

**Africa Statement on Human Germline Genetic Editing
Contribution from the Ethics, Community Engagement and Patient Advocacy Working
Group, GET Consortium.
December 2, 2018**

The Ethics, Community Engagement, Patient Advocacy and Support (ECEPAS) working group operates under the Global Emerging Pathogens Treatment Consortium (GET) (<https://www.getafrica.org>) which aims at promoting and protecting the welfare of and respect for communities and research participants, affected by biosecurity threats. ECEPAS considers it extremely important to provide a statement following news of the birth of the first genetically edited twin girls in China.

Background

Dr Jiankui HE released a public announcement at the recently concluded second International Summit on Human Genome editing in Hong Kong. Dr Jiankui HE claims to have edited the genes of human embryos using CRISPR/Cas9 technology for a total of seven couples. The twin girls whose DNA were altered by Dr HE, were born this month. (Marchione, 2018). Dr HE has been on leave without pay since February 2018 (through 2021) from the Southern University of Science and Technology (SUSTC). SUSTC has issued a press release distancing themselves from his claims and stating that they are deeply shocked by what has occurred. It has also been stated that the conduct by Dr HE is a serious academic and ethical violation of prescribed codes of conduct. (SUSTC, 2018). Dr HE stated that, in providing fertility treatments, he edited the genes of embryos in order to provide the gene-edited babies with the ability to resist HIV infection. Although the couples were said to have voluntarily consented to the gene editing experiments, there is no evidence of ethics approval by any institutional review board or committee supporting the conduct of this interventional research. All seven couples also remain anonymous. At the time of this memo, there has been no independent verification of Dr HE's claim.

The Oviedo Convention on Human Rights and Biomedicine held in Spain in 1997, produced an international, legal document which clearly addresses human rights and ethics in the biomedical space. Article 13 of the document states that;

“An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.”

(Oviedo Convention, 1997).

ECEPAS Statement

The ECEPAS Working Group would like to state that this event has caused alarm and debate amongst African bioethicists and the medical fraternity. This trial sets a dangerous precedent and sends the message that a scientist can bypass established regulatory and ethical systems and conduct relatively high-risk research on the sidelines, in pursuit for new knowledge and fame, without due consideration of the welfare and respect for the research subjects and the society at large. The alteration of genes from embryos can be passed down to future generations, posing unknown risks for present and future generations. Questions also arise as to Dr HE's choice of gene modification technology, a method with relatively unknown levels of risk in managing a condition which has alternative therapeutic interventions not requiring gene editing. There was also no ethics or scientific clearance, debate, peer review feedback; instead these fundamental requirements guiding the conduct of biomedical research appear to have been completely circumvented. In addition, lack of transparency and total neglect for public engagement and inclusive research (all of which are particularly important to conduct of biomedical research in middle and low-income countries including Africa) attract negative societal implications. Possible follow-up studies may endorse this unethical practice and future actions which could follow the same path. Deliberate violations of established laws and regulations/frameworks set a dangerous systematic precedent in the use of readily available technologies.

ECEPAS working group hereby condemns these actions and advises colleagues in similar pursuits to respect and abide by ethics regulations and internationally acceptable laws guiding the conduct of research on human genome editing.

References

Marchione, M. Chinese researcher claims first gene-edited babies (2018, November 26). Associated Press. Retrieved from <https://apnews.com/4997bb7aa36c45449b488e19ac83e86d>

Oviedo Convention. (1997) The Oviedo Convention: protecting human rights in the biomedical field. Spain. Retrieved from <https://rm.coe.int/168007cf98>

Southern University of Science and Technology. (SUSTC) (2018, Nov 26). Statement On the Genetic Editing of Human Embryos Conducted by Dr. Jiankui HE, Retrieved from http://sustc.edu.cn/en/info_focus/2871