Genome editing in human cells

On-going activities related to genome editing

Nuffield Council on Bioethics - The Nuffield Council on Bioethics has recently launched a project on genome editing. It will be carried out in stages considering first the impact of genome editing in research and the range of questions to which this gives rise, and then developing practical ethical guidance for specific field(s) of application.

Hinxton Group - Together the Medical Research Council and Wellcome Trust are funding a meeting of the Hinxton Group on "Technological Convergence: Gene Editing, Stem Cell Research and Human Germline Modification" in September 2015.

The Hinxton Group has worked together since 2006 to address the most difficult ethical issues facing stem cell researchers internationally; the steering group includes specialists in science, policy and ethics from the UK and USA. The meeting will be international, and aims to encompass the science, ethics, sociology, and policy/regulation of human germlines.

National Academy of Sciences and National Academy of Medicine - The US National Academy of Sciences and National Academy of Medicine have announced an initiative on human gene editing. This initiative will include an international summit in December 2015 to convene researchers and other experts to explore the scientific, ethical, and policy issues associated with human gene-editing research.

In addition, a multidisciplinary, international committee has been appointed to begin a comprehensive study of the scientific underpinnings and clinical, ethical, legal, and social implications of human gene editing.

UK - Current regulatory and legislative provisions

The UK has an exemplary framework for approval of new innovations into therapies. On matters relating to research and treatment involving human tissues and cells the UK regulatory environment is carefully structured to ensure cautious progression of complex and sensitive issues. This environment is enabled by independent and focused regulation agencies and clear demarcation of research and clinical applications.

Editing of human germ cells or embryo's would be regulated by the Human Fertilisation and Embryology Authority (HFEA), a regulatory agency established by Parliament through the Human Fertilisation and Embryology Act of 1990. Under this Act, research can only be undertaken on embryos of up to 14 days of age, and under the auspices of a specific HFEA licence. Within these confines such editing could only be done in a research context, with the use of such material in humans or for treating patients expressly prohibited.

Editing of somatic cells in a research or clinical context would be overseen by the Human Tissue Authority (HTA), created by the Human Tissue Act 2004, which regulates matters relating to human bodies, organs and tissue for research and transplantation. Clinical application of somatic cell therapies are included in Advanced-therapy-medicinal-product scope, and in the case of somatic therapies would be regulated by the HTA (and licensed by the MHRA).