Analysis of China's CRISPR babies using the Emanuel Framework

Dr. Sofía P. Salas

Center of Bioethics, Faculty of Medicine

Clínica Alemana Universidad del Desarrollo

Santiago, Chile

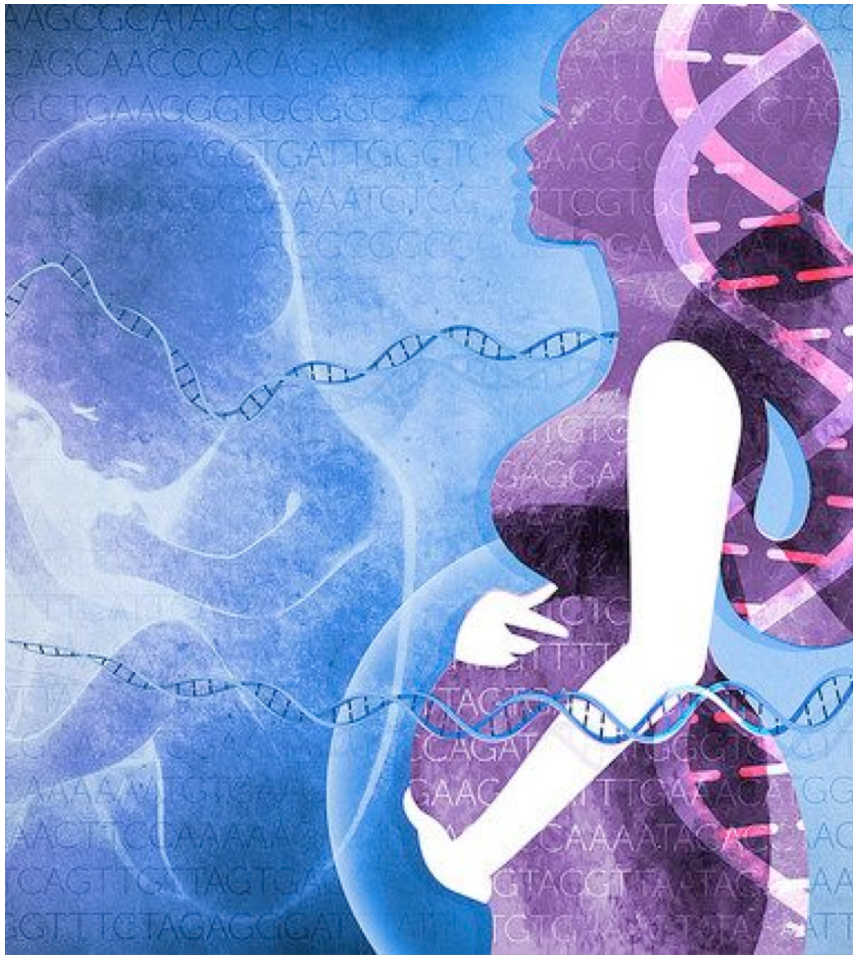
What makes clinical research ethical?

1. Social value
2. Scientific validity
3. Fair subject selection
4. Favorable risk-benefit ratio
5. Independent ethics review
6. Informed consent
7. Respect for participants

Emanuel EJ, Wendler D, Grady C. What makes clinical research ethical? JAMA 2000;283(20):2701-2711

1. Social value

- Who will benefit from the research?
- What is the potential benefit for them?



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1. Social value of CRISPR babies

- Genetically modified embryos were healthy.
- Unknown risks for the newborns.
- Other ways of protecting them from HIV infection.

2. Scientific validity

- The study should produce reliable & valid information.
- He's study protocol and corresponding data did not follow a formal peer review process.

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3. Fair subject selection

- The scientific goals of the study should be the primary basis for recruitment.
- Subjects should be selected to minimize risks and enhance benefits.

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4. Favorable risk-benefit ratio

- Clinical research can be justified only if:
  - The potential risks to individual subjects are minimized.
  - The potential benefits are enhanced.
  - The benefits to individuals and society are proportionate or outweigh the risks.

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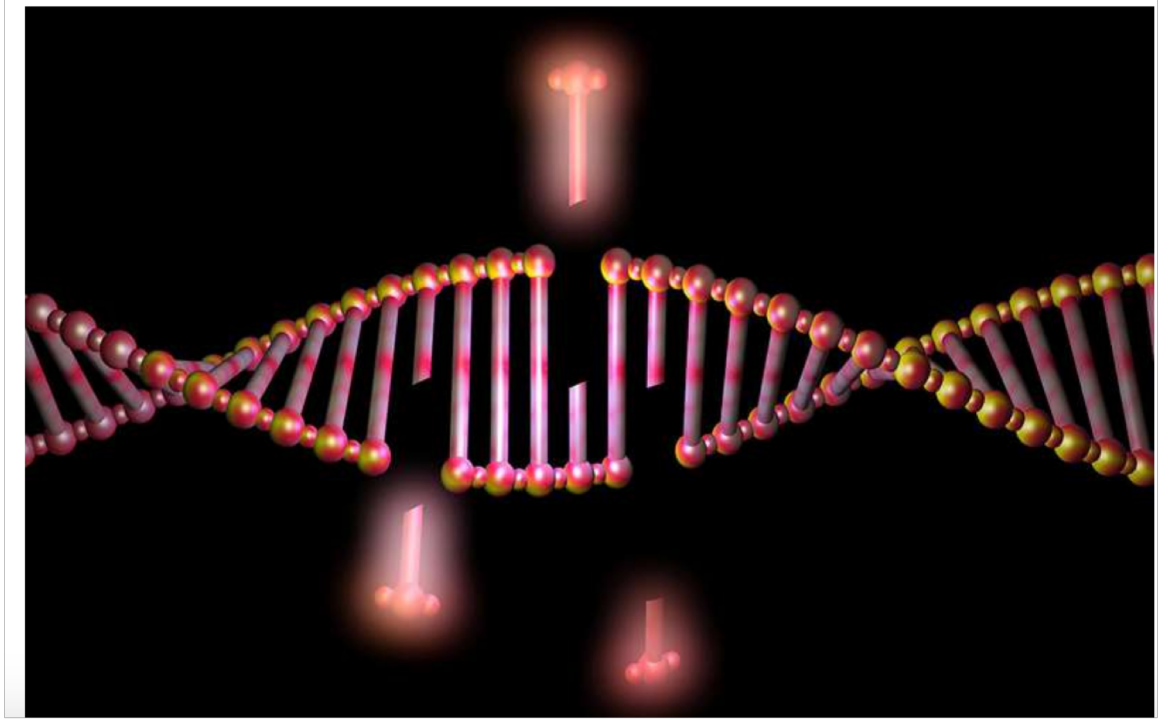
4. Favorable R/B ratio of CRISPR babies

CRISPR gene editing is not quite as precise and as safe as thought



New Scientist, 26 julio 2018

5. Independent Ethics Review

- Human research protocols should have prior IRB approval:
  - It helps minimize the potential impact of conflict of interest.
  - It contributes to social accountability of clinical research.
  - It assures that the trial is ethically designed.

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5. Lack of independent review

Southern University of Science and Technology Statement On the Genetic Editing of Human Embryos Conducted by Dr. Jiankui HE

Nov 26, 2018 Latest News

On November 26, 2018, the Southern University of Science and Technology (hereafter SUSTech or the University) was informed through media news reports that Dr. Jiankui HE (who has been on no-paid leave from February 2018 through January 2021) released a public announcement that he has carried out genetic editing on human embryos.

The University was deeply shocked by this event and has taken immediate action to reach Dr. Jiankui HE for clarification. Dr. Jiankui HE's previous affiliation, the Department of Biology (hereafter the Department) called an emergency meeting of the Department Academic Committee.

Based on the information collected by the time of this release, SUSTech hereby wishes to make the following preliminary statement:

1. The research was conducted outside of the campus and was not reported to the University nor the Department. The University and the Department were unaware of the research project and its nature.
2. The SUSTech Department of Biology Academic Committee believes that Dr. Jiankui HE's conduct in utilizing CRISPR/Cas9 to edit human embryos has seriously violated academic ethics and codes of conduct.
3. All research conducted at SUSTech is required to abide by laws and regulations, and comply with international academic ethics and codes of conduct.

The University will call for international experts to form an independent committee to investigate this incident, and to release the results to the public.

http://sustc.edu.cn/en/info_focus/2871

6. Informed consent process

- A full consent process requires:
  - Complete information
  - Understand this information
  - Voluntary decision

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6. Informed consent of CRISPR babies study

The research team is launching an AIDS vaccine development project.

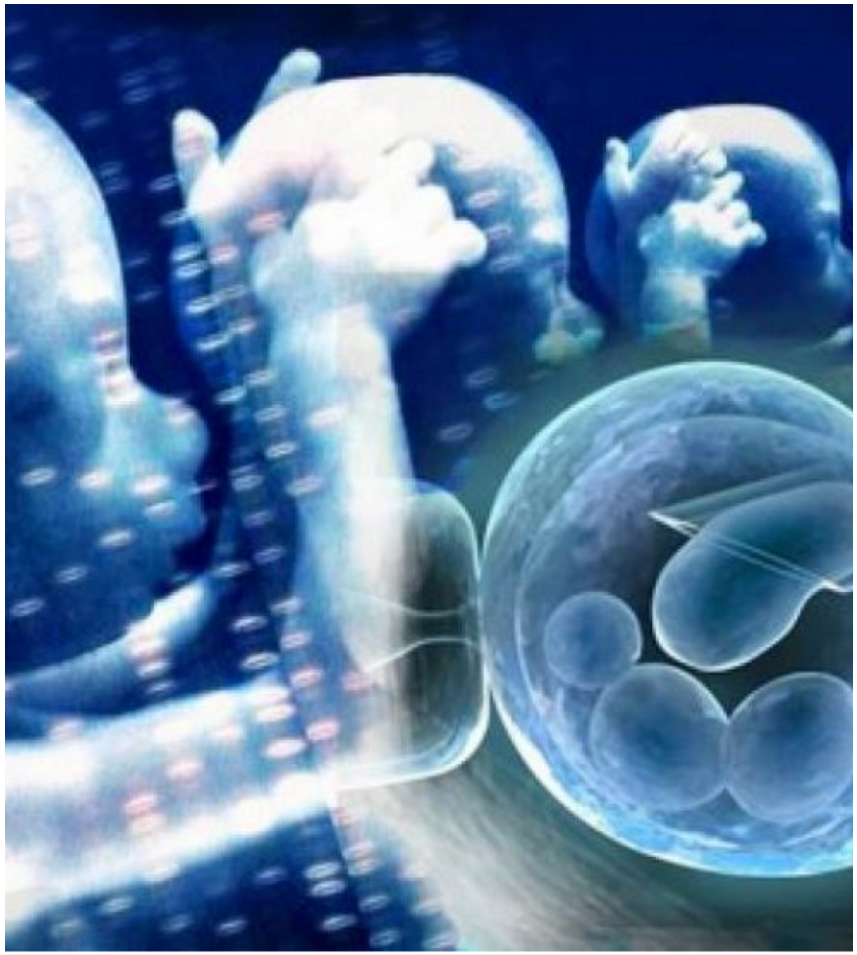
Article 1 Why conducting this research?

1. The theoretical basis of the experiment: **Based on the human assisted reproductive technology, with the core of the CRISPR / Cas9 gene editing technology, gene editing of the CCR5 gene in the embryo would knock out the CCR5 gene. It would help these CCR5 gene editing babies to obtain the genotype of the Northern European to naturally immunize against HIV-1 virus;**

Zhai, 2019. The Hastings Center

7. Respect for participants

- Respect for participants is an on-going process:
  - Respect their privacy.
  - Allow subjects to withdraw.
  - Provide new information.
  - Monitor their welfare.
  - Inform them what was learned.



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In conclusion

- A critical analysis of Dr. He's experiment is a useful tool for students and research ethics committee members to put in to practice Emanuel ethical framework.

- My personal view is that there is no need of a global moratorium on this technique, providing that high ethical standards are met during the review process of future experiments using CRISPR human germline editing.

A final word from Chile