "I think it will happen. I think it will be great to get rid of these genetic diseases. But that doesn't mean we should all run around expecting it to happen tomorrow morning."

As for regulated permission of germline genetic editing, it could allow for a wide range of permission on what and how germline genetic editing could be regulated. For example, it could entail similar legislation as Argentina on IVF in allowing access to germline editing in certain cases because a total ban would violate the rights to health. In this instance, we could see legislation allowing germline editing in the most severe cases of disease in which there is no treatment or cure such as - such as Huntington's disease, cystic fibrosis (C.F.), Duchenne MD, muscular dystrophy - following NASEM's 2017 criteria.[26] The reason for prioritizing people with diseases with little to no treatment of cure readily available as the primary candidates is to ensure we are proceeding cautiously with gene editing technology. Rather than taking a risk to edit the germline for a curable or preventable disease, such as in the Chinese scientist's case, it is more ethical and medically relevant to limit the procedure to those with a diseases with no cure or treatment available. Legal oversight mechanisms will need to be put into place in order to ensure rogue gene editing doesn't happen - where international standards are enforced by national and state or territorial levels.

Unregulated permission for germline editing would entail physicians using their own judgment on a case by case basis. As explained in the IVF precedent case, the practice would become completely "de facto," 'leaving the ethical and practical challenges of [germline genetic editing] directly in the hands of doctors' (Hevia and Herrera Vacafor 61). This would limit the knowledge of research and clinical trials conducted because of the lack of exchange typically

[26] Reference page 17

required by regulatory bodies. In order for there to be sufficient exchange of knowledge for improving a medical technology, a regulatory framework must be enforced. This is why unregulated permission cannot be a possibility with germline genetic editing.

Table 1

Complete Ban		Regulated Permission		Unregulated Permission	
Somatic	Germline	Somatic	Germline	Somatic	Germline

In making policy recommendations related to scientific technologies, it is important to consider their processes. Understanding how a technology functions allows for more complete policy recommendations and guidelines to base future decisions. For example, in understanding how CRISPR technologies, such as CRISPR-Cas9 and CRISPR-Cpf1, function there is a heightened understanding of associated possibilities and pitfalls. In considering the scientific recommendations for a technology, law and subsequent policy will be more sound, serving to better protect the people.

The relevance of updating law and policy as medical technologies improve directly correlates with the temporal advancements of clinical trials and implementation. If the law is lax and allows for the beginning of clinical trials before the technology is sufficiently mature, in response to investor pressure, then there is more room for error. The risks possible with CRISPR and other tools for genetic manipulation are off-target effects[27], unwanted DNA deletions[28], unintended consequences for future generations, and the possibility of use in biological attacks.

[27] The basic reason for such "off-target effects" is that CRISPR's guide molecule, which is usually 20 genetic letters long, isn't as precise as often advertised and will sometimes find regions with 18 or fewer base pairs to 'edit' https://www.statnews.com/2018/03/05/crispr-off-target-editing/

[28] See more at: https://www.nature.com/articles/d41586-018-05736-3

These risks would directly affect patients in clinical trials. Currently there are international conventions in place that offer guidelines, such as the Convention on Biological Diversity, FAO Treaty, and the 2002 Bonn Guidelines, yet until guidelines such as these are adopted into national law, there is little recourse for states that participate in behavior contrary to previously mentioned guidelines. Take for example the Chinese physicist He Jiankui who conducted a germline gene editing trial on viable fetuses - although there are international declarations against such action, the trial was conducted regardless and resulted in two children. Only one of the children's DNA was successfully edited to remove the ability to contract HIV, yet there was little consideration by the scientists on the resulting unknown adverse effects of the procedure nor fully informed consent of the patient and subsequent offspring. Furthermore, He's team '*disabled* a normal gene in an attempt to reduce the risk of a disease that neither child had—and one that can be controlled' (Yong). There are already ways of preventing fathers from passing HIV to their children. There are antiviral drugs that prevent infections. There's safe-sex education. "This is not a plague for which we have no tools," says Paula Cannon' (Yong). The repercussions have yet to be enacted on the Chinese scientist because of the lack of national restrictions on the matter.

The regulation of genetic editing continues to be a domestic matter, since 'previous attempts to create international binding regulations have ended so far in pyrrhic victories' (De Miguel Beriain 671). Martin Hevia, Carlos Herrera Vacaflor and Iñigo De Miguel Beriain all show that when states have separate regulations, it creates divides in the understanding of both technologies and their implications. They also show through their research that if left without international regulation, countries will create their own regulations or worse, fail to regulate. The

questions we must ask are: Do we want to maintain the status quo to allow individual countries to determine what they do, or is it significant enough with this new and unique technology that something else is warranted? Should we push for international regulation? I believe the answer is yes.

As mentioned in the Introduction, there is a dire need for updating currently existing regulations since 'most of currently existing regulation was created in a time when CRISPR-Cas9 was not even conceived and some of its clauses do not fit well with the state of the art technology' (De Miguel Beriain 670). An exemplary representative case is in EU regulation because it is scarce and imprecise by addressing eugenic practices but not genetic regulation[29], relates to intellectual property rights issues but does not ban genetic editing of the germline[30], and lack clarification on the sense and limits of how to preserve human 'genetic identity'.[31] These issues play into further dilemmas of international regulation because in IVF, there was a trend towards letting states handle it, so the natural policy outcome with genetic editing would follow suit in supporting state sovereignty and allowing states to govern themselves. But that cannot happen because this technology offers much more of a concern ethically, ecologically, and scientifically than previous technologies. Genetic editing cannot be left up to countries to create their own regulations or worse, fail to regulate, because it has raised more of a dilemma for personhood than previous techniques or technologies such as IVF and PGD. The international community must take action to regulate genetic editing rather than letting individual countries decide policies and regulations for themselves, as has been done in past cases.

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[29] Article 3 of the EU Charter of Fundamental Rights
[30] EU Directive on Biotechnological Interventions (Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions)
[31] Article 9.6 of the EU Directive 2001/20/EC, EU Regulation No 536/2014 of the European Parliament and Council of 16 April 2014 on clinical trials on medicinal products for human use

In creating concise regulations on genetic editing at the international level, there can then be a concerted national effort of coordinating policies that both uphold and enforce the international regulations. As Hellsten identified, in order to uphold human rights and the personhood status of humans with emerging technologies, the same process of debate and theory testing, enforcement of international covenants and agreements, and then creation of national laws and regulations must be done. With genetic editing technology having unprecedented potential effects on both the human genome and the wider sociopolitical contexts, taking the steps to thoroughly accommodate the risks and benefits associated with genetic editing is a must before states begin separately regulating the technology in the interim period, thus making international regulation essentially null and void.

Genetic editing needs to be an international matter because countries proceeding differently creates divides in our understanding of CRISPR genome editing technologies, and will only serve to further separate our understandings of the technology. The example of China beginning with genetic editing trials and also completed a germline genome editing trial on twins in vitro. Lacking an international consensus and legal support will only serve to permit countries like China to begin clinical trials, further exacerbating the negative consequences of a technology not yet mature enough for such a step.

Conclusion

I began this study by seeking to answer the questions on how we will regard the legal status of personhood with the introduction of technologies that have the ability to edit a human's genetic material at the base level, as well as the overarching question of how policy should develop to accommodate for the improving medical technology of genetic editing. To examine the first question, it was relevant to examine the specifics of genetic editing, legal definitions of

personhood, arguments surrounding personhood in IVF and fetal personhood debates, and the legal implications of each definition of personhood on one's rights. What I found is that there is a need for the legal definition of personhood to be revised, to aid in clarifying what rights the person and embryo has and does not have. The prospect of beginning clinical trials with CRISPR technologies requires revision of the legal definition of personhood because of its implications on human embryo trials. Without having a universal legal definition of personhood, it allows for the possibility of differing interpretations of subsequent law as a result.

I evaluated the medical practice of IVF's outcomes on health law as a precedent case for understanding how policy may develop for genetic editing. I thought that I would find fairly concrete policy prescriptions that could easily be transferred over to genetic editing, but instead, I found that there was a trend towards letting states handle IVF legislation and an emerging trend of states having autonomy to create and manage genetic editing technologies' regulations as in China's case. Thus, it is reasonable to predict that the natural policy outcome with genetic editing is beginning to follow suit in supporting state sovereignty and allowing states to govern themselves. This connection made proves that genetic editing regulation requires immediate international attention, followed by defined and enforced guidelines and regulations on how to proceed with this groundbreaking technology.

When evaluating the concerns surrounding genetic editing, I found that it presents much more of a concern ethically, ecologically, and scientifically than previous technologies.[32] In states self-regulating genetic editing technologies, it raises more dilemmas for personhood than previous techniques or technologies such as IVF and PGD. The reason there are increased

[32] Reference page for explanation on the concerns related to genetic editing.

dilemmas for personhood is because of the way genetic editing functions as a medical technology, as well as how it can be implemented. Whereas IVF provides a means by which couples who are otherwise unable to have children a solution, and PGD offers a way to select the healthiest embryo(s) for implantation, germline genetic editing provides a way to change the sequencing of DNA in order to create a child devoid of the disease they would have had without the technology's use. As a result, because of the unknown nature of where edits will take effect beyond the selected region, there are subsequent issues of off-target effects on the DNA, unwanted DNA deletions or mutations, ecological damage and unintended consequences for future generations, legal ramifications of lack of informed consent, and the possibility of genetic editing being used in biological attacks. Most of these risks would directly affect patients in clinical trials, which adds to the dire need to successfully regulate genetic editing at the international level.

There is also a huge benefit to using CRISPR-Cas9 gene editing: affording individuals a full life, void of harm or hurt, when other forms of medical treatment or medicine are not available. In creating and enforcing international regulation, it will necessarily protect individuals whom have no other alternative to their disease-effectively following the nonmaleficence and beneficence principles of ethical medical practice. However, as long as isolationists are hiding behind the guise of state sovereignty, they are missing part of the bigger picture: state regulation isn't sufficient. I found that there is a tension between state sovereignty and overarching international laws because of the precedent of state self governance. Where state sovereignty is overly limited when it comes to emerging technologies, international laws and regulations are not limited in that they have the ability to ensure the world is progressing in a

joint effort. Lacking an international consensus and legal support will only serve to permit countries to begin clinical trials, as in China's case, further exacerbating the negative consequences of a technology not yet mature enough for such a step.

I used the case of Chinese physicist He Jiankui who conducted a germline gene editing trial to remove the ability to contract HIV to illustrate what can and will happen when there is a lack of oversight on international and national restrictions on germline genetic editing. In doing so, He failed to follow NASEM's 2017 regulatory framework for clinical trials using heritable genome editing and national regulatory standards set by the Chinese ministry of health. The reasoning behind needing a concerted effort for understanding and improving CRISPR technologies is to ensure both the integrity of the human species and contemplate the serious social, ethical, philosophical, and theological consequences of the technology, because 'such great consequences require deep reflection' (Collins & Wolinetz 2019). I used this information to conclude that effective national oversight will play a large role in upholding the restrictions set internationally.

South Korea's BioAct legislature and South America's differing IVF jurisprudence served as useful precedents to developing three logical policy prescriptions for regulating genetic editing. In explaining the differences between a complete ban on genetic editing, regulated permission, and unregulated permission, I found that there is one logical possibility moving forward with germline genetic editing: establishing a moratorium on germline editing. Only once there are established legal oversight mechanisms enforcing international standards at national and state/territory levels and the technology is sufficiently mature as to avoid off-target effects, will it be reasonable to consider regulated permission. Only then would germline editing be

allowed in the most severe cases of disease in which there is no treatment or cure such as - such as Huntington's disease, cystic fibrosis (C.F.), Duchenne MD, Muscular Dystrophy - following NASEM's 2017 criteria.

This project provides a normative approach to how policies should develop with genetic editing technologies. In connecting the importance of coming to a consensus on the definition of personhood to policy development, the goal was to show that one cannot be done effectively without the other because if so, the result would be differing interpretations of laws. Although a concise and uniform set of international regulations should be developed as proposed, without national adherence and enforcements of the international regulations, the enforcement mechanism will be lacking. As such, member states will need to adhere to and enforce the forthcoming international regulations in order for genetic editing technologies to have a positive effect on society. Otherwise, the outcome could very well follow with China's current situation of national regulations not being enough to provide adequate oversight and enforcement over the technology, and create a divide in our understanding of the technology for its improvement.

Ultimately, germline genetic editing technologies hold much more serious implications on the human race than any other previous technology, and because of this international regulation is needed now. It will remain crucial to continually reevaluate the effects, both positive and negative, of this technology on the ethical, social, philosophical, and religious concerns regarding the appropriateness of this degree of intervention in nature and the potential effects of such changes on acceptance of children born with disabilities in order to ensure both the integrity of the human species, because 'such great consequences require deep reflection'.

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Appendix 1

2002 Bonn Guidelines

(a) Contracting Parties which are countries of origin of genetic resources, or other Parties which have acquired the genetic resources in accordance with the Convention, should:

(i) Be encouraged to review their policy, administrative and legislative measures to ensure they are fully complying with Article 15 of the Convention;
(ii) Be encouraged to report on access applications through the clearing-house mechanism and other reporting channels of the Convention;
(iii) Seek to ensure that the commercialization and any other use of genetic resources should not prevent traditional use of genetic resources;
(iv) Ensure that they fulfil their roles and responsibilities in a clear, objective and transparent manner;
(v) Ensure that all stakeholders take into consideration the environmental consequences of the access activities;
(vi) Establish mechanisms to ensure that their decisions are made available to relevant indigenous and local communities and relevant stakeholders, particularly indigenous and local communities;
(vii) Support measures, as appropriate, to enhance indigenous and local communities' capacity to represent their interests fully at negotiations

(b) In the implementation of mutually agreed terms, users should:

(i) Seek informed consent prior to access to genetic resources, in conformity with Article 15 , paragraph 5, of the Convention;
(ii) Respect customs, traditions, values and customary practices of indigenous and local communities,
(iii) Respond to requests for information from indigenous and local communities;
(iv) Only use genetic resources for purposes consistent with the terms and conditions under which they were acquired;
(v) Ensure that uses of genetic resources for purposes other than those for which they were acquired, only take place after new prior informed consent and mutually agreed terms are given;
(vi) Maintainallrelevantdataregardingthegeneticresources, especially documentary evidence of the prior informed consent and information concerning the origin and the use of genetic resources and the benefits arising from such use;
(vii) As much as possible endeavour to carry out their use of the genetic resources in, and with the participation of, the providing country;
(viii) When supplying genetic resources to third parties, honour any terms and conditions regarding the acquired material. They should provide this third party with relevant data on their acquisition, including prior informed consent and conditions of use and record and maintain data on their supply to third parties. Special terms and conditions should be established under mutually agreed terms to facilitate taxonomic research for non-commercial purposes;
(ix) Ensure the fair and equitable sharing of benefits, including technology transfer to providing countries, pursuant to Article 16 of the Convention arising

> from the commercialization or other use of genetic resources, in conformity with the mutually agreed terms they established with the indigenous and local communities or stakeholders involved;

(c) Providers should:

(i) Only supply genetic resources and/or traditional knowledge when they are entitled to do so;

(ii) Strive to avoid imposition of arbitrary restrictions on access to genetic resources.

(d) Contracting Parties with users of genetic resources under their jurisdiction should take appropriate legal, administrative, or policy measures, as appropriate, to support compliance with prior informed consent of the Contracting Party providing such resources and mutually agreed terms on which access was granted. These countries could consider, *inter alia*, the following measures:

> (i) Mechanisms to provide information to potential users on their obligations regarding access to genetic resources;
> (ii) Measures to encourage the disclosure of the country of origin of the genetic resources and of the origin of traditional knowledge, innovations and practices of indigenous and local communities
> in applications for intellectual property rights;
> (iii) Measures aimed at preventing the use of genetic resources obtained without the prior informed consent of the Contracting Party providing such resources;
> (iv) Cooperation between Contracting Parties to address alleged infringements of access and benefit-sharing agreements;
> (v) Voluntary certification schemes for institutions abiding by rules on access and benefit-sharing;
> (vi) Measures discouraging unfair trade practices;
> (vii) Other measures that encourage users to comply with provisions under subparagraph 16 (b) above.