



Our position on Responsible Care and Use of Animals

What is the issue?

To get ahead of disease we must continue to discover and develop new vaccines and medicines - all of which must be studied and tested to ensure that they work and are safe for patients.

Technological advances such as computer modelling, isolated cells, tissues, and complex in vitro models means that much of our research can be done using non-animal methods. However, at this moment in time these methods do not always provide the exact insight our scientists need to determine how a potential vaccine or medicine affects disease mechanisms or biological systems.

Studies in animals are therefore still needed. Humans are biologically 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. Research in animals is needed to establish whether a medicine or vaccine is safe and effective.

We recognise animal research is a sensitive subject that presents concern and ethical dilemmas. This paper sets out our view on current and future approaches to animal research and our commitments and responsibilities to ensuring high standards of care, welfare and treatment for animals involved in research and quality control.

What is GSK's view?

- GSK would like to see the health benefits of research achieved and applied to humans without the need for animals. However, the journey towards this goal must always be driven by scientific evidence. Many factors must be considered, including different approaches across different therapy areas and drug modalities; further development, characterisation, and refinement of new technologies; and how regulatory frameworks can facilitate use of alternative methods of research.
- GSK is committed to the replacement, reduction, and refinement of animal studies (3Rs). We are actively engaged in efforts to develop and validate experimental methods that can provide alternatives to the use of animals in research. Wherever possible, we use these alternatives. More information can be found [here](#).
- For now, animal studies remain a small but vital part of our research. Currently, they are the only method that can show the effects of a potential new treatment or intervention in a complex living body. At the same time, worldwide regulatory authorities 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.
- GSK is fully committed to high standards of humane care and treatment for our animals. Our internal company-wide policy defines expected practices for the care, welfare, and treatment of research animals, irrespective of whether our studies are conducted in GSK facilities or by partner institutions.

Our commitments and responsibilities

Reviews

The need for animals to be used in a study is determined after a scientific and ethical review, or by regulatory requirements that also include an ethical review. Reviews are carried out by experienced GSK scientists such as veterinarians, biologists, statistical experts, clinicians, chemists and representatives of the public.

The 3Rs

We apply the 3Rs of 'replace', 'reduce', and 'refine' each time we consider the need for animal testing. Through discussion, ethical debate and independent scientific review, GSK seeks to replace animal



studies wherever possible. We also aim to reduce the animal numbers required per study, and finally refine the study paradigm to reduce pain and distress animals experience during our studies.

For example, we are expanding the use of CIVM (Complex In Vitro Models), sometimes called “organ on a chip” or microphysiological systems, as an alternative to using animals for testing. This supports our strategy of replacement, as we further develop our understanding of human genetics.

Standards

GSK commits to high standards of humane care and treatment for all animals in our laboratories. Veterinarians are employed to ensure robust veterinary care programmes exist at all research sites, and all staff caring for animals undertake specific training. Every site, independent of ownership by GSK or country location, must meet our principles on the care, welfare, and treatment of animals.

Staff

Every GSK staff member working with animals is specially trained to understand the behaviour and needs of specific animals and the science of the study. Every facility has veterinarians designated and trained in laboratory animal medicine.

Animals

Our work in the discovery, development, and testing of new treatments (including vaccines), is mostly done in rodents (mice, rats, and guinea pigs). Over the past decade rodents and rabbits have accounted for over 98% of the animals we use for research. A small number of rodents are genetically altered to be more closely aligned with human diseases. This is only carried out once the required ethical and scientific questions have been answered. Mini-pigs, dogs, and monkeys make up the remaining 2% of animals GSK use.

All our animals are bred specifically for research. We only purchase from sources approved by governments and accreditation bodies such as [AAALAC International](#).

We pledge to never use great apes.

Genetically altered animals (GAA)

GAA animals (rats or mice) are only used when scientifically validated. As with all animals we have, the care, welfare and treatment of GAA animals is provided by trained staff, including veterinarians.

Monkeys

We still need to use monkeys but this research is kept to an absolute minimum, and monkeys are used only when scientifically necessary, for example a new medicine may be based on a molecule produced only in primates, including humans, and would be destroyed by the immune system of other species. We have special practices in place and staff specifically trained in monkey behaviour and our work with monkeys is designed to allow for normal behaviours, such as climbing and swinging.

Cloning

We pledge never to clone animals.