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Ma Xiaowei
Director
National Health Commission Medical and Medical Administration Bureau
No. 38, North Lishi Road
Xicheng District, Beijing, 100044

Re: ISSCR Comments Regarding New Biomedical Technology Application Management Regulations (Draft for Comment)

Dear Minister Ma Xiaowei,

On behalf of the International Society for Stem Cell Research (ISSCR), I write to share our comments regarding the draft New Biomedical Technology Application Management Regulations. 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 draft New Biomedical Technology Application Management Regulations and offers the following recommendations to improve compliance, adequately inform clinical trial participants, and align the regulations with international standards.

Ensuring Compliance with Ethical Research Standards

The New Biomedical Technology Application Management Regulations present China with an opportunity to demonstrate to the world and the scientific community that research conducted in China is consistent with internationally accepted standards for ethical research and the protection of human subjects. A strength of these draft regulations is that they establish a multi-tiered accountability system that holds investigators, host institutions, regional regulators, and national regulators accountable to a uniform set of standards for ethically conducted research. Additionally, the regulations require regulators to consider the scientific necessity and rationale of the research, the qualifications of the researcher and institution, and the protocols to mitigate public health risks.

We are concerned that the new regulations may prove ineffective without an adequate enforcement organization, however. While we appreciate that

Article 46 of the draft regulations provides for regular and random inspections, we believe it is imperative for China to establish an independent and well-resourced oversight body to ensure compliance with bioethics standards and the protection of human subjects in research. For example, China could consider adopting a model similar to that in the United States, where the Department of Health and Human Services Office for Human Research Protections has the authority to independently conduct investigations to ensure compliance and the protection of human subjects in research.

Standards of Informed Consent

The high-risk new biomedical technologies included in the draft regulations 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. We applaud the inclusion of many internationally accepted standards of informed consent in Article 20 of the draft regulations, but we believe that these requirements should be augmented. For example, we believe that researchers should disclose as part of the informed consent process that many of the new biomedical technologies cannot be removed after they have been administered to patients (Recommendation 3.3.2.6 of the ISSCR Guidelines). We also believe it is important to ensure that the potential benefits of investigational products are not overstated by researchers or misunderstood by patients (Recommendation 3.3.3.1 of the ISSCR Guidelines). Finally, we believe it is important for patients to be informed about the clinical alternatives that exist for their particular disease or condition (Recommendation 4.3 of the ISSCR Guidelines).

International Standards for Human Embryo Genome Modification

The ISSCR believes it is important for the international community to develop guidelines regarding the scientific, ethical, and societal implications of human embryo genome research. Earlier this year, the World Health Organization formed an expert advisory committee to develop global standards for regulating human embryo genome editing. Additionally, several national academies of medicine and science from around the world are examining the scientific, ethical, and societal issues of human embryo genome editing.

We encourage China to continue engaging in the process of transparently considering the potential benefits and challenges posed by this new technology. We believe it is important for the international community to harmonize rules to prevent rogue scientists from preforming additional unethical experiments involving the modification of the human germline. ISSCR believes that research should continue in this area but that nuclear genome editing should not be performed in human embryos that are used for reproductive purposes until the risks are better understood and there is consensus regarding the circumstances in which such approaches are appropriate.

Thank you for considering our suggestions regarding the draft New Biomedical Technology Application Management Regulations. 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