CENTER of EXCELLENCE for ENGINEERING BIOLOGY

GP-write

Pilot Project Proposal

(Not to exceed two pages)

Name of Project: *"Re-writing Regulation? A Comparative Policy Study of "Natural" vs. "Synthetic" Cells, Organoids and Human Genomes"*

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Background: The Genome Project-write aims, among other goals, to tackle current health challenges by enabling human genome-scale synthesis and editing through the development of tools, methods and foundational technologies. It draws on interconnected disciplines: from genetics, biotechnology and engineering, to computing and regenerative medicine. Likewise, its applications are directed to a wide range of fields such as agriculture and human medicine.GP-write seeks to be disruptive, defying existing conceptual and technical limits. Similarly, it will significantly confront the boundaries of governing national 'policy frameworks' or 'legal systems' (i.e. norms, principles, institutions, etc.)[1]. Influenced by historical contexts, these frameworks and systems reflect ethical or moral values as well as societal priorities. Thus, an important step to support GP-write goals is to determine if the policy *status quo*, as developed and implemented, is fit-for-purpose. As GP-write is also interdisciplinary and global, the latter requires identifying and understanding differences and similarities in national approaches, as well as the ethical principles and societal values underpinning them[2]. Consequently, central questions to be addressed are: How these policy frameworks vary across scientific disciplines and their applications? Which legal (e.g. laws, regulations) and self-regulatory measures (e.g. professional guidelines, best practices, codes of conduct, etc.) are necessary to promote responsible innovation?[3]

Technical Idea: GP-write activities will integrate human genetics, stem cells, engineering, among other areas that had been, and continue to be, subject to particular public scrutiny. Around the world, policies governing these scientific fields extend across a continuum that differentiates between degrees of regulatory control (i.e. restrictive vs. liberal) and harmonization. The purpose of this Pilot Project is to conduct an international comparative policy study of the core overarching scientific human applications that HGP-write in particular will focus on. GP-write/HGP-write activities related to human whole-genome engineering will be limited to cells and organoids in recognition to its socio-ethical and policy implications, some of which still remain largely uncertain. Therefore, we will 'map' national policy frameworks regulating the use of 'natural' human cells and organoids, and contrast these approaches to the regulation of their engineered and synthetic counterparts. We propose to cover select jurisdictions participating at the GP-write Consortium (e.g. Australia, Germany, Singapore, United States and United Kingdom) and to integrate

our work with the activities carry out by the ELSI and other relevant Working Groups given our team multidisciplinary expertise (law/policy, ethics and genetics).

Utility: Our aim is to refine the current knowledge and understanding of the policy and regulatory frameworks applicable to GP-write and HGP-write. In particular, we will identify, describe and analyze national policy approaches to the regulation of 'natural' versus engineered/synthetic human cells and organoids which is a fertile area of study. By mapping the policy landscapes, we will explore their strengths and challenges, as well as their ability to adapt to scientific advances, evolving technological uptake as well as social interests. It will further assist in determining whether the issues arising in GP-write fall within, or outside, the remit of existing policy dealing with interconnected scientific fields. Our work will help elucidate the consistency of the ethical principles, social values and scientific rationale underlying the policy choices. This pilot project is designed to set the groundwork for more comprehensive international policy 'roadmap' and analysis, in terms of scope (i.e. expand jurisdictional ambit, such as China, France, etc.) and breadth (scientific disciplines and applications). It is also designated to be complementary to the activities conducted by the ELSI Working Group

"Fit" For GP-write: GP-write in general, and the Human Genome Project-write (HGP-write) in particular, draws on interconnected disciplines (genetics, engineering, stem cells, regenerative medicine, computing, etc.). The latter will also focus inhuman whole-genome engineering activities in human cells and organoids. This project will contribute to designing the necessary ethical and policy roadmap to achieve their stated objectives.

[1] Boeke J.D., et. al. The Genome Project-Write. Science (2016) 353(6295):126-27.
[2] Isasi R., et. al. Editing Policy to Fit the Genome? Science (2016) 351(6172):337-39.
[3] Presidential Commission for the Study of Biological Issues. New Directions: The Ethics of Synthetic Biology and Emerging Technologies (2010) Washington D.C.