

Roche Position on Animal Research

Background

Animal research is a very sensitive issue and involves ethical issues which should be openly discussed. Roche is well aware of the public concerns about animal research and takes them very seriously. We are committed to dialogue and believe that it is important to explain the need for animal research, our efforts to develop alternative methods and the scientific limits to those efforts (for further information see “FAQs on Animal Research”).

Roche’s Position

Roche’s Mission. As an innovation-driven global healthcare leader, Roche aims to improve the quality of human life by providing products and services for prevention, diagnosis and treatment of diseases. Roche’s goal is to help alleviate human suffering caused by diseases.

Responsibility and Standards. At this time, the use of animals in basic research and in the development of drugs and technologies is an indispensable part of biomedical research, both for scientific and legal reasons. In particular, like all healthcare companies, Roche is required by regulatory authorities to test the safety and efficacy of new drugs in animals, before they may be introduced to humans.

Therefore, Roche is committed to using animals appropriately and responsibly, and complies with international, regional and national laws and regulations, as well as meeting or exceeding industry standards (for further information see “Animal Research - Principles of Care and Use”). All employees within Roche, and all external contractors who perform animal research for Roche, are required to obey these laws at all times and to conduct their research by applying high standards of welfare and respect for the animals in their care.

Roche’s Efforts for Animal Welfare

Animal welfare measures. Roche has established mechanisms to ensure high standards of animal care. One example is Roche’s Ethics Committee on Animal Welfare which provides support and guidance on ethical issues raised by Roche employees or external persons, as well as on the application and promotion of alternative methods to animal research, the so-called 3Rs’ (Reduce, Refine, Replace; see below) within the Roche Group. The Committee develops recommendations and oversees in particular that studies

involving non-human primates are ethically justified and that potential alternatives have been considered. In addition, the Committee aims to develop prospective strategies for improvements in animal welfare going beyond local legislation.

In regards to contractors, Roche reviews and recommends animal welfare provisions in their contractual agreements. Roche has a formal auditing process in place for contractors and animal breeders based on global auditing guidelines.

Roche was one of the founders of the new Swiss Charter on Animal Welfare, adopted in 2010 by Interpharma, the association of research-based pharmaceutical companies in Switzerland. The Charter commits Interpharma's members to join efforts for consistently applying high standards of animal welfare, for discussing and working on internal and external auditing processes, for further fostering employee training, stakeholder dialogue and promotion of the 3Rs. We will report annual progress in implementing the Charter.

Search for Alternatives. Roche is committed to using the fewest possible number of animals without putting at risk the reliability and validity of research and test results. Roche's employees follow the guiding principles of the "3Rs":

- Reduction – by using the minimum number of animals necessary,
- Refinement – by tailoring laboratory procedures to minimize pain and discomfort and ensure better care of animals, and
- Replacement – by using other methods that do not involve animals or methods that use only cells or tissues of animals (e.g. computer simulation, testing on tissues or cell cultures), provided that it is approved by the regulatory authorities.

In line with the commitment and responsibility to advance alternative methods, Roche established the internal "Roche 3Rs Award" to reward its employees' achievements in the area of new methods to reduce the number of animals used, to refine testing and to increase animal wellbeing. As another approach to promote the 3Rs', Roche initiated the "3Rs Day", a training day inviting employees to look at the 3Rs concept in detail; it is planned to continue and extend the scope to other Roche Pharma research sites. Roche also supports external institutions, in our pursuit of methods that reduce the need for animals.

Outlook. Over the years, Roche has maintained a strong commitment to animal welfare and intends to remain a driving force at the forefront of developing alternatives to the use of animals in biomedical research.

For further reading, please see:

- FAQs on Animal Research: www.roche.com/ar_FAQs.pdf
- Animal Research - Principles of Care and Use
http://www.roche.com/ar_principles.pdf

This position paper was updated and approved by the Corporate Sustainability Committee on April 28, 2011. It was reviewed in April 2012.