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CRISPR Humans: Ethics at the Edge of Science

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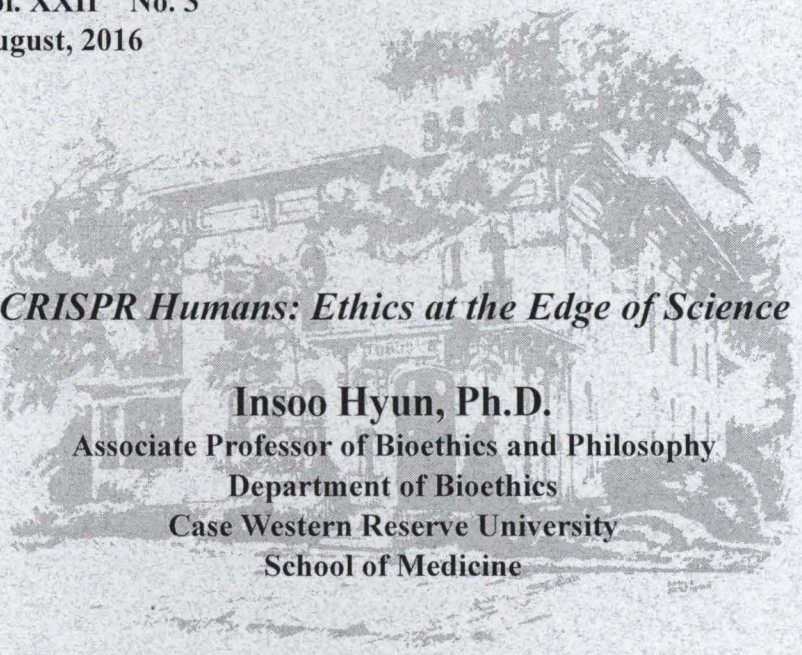

CRISPR Humans: Ethics at the Edge of Science

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Center for the Study of Ethics in Society

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CRISPR Humans: Ethics at the Edge of Science

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Insoo Hyun, Ph.D.

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Dr. Insoo Hyun

Dr. Insoo Hyun is Associate Professor of Bioethics and Philosophy at Case Western Reserve University School of Medicine in Cleveland, Ohio. Prior to coming to CWRU, Dr. Hyun taught in the Philosophy Department at Western Michigan University. His research interests include ethical and policy issues in stem cell research, research ethics and informed consent, and medical decision-making.

In 2005, he was awarded a Fulbright Research Award by the U.S. Department of State to study the ethical, legal, and cultural dynamics of human research cloning in South Korea. In 2006 he chaired the Subcommittee on Human Biological Materials Procurement for the International Embryonic Stem Cell Guidelines Task Force, a multinational, multidisciplinary working group for the ISSCR (International Society for Stem Cell Research). In 2007 he served as Co-Chairperson of the ISSCR Task Force on International Guidelines for the Clinical Translation of Stem Cells. He is also the past Chairperson of the ISSCR's Ethics and Public Policy Committee. Currently, Dr. Hyun is a member of the ISSCR Working Group that revised the ISSCR guidelines for basic and translational stem cell research.

Dr. Hyun received his B.A. and M.A. in philosophy from Stanford University and his Ph.D. in philosophy from Brown University. Dr. Hyun's bioethics articles have appeared in *Science, Nature, Cell Stem Cell, The Hastings Center Report*, and *The Kennedy Institute of Ethics Journal*, among many others. His book *Bioethics and the Future of Stem Cell Research* was published by Cambridge University Press.

Dr. Hyun presented this talk as a keynote address at the Bioethics: Preparing for the Unknown conference held to observe the Ethics Center's 30th anniversary.

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CRISPR Humans: Ethics at the Edge of Science

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I

Advances in human gene editing have raised considerable attention among researchers, regulators, and the public in recent months. In this paper, I begin by offering a brief account of both the "tools of the trade" and the main applications of human gene editing. Then I describe recent efforts toward the formation of international guidelines. I conclude with some reflections on ethics at the edge of science.

Genetic engineering has come a long way in the past 40 plus years. The latest laboratory tools – zinc finger nuclease, TALEN, and CRISPR Cas9 – allow researchers to make precise deletions and substitutions along the genomes of any species. Among these tools, CRISPR Cas9 has garnered the most attention in recent months because it offers by far the fastest and easiest means to edit genes.[1] Anyone can learn to use it in one day.

The CRISPR system is a naturally occurring acquired immune system found in bacteria and archaea. It allows single-cell organisms

[1] In the past few months, hundreds of news articles have appeared around the world in the popular and scientific press about the CRISPR revolution, including this *New York Times Magazine* piece, "The CRISPR Quandary," *NYT Magazine*, November 9, 2015: http://www.nytimes.com/2015/11/15/magazine/the-crispr-quandary.html?_r=0.

to cut and deactivate foreign genetic elements introduced by invading viruses and plasmids. Researchers discovered a couple of years ago that a specific nuclease (enzyme) in the CRISPR system, Cas9, could be used to add, silence, or alter DNA at any location by using the proper guide RNAs to target the desired sequence. CRISPR Cas9 is so precise that it can even be used to edit a single base pair within a gene. Now other CRISPR nucleases are being discovered that could broaden the genetic engineering toolkit even further.[2]

Lately scientists have been using CRISPR Cas9 and other gene editing technologies experimentally to modify the somatic (body) cell DNA of individuals suffering from serious genetic diseases. Most recently, an infant suffering from a rare and aggressive form of leukemia was treated in London using "off the shelf" T cells that were genetically modified using TALEN to enable them to hide from her own immune system. By all accounts, she is doing very well.[3] In another study reported in *Science*, researchers were able to use CRISPR to heal mice affected with Duchenne muscular dystrophy (DMD), allowing the animals to make an essential muscle protein called dystrophin in their muscle stem cells.[4] Without dystrophin to strengthen and protect muscle fibers, people with DMD die by around age 25. With more precise gene editing tools at their disposal, scientists are starting to believe that the full promise of somatic cell "gene therapies" might finally be within reach. In recognition of these rapid and important advances, *Science* has hailed CRISPR as the 2015 Breakthrough of the Year.[5]

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[2] See Jacob, Julie A. (2015). "Four New CRISPR Nucleases Characterized," *JAMA* 314 (24): 2607.

[3] "Gene Editing Saves Girl Dying From Leukaemia in World First," *The New Scientist*, November 5, 2015.

[4] Tabebordbar, M., *et al.* (2015). "In Vivo Gene Editing in Dystrophic Mouse Muscle and Muscle Stem Cells," *Science* DOI: 10.1126/science.aad5177.

[5] McNutt, Marcia. (2015). "Breakthrough to Genome Editing," *Science* 350 (6267): 1445.

Despite the growing excitement over CRISPR applications for patients, deep-seated ethical and social concerns loom on the horizon. The first (often overlooked) critical aspect of gene editing involves the unknown dangers of attempting to use CRISPR nucleases to edit the genes of living people for their health benefit. As early experience with gene transfer research nearly two decades ago suggests, the use of genetic engineering interventions during the course of a clinical trial can come with unexpected adverse events, such as was the case with Jesse Gelsinger, a 19 year-old patient who volunteered for an early phase safety study of a gene therapy protocol at the University of Pennsylvania. A few days after he entered the study, Gelsinger died suddenly due to an unanticipated immune reaction to a gene therapy vector introduced into his liver by investigators. This catastrophic outcome effectively shut down clinical trials of gene transfer research for many years as the FDA and federal regulators tried to assess the causes of this event and the steps necessary to minimize the likelihood of such an occurrence in the future. Another Gelsinger-like adverse event, this time for CRISPR-mediated interventions for genetic disease, could stall the promise of gene editing for patients for years if investigators are too cavalier about possible risks. Just because we have already been down the road of somatic cell gene interventions for patients does not mean that this is a road free of potential pitfalls.

A second, much more scrutinized area of human gene editing lies its potential effect on future generations. In addition to designing somatic cell therapies, some researchers have also become interested in discovering whether CRISPR Cas9 and other nucleases can be used to alter the human germ line, i.e., the lineage of cells from which human germ cells (sperm and eggs) are derived. In theory, the human germ line could be modified by altering the genes of sperm, eggs, or zygotes. Unlike somatic cell modifications, any changes to the germ line would be passed to subsequent generations. Where do the ethical

limitations of this new technology lie? Some worry that scientists may be going too far too quickly. The purpose of human germline editing would be (at least initially) to replace known harmful genes, such as the gene responsible for cystic fibrosis, so that parents who are carriers can avoid transmitting genetic harms to their offspring while remaining otherwise genetically connected to their children. For individuals with a family history of a serious genetic disease, one perceived benefit of human germline modification would be to remove the threat of the disease for all their descendants. Although society has pondered for decades the possibility of one day creating "designer babies," first to overcome genetic diseases, then later to include socially-desirable genetic traits, recent advances in gene editing technology have rapidly moved these discussions from the realm of science fiction toward science reality.

So far, CRISPR-mediated germline editing has been shown to work in a number of different animal species, including non-human primates. Transgenic animal models for research can now be generated in just one gestation cycle, as opposed to one year or more using the previous method of cross-breeding stem cell-derived chimeric animals. Before human germline editing can become a reality, however, extensive preclinical research *in vitro* will have to be performed using human reproductive materials. Currently, most researchers believe gene editing would have to be applied to a germ cell or a single cell embryo *in vitro* in order to avoid genetic mosaicism arising from trying to use CRISPR Cas9 on multiple cells at once. For this reason, the use of surplus fertility clinic embryos (which are stored after the zygote stage) is not likely to provide a resource for preclinical human germline editing research. Instead, scientists will have to create their own embryos for research using donated human germ cells, a form of research that cannot be federally funded in the U.S. and many other countries at this time.

Despite legal restrictions in the U.S. and some other countries that hinder the ease of preclinical human germline gene editing research, let alone permit the transfer of genetically-altered embryos into a womb to produce a pregnancy, some researchers in more permissive jurisdictions, such as China, have reported research using CRISPR Cas9 to modify human embryos *in vitro*. Recognizing the need for international consensus on using CRISPR Cas9 technology to modify the human genome, particularly with respect to germline modifications, an international summit was called in Washington DC in December 2015 (of which I was a participant). In the meantime, while scientists and bioethicists are barely beginning their efforts to draft international guidelines on human gene editing, research teams in permissive jurisdictions continue their research on modifying the human germ line and continue to submit their research papers to leading scientific journals (for which I was twice a reviewer).

The advent of CRISPR technology raises two central questions: (1) the *scientific* question of what can be achieved using this technology; and (2) the *ethical* question of how far human gene editing ought to be pursued. The efficiencies and precision of CRISPR technology are improving every day,[6] so these two questions urgently need to be addressed. At the International Summit on Human Gene Editing last December, scientists, ethicists, and policy makers agreed that an ongoing discussion was necessary concerning the many ethical issues raised by CRISPR technology. The discussants also agreed that the scientific and ethical questions should be pursued *simultaneously*.

I agree with this conclusion. However, during the course of the summit, it became apparent that the discussants seemed far more comfortable talking to one another about the science of CRISPR and less at ease delving into the complex ethical issues. Often the discus-

[6] Kleinstiver, B., *et al.* (2016). "High-Fidelity CRISPR-Cas9 Nucleases With No Detectable Genome-Wide Off-Target Effects," *Nature* DOI:10.1038/nature16526.

sants conflated ethical concerns with ("mere") regulatory FDA-level requirements regarding safety (an important but not ethically-exhaustive set of worries). A sustained exploration of the ethical issues surrounding all aspects of human gene editing research is necessary.

We are already at the point where we need to take seriously the ethics of this emerging area of science. The first publication on human embryo (germline) editing was presented by a group of Chinese scientists in 2015.[7] This form of research immediately raises four important questions concerning human embryo editing: (1) what are the technical challenges and how do these challenges impact the ethics of attempting to use embryo editing in an assisted reproduction context; (2) what are the clinical and non-clinical (basic science) applications of human embryo editing research; (3) what are the ethical issues surrounding the procurement of human gametes and embryos for gene editing research; and (4) what are the prospects of pursuing non-reproductive embryo editing without opening the door to reproductive use?

Embryo editing for reproductive purposes is banned in several countries. Nevertheless, scientists want to pursue embryo editing research to answer certain questions in developmental biology. These inquiries include understanding how genes direct early embryonic development (by using CRISPR nucleases to turn on and off certain genes), understanding how non-embryonic cells are formed, and learning how human germ cells differentiate. Do the scholarly benefits of such intellectual pursuits justify the creation and destruction of human embryos for research?

This question is complicated by the fact that laws and ethical expectations differ around the world when it comes to human gene editing. Some countries, such as the U.S. and the U.K., have very

[7] Liang, P., et al., (2015). "CRISPR/Cas9-Mediated Gene Editing in Human Tripronuclear Zygotes," *Protein and Cell* 6 (5): 363-372.

strict regulatory standards about the creation of embryos for research and for the introduction of genetically manipulated cells into patients, while other countries operate with more lax rules. Furthermore, scientific journal publishing standards for this controversial area of research are still evolving. As the editors of a top-tier scientific journal recently told me, in the absence of uniform international standards, it is not clear what editors should do when they receive manuscripts that describe research which conforms to the authors' local ethical and regulatory standards but which falls far short of research ethics standards in the West. CRISPR ethical standards are needed not only for scientific collaboration internationally, but also for the publication of research results in top scientific journals.

In the meantime, the recently updated professional and ethical guidelines of the International Society for Stem Cell Research (ISSCR) can help fill the void in research standards for CRISPR-based genome editing.[8] As mentioned above, germline editing research *in vitro* will require the procurement of human gametes, the creation of embryos for research, and the oversight for embryo research for basic scientific studies at the bench side. The revised ISSCR guidelines provide guidance for all of these areas, and in that way the guidelines will provide needed standards for this type of rsearch internationally, as other scientific societies proceed to draft more CRISPR-specific professional research standards.

As I reflect on many of the issues raised by the application of CRISPR technology to the human genome, I cannot help but have a feeling of inevitability about the prospect of human germline modifications. The edge of science only cuts forward; it never moves back. Already we have taken a baby step toward germline modification for reproduction: mitochondrial replacement therapies, which would result in heritable changes to future generations, were approved by the

[8] Kimmelman, J., et al., (2016). "Scientists Set Global Standards for Stem Cell Research." *Nature* 533: 311-313.

UK Parliament last year, with the U.S. Institute of Medicine following suit in an FDA advisory report echoing similar recommendations for clinical trials research. If mitochondrial replacement therapies are approved, then one wonders whether these interventions are really all that conceptually different from germline modifications that would occur within the nuclear genome. Why should the "geography" of where the alteration happens in the germ cell matter ethically?

Just as the edge of science always cuts forward, one also may begin to wonder whether scientists' self-imposed "lines in the sand" cannot also be redrawn, on occasion, to facilitate where the next cut in scientific advancement can be achieved. One very timely example of this is the current debate over the so-called "14-day rule" for human embryo research.[9]

Human embryo research is permitted, in many jurisdictions, as long as embryos are maintained in culture for less than 14 consecutive days of development, and experimentation is concluded before the appearance of the primitive streak (a faint band of cells marking the beginning of the embryo's head-to-tail axis). This 14-day limit is encoded in many countries' laws governing assisted reproduction and embryo research. It is also embodied in numerous national commission recommendations and scientific guidelines for embryo and assisted reproduction research spanning nearly four decades.

As a public policy instrument, the 14-day rule has been a tremendous success. It has offered – at least until now – a clear and legally enforceable boundary for scientific activity. One can count the number of days an embryo is cultured in a dish. The primitive streak is something one can actually see. Additionally, the 14-day rule has the practical virtue of providing a publicly-negotiated approach to managing human embryo research, one that is accommodating of many differing views on the moral status of early embryos. The two outermost alternatives to the 14-day rule – of favoring either a zygote

protection position that would disallow embryo research altogether or a laissez-faire stance that would impose zero restrictions on embryo use – would not have made for good public policy in a pluralistic society.

Under the aegis of the 14-day rule, human embryo research has flourished. One of the most important advances to emerge from this protected space is human embryonic stem cell research, which derives cells from 5-day old pre-streak embryos *in vitro*. Now, through an ironic twist of fate, a new line of stem cell research – self-organizing embryo-like structures and intact embryo culture – might begin to challenge the 14-day rule that helped enable its invention.

Some may be unsettled by the prospect of revising this research limit. But the 14-day rule is not unique in this regard. There are numerous examples of similarly declared limitations averred to protect the advancement of anxiety-provoking science: yes to human-animal chimera research – but not at the embryo stage; yes to human cloning for *in vitro* research – but not for reproduction; yes to payments for research egg donors' direct expenses – but not for their non-financial burdens. Limitations such as these can be difficult to maintain in the face of evolving science.

Since it seems to be only a matter of time before human embryo modifications for reproduction become a reality, it is important to acknowledge that there will always be a role for ethics and philosophical reflection at the edge of science. The prospect of CRISPR humans raises profound philosophical and ethical questions that traditionally our secular ethical approaches are not very well suited to address. The two main approaches in bioethics today are consequentialist and rights-based moral frameworks. These frameworks, however, may not be very useful for thinking about the ethics of human germline modification. Unlike a harm-based or rights-based ethical approach, which presupposes the existence of either a being that

[9] Hyun, I., et al., (2016). "Revisit the 14-Day Rule." *Nature* 533: 169-171.

could be harmed by an intervention or a rights-bearer that is wronged, germline modifications would create a human being who would otherwise not have existed but for the genetic intervention. There is no being or rights-bearer prior to the intervention, and thus it is not coherent to say that an individual is *wronged as a result* of gene editing; his or her only other alternative is non-existence. If embryo editing is deemed to be morally wrong, then is it because it is wrong *for someone* (i.e. because it violates a person-affecting moral principle) or is it wrong because of some other, non-person-affecting reason. If the latter, then what would be the relevant non-person-affecting moral principle? This conundrum is what Derek Parfit calls the Non-Identity Problem, which involves the ethics of bringing certain types of people into existence rather than other types of people, or what Parfit calls "different people choices." [10]

Any non-person affecting moral principle up to the task of justifying (or condemning) human germline editing would have to draw on values that relate to what types of people should be brought into existence and lay bare what we think these desirable qualities are. I conclude my thoughts on CRISPR and its potential use in humans by calling the reader's attention to the metaphor of gene editing. This apt metaphor suggests that gene editing is an intentional activity by which the gene editor seeks to delete errors and insert improvements within the biological text of the human genome. Gene editing, like literary editing, presupposes that the editor must employ a set of background values that guide her editing decisions. Choices have to be ranked on a scale from better to worse, and there must be a rational way to select the best changes. As my brief discussion suggests, human gene editing is a new technological power that calls into action our deepest moral commitments and values.

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[10] Parfit, Derek. (1986). *Reasons and Persons.* (Oxford: Oxford University Press).

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