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Academy calls for additional oversight of sensitive research using animals containing human material

A new report by the Academy of Medical Sciences, examining the use of animals containing human material (ACHM) in biomedical research, identifies areas of sensitivity including cognition, reproduction or creating visual characteristics perceived as uniquely human and calls for additional oversight to ensure innovative science can flourish within clearly defined ethical boundaries with public support.

Important new opportunities to understand how the human body functions and the processes and treatment of disease are opening up thanks to the sophistication of techniques to incorporate human cells or genetic information into animals. These techniques are already widely used to refine research methods, creating animal models that better represent the human condition. They are also used to develop and produce new drugs and to lead the fight against life-changing conditions and debilitating diseases, including infertility, cancer, HIV and hepatitis.

Although the great majority of such research does not raise new ethical or regulatory concerns, the Academy's report indicates that the fast moving pace of this science, might lead to the development of types of ACHM that approach ethical or regulatory boundaries. While the UK has one of the strictest systems of animal research regulation, scientists and the public agree that this must stay ahead of emerging research practices.

Professor Martin Bobrow CBE FRS FMedSci, chair of the Academy working group that produced the report said, *'This is a complex research area and there should be ongoing dialogue between scientists, regulators and the wider public to address emerging issues. Our report recommends that the Home Office puts in place a national expert body, within the existing*

stringent system of animal research regulation, to provide specific advice on sensitive types of ACHM research.'

The working group considered evidence from experts in academia, government, industry, animal welfare groups and professional bodies. An independent public dialogue programme, led by Ipsos MORI was commissioned to provide insight into how ACHM research is viewed by the public. This revealed that the majority of participants supported ACHM research conducted to improve human health or to combat disease.

Professor Bobrow added, 'We suggest classifying ACHM research in 3 categories to determine the level of regulatory scrutiny required. The very great majority of experiments present no issues beyond the general use of animals in research and these should proceed under current regulation; a limited number of experiments should be permissible subject to scrutiny by the expert body we recommend; and a very limited range should not be undertaken, at least until the potential consequences are more fully understood.'

The placement of research within this system should be regularly reviewed. We are not aware of research of the third type taking place in the UK today. We have started the conversation now so that future decisions can be made with the support of both scientists and the public.'

Experiments that were of concern to both the public and the scientific community focus on research studies involving modification of the animal brain that could potentially lead to human-like 'cerebral' function, experiments which might lead to fertilisation of human eggs or sperm in an animal; and modification of an animal to create characteristics perceived as uniquely human, such as facial shape, skin texture, or speech.

ACHM is widely used as a technique across the whole spectrum of scientific endeavour from neuroscience and reproductive biology to immunology. They are used to study human biological functions or

diseases which cannot be accurately modelled in cell cultures or through computer simulation; where experiments using humans are unfeasible or considered unethical; and where modification of an animal either makes it more closely represent the human situation or allows human genes or cells to be studied within the context of a whole animal with appropriate developmental and physiological processes.

Some examples of ACHM include:

- Mice carrying human genes are widely used to study many diseases, including neurological and anxiety disorders, osteoporosis, heart disease and cancer.
- Goats which have a human gene incorporated in their genome are used to produce a human protein (an anti-thrombin) which is used to treat blood clotting disorders.
- Mice implanted with sections of human tumour are used in cancer research to study how cancers develop and spread, and to test new drugs and therapies.
- Introducing human stem cells into rats can provide an opportunity to study the human brain's potential for repairing the damage caused by stroke.
- Mice which have their immune systems or livers reconstituted with human cells are used to study diseases such as HIV or hepatitis.

Professor Sir John Bell FRS HonFREng PMedSci, President of the Academy of Medical Sciences commented, *'This is an area of research with real potential to deliver scientific advances and bring new treatments to the clinic. Several different UK regulators are involved in regulation of this research, and it is vital to ensure they are closely coordinated. The current transposition of the EU Directive on the use of animals in research provides an important opportunity for the Home Office to act on the Academy's recommendations, and put in place a national expert body to advise on ACHM. I believe that the UK scientific community is well placed to raise international awareness of these issues and provide leadership in this challenging area of biomedical science.'*

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A selection of images showing the types of animals used in this kind of research are available for press use. High resolution files are available from the contacts above.

Notes for Editors

Academy of Medical Sciences

The independent Academy of Medical Sciences promotes advances in medical science and campaigns to ensure these are translated into benefits for patients. The Academy's Fellows are the United Kingdom's leading medical scientists and scholars from hospitals, academia, industry and the public service.

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Study scope and terms of reference

The aim of the study was to: examine the scientific, social, ethical, safety and regulatory aspects of research involving animals, and non-human embryos, containing human material.

The study's terms of reference were to:

- Agree definitions for animals, and animal embryos, containing human genetic or cellular material.
- Describe the current use of animals containing human material in medical research, and to anticipate future research directions and challenges for this work.
- Assess future applications of research involving animals containing human material - including potential requirements for preclinical (animal) studies of candidate human stem cell therapies.
- Address safety concerns surrounding the generation and use of animals containing human material in research, and to consider welfare issues which apply specifically to animals containing human material.
- Explore societal and ethical aspects of medical research involving the creation of animals that include significant amounts of human material, and to develop a constructive public dialogue in this area.
- Explore the current and future regulation of the use of animals and embryos

containing human material for research purposes, including primary legislation, regulations and guidelines.

- Draw conclusions and make recommendations for action.

To avoid replication of previous work and debates, several wider areas were excluded from the study scope. These are not addressed in any depth:

- Scientific or ethical issues relating to the general use of animals in research.
- The use of human admixed embryos in research.
- Broader issues relating to the genetic modification in a wider sense and not involving human material, such as the genetic modification of animals, or plants, for agricultural purposes.

Working group members:

- **Professor Martin Bobrow** CBE FRS FMedSci (Chair) Emeritus Professor of Medical Genetics, University of Cambridge
- **Professor Tom Baldwin**, Editor, Mind, and Chair, Board of Studies of School of Politics, Economics and Philosophy, University of York
- **Revd Dr Michael Banner**, Dean, Trinity College, Cambridge
- **Professor Peter Brophy** FRSE FMedSci, Director, Centre for Neuroregeneration & Professor of Anatomy, University of Edinburgh
- **Ms Tara Camm**, General Counsel and Company Secretary, Plan International
- **Professor Dame Kay Davies** CBE FRS FMedSci, Head of Department, Physiology Anatomy and Genetics, and Director MRC Functional Genomics Unit, University of Oxford
- **Professor John Harris** FMedSci, Lord Alliance Professor of Bioethics, and Director, Institute for Science, Ethics and Innovation, The University of Manchester
- **Professor Roger Lemon** FMedSci, Sobell Chair of Neurophysiology and Head of the Sobell Department of Motor Neuroscience and Movement Disorders at the Institute of Neurology, University College London
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- **Professor Jack Price**, Professor of Developmental Neurobiology at King's College London
- **Professor Terence Rabbitts** FRS FMedSci, Director, Leeds Institute of Molecular Medicine
- **Professor Martin Raff** CBE FRS FMedSci, Emeritus Professor, MRC Laboratory for Molecular Cell Biology, University College London
- **Professor Trevor Robbins** FRS FMedSci, Professor of Cognitive Neuroscience, University of Cambridge
- **Professor Nikolas Rose**, Martin White Professor of Sociology and Director, BIOS Centre for the study of Bioscience, Biomedicine, Biotechnology and Society, London School of Economics and Political Science
- **Professor Christopher Shaw** FMedSci, Professor of Neurology and Neurogenetics, Institute of Psychiatry and Head of the Department of Clinical Neuroscience, Kings College London and Director of the MRC Centre for Neurodegeneration Research

- **Professor Veronica van Heyningen** CBE FRS FRSE FMedSci Group Leader and joint Section Head, Medical and Developmental Genetics Section, MRC Human Genetics Unit, Edinburgh