

New report examines the use of animals containing human material in biomedical research

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(Medical Xpress) -- A new report looking at the use of animals containing human material (ACHM) in biomedical research has identified areas of sensitivity - including cognition, reproduction and 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 report by the Academy of Medical Sciences, part-funded by the Wellcome Trust, indicates that the fast-moving pace of this science might lead to the development of types of ACHM that approach ethical or regulatory boundaries. The UK has one of the strictest systems of animal research regulation, but scientists and the public agree that this must stay ahead of emerging research practices.

Professor Martin Bobrow, Chair of the 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 three 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 are widely used across the whole spectrum of scientific endeavour from neuroscience and reproductive biology to immunology. They are used to study human biological functions or diseases that 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.

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 that have a human gene incorporated in their genome are used to produce a human protein (an antithrombin) 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 that have their immune systems or livers reconstituted with [human cells](#) are used to study diseases such as HIV or hepatitis.

Commenting on the report, Sir Mark Walport, Director of the Wellcome Trust, said: "It is absolutely right for the scientific community to be open about the work we do and any potential ethical issues it might raise.

Research using animals that have been altered to contain human material has enabled scientists to understand diseases such as HIV, hepatitis and cancer much better, speeding up progress in developing new treatments for these serious conditions. There are already innovative drugs in use that just would not have been developed without such work.

"We recognise ethical issues may emerge as the field grows, however, and fully agree that proper regulation is required to ensure that research in this area is acceptable and in all our best interests."

Provided by Wellcome Trust

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