ISSCR INTERNATIONAL SOCIETY FOR STEM CELL RESEARCH

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Li Zhanshu
Chairman, National People's Congress Standing Committee
No. 1 West Qianmen Avenue,
Xicheng District, Beijing 100805

Re: ISSCR comments regarding the second draft of the Civil Code Part on Personality Rights

Dear Chairman Li,

On behalf of the International Society for Stem Cell Research (ISSCR), I write to share our comments regarding the second draft of the Civil Code Part on Personality Rights. The ISSCR is the leading professional organization of stem cell scientists and represents more than 4,000 members in China and 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. Our Guidelines for Stem Cell Research and Clinical Translation have helped regulators and the field address the ethical, societal, and scientific challenges related to stem cell research and its translation to medicine.

The ISSCR appreciates China's commitment to ensuring compliance with ethics rules for biomedical research through the proposed changes to the Civil Code. However, we are concerned that the impact of the proposed changes will be minimal unless the underlying ethics rules for new biomedical technologies are strengthened and enforced. In March, the ISSCR commented on the draft New Biomedical Technology Application Management Regulations and offered suggestions to improve compliance, adequately inform clinical trial participants about potential risks, and align the regulations with international standards.

We encourage China to coordinate revisions of the Civil Code with changes in the new biomedical technology regulations to develop a regulatory system that protects human research subjects and is consistent with international standards.

Ensuring Compliance with Ethical Research Standards

China's proposed changes to the Civil Code demonstrate your commitment to ensuring that research conducted in China is compliant with national rules by adding another layer of accountability. The impact of the new articles of the Civil Code can be amplified with coordinated improvements to the regulation and enforcement of new biomedical technologies by the National Medical Products Administration.

In our March comments regarding the draft new biomedical technology regulations, we offered several recommendations for improving compliance and harmonizing China's rules with internationally accepted standards. We believe it is imperative for China to establish an independent and well-resourced national oversight body to ensure adherence to bioethics standards and the protection of human subjects in research.

Standards of Informed Consent

The experimental therapies impacted by the proposed additions to the Civil Code are complex and come with unique risks, necessitating a thorough informed consent process to ensure patients are aware of the specific risks associated with these technologies. In comments on the draft New Biomedical Technology Application Management Regulations, we offered several recommendations for improving the informed consent process for new biomedical technologies. We remain concerned about the informed consent process for clinical research in China and urge China to ensure that:

- Clinicians and researchers disclose the fact that many stem cell-based interventions cannot be removed after they have been administered to patients (Recommendation 3.3.2.6 of the ISSCR Guidelines).
- The potential benefits of unproven products are not overstated by researchers or misunderstood by patients (Recommendation 3.3.3.1 of the ISSCR Guidelines). This has been a major problem in countries that lack adequate regulation, or that fail to enforce regulations.
- Patients are informed about the clinical alternatives that exist for the specific disease or condition being treated (Recommendation 4.3 of the ISSCR Guidelines).

International Standards for Human Embryo Genome Modification

The ISSCR encourages China to continue engaging in the process of transparently considering the potential benefits and challenges of new biomedical technologies like human embryo genome editing. We support the international efforts led by the World Health Organization and several national academies of medicine and science to develop guidelines regarding the scientific, ethical, and societal implications of human embryo genome research. We believe it is important for the international community to harmonize rules to prevent rogue scientists from performing additional unethical experiments involving the modification of the human germline. As a global leader in the field of regenerative medicine, we urge China to transparently engage in the international collaboration to develop standards.

Thank you for considering our views regarding the second draft of the Civil Code Part on Personality Rights and the regulation of new biomedical technologies. As China continues to evaluate the regulatory scheme for stem cell-based interventions and other new biomedical technologies, the ISSCR would be delighted to serve as a resource. If

the ISSCR can clarify any of these views or be of assistance, please contact Eric Anthony, ISSCR's Director of Policy at eanthony@isscr.org.

Sincerely,

Douglas A. Melton, PhD
President, ISSCR
Xander University Professor, Harvard University
Co-Director, Harvard Stem Cell Institute