NOVARTIS | Reimagining Medicine

Animal Welfare Policy

Novartis Global Policy

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NIBR

Animal Welfare Compliance

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1. Introduction

Novartis is committed to transparently sharing its commitment to animal welfare, as reflected in the Code of Ethics [1], *the Novartis In Society Environmental, Social, and Corporate Governance (ESG) Report* [2], and on Novartis.com ensuring that all Novartis and members of the public can be aware and assured of our animal welfare principles and requirements.

This Policy is derived from principles described in the US Guide for the Care and Use of Laboratory Animals, The Guide for the Care and Use of Agricultural Animals in Research and Teaching, and the European ETS 123 and as such is aligned with applicable laws, industry codes and geography. The Policy is to be implemented in countries with less or equally stringent laws and industry codes. 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.

During the discovery of new treatments and to ensure their efficacy and safety, Novartis relies on knowledge that can only be acquired through studies with animals. 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 with animals are performed to determine the efficacy and safety of new therapies.

1.1. Purpose

This Policy describes the key principles, and responsibilities relating to animal welfare in Novartis-initiated animal studies, whether conducted within Novartis or at a Third Party; including Novartis' commitment to refining, reducing, and replacing animal studies and to upholding high ethical and animal welfare standards.

1.2. Scope and Applicability

1.2.1. Scope

The scope of this Policy is global.

1.2.2. Applicability

This Policy applies to all associates, as well as those at Third Party animal facilities performing work on behalf of Novartis.

1.3. Roles and Responsibilities

Role	Responsibilities
All associates	• Awareness of, and compliance with, this document • Direct any inquiries about Novartis sponsored animal research to their unit or local Communications team.
Managers of associates with Animal Research roles	• Ensure compliance with this Policy and in particular that all in-scope animal research activity commissioned by their functional area is either described in an approved animal use protocol or license if internally conducted, or if the activity is conducted externally, is submitted for review and approval by Animal Welfare Compliance. • Ensure that associates receive the support needed to complete necessary training and ensure competence related to *in vivo* research.
Animal Welfare Compliance	• The management of this document. • Oversight of the ethical review process and compliance of Novartis sponsored animal studies with this document and associated industry standards, whether conducted internally or at Third Party organizations (CRO, academic collaborators, animal breeder, etc.).

2. Principles

2.1. Novartis Animal Welfare Commitments

- **Following 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 research with animals and (b) experienced with the species on study.
- **Adopting the 3R principles** (Reduce, Refine, Replace) and actively pursuing their advancement.
- **Enrolling Great Apes on study only when required** by regulatory authorities. In these rare cases, such studies must be approved by the Global Head of Animal Welfare Compliance and the CEO of Novartis.
- Requiring that studies or practices involving Non-Human Primates must undergo **scientific and ethical review and receive authorization** by a specific Novartis ethical committee dedicated to this responsibility.
- **Applying this Policy and industry standards equally** to Novartis sponsored animal studies and procedures performed in Novartis facilities and at Third Party animal facilities (e.g., CRO, universities, other companies). Regular audits of Third Party animal facilities are conducted to ensure compliance.
- Ensuring that all **associates are informed** about this policy and their respective responsibilities.
- Ensuring that animals needed for research are **treated and cared for respectfully**. Special attention is given to their species-specific needs (e.g., positive reinforcement, low stress handling, social housing, environmental enrichment, opportunities for exercise) as defined by current veterinary care and practice guidelines.
- **Minimizing discomfort, distress, and/or pain**, following current veterinary practices. Appropriate methods for sedation, analgesia or anesthesia are to be used whenever possible.
- **Supporting rehoming and retirement** of animals as appropriate for the health and well-being of the animal, the scientific aims of associated studies, and per all applicable regulations and requirements.
- Enrolling study animals that are **purpose bred**, either by internal breeding units or by certified breeders.
- Devoting particular **care and attention to the transport** of animals needed for research. Appropriate and adequate devices and/or facilities for their transport must be supplied following current applicable guidelines and legal requirements.

3. Internal Controls

Internal controls for this document are maintained in the Internal Control Register at ‘go/controlregister’.

4. Breach of this Policy

Breaches of this Policy will result in remedial, corrective, or disciplinary actions up to and including termination of employment. Actual or suspected incidents of misconduct should be reported to the SpeakUp Office. Novartis guarantees non-retaliation and confidentiality, to the extent legally possible, for good-faith reports of such breaches.

5. Exceptions

Exceptions to this Policy are not permitted.

6. Adaptations

Adaptations to this Policy are not permitted.

7. Definitions

Term/word	Definition
3Rs Principles	Replace: Develop and implement alternatives to replace animal studies. Reduce: Improve study methods so fewer animals are required. Refine: Optimize studies such that animals experience as little stress and as much comfort as possible.
Animal	All living vertebrates.
Animal study	Any engagement of a living animal in an experimental setting dedicated to answer a specific scientific question.
Contract Research Organization	A third party that may conduct Novartis sponsored animal studies.
Great Apes	The species *Ponginae Pongo* (Orangutan), *Gorillini Gorilla* (Gorilla) and *Panina Pan* (Chimpanzee).
Novartis initiated animal studies and procedures	Animal studies and procedures that are performed on request and/or under contract, for Novartis.
Third Party	Any person, including a legal entity, with whom Novartis interacts and that is not a Novartis company or associate.

8. Abbreviations

Abbreviation	Description
3Rs	Reduce, Refine, Replace
CRO	Contract Research Organization
NHP	Non-human Primate
NIBR	Novartis Institutes for BioMedical Research

9. References

Reference #	Document Name
1	Code of Ethics
2	Novartis In Society Environmental, Social, and Corporate Governance (ESG) Report