

## LEO POSITION

# Animal welfare

Animal experimentation is an important part of our research and drug development activities at LEO Pharma, where it plays an invaluable role in assessing the efficacy and safety of a new drug candidate. Furthermore, establishing safety of new drugs in animals prior to studies in humans is a prerequisite from Health Authorities.

Animal experimentation raises continuous ethical questions. This position describes the overall principles for the use of animals for scientific purposes at LEO Pharma.

### COMPLIANCE WITH HIGH ETHICAL STANDARDS

At LEO Pharma, we aim to ethically balance benefits to patients against harm to animals used in research, and we deploy a science-based approach while ensuring compliance with high animal welfare standards. Animal welfare standards differ across the world. We have decided to follow very high standards, defined by Danish legislation and the EU Directive on the Protection of Animals Used for Scientific Purposes, regardless of where in the world the use of animals for experimental work is taking place.

To ensure compliance with LEO Pharma's animal welfare standards, we audit third parties such as contract research organisations, academia, and other partners involved in or performing animal experiments on behalf of LEO Pharma. Compliance with the LEO Pharma standards is a prerequisite for collaboration.

### FOCUS ON THE 3RS AND CULTURE OF CARE

Whenever animal experimentation as well as housing and care of laboratory animals are required, we must proactively work to develop and implement activities in relation to the following principles:

**1. Replacement** - the use of non-animal methods:

Replacement involves the use of methods that avoid or replace the use of animals in an area where they would otherwise have been used. Where permitted by local law and regulations, we shall prefer the development and use of alternative methods that do not involve the use of animals, but can provide equivalent and valid scientific data.

**2. Reduction** – the use of fewer animals:

Reduction includes the use of methods that minimise animal use and enable researchers to obtain comparable levels of information from fewer animals or more information from the same number of animals.

**3. Refinement** – the initiatives which minimise actual or potential pain, suffering, distress or lasting harm and/or improve animal welfare:

Refinement applies to the lifetime experience of the animal. Minimisation or avoidance of pain, distress, and discomfort of the animal before, during, and after a procedure must be sought. We must always treat experimental animals with respect and ensure their proper care to enhance the animals' welfare.

### CULTURE OF CARE

The term Culture of Care is used to indicate a commitment to constantly improving animal welfare when working with experimental animals. It goes beyond being compliant with the wording of relevant legislation, and strives to achieve the full intent of established rules and regulations. At LEO Pharma, we embrace the principles of Culture of Care and implement it in all of our experimental animal activities.