

Ethical and Policy Issues in Human Germ line Modifications

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COI Disclosure

*I have no competing interests with
the position of my presentation.*

Chinese Regulatory Framework

- There is an extensive regulatory framework in place in China. Briefly, these include:
 - The Interim Procedures for Human Genetic Resources Management in 1998 (revised 2016)
 - Ethical Principle on ART and Human Sperm Bank in 2003 (9)
 - Ethical Principle on Human Embryo Research (6)
 - GCP in 1998, Revised in 2003

Chinese Regulatory Framework

- **The Ethical Review of Biomedical Research Involving Human Subjects in 2007 (revised 2016, 2018)**
- **Regulations of Management on Human Genetic Resources Management (2012)**
- **Regulations of Management on Biotech Research and Development (2017)**

Chinese Regulatory Framework

- **Chinese regulations already ban genomic research for reproduction purposes.**
- **Both before and after the publication of the experiment, there has been an intensive public debate about the ethical issues raised by such research.**

Consensus

- The ability to genetic editing raises a number of very challenging ethical and policy issues ranging from safety concerns to considerations of the implications of human germ-line genetic modification;

Consensus

- We need to provide guidance regarding appropriate oversight and ethically acceptable modes of pursuing this research, thereby reducing the likelihood that will result in obstacles to ethically and scientifically defensible research, and facilitate formation of proper policies for research.

Consensus

- **Oversight structures must be in place prior to any attempts to conduct this research for the purpose of human reproduction.**
- **In considering policies governing the regulation of application, a distinction should be made between objections that are based on technical or safety concerns and objections that reflect other moral considerations.**

Consensus

- **Technical and safety concerns have the potential to be resolved over time by additional scientific research and advances, while other moral considerations may continue to be the focus of public debate.**

Consensus

- **Public policies carry great power to facilitate or restrict scientific exploration in the area of biomedical research.**
- **Policy makers should pay careful attention when regulating science. When enacted, policies governing science nationally and internationally ought to be flexible, so as to accommodate the rapidity of scientific advance as well as changes of social values.**

Consensus

- **Society have the authority to regulate science, and scientists have a responsibility to obey the law.**
- **However, the regulations should not just be based solely on divergent moral convictions.**
- **Any interference with scientific inquiry (good governance) should be derived from reasonable concerns about demonstrable risk of harm to persons, societal institutions, or society as a whole.**

Consensus

- In the case of GM/GE, as with all science it is important to target policies specifically to those dimensions of the research or its applications that have proved to be ethically unacceptable .
- These policies should be proportionate to the magnitude of what is morally at stake.

*Thank you very much
for Your attention*