CENTER *of* EXCELLENCE
for ENGINEERING BIOLOGY

Statement of Principle

The mission of Genome Project Write (GP-write) consortium is to promote and develop genome engineering and large scale DNA synthesis technologies. Genome engineering technology can be leveraged to advance medicine, agriculture, and the development of biofuels. GP-write aims to reduce the costs of engineering and testing large genomes in cell lines and organoids derived from cell lines, which are groups of cells that provide simple, tractable models for human organs. To carry out its mission, the consortium strives to proceed in an open, transparent, and inclusive manner. To date, 200 affiliates of GP-write come from some 100 institutions and companies and 15 different countries. They have varied and complementary areas of expertise, including technical, scientific, biological, engineering, legal, social, and ethical backgrounds. GP-write affiliates recognize the significant potential that genome engineering technology holds for benefiting and improving human life, but also acknowledge its tremendous power and potential for misuse.

GP-write has publicly stated that the consortium, and members who perform science as part of their affiliation with the consortium, will not use genome engineering technologies to create or modify human embryos.(1) The use and genetic modification of induced pluripotent stem cells is planned by the consortium (to create cell lines and organoids). Induced pluripotent stem cells are created from non-embryonic cells; in other words, no human embryos are created or destroyed as part of the consortium's research. Still, the eventual creation of genome engineering technology would in principle further *enable the ability* to engineer the genome of cells that are used to create and/or modify human embryos. Nevertheless, GP-write as a consortium has committed to a policy that it will not do so.

A recent *MIT Technology Review* profile of Bryan Bishop, as well as his partner Max Berry, details their aspirations to use human germline editing to pursue human enhancement.(2) As both Bishop and Berry are affiliated with GP-write, the article has spurred much

ongoing debate and discussion among GP-write leaders, scientists, and members of the working groups, including its ethics advisory board. As a consortium, GP-write would like to clearly state: Bishop and Berry's research and commercial plans relating to heritable germline editing were not and are not in any way connected with GP-write. While GP-write is sustained by the work of individuals affiliated with the project, these individuals also pursue their own research interests. GP-write urges all independent, academic, and industry scientists to pursue their work and research in accordance with local, state, and national regulations. The consortium leadership supports the recommendations outlined in the United States National Academies of Sciences, Engineering, and Medicine (NASEM) 2017 report on human genome editing, which state that clinical trials involving human germline editing should only proceed under very strict circumstances.(3)

In the United States, the FDA retains authority over all clinical research using drugs, biological products, as well as genetically modified cells and/or their derivatives. A rider first added by Congress to the omnibus spending bill in 2015 has since been renewed and remains in effect; it prevents the FDA from reviewing any new drug or biological product that involves genetic modification of a human embryo: "None of the funds made available by this Act [to the FDA] may be used to notify a sponsor or otherwise acknowledge receipt of a submission for an exemption for investigational use of a drug or biological product… in research in which a human embryo is intentionally created or modified to include a heritable genetic modification. Any such submission shall be deemed to have not been received by the Secretary, and the exemption may not go into effect."(4) This regulation effectively bans intrauterine transfer of genetically modified embryos as well as any entity —whether independent, academic or corporate—from legally initiating clinical trials that involve intentional genetic modification or creation of human embryos. Laboratory research that involves genetic modification of human embryos is legal in the United States, but pursuant to the Dickey-Wicker Amendment, cannot be supported with federal dollars. GP-write policy could shift in the future, depending on shifts in national or international guidelines.

It is important to stress that GP-write is not pursuing human germline modification. Research conducted in the U.S. involving induced pluripotent stem cells (iPSCs) and NIH-approved embryonic stem cell lines (ESCs) will follow guidance from the National Institutes of Health Guidelines for Human Stem Cell Research and be subject to oversight from institutional committees.(5) Further, the consortium reiterates that it will follow all local, state, national and international regulations to conduct its non-clinical research. The consortium calls upon all scientists and members to do likewise.

If a scientist or member pursues research (such as modification of the human germ line) that violates a fundamental principle of the Consortium, they should not be allowed to remain with the project in good standing and should not be allowed to participate as members of GP-write Working Groups, committees or leadership, or participate in Pilot Projects.

GP-write may be followed at engineeringbiologycenter.org.

1. Center of Excellence for Engineering Biology/ GP-write FAQ (webpage). Available at https://engineeringbiologycenter.org/faq/ at #8: "Does this project propose the creation of so-called 'parentless babies'? No. The proposed project explicitly does not involve ova or embryos since it is focused on cell culture (from many organisms). This was true from the first time we discussed it as a group."; See also Pollack, Andrew. Scientists Announce HGP-Write, Project to Synthesize the Human Genome. *The New York Times*, June 2, 2016. Available at https://www.nytimes.com/2016/06/03/science/human-genome-project-write-synthetic-dna.html: "The authors of the paper in *Science* say they do not want to create babies but maintain that focusing on a grand challenge like synthesizing an entire human genome would be the best way to galvanize advances in DNA synthesis that could be used for more practical purposes, such as engineering plants, animals and microbes."

2. Regalado, Antonio. The DIY designer baby project funded with Bitcoin. *MIT Technology Review*. February 1, 2019. Available at https://www.technologyreview.com/s/612838/the-transhumanist-diy-designer-baby-funded-with-bitcoin/.

3. National Academies of Sciences: National Academy of Medicine; National Academies of Sciences, Engineering, and Medicine. Committee on Human Gene Editing: Scientific, Medical and Ethical Considerations. "Human Genome Editing: Science, Ethics and Governance." 2017. Available at https://www.nap.edu/catalog/24623/human-genome-editing-science-ethics-and-governance.

4. Cohen, I.G. and E.Y. Adashi. The FDA is prohibited from going germline. *Science* 05 Aug 2016: 545-546. Available at http://science.sciencemag.org/content/353/6299/545; Consolidated Appropriations Act of 2016, Public Law 114-113 (adopted December 18, 2015) https://www.congress.gov/bill/114th-congress/house-bill/2029/text; H.J. Res.

31- Consolidated Appropriations Act, 2019, 116th Congress, https://www.congress.gov/bill/116th-congress/house-joint-resolution/31/text?q=%7B%22search%22%3A%5B%22appropriations+act%2C+2018%22%5D%7D&r=20&s=4; See also The Editorial Board. The Science of Gene Editing Demands Caution and Consensus. *Bloomberg.* December 12, 2018. Available at https://www.bloomberg.com/opinion/articles/2018-12-12/crispr-babies-gene-editing-in-embryos-demands-caution-consensus.

5. National Institutes of Health, U.S. Department of Health and Human Services. National Institutes of Health Stem Cell Information Home Page. National Institutes of Health Guidelines for Human Stem Cell Research. Effective date July, 2009. Available at stemcells.nih.gov/policy/2009-guidelines.htm.