

GSK Public Policy Positions

The Care, Welfare and Treatment of Animals

The Issue

At GSK we research, develop and manufacture innovative medicines, vaccines and consumer healthcare products. Animal studies represent a small but vital part of our research efforts and, while it is a long-term aspiration, at present it is not possible to eliminate animal studies from these efforts. Our company-wide policy defines expected practices for the consistent care, welfare and treatment of research animals, irrespective of whether our studies are conducted within GSK facilities or by partner institutions.

We recognise animal research can be a sensitive subject and a topic of debate for many people. This paper describes our approach and sets out the philosophy underpinning the conduct of GSK animal research wherever it takes place.

GSK's Position

- GSK is committed to the replacement, reduction and refinement of animal studies (“The 3Rs”). We are actively engaged in efforts to develop and validate experimental methods that can provide alternatives to the use of animals in research. Ultimately, GSK would like to see the important benefits of research being achieved and applied to humans without the need for animals in research; however, we do not believe this can be accomplished in the foreseeable future.
- Animal studies remain a small but vital part of our research. They are currently the only method that can show the effects of a potential new treatment or intervention in a living body. World-wide regulatory authorities therefore require safety studies in animals before they will approve the use of a compound in clinical trials, or license a new medicine for use in humans.
- We only test non-medicinal products on animals where there is a specific legal or regulatory requirement to do so, in order to make a health benefit claim. We do not carry out animal testing for products whose primary use is to improve the appearance of individuals (i.e. aesthetic purposes). When scientifically needed, animal studies will be performed using as few animals as is scientifically feasible.
- GSK is committed to high standards of humane care and treatment for our animals. Veterinarians are employed to ensure robust veterinary care programmes exist at all research sites, and all staff caring for animals undertake specific training.
- All animals used in GSK studies are specifically bred for research. If, on rare occasions, an exception to this policy is required, the specific request will be reviewed by the Chief Veterinary Officer and approved by a member of the Corporate Executive Team.
- GSK is committed to using NHPs only when scientifically necessary and where they are an appropriate, human-relevant animal species. There is an expectation that the lowest order species that meets an evidence based and scientifically justifiable level of human-relevance is used. As such, in 2008, GSK introduced a voluntary ban on the use of great apes (i.e. chimpanzees) in research.
- In line with the majority of the biomedical research community, GSK uses Genetically Altered Animals (GAA), subject to stringent control including government regulations and oversight, independent animal care and welfare accreditation as well as internal GSK oversight. Our approach to the care, welfare and treatment of GAA does not differ from those associated with other animals used in biomedical research.
- GSK does not clone animals.
- GSK is committed to transparency, and we report annually on the number of animals used in our research programmes in our [Responsible Business Supplement](#) available on GSK.com.

Background

The importance of Animal research

Today, many diseases that cause suffering or death - including cancer, malaria and Alzheimer's - are in need of new treatments. Much research work can be done using non-animal methods, such as computer modelling, isolated cells, tissues and complex in vitro models and we use these wherever possible. However, these methods cannot always give the insight into how a potential medicine affects disease mechanisms or biological systems. Studies in animals are still a requirement; humans are biologically very similar to other mammals, with most of the same organs performing similar functions and controlled by comparable mechanisms, such as the circulatory and nervous system.

External regulation

Prescription medicines: Regulatory authorities worldwide require that all new prescription medicines and vaccines must be studied in animals before any studies can be commenced in humans and before new treatments are approved for use in patients. These requirements were developed to help understand the risks and benefits of potential new medicines.

OTC Medicines: GSK manufactures and sells over-the-counter medicines that people can buy without a prescription. Information about the safety and efficacy of the medicinal ingredients used in these OTC medicines is available before they are offered for sale to consumers. Consequently, our policy is not to test them on animals unless required to do so by regulatory authorities to substantiate safety. Even then, animal tests would only be undertaken following a comprehensive internal review to ascertain that the product had proven therapeutic benefits, and there were no alternatives to animal tests.

Non-medicinal products: GSK also makes a wide range of non-medicinal products, from nutritional drinks to dietary supplements. The definition of a non-medicinal product can vary between governments, as do the different regulatory testing requirements. Some countries may require animal testing to support safety or efficacy claims of non-medicinal products or ingredients. GSK does not carry out animal testing of non-medicinal products unless there is a specific legal or regulatory requirement to support a health benefit claim.

We do not carry out animal testing for products designed primarily to improve the appearance of individuals. For products with both aesthetic and healthcare uses and/or those classified as cosmetics by regulators, GSK will only test in animals when it is required by regulators and when the primary use and marketing claim relates to its healthcare benefits.

Site Inspections and Accreditation: Animal research is highly regulated and all of GSK's facilities and programmes comply with national laws, guidelines and codes of conduct. Inspectors from many regulatory agencies, including the UK Home Office, the US Department of Agriculture and the US Food and Drug Administration, conduct unannounced visits to check that our projects and animal care and use programmes meet all statutory requirements.

We voluntarily undergo independent accreditation of animal care, for example by AAALAC-I, a private, non-profit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programmes.

GSK's approach

GSK's policy requires that scientists try to devise tests that do not require any animals at all, and if that is not possible, they try to obtain the information they need from the smallest number of animals, while minimising pain and distress.

GSK is actively engaged in research to develop and validate experimental methods that can provide more and better alternatives to the use of animals in research. This is encouraged by the GSK Animal Welfare Awards which recognise exceptional contributions by GSK colleagues in this area. We also collaborate with national and international organisations to promote the 3Rs and actively participate in efforts to identify alternatives to animals.

We have a company-wide policy that defines and drives the acceptable standards for our animal work. The Core Principles which underpin our policy mandate that, at a minimum, all animals in our care must have access to food, water and housing that is appropriate to their species; to humane care; and to a programme of veterinary care. All animal studies carried out by or on behalf of GSK must comply with these principles.

Our policy also outlines requirements for study design and approval, including that studies must:

- be supported by a relevant scientific justification/rationale
- be reviewed by an ethical review panel and subjected to an independent scientific review
- minimise any pain or distress to animals
- be performed by appropriately trained and competent staff

Standards of Care

Staff involved in animal research are trained to standards that are approved by recognised professional bodies and that adhere to national guidelines. Qualified veterinarians are available at all times for advice and help in the care of animals and in the conduct of the research. All due measures are taken to prevent or minimise pain and distress before, during and after experimental procedures. Failure to meet our company standards, the maltreatment of animals or non-compliance with the laws governing animal studies by staff can lead to disciplinary action up to and including dismissal.

Engagement with Third Parties

When GSK engages other entities to breed animals, perform animal studies on our behalf or supply materials for use in *in vivo* studies on GSK's behalf, we require that such entities meet all applicable legal and regulatory requirements and require that they adhere to our Core Principles for animal care and welfare. We implement review processes to ensure that we are aware of, and monitor the use of, animals in research that we sponsor via contractors and academic partners.

Use of Genetically Altered Animals

A Genetically Altered Animal (GAA) is one which has been altered to have specific characteristics it otherwise would not have. Generally speaking, GAAs have either DNA added or have their existing DNA altered. Currently over 95% of GAAs used in biomedical research are rodents, overwhelmingly mice. Other Genetically Altered species exist such as pig and sheep, however their use to date has been limited by technical constraints. Recent technological gene editing advances are opening up the opportunity for the use of alternative species of GAA.

GAAs have a number of critical roles in the identification of new drug targets, disease modelling and drug development. As for all animal work, the development and use of GAAs in research is subject to stringent control including government regulations and oversight, independent animal care and welfare accreditation as well as internal GSK oversight. Our approach to the care, welfare and treatment of GAA does not differ from those associated with other animals used in biomedical research.

Use of Non-Human Primates

For some diseases, the evaluation of potential new products can only be achieved in certain species of non-human primates (NHPs). NHPs may be needed to evaluate how potential new medicines are absorbed, distributed, metabolised and excreted. Additionally, they may be required for safety testing in a small number of cases.

GSK is committed to using NHPs only when scientifically necessary and where they are an appropriate, human-relevant animal species. There is an expectation that the lowest order species that meets an evidence based and scientifically justifiable level of human-relevance is used. Most of the NHPs are Old World Monkey species; e.g. Macaque monkeys such as cynomolgus (long tailed) monkeys. We have developed a set of guiding principles for consideration by scientists in determining the scientific need for studies with NHPs.



GSK prohibits the commissioning of any work involving great apes; specifically, chimpanzees. Great apes are gorillas, chimpanzees, orangutans and bonobos. The common chimpanzee (*Pan troglodytes*) has been involved in biomedical research for over four decades. The other great apes – gorillas, orangutans and bonobos - have not been used in such research.

NHPs used by GSK are specifically bred for research. GSK would only use wild caught primates under exceptional circumstances and only with specific authorisations by appropriate authorities, with the approval of the Chief Veterinary Officer as well as a member of the Corporate Executive Team.

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