

Animal Research

Roche Principles of Care and Use

The overall goal for Roche, as a leading healthcare company, is to create, produce and market innovative solutions of high quality for unmet medical needs. Roche's products and services help prevent, diagnose and treat diseases, thus enhancing people's health and quality of life. We do this in a responsible and ethical manner and with a commitment to respecting the needs of the individual, society and the environment.

Many serious diseases such as cancer, autism, Alzheimer's disease, Parkinson's disease, hepatitis, diabetes, cardiovascular or inflammatory diseases are not yet fully understood and research still faces numerous challenges. New and more effective therapies and diagnostics are needed to improve the quality of patients' lives. However, before human trials can be conducted, animal testing of drug candidates is required. Thus, the appropriate and responsible use of animals is an indispensable component of pharmaceutical product discovery and safety assessment processes.

For Roche, the proper care and use of animals used in research is of fundamental importance. Every individual who works with animals within Roche or on behalf of Roche is required to act ethically and to treat the animals under their care with respect. In addition, the Roche Ethics Committee on Animal Welfare (ECAW) 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 following principles have been developed to outline the measures in place for the care and use of all animals for which Roche is responsible:

1. Compliance with laws, regulations, scientific and ethical standards

- Roche is in compliance with existing **international** (e.g. the ICH Guidelines), **regional** (e.g. the EU Directive on the protection of animals used for scientific purposes, 2010/63/EU) and **national laws and regulations**, as well as with applicable **industry standards**, for animal research. In addition to the applicable local laws and regulations, every Roche research site conforms to the **standards established by the International Association for the Assessment and Accreditation of Laboratory Animal Care (AAALACi)**.

- Procedures involving animals are designed and performed with respect to their **relevance to human or animal health, advancement of knowledge, and the benefit to society.**

2. Reduction, Refinement and Replacement - the 3 Rs

Roche is **dedicated to following the guiding principles of the “3 Rs’ ”** for animal research, and encourages the development of alternatives to the use of animals in research:

- **“Reduction”** pertains to using the **minimum number of research animals** necessary in order to obtain valid scientific data as well as to **improving the development of alternative methods that require fewer animals. Unnecessary duplication** of experiments is avoided by integrating Roche’s various research sites into a more global organisational structure.
- **“Refinement”** means tailoring laboratory animal procedures to **minimize discomfort and to ensure proper and ethical care** of animals.
- **“Replacement”** involves the development and use of **alternative methods** that do not require the use of animals but can provide equivalent, valid, scientific data such as mathematical models, computer simulation, and in-vitro and cellular biological systems. Where the law and regulatory authorities allow and where it is scientifically possible and ethical, Roche employs procedures that do not require the use of animals.

3. Principles related to the use of animals (during research)

- Planned animal studies undergo rigorous internal and external reviews to assure that:
 - they are **scientifically justified,**
 - **correct species are selected,**
 - **appropriate numbers of animals will be used and**
 - **pain and distress among research animals will be alleviated or minimized.**
- Research personnel (e.g. study directors, lab technicians, animal care takers, veterinarians and animal welfare officers) place a **high priority on the comfort and well-being** of laboratory animals throughout the research process. **Mistreatment of animals is never tolerated.** Violations result in most severe disciplinary actions.
- The ethical and scientifically sound use of animals is imperative. Procedures that may cause more than momentary or minor pain or distress are performed with appropriate sedation, anaesthesia, or analgesia. Exceptions must be clearly defined, justified, and approved by appropriate authorities.

- Euthanasia of research animals is conducted **with minimum infliction of pain and distress**, using an approved method appropriate for the species.

4. Principles related to the care of animals (animal husbandry)

- Animals for research purposes are procured from reputable, **approved vendors and research facilities**.
- **Modern, fully-equipped animal facilities** and **species-appropriate husbandry practices** contribute to the animals' overall health and well-being.
- **Excellent sanitation and peer-reviewed veterinary care programmes** are high priorities in Roche's animal facilities.

5. Personnel education and training

- All investigators and personnel (e.g. study directors, lab technicians, animal care takers, veterinarians and animal welfare officers) are **appropriately educated and trained** in the care and use of laboratory animals. **In-service and/or external training** is provided as a means for continuous improvement and according to local requirements.

6. Supervision

- All experimentation on research animals is conducted under **close supervision of qualified and experienced personnel**.
- **Internal review and audits** are performed by animal welfare officers and/or committees that exist specifically for this purpose.
- Procedures are **submitted for approval by the Institutional Animal Care and Use Committee (IACUC) and/or by appropriate governmental agencies responsible for animal welfare** in compliance with local laws and regulations.

This updated document was proposed by the Corporate Sustainability Committee and adopted by the Corporate Executive Committee on May 13, 2013 and entered into force the same day. It replaces the version from October 13, 2004.