

## AUSTRIAN ACADEMY OF SCIENCES POSITION ON GENOME EDITING IN THE LIGHT OF RECENT REPORTS ABOUT GENE-EDITED BABIES

Following reports on the birth of gene-edited babies using CRISPR technology in China, the Austrian Academy of Sciences (OeAW) dealt with the topic of genome editing in humans at its General Assembly on 14 December 2018. The OeAW distances itself from human trials performed without prior permission and ethical assessment by the appropriate institutions, and in violation of both the local legal provisions and the international consensus of the scientific community.

The OeAW welcomes responsible research to understand and develop genome editing technologies including CRISPR. These technologies greatly enrich basic biomedical research and have great potential for the treatment of genetic diseases. It is important that such research is conducted in strict compliance with local, national, and international laws and regulations. In addition, research in this area should be conducted in close dialogue with the international scientific community, involving biologists and medical researchers, as well as ethicists, social scientists, and community representatives, such as those from patient organizations.

Within the scientific community, there is a broad consensus that human germline interventions with the goal of human enhancement are completely unacceptable. By contrast, human genome editing for the treatment of severe genetic diseases may be acceptable if there is a clear positive benefit-risk ratio, no suitable alternatives, extensive preparatory work demonstrating feasibility, full legal and regulatory compliance, and a strong framework of ethical guidance and supervision.

Specifically, the OeAW takes the following positions regarding potential applications of CRISPR technology for editing genomes in biomedical research and therapy:

1. *CRISPR editing of laboratory-grown cells* (e.g., genetic screening for potential drug targets in cell lines): permissible and acceptable provided that established standards for laboratory safety and genetic engineering are met.
2. *CRISPR editing in model organisms* (e.g., establishment and characterization of transgenic mouse models for the study of human diseases): permissible and acceptable within the highly stringent regulations for animal testing in Austria and Europe.
3. *CRISPR editing for somatic gene therapy* (e.g., repair of diseased tissue): permissible and acceptable within the very stringent regulations for clinical trials in the field of gene therapy, and only after extensive validation of the technology in preclinical models.
4. *CRISPR editing of the germline as a gene therapy* (e.g., correction of a genetic defect during in vitro fertilization to prevent severe genetic diseases): currently not acceptable, highly premature, and illegal in much of the world. However, it is possible that strictly regulated germline editing that is limited to severe genetic diseases will become acceptable within the next 10 to 20 years.
5. *CRISPR editing of the germline with the goal of human enhancement* (e.g., changing genes beyond their normal state to improve the human body): never justifiable and highly unethical because it creates unforeseeable risks, not only for the individual and its offspring (risk of side effects), but also for society as a whole (new sources of inequality and discrimination).

Researchers at institutes of the OeAW, like those at the CeMM – Research Center for Molecular Medicine and the IMBA – Institute of Molecular Biotechnology, currently use the CRISPR technology in applications according to the above points 1 and 2, but not in the other areas (points 3, 4, and 5). Research corresponding to points 3 and 4 is currently underway at renowned and responsible institutions elsewhere. However, no responsible research institution would undertake, support, or tolerate work with the goal of CRISPR editing of the germline for the purposes of human enhancement (point 5), and the OeAW strongly rejects any work in this direction.

As the largest non-university research and science institution and scholarly society in Austria, the OeAW is a lively place for the mediation and discussion of scientific achievements and insights. It is committed to engaging in a broad societal dialogue on CRISPR technology, genome editing, and other new developments in the life sciences. These advances should not only be made at highly specialized research institutions and discussed internally, but should be part of a broad public discussion on opportunities and risks. With its multidisciplinary and broad expertise, the OeAW is ideally suited to promote such societal opinion making. An essential prerequisite for a constructive, fact-based discussion is adequate information and clear explanation of the important scientific, medical, ethical, and societal aspects of this research. The OeAW is therefore particularly committed to promoting genetic literacy in the general population.