

STATEMENT ISSUED BY THE SPANISH BIOETHICS COMMITTEE ON GENOME EDITING IN HUMANS

At a Plenary Meeting of the Spanish Bioethics Committee held on 16 January 2019, the following Statement was approved.

The Spanish Bioethics Committee has learnt through the general and specialised mass media, both national and international, of the alleged birth in China of twin girls following genetic embryonic modification (genome editing) performed by the Chinese researcher, He Jiankui, using the widely known CRISPR/Cas9 (*clustered regularly interspaced short palindromic repeats and CRISPR-associated protein 9*) technique. The aim was to render the girls immune to the HIV virus (the girls' father is allegedly infected with HIV) by editing the CCR5 gene. Although the facts are still not altogether clear, and the explanations given by the researcher himself at an international scientific meeting in Hong Kong have not gone towards ascertaining exactly what occurred, we should like to make the following known:

1. The use of genome editing and DNA modification through insertion, elimination or replacement of DNA at a time when the human being is still at such an early stage of development, namely embryonic, when tissue -and germinal tissue in particular- has not yet become differentiated, is an issue which, at a general level, gives rise to important conflicts and problems that are not only scientific, but also ethical and social.
2. Genome editing techniques such as CRISPR/Cas9 above, whose scientific bases are precisely to be found here in Spain in the work of the renowned researcher, Francisco J. Martínez Mojica, hold out enormous hope in the fight against many diseases of genetic origin, and amount to a technological revolution which has had an extraordinary impact, particularly in the case of biomedical research laboratories, allowing for the performance of genetic experiments which, only a few years ago, were completely out of reach. Even so, the current state of such techniques (i.e., beyond the ethical doubts that they raise) does not meet the safety level required for their clinical use on humans, owing to the possibility of, among other things, altering similar genome sequences which fall outside the designated target area.
3. The decision to apply genome editing and the corresponding gene therapy to humans may in no case come from private one-off initiatives, but must instead be taken within a general framework of reflection, deliberation and consensus, guided by recommendations already approved or to be approved by organisations and institutions having authority and legitimacy in the matter, and in all cases subject to rigorous scientific evaluation by experts, both beforehand (see, research committees and the like) and afterwards with respect to the results (see, for example, peer review).

4. Although the use of such techniques in a strictly curative context is not free of ethical problems, their use for the purpose of direct or indirect enhancement (*mere biological or genetic enhancement*), as happened in the case of the two girls born in China, is totally unacceptable and inadmissible. This is demanded, not only by the essential values of dignity and equality of human beings, in that it constitutes a mere eugenics programme, but also by the principles of precaution and proportionality, in that other alternatives are at present available for the therapeutic approach to and prevention of HIV transmission.
5. There is clear international consensus in bioethics circles in currently rejecting the use of germinal gene therapy for safety and ethical reasons, a sentiment that is reflected in the Universal Declaration on the Human Genome and Human Rights 1997 and the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine 1997, among others.
6. Accordingly, the Spanish Bioethics Committee wishes to call on the scientific community and society in general to ensure that the use of these techniques is made subject to respect for the dignity and equality of all human beings, and the principles of responsibility, precaution and safety.

Madrid, 16 January 2019.