Home Office

Guidance on the use of Human Material in Animals

Advice Note 01/16

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Contents

Introduction

This note provides guidance on the regulation of scientific research involving the use of human material in animals.

While most research of this sort will only require licence authority from a single regulator, some may require submission to more than one and/or referral to the national expert body[1] before licence authorities can be granted. Investigators should therefore make early contact with at least one of the regulators (see below) for advice on the authorities they will require.

This brief note should be read in conjunction with the report on Animals Containing Human Material (ACHM) published by the Academy of Medical Sciences in July 2011[2]; the statutory Guidance on the Operation of the Animals (Scientific Procedures) Act 1986[3] and the UK Stem Cell Tool Kit[4] which provides regulatory information on human stem cell research.

Structure of this guidance

The guidance is in five parts.

Part A provides background information on relevant legislation.

Part B sets out the proposals for the classification of experiments included in the Academy of Medical Sciences report on Animals Containing Human Material published in July 2011. Part B also provides examples of work in the relevant categories that is currently feasible and licensed.

Part C provides guidance on the regulatory pathways applicable to different types of research involving the use of human material in animals.

Part D provides contact details for regulators.

Part E provides a glossary of relevant terms and abbreviations.

[1] The Animals in Science Committee set up under the Animals (Scientific Procedures) Act 1986 (as amended by SI 2012/3039).
[2] http://www.acmedsci.ac.uk/p99puid222.html
[3] https://www.gov.uk/government/publications/operation-of-aspa
[4] http://www.sc-toolkit.ac.uk/home.cfm

Part A: Legislation

Part A covers the following legislation:

- The Animals (Scientific Procedures) Act 1986 (as amended by SI 2012/3039[5])
- The Human Fertilisation and Embryology Act 1990 (as amended[6])
- The Human Tissue Act 2004.

The Animals (Scientific Procedures) Act 1986

The Animals (Scientific Procedures) Act 1986 (ASPA)[7] regulates procedures that are carried out on 'protected animals' for scientific research and testing that may cause pain, suffering, distress or lasting harm to those animals. ASPA also regulates the breeding and supply of certain species of animals for use in regulated procedures and the breeding of animals for the use of their organs or tissues in procedures.

What is a regulated procedure under ASPA?

A procedure is regulated if it is carried out on a protected animal and may cause that animal a level of pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by inserting a hypodermic needle according to good veterinary practice.

What animals are protected under ASPA?

ASPA protects *all living vertebrates, other than man, and any living cephalopod*.

Fish and amphibia are protected once they can feed independently and *cephalopods* at the point of hatching.

Embryonic and fetal forms of mammals, birds and reptiles are protected during the last third of their gestation or incubation period.

In addition, *embryonic and fetal forms* are protected from an earlier stage of development if two conditions are both met:

a) the animal is to be allowed to live until after it attains the stage of its development when it becomes a protected animal;

   and

b) the procedure is likely to cause the animal pain, suffering, distress or lasting harm after they have developed to that stage.

For example, the entire process of producing a genetically altered animal by making a genetic change to an egg will be regulated where any adverse effects may not be seen until the animal reaches the protected stage, or, until the animal is an adult.

[5] The Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012
[6] Amended by the Human Fertilisation and Embryology Act 2008
[7] https://www.gov.uk/research-and-testing-using-animals#animals-scientific-procedures-act-1986

What licences are required under ASPA?

ASPA has a three-level licensing system:

- those carrying out procedures must hold a '*personal licence*', which ensures that they are qualified and suitable;
- the programme of work in which the procedures are carried out must be authorised in a '*project licence*';
- the place at which the work is carried out must hold an '*establishment licence*' (issued under ASPA section 2C).

What restrictions apply under ASPA?

ASPA requires that before a project licence is issued the Secretary of State must weigh the benefits to humans, other animals, or the environment against the harms to the animals involved.

A licence cannot be granted if the work could be carried out without using animals (see also the section on the Human Fertilisation and Embryology Act 1990 below). The Secretary of State must exercise his or her functions with a view to ensuring compliance with the principles of replacement, reduction and refinement. If scientifically satisfactory methods which do not use protected animals are available they must be used, the number of protected animals used should be reduced to a minimum and the pain, suffering, harm and distress caused should be kept to a minimum.

The Secretary of State may refer applications for project licences to the Animals in Science Committee (see Part C, below), or external expert assessors, for independent scientific or ethical advice.

Under ASPA, project licences may be granted for programmes of work of up to five years duration.

Permissible purposes under ASPA

A project licence cannot be granted unless the programme of work is for one of the following purposes:

a) basic research;

b) translational or applied research with one of the following aims:

(i) the avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality, or their effects, in humans, animals or plants;

(ii) the assessment, detection, regulation or modification of physiological conditions in humans, animals or plants; or

(iii) the improvement of the welfare of animals or of the production conditions for animals reared for agricultural purposes;

c) the development, manufacture or testing of the quality, effectiveness and safety of drugs, foodstuffs and feed-stuffs or any other substances or products, with one of the aims mentioned in paragraph (b);

d) the protection of the natural environment in the interests of the health or welfare of humans or animals;

e) research aimed at preserving the species of animal subjected to regulated procedures as part of the programme of work;

f) higher education or training for the acquisition, maintenance or improvement of vocational skills;

g) forensic inquiries.

Applying for a project licence under ASPA

Project licence applications may take some time to prepare, especially if they describe a novel or complex programme of work or raise matters of significant public interest.

It is usually helpful, at an early stage, for the applicant to discuss a draft application with a Home Office inspector as well as with other experienced project licence holders. The named veterinary surgeon(s) and named animal care and welfare officer(s) at the establishment at which the work will be carried out should also be consulted.

All applications should also be reviewed by the local animal welfare and ethical review body (AWERB) at the establishment. The AWERB has several functions (for more detail see p17) and will advise on any local issues or policies relevant to the proposed work. Their conclusions will assist the decision by the establishment licence holder whether to support the application to work at their establishment. The complete application needs to be signed by the relevant establishment licence holder before it is submitted.

Application forms and details of where to send them are available at https://www.gov.uk/research-and-testing-using-animals#animals-scientific-procedures-act-1986.

The Human Fertilisation & Embryology Act 1990, as amended

What is regulated under the 1990 Act?

The Human Fertilisation and Embryology Act 1990 (as amended by the Human Fertilisation and Embryology Act 2008) (1990 Act) regulates, for research purposes, the creation, keeping and use of human embryos, the storage and use of human gametes to create embryos, and the creation and use of human admixed embryos (human/animal hybrid embryos).

The 1990 Act defines, and places clear limits on, the use of human embryos and human admixed embryos in research. Certain activities are prohibited other than when conducted under licence from the statutory regulator set up under the 1990 Act, the Human Fertilisation and Embryology Authority (HFEA).

In October 2009, amendments were made to the 1990 Act, to bring into legislation the ability to create human/animal hybrid embryos for use in research, where the human DNA would be

dominant ("Human Admixed Embryos"). Prior to these changes the 1990 Act did not prohibit the creation of such embryos and their use in research; the amendments brought about a defined regulatory structure.

The amendments also inserted a definition of "Human Admixed Embryo" into the 1990 Act, see below, and prohibited the placing of such embryos in either a human[8] or an animal[9]. The amendments also applied the controls and restrictions already applicable to human embryos created and/or used in research to human admixed embryos. These are that:

- embryos can only be created and/or used for research purposes if a research licence for that project has first been granted by the national regulator, the Human Fertilisation & Embryology Authority (HFEA)[10].

- before granting a research licence the HFEA must be satisfied that:

    - any proposed use of embryos or human admixed embryos is necessary for the purposes of the research[11],

    - the research is necessary or desirable for the principal purposes set out in the Act[12].

- embryos or human admixed embryos cannot be kept or used after the appearance of the primitive streak or for longer than 14 days (beginning with the day on which the process of creating the embryo began, not counting any time during which the embryo was in storage[13]), whichever is the shorter[14].

The HFEA has the power to grant research licences for up to three years for individual research projects. All licence applications are evaluated by the HFEA's Licence Committee.

What is a 'human admixed embryo'?

Subsection 4A(6) of the Human Fertilisation & Embryology Act 1990, as amended, defines a "human admixed embryo" as:

(a) an embryo created by replacing the nucleus of an animal egg or of an animal cell, or two animal pronuclei, with—

(i) two human pronuclei,

(ii) one nucleus of a human gamete or of any other human cell, or

(iii) one human gamete or other human cell,

(b) any other embryo created by using—

(i) human gametes and animal gametes, or

[8] Subsection 4A(1) of the Human Fertilisation & Embryology Act 1990, as amended.
[9] Subsection 4A(4) of the Human Fertilisation & Embryology Act 1990, as amended.
[10] Subsection 3(1) and (1A) of the Human Fertilisation & Embryology Act 1990, as amended.
[11] Paragraph 3(5) of Schedule 2 to the Human Fertilisation & Embryology Act 1990, as amended.
[12] Paragraph 3A)(1) of Schedule 2 to the Human Fertilisation & Embryology Act 1990, as amended.
[13] Subsection 3(3) of the Human Fertilisation & Embryology Act 1990, as amended.
[14] Subsection 3(4) of the Human Fertilisation & Embryology Act 1990, as amended.

(ii) one human pronucleus and one animal pronucleus,

(c) a human embryo that has been altered by the introduction of any sequence of nuclear or mitochondrial DNA of an animal into one or more cells of the embryo,

(d) a human embryo that has been altered by the introduction of one or more animal cells, or

(e) any embryo not falling within paragraphs (a) to (d) which contains both nuclear or mitochondrial DNA of a human and nuclear or mitochondrial DNA of an animal (''animal DNA'') but in which the animal DNA is not predominant.

In what circumstances does section 4A(6)(e) apply?

There is no definition in law as to the meaning of the word predominant, however in October 2008, the House of Lords Parliamentary Under-Secretary of State in the Department of Health, at the time, Lord Darzi highlighted the following:

> ***"If it were considered that an embryo was to be created in which the human DNA would ultimately predominate, an application for an admixed research licence would have to be made to the HFEA at the outset. This is because a licence is required to bring about the creation of a human admixed embryo. If a researcher was intending to create an embryo that would at some stage be predominantly human, for however short that time might be, they would need a licence to do so.***
>
> *The noble Lord, Lord Walton, also referred to tetraploid complementation where the cells of an early animal embryo are altered so that they contain twice the usual complement of DNA. These cells could give rise only to extra-embryonic tissue—for example, a placenta—and any human cells placed within it could give rise to the embryo proper. It would be an admixed embryo for the purposes of the new catch-all category that the Bill is adding to the definition of human admixed embryo at Clause 4.*[15]

The HFEA's Licence Committee can only make a decision by applying the tests required by the Act. The assessment will therefore also consider whether or not the entity should be classed as a human admixed embryo, in which human "functionality" may predominate. However, here it is important to note, the law prohibits embryos or human admixed embryos being kept or used after the appearance of the primitive streak or for longer than 14 days.

Due to the complexity of research proposals in this area they will be considered on a case by case basis. This will be carried out by the ASC with appropriate co-opted experts.

The principal purposes for which embryos and human admixed embryos may be used in research

The principal purposes are set out in paragraph 3A(2) of Schedule 2 to the Human Fertilisation & Embryology Act 1990, as amended. They are:

(a) increasing knowledge about serious disease or other serious medical conditions,

(b) developing treatments for serious disease or other serious medical conditions,

[15] Lords Hansard, 29 October 2008, Column 1624

(c) increasing knowledge about the causes of any congenital disease or congenital medical condition that does not fall within paragraph (a),

(d) promoting advances in the treatment of infertility,

(e) increasing knowledge about the causes of miscarriage,

(f) developing more effective techniques of contraception,

(g) developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation, or

(h) increasing knowledge about the development of embryos.

Offences under the HFE Act 1990 (as amended)

Investigators should be aware that according to Section 41(1)(a) of the *HFE Act 1990* (as amended), a person who:

(a) Mixes human gametes with animal gametes,
(b) Brings about the creation of a human admixed embryo, or
(c) Keeps or uses a human admixed embryo,

without an HFEA licence is guilty of an offence and liable to prosecution and liable on conviction or indictment to a term of imprisonment or a fine or both.

The use of alternatives under the ASPA 1986 and the HFE Act 1990

The ASPA stipulates that a licence cannot be granted, under that Act, if the research can be conducted without using animals or animal tissue. A similar requirement appears in the HFE Act 1990, in that human embryos or human admixed embryos may not be used in research if the aims of the project can be achieved by other means. However, there are no powers under ASPA to require that a non-animal alternative that would involve a human embryo or human admixed embryo must be used in a research programme, the decision on that would still fall to the HFEA.

Lord Taylor (Home Office Minister) has given assurance during the passage of the regulations, in a response in December 2012, that:

> *Under the Animals (Scientific Procedures) Act 1986, we cannot license work involving protected animals if there is a non-animal alternative. However, there is no power in the 1986 Act to require the work to be carried out under an alternative method. It would be for the HFEA to deal with anything that involved human embryos. There is therefore no risk of that drive occurring.*[16]

Applying for a research licence under the HFEA

The first step, in obtaining a research licence from the HFEA, is to complete an initial enquiry form. The initial enquiry form informs the HFEA of the intended activities to be carried out under the licence. The form may be found at: http://www.hfea.gov.uk/3388.html. Once completed the form should be sent, via email, to regulationofresearch@hfea.gov.uk.

[16] Lords Hansard, 13 December 2012, Column GC397-398

The use of human stem cells in research

The use of human stem cells in research follows a different pathway to that of embryos. Unlike embryo research, there is no licensing structure. There is also no prohibition on the use of human stem cells if the aims of the research could be achieved by other means. The HFEA's regulatory interest ends once stem cells are derived from the embryo.

The Gene Therapy Advisory Committee (GTAC) is the UK national Research Ethics Committee (REC) for clinical trials of gene therapy, other advanced therapy medicinal products and certain other types of research. The Health Research Authority (HRA) Board, in its capacity as the Appointing Authority for the GTAC, agreed new arrangements for ethics applications to GTAC at its Board meeting on 25 October 2012[17].

In addition to its legal responsibility for trials of gene therapy medicinal products, GTAC is the national flagged REC for the following types of research:

- trials of stem cell therapy involving cells derived from stem cell lines;
- trials of other Advanced Therapy Medicinal Products (ATMPs), i.e. somatic cell therapy and tissue engineered products;
- trials of vaccines involving recombinant vectors or vectors with potentially immuno-regulatory mediator molecules;
- first in human trials of vaccine vectors (or variants of vectors in use) or of engineered antigen molecules; and
- other non-CTIMP gene therapy research (e.g. non-interventional trials).

Research studies involving well-established adult stem cell therapies (for example, bone marrow transplantation) or types of vaccine may be reviewed by any appropriate REC.

The UK stem cell tool kit[18]

The UK Stem Cell Tool Kit is a reference tool for those who wish to develop a programme of human stem cell research and manufacture, including clinical applications. It includes a scenario for use of embryonic stem cells in animals which shows the regulatory route to follow, this can be found at http://www.sc-toolkit.ac.uk/scenarios/laboratory-restricteduseofembryonicstemcellsinanimals.cfm

The Tool Kit was reviewed and updated in 2012 by all of the relevant the Regulators, including the Home Office and the HFEA.

[17] See http://www.hra.nhs.uk/hra-news-and-announcements/new-arrangements-for-the-gene-therapy-advisory-committee/
[18] http://www.sc-toolkit.ac.uk/home.cfm

The Human Tissue Act 2004

Scope and purpose

The Human Tissue Act 2004 (the HT Act) is the legal framework in England, Wales and Northern Ireland regulating the storage and use of human organs and tissue from the living, and the removal, storage and use of tissue and organs from the deceased, for health-related purposes and public display.

The Act is principally intended to ensure that appropriate consent is in place to enable the lawful retention and use of body parts, organs and tissue, for 'scheduled purposes', which include certain types of health-related research. The Act also prohibits certain forms of DNA analysis without consent throughout the UK.

The HT Act applies to human bodies and human tissue that consist of, or contain, human cells *other than*: hair and nails from living people; human gametes and embryos; and other human material created outside the human body (e.g. human cell lines).

Subject to exceptions, it prohibits the possession of 'bodily material' (from a living or deceased human body, consisting of, or including, human cells, including hair, nails and gametes) with the intention of analysing its DNA without consent. Except to the extent of the prohibition above, DNA itself (extracted human DNA, where no whole cells remain) is not regulated by the Act.

The Human Tissue Act 2004 regulates the removal, storage and use of human tissue for a range of "scheduled purposes" which include research "in connection with disorders, or the functioning, of the human body". Tissue that is subject to the requirements of the Act is termed "relevant material" which is defined as "material, other than gametes, which consists of or includes human cells". This brings within its scope human tissue xenografts, i.e. the transplantation of human tissue into another species.

The Human Tissue Authority (HTA) policy statement on human tissue xenograft can be found at http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/policyonhumantissuexenograft.cfm

Application of the Human Tissue Act 2004 to the use of animals containing human material in research

Licensing requirements under the HT Act 2004

The application of human tissue xenografts is not considered a method of storing human tissue or cells and therefore does not require a storage licence. However, where human tissues and cells are being stored for a scheduled purpose (such as "research in connection with disorders, or the functioning, of the human body") before they are transplanted into a recipient species, a licence for storage may be required.

Consent requirements under the HT Act 2004

When consent is obtained for tissue and/or cells to be used in research and it is known at the time of obtaining consent that this would involve the transfer of the material to animal models, this should be explained to the individual and consent should be obtained for this. This is based on the requirement that for consent to be valid the individual should understand the nature and purpose of what is proposed and they should be told how the tissue will be used. The transfer of tissue and/or cells to an animal model is a significant step that the individual should be informed of and consent to.

Review by a research ethics committee appointed by the Health Research Authority (or equivalent in the Devolved Administrations) is required for research that involves material consisting of or including human cells where the research involves:

- storage or use of material from living persons collected on or after 1 September 2006 and the research is not within the terms of consent for research from the donor (in England, Wales or Northern Ireland); or
- material from living or deceased persons which is not held on premises with a licence from the Human Tissue Authority for research (in England, Wales or Northern Ireland); or
- analysis of DNA in material from living persons and the research is not within the terms of consent for research from the person whose body manufactured the DNA (anywhere in the UK).

Applying for a licence under the HTA

To apply for a licence, an application form should be downloaded from the HTA's website and completed prior to submission. Application forms and further information are available at:

http://www.hta.gov.uk/licensingandinspections/licenceapplicationguidance/licenceapplicationformsandguidancedocuments.cfm.

Human Tissue (Scotland) Act 2006

There is separate legislation in Scotland - the Human Tissue (Scotland) Act 2006. The key provisions of this Act are the same as the HT Act 2004 but the methods of authorisation are different. For further details see http://www.legislation.gov.uk/asp/2006/4/contents

Part B: The Academy of Medical Sciences report on Animals Containing Human Material

Scope and purpose

The Academy of Medical Sciences published its report on Animals Containing Human Material, in July 2011[19]. This considered how human material is used in animal experiments and the associated ethical issues and regulations.

Government response to the AMS report

The Home Office, HFEA and Department of Health have accepted the recommendations set out in the AMS report and have agreed to work together to ensure a smooth regulatory process for UK investigators.

Classification of experiments involving animals containing human material (ACHM)

The AMS report proposed that experiments involving animals containing human material (ACHM) could usefully be classified into three categories.

Category 1

Category 1 covers the great majority of ACHM experiments which do not present issues beyond those of the general use of animals in research. The AMS recommended that these experiments should be subject to the same oversight and regulation under ASPA as other animal research.

The following types of Category 1 experiment are technically feasible and currently licensed and carried out under ASPA:

- The breeding and use of protected animals that have been genetically modified by the insertion of human DNA, usually single genes, or small numbers of related genes, but occasionally parts of or whole chromosomes, to produce models of human disease. The DNA is introduced into mouse embryonic stem cells and embryos derived from these are created *in vitro* then implanted into the uterus of adult mice. The offspring produced contain the DNA of interest and its functional effects and control can be studied in an *in vivo* environment.

- The insertion of human cancer cells to grow and spread in protected animals to study disease. Mice, often with defective immune systems, are used so that the human cells can grow, usually under the skin or in other organs, and the cancer cells and the disease can be studied in an *in vivo* environment. Drugs may be tested to kill the cancer cells and cure the disease.

- The creation of genetically altered mice which express human antibody genes, or mouse antibody genes modified to contain human parts. The resulting antibodies have the same specificity as human antibodies and may be produced in large amounts to be used therapeutically in humans e.g. to treat cancers and rheumatoid arthritis.

[19] http://www.acmedsci.ac.uk/p99puid222.html

- The modification of mice to carry functioning cells, tissues, and/or ‘organoids’ (structures resembling organs, particularly of the immune system). These are commonly used animal models in biomedical research. Examples include mice modified to contain elements of the immune system including structures resembling lymphoid organs such as lymph nodes and thymus.

- The reproduction of key parts of the human blood-producing haemopoeitic system in mice to generate functional human blood cells *in vivo* for the study of blood producing mechanisms and blood disorders such as anaemia and leukaemia.

- The study of infectious diseases such as HIV and malaria using mice containing human cells susceptible to infection (mouse cells are not susceptible). Humanised mice are being used to study pathogenesis and vaccination protocols for these and other diseases.

- In similar fashion, animal models of autoimmune diseases such as diabetes and rheumatoid arthritis have been established. The advent of regenerative medicine techniques has led to the use of mouse models for pre-clinical studies of human cell lineages derived from embryonic stem cells. These are used to test the development and function of the cells and their possible problems before studies are carried out in humans.

Category 2

Category 2 would currently include research involving:

- substantial modification of an animal’s brain that may make the brain function potentially more ‘human-like’, particularly in large animals;

- experiments that may lead to the generation or propagation of functional human germ cells in animals;

- experiments that could be expected to significantly alter the appearance or behaviour of animals, affecting those characteristics that are perceived to contribute most to distinguishing our species from our close evolutionary relatives; and

- experiments involving the addition of human genes or cells to non-human primates (NHPs).

The AMS recommended that these types of ACHM research may be permissible, subject to a positive harm/benefit assessment and additional specialist scrutiny by a national expert body (see below).

Category 3

Category 3 covers a very narrow range of experiments which the AMS suggested should not, for now, be licensed because they either lack compelling scientific justification or raise very strong ethical concerns.

The AMS recommended that the list of such experiments should, at present, include:

- allowing the development of an embryo, formed by pre-implantation mixing of NHP and human embryonic or pluripotent stem cells, beyond 14 days of development or the first

signs of primitive streak development (whichever occurs first); unless there is persuasive evidence that the fate of the implanted (human) cells will not lead to 'sensitive' phenotypic changes in the developing fetus;

- transplantation of sufficient human-derived neural cells into an NHP as to make it possible, in the judgement of the national expert body, that there could be substantial functional modification of the NHP brain, such as to engender 'human-like' behaviour. Assessing the likely phenotypic effect of such experiments will be informed by prior work on other species (possibly including stem cell transfer between NHPs) or by data on the effects of 'graded' transplantation of human cells into NHPs; and

- breeding of animals that have, or may develop, human derived germ cells in their gonads, where this could lead to the production of human embryos or true hybrid embryos within an animal.

The AMS recommended that the list of such experiments should be kept under continuous review by the proposed national expert body (see below).

Part C: Regulatory pathways for different types of research involving the use of human material in animals

Regulation of category 1 experiments

All Category 1 experiments currently carried out *in vivo* come under ASPA either due to the effect on the animal source of the cells/tissues; on the recipient animal; or on the potential animal offspring.

Regulation of category 2 experiments

Category 2 experiments will only be regulated solely under ASPA if they do not involve human embryos, or human gametes.

Experiments involving human embryos, human gametes that will be used to create an embryo, or human admixed embryos in which the human component is predominant will also require authorisation by the HFEA.

Where the necessary authorisation is unclear or uncertain, advice should be sought from both the HFEA and Home Office. In such cases, the HFEA and Home Office will liaise to determine what regulatory framework(s) are appropriate and advise the research body accordingly.

In all cases advice will also be sought from the Animals in Science Committee (see below).

Note that, where human tissues and cells are being stored for research ‘in connection with disorders, or the functioning, of the human body’, before they are transplanted into a recipient species, a Human Tissues Act (HTA) licence for storage may be required.

Regulation of Category 3 experiments

Projects that fall into Category 3, or could do so, will always undergo detailed scrutiny by the Home Office and the HFEA and advice will also be sought from the Animals in Science Committee. An application for a licence from the Human Fertilisation and Embryology Authority (HFEA) would be required if human or human admixed embryos can be created.

Animals in Science Committee (ASC)

The Animals in Science Committee (ASC) is an independent non-departmental public body. It is responsible for providing impartial, balanced and objective advice to the Secretary of State (Home Office) and to local animal welfare and ethical review bodies (AWERBs, see below) on issues relating to ASPA and the use of animals in scientific procedures. This advice is not binding.

Applications for project licences under ASPA which raise novel or contentious issues, or are likely to give rise to serious societal concerns, will be referred automatically to the Animals in Science Committee for advice. These will include applications involving experiments falling into ACHM Categories 2 and 3 and, where necessary, ACHM Category 1. The ASC will also act as the national expert body envisaged by the Academy of Medical Sciences.

In carrying out its work the committee must consider both the legitimate requirements of science and industry and the protection of animals from avoidable suffering and unnecessary use in scientific procedures. Its members are appointed according to their skills, expertise and experience and not to represent any organisation or interest group. They are expected to work in the public interest.

The committee's members have wide-ranging expertise, including in the welfare of animals, veterinary science and neuroscience research. The Committee also includes lay members with an interest in the ethical issues arising from the use of animals in scientific research. The Committee can co-opt members with particular expertise to assist in its consideration of more specialised issues.

Animal welfare and ethical review bodies (AWERBs)

Every establishment licensed under ASPA must have an animal welfare and ethical review body (AWERB). The AWERB must comprise (as a minimum) at least one person responsible for overseeing the welfare and care of the animals kept at the establishment[20] and, in the case of a scientific procedure establishment, a scientific member. The AWERB must also take advice from a veterinary surgeon with expertise in laboratory animal medicine[21] and is encouraged to take into account the views of people who do not have responsibilities under ASPA, as well as someone who is independent of the establishment.

The roles of the AWERB include the following:

- providing a forum for discussion and development of ethical advice to the establishment licence holder on all matters related to animal welfare, care and use at the establishment; and

- reviewing all applications for new project licences and amendments to existing licences from a local perspective, consider how the 3Rs are being applied and advise the establishment licence holder on the acceptability of proposals, bringing local knowledge and local expertise to bear.

[20] Named Animal Care and Welfare Officer (NACWO)
[21] Named Veterinary Surgeon (NVS)

Part D: Contacts

Home Office
Animals in Science Regulation Unit,
1st floor Peel Building,
2 Marsham Street,
London SW1P 4DF
Tel: 020 7035 0454
https://www.gov.uk/research-and-testing-using-animals

HFEA
Human Fertilisation and Embryology Authority,
Finsbury Tower,
103-105 Bunhill Row,
London EC1Y 8HF
Tel: 020 7291 8200
Email: enquiriesteam@hfea.gov.uk

HTA
Human Tissue Authority,
151 Buckingham Palace Road,
London SW1W 9SZ
Tel: 020 7269 1900
Email: enquires@hta.gov.uk

Animals in Science Committee
1st floor Peel Building
2 Marsham Street
London
SW1P 4DF
Tel: 020 7035 4776
Email: asc.secretariat@homeoffice.gsi.gov.uk

Health Research Authority
Skipton House
80 London Road
London SE1 6LH
Tel: 020 797 22545
Email: contact.hra@nhs.net

Part E: Glossary

ASPA

Animals (Scientific Procedures) Act 1986. ASPA as (amended by SI 2012/3039) transposes European Directive 2010/63/EU on the protection of animals used for scientific purposes. ASPA (as amended) came into force on 1 January 2013.

Animals in Science Regulation Unit (ASRU)

The Home Office unit responsible for implementation of the Animals (Scientific Procedures) Act 1986 in England, Scotland and Wales.

Chimaera

A biological entity composed of two or more genetically distinct types of cells.

Department of Health, Social Services and Public Safety Northern Ireland (DHSSPSNI)

The department responsible for the implementation of the Animals (Scientific Procedures) Act 1986 in Northern Ireland.

Human admixed embryo

Embryo created using cells of both human and animal origin, where the human DNA is predominant (see also Part A of this document).

Human Fertilisation and Embryology Act 1990

The Human Fertilisation and Embryology Act 1990, as amended by the Human Fertilisation and Embryology Act 2008.

This Act regulates: (i) fertility treatments involving the creation of human embryos outside the body and/or the use of donated human gametes (sperm and eggs) and embryos, (ii) the donation, procurement, testing, process, preservation, storage and distribution of human gametes and embryos intended for human application and (iii) the creation, storage and use of human embryos and human admixed embryos for research purposes. The 1990 Act came into force on 1 August 1991. The amendments made by the 2008 Act came into force on 1 October 2009.

Human Fertilisation and Embryology Authority

The UK wide regulatory body for activities covered by the Human Fertilisation and Embryology Act 1990, as amended.

Human Tissue Act 2004

The Human Tissue Act 2004 (the HT Act) is the legal framework in England, Wales and Northern Ireland regulating the storage and use of human organs and tissue from the living, and the removal, storage and use of tissue and organs from the deceased, for health-related purposes and public display.

Human Tissue Authority

The regulatory body for activities covered by the Human Tissue Act 2004.

Human tissue (Scotland) Act 2006

The Human Tissue (Scotland) Act 2006 is the legal framework in Scotland. It operates to the same principles as the HT Act but differs in the methods of authorisation.

Humanised

An aspect of the biology of an animal (including for example a gene, protein, organ, element of external appearance or behavioural characteristic) that has been modified so that it more closely resembles that of the human.

Humanised antibody

An antibody produced by an animal (typically a mouse) whose antibody producing genes have been replaced by human DNA sequence, causing it to produce antibody molecules that resemble those of the human.

Hybrid

An animal or plant that is the offspring of individuals of different kinds (usually, different species).

Stem cell

A stem cell is a cell that can continuously produce unaltered daughters and has the ability to produce daughter cells that have different, more restricted properties.

Pluripotent

See potency.

Potency (or potential)

Generic terms to denote the range of specialised cells that a stem cell may/can give rise to. Stem cell potency can be more specifically described as unipotent, multipotent or pluripotent.

Primitive streak

The primitive streak is a structure that forms during the early stages of mammalian embryogenesis.

Tetraploid complementation

A technique in biology in which cells of two mammalian embryos are combined to form a new embryo.