



Animal Welfare Policy

Novartis Global Policy

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Animal Welfare
Compliance

1 Introduction

Novartis' mission is to discover new ways to improve and extend people's lives. Using science-based innovation, Novartis delivers better outcomes for patients and addresses the evolving healthcare needs of society. It focuses on growing areas of healthcare where innovation plays an important role: pharmaceuticals, eye care and generic medicines. During the discovery of new treatments and to ensure their efficacy and safety, Novartis relies on knowledge that can only be acquired through studies involving the use of animals.

In many cases animal experiments are essential to determine the therapeutic relevance of novel treatments for a multitude of human diseases. In addition, international conventions as well as Health Authority and/or other governmental regulations and guidelines within the countries in which Novartis operates, require that studies involving the use of animals are performed in order to determine the efficacy and safety of its products.

1.1 Purpose

This Policy describes the key principles, requirements and responsibilities relating to animal welfare in Novartis-initiated animal studies and procedures, may they be conducted within Novartis or at a Third Party.

It contains Novartis' commitment to refining, reducing and replacing animals in research and to upholding the highest standards in animal welfare. This is also enshrined in the Code of Conduct which states that we are committed to minimizing discomfort and pain of animals used in Novartis and to using alternatives to animal research whenever possible. This policy sets forth the principles and rules for the implementation of this commitment.

1.2 Scope and Applicability

This Policy applies to all Novartis Divisions, Units, Institutions and any contracted Third Party engaged in animal studies and procedures.

This Policy contains general principles and requirements which guide Novartis' engagement for animal welfare and responsible use of animals. It also defines operational responsibilities for the implementation of the Policy on a global and local level.

This Policy is based on a strict interpretation of the US animal welfare legislation and as such is aligned with applicable laws and industry codes. The Policy is to be implemented in countries with less or equally stringent laws and industry codes as the US. In some countries, local laws and regulations may be more stringent than the principles set out in this Policy. Where this is the case, the more stringent rules apply.

Good scientific and ethical practices require that all animal welfare issues are properly considered and dealt with. Animal welfare is of primary concern with regard to the accuracy and usefulness of all scientific studies.

This Policy enters into force as of August 1 2012 (updated April 1, 2016). It replaces the Novartis Global Animal Welfare Policy adopted in 2005 (revised 2007). It must be implemented by all Novartis affiliates.

2 Principles and Rules

2.1 Basic Rule Applicable to all Associates

- I. Novartis promotes the welfare of animals used in studies and procedures whenever possible.
- II. Novartis is committed to comply with currently applicable scientific, legal, regulatory, and ethical requirements, guidelines and policies to ensure animal welfare. Studies are carried out by individuals who are (a) trained and qualified in science and in the proper care, handling and use of animals and (b) experienced with the species being studied.
- III. Novartis is committed to the 3R principles (Reduce, Refine, Replace) and shall actively pursue their promotion.
- IV. Novartis ensures that animals used in all studies and procedures are treated and cared for respectfully. Special attention is given to the particular needs of different species (e.g., group housing, environmental enrichment) as defined by current veterinary care and practice guidelines for animals in used in experiments.
- V. Novartis is committed to taking all necessary measures, in accordance with current veterinary practices, to ensure that animals experience the minimum amount of discomfort, distress and/or pain. Appropriate methods for sedation, analgesia or anaesthesia are to be utilized whenever possible.
- VI. Novartis is committed to ordering and using only animals that are specifically bred for research purposes, either by its own breeding units, or by certified breeders.
- VII. Novartis will not use Great Apes unless required or recommended by regulatory authorities, or when necessary to answer a specific bio medically relevant question. In these rare cases such experiments must be approved by the Global Animal Welfare Committee and the CEO of Novartis.
- VIII. Scientific and ethical review of studies or practices involving the use of Non-Human Primates as well as authorization of the work is performed by a specific Novartis ethical committee dedicated to this responsibility.
- IX. Particular care and attention shall be devoted to the transport of animals for experimental use. Appropriate and adequate devices and/or facilities for transport must be provided in accordance with current applicable guidelines and legal requirements.
- X. The Novartis Animal Welfare Policy and Standards apply equally to Novartis initiated animal studies and procedures performed at Third Party animal facilities (e.g., contract research organizations, universities, other companies). Regular audits of Third Party animal facilities are conducted to ensure compliance.

Novartis ensures that all associates to whom this policy applies are informed about this policy and their respective responsibilities.

2.1.1 Definitions

Definition 1	Animals in the meaning of this Policy include all living vertebrates.
Definition 2	Animal study means any use of a living animal in an experimental setting dedicated to answer a specific scientific question.

Definition 3	Great Apes are the species Ponginae Pongo (Orangutan), Gorillini Gorilla (Gorilla) and Panina Pan (Chimpanzee).
Definition 4	Novartis initiated animal studies and procedures refer to animal studies and procedures that are performed on request and/or under contract, for Novartis.
Definition 5	Third Party is any person, including a legal entity, with whom Novartis interacts and that is not a Novartis company or associate.

2.1.2 References

- Novartis animal welfare standards (2011)
http://www.novartis.intra/animalwelfare/docs/globalaw/policies/Novartis_Animal_Welfare_Standards.pdf
- NRC Guide for the care and use of laboratory animals (©2011)
<http://oacu.od.nih.gov/regs/guide/guide.pdf>
- FASS Guide for the care and use of agricultural animals in agricultural research and teaching (2010)
http://www.fass.org/docs/agguide3rd/Ag_Guide_3rd_ed.pdf
- EU Directive 2010/63 on the protection of animals used for scientific purposes (2010)
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:En:PDF>

3 Implementation

3.1 Training

All National/Local Animal Welfare Officers and animal welfare related functions must familiarize themselves with this Policy and participate in animal welfare training sessions that will be periodically held (e.g., at the animal welfare forum or at local site animal welfare training programs for all scientific and/or animal care staff).

3.2 Reporting Potential Misconduct/Non-Retaliation

Any Associate who learns of a potential violation of applicable laws or this Policy is required to report his or her suspicion promptly in accordance with the section of the Novartis Code of Conduct entitled 'How to report potential misconduct.'

Anyone who reports a possible violation of applicable laws or this Policy will be protected from retaliation in any form.

3.3 Breach of this Policy

Breaches of this Policy will not be tolerated and can lead to disciplinary and other actions up to and including termination of employment.

3.4 Exceptions

This Specific exceptions are permissible from the terms of this Policy but these can only be granted by the Global Animal Welfare Committee (GAWC) when business is significantly affected and the exception is in line with sound scientific and ethical considerations. All exceptions must be justified and documented before being implemented. No exceptions can be granted from compliance with applicable laws and regulations.

3.5 Entry into Force and Implementation

Novartis has established clear roles for global and national/local implementation of this Policy. A Corporate Animal Welfare Officer and divisional Global Animal Welfare Officers (GAWOs) form the GAWC. The GAWC is supported by other functions as required (e.g., National/Local Animal Welfare Officers, Public Affairs/Relations). The GAWC steers and coordinates all animal welfare related activities, including a global Third Party audit program.

Novartis sets out responsibilities for heads of Novartis organizations performing animal studies, study directors, investigators, animal technicians, animal caretakers and supervisors involved in using animals internally/externally to Novartis. Associates must ensure that animal work is conducted in accordance with this Policy and animal welfare issues are discussed with the National/Local Animal Welfare Officers. Associates must inform the GAWO of Novartis initiated external animal studies prior to their start so that a Third Party audit and adherence to this Policy are ensured. Only animal welfare approved Third Parties can be used for any animal related study or service.

Roles and responsibilities may be regularly updated to organizational requirements.

3.6 Policy Owner

The owner of this Animal Welfare Policy is the Global Animal Welfare Committee.