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8 May 2020

Justice Edwin Cameron
Margaret Ann Hamburg
Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing
World Health Organization
Avenue Appia 20
1211 Geneva, Switzerland

Dear Justice Cameron and Dr. Hamburg,

On behalf of the International Society for Stem Cell Research (ISSCR), I write to share our perspective on the proposed registry for genome editing research. The ISSCR is the leading professional organization of stem cell researchers and represents more than 4,000 members around the world. Our members are scientists, clinicians, ethicists, and educators dedicated to the responsible advancement of stem cell research and its translation to the clinic. The proposed registry for genome editing research must be carefully designed to attract legitimate submissions of fundamental and preclinical research and avoid abuse by businesses seeking to prematurely commercialize genome editing technologies.

Due to the highly competitive environment for biomedical research, a public registry composed of fundamental, preclinical, and clinical research involving genome editing is unlikely to attract submissions of unpublished research voluntarily. While many countries require clinical trials to be registered in public databases, the specific objectives and details of fundamental and preclinical research are not typically announced until investigators speak about their results at scientific meetings and publish the results in peer-reviewed journals. We encourage you to consider segmenting the genome editing registry into public and private databases. A private registry of fundamental and preclinical research would enable the WHO and other regulators to privately collect data on unpublished research and monitor arising bioethical issues. In parallel, a public registry of clinical trials involving genome editing would similarly allow the WHO and other regulators to monitor research, while providing a resource for the identification of clinical trials and the recruitment of patients.

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Unless the public registry of clinical trials is consciously designed and actively monitored, we are concerned that it may be vulnerable to abuse by unscrupulous businesses. In the stem cell field, unscrupulous clinics misuse public clinical trial registries to give the appearance that their approaches have undergone a formal review and approval by government agencies in an effort to promote their treatments to patients searching for clinical trials. These abuses are particularly problematic with the ClinicalTrials.gov database, which has contained false and misleading information, including links to sensational news stories and spurious claims that their interventions have a therapeutic benefit. We recommend creating a process for flagging and reviewing claims that are ethically inappropriate, inaccurate, misleading, or otherwise dubious. The WHO should include a mechanism for the public to flag dubious listings for review by WHO and other regulators, like Facebook's and Twitter's mechanisms for flagging inappropriate content. Any listing that has been flagged should be moved to the private registry for review by WHO and other regulators. At a minimum, flagged clinical trial listings should include a prominent warning that the listing may contain false or misleading information, or offer a biologically implausible intervention.

Thank you for considering our perspective on the design of the genome editing registry. We hope the ISSCR can continue to serve as a resource for WHO on the development of standards and oversight for genome editing research. If the ISSCR can clarify any of these views or be of further assistance, please contact Eric Anthony, ISSCR's Director of Policy at eanthony@isscr.org.

Sincerely,

Deepak Srivastava, MD
President, ISSCR
President, Gladstone Institutes