Animal Ethics Policy

1. Background

Cochlear manufactures a range of implantable hearing devices which have revolutionised the management of hearing loss, facilitating significant improvements in language acquisition, speech recognition, and quality of life for hundreds of thousands of recipients around the world.

To ensure safety and efficacy, Cochlear must adhere to relevant regulations, guidelines, and international standards during product development. Resulting documentation is submitted to organisations such as the Therapeutic Goods Administration (**TGA**) in Australia and the Food and Drug Administration (**FDA**) in the United States, as well Notified Bodies in Europe for CE Mark, and contribute towards regulatory approval.

Where an assessment of biological safety or performance is required and/or animal studies are mandated by the regulations or guidelines, Cochlear subcontracts studies to experienced and accredited contract research organisations (**CROs**) with study protocols governed by local regulations, animal research and ethics committees, and international standards. All research involving animal subjects is led by the 3R principles of animal research; replacement of animals, reduction in the number of animals used and refinement of conditions and methodology to reduce suffering.

Additionally, Cochlear provides funding and/or in-kind support to world-class universities in Australia, the United States, and Europe for medical research into hearing loss and its treatment. Animal studies may be necessary where alternative models are not available or are unsuitable to address the complex research questions being asked in these studies.

Overall, the use of animal studies for biomedical purposes enables inquiry into complex biological systems and provides an analogue of human disease states that may be otherwise unachievable in the laboratory. Such animal studies are utilised to demonstrate pre-clinical safety of new clinical interventions, enabling clinical studies and product development. They also underpin the discovery of new clinical treatments through the investigation of a disease state and establishing proof-of-concept of treatments.

2. Scope

This policy outlines the core ethical principles in the respectful and humane use of animal subjects when required to be used in scientific research and medical device product development. It is Cochlear's responsibility to ensure that the impact on welfare of animals is minimised. This policy outlines our commitment to following the best practices of the 3R principles in our animal research to minimize impacts on animals and improve animal welfare.

3. Policy

In Australia, animal research is guided by the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (the **Australian Code**) published by the National Health and Medical Research Council (**NHMRC**).

Cochlear applies the 3R principles set out in the Australian Code, as the global standard for animal research to guide the decision to use animals in research, and subsequent design and planning of responsible animal research studies.

(a) **Replacement** – Cochlear prioritises non-animal alternatives wherever possible. We utilise a range of *in vitro* biological and chemical tests, computer modelling, cadaveric temporal bone analyses and other non-invasive methods to avoid or reduce the number of animals used in our projects.

(b) **Reduction** – In cases where animal testing is deemed necessary, we use the minimum number of animals required to obtain scientifically valid results. This is achieved by using appropriate sample sizes, statistical methods, and by sharing data and samples with other research groups to reduce duplication of animal use.

(c) **Refinement** – We will ensure that our experiments are designed and conducted in a way that minimises animal suffering and stress and all personnel involved in animal experiments have received training in animal handling and welfare. We provide appropriate housing, feeding, and veterinary care for the animals used in our projects.

Whenever possible, Cochlear will work with research partners and laboratories accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (**AAALAC International**).

3.1 USE OF ANIMALS AS REQUIRED BY LAW & GLOBAL REGULATORY BODIES

Cochlear engages with test houses (such as NAMSA) that have their own independent research ethics committee and procedures and are governed by local laws. These test houses should be accredited with ISO 17025 or follow GLP (e.g. 21 CFR Part 58), and are reviewed by Cochlear prior to engagement in any projects while maintaining up-to-date records of all accreditations.

(a) **Biocompatibility testing**

Biocompatibility testing is an essential part of the product development process, aimed at identifying and mitigating potential biological hazards associated with new products. Cochlear references previous animal testing on predicate devices where possible and justifies their relevance to the new device being assessed. The biocompatibility testing follows EN ISO 10933-1, and animal welfare is addressed to EN ISO 10993-2 when animal testing is required. Where possible and deemed sufficient by the regulators, animal testing is replaced with chemical characterisation based on risk assessment of existing data.

(b) **Formal GLP toxicology studies**

Development of combination devices (i.e., a drug combined with a cochlear implant) may require formal Good Laboratory Practice toxicology studies. These studies are a mandatory part of any drug development program which include dose escalation, chronic exposure and are usually required in 2 different animal species. Cochlear will only engage test houses to undertake toxicology studies when there is not sufficient data available from past studies

3.2 USE OF ANIMALS IN COLLABORATIVE PARTNERSHIPS AND EXPLORATORY RESEARCH

Cochlear requires that all research agreements include clear terms with research partners regarding recognition, application, and adherence to the 3R principles for studies requiring animal research. For such studies, Cochlear engages with world-leading experts that are typically affiliated with universities, research institutions, and/or CROs typically with AAALAC certification. These collaborators typically have their own independent ethics committee, and procedures, and are governed by local laws. The accreditation for animal research varies by jurisdiction, however Cochlear prefers to collaborate with AAALAC certified research partners, encourages certification and ensures justification is reviewed and approved by the Cochlear Animal Ethics Committee (**AEC**) when not possible.

4. Cochlear Animal Ethics Committee

The Cochlear AEC is responsible for ensuring Cochlear's scientific research relating to the use of animals is conducted in compliance with the Australian Code for the Care and Use of Animals for Scientific Purposes. In this capacity, the AEC will ensure that all animal use is justified, adequate provision is made for the welfare of animals, as well as the incorporation of and adherence to the 3R principles of Replacement, Reduction, and Refinement.

5. Reporting

The AEC will annually report to the Cochlear Medical Science Committee on:

(a) Numbers and types of research projects and activities assessed, approved or rejected;

(b) Any actions that have supported the educational and training needs of AEC members and people involved in the care and use of animals;

(c) Outcomes of project reviews including any administrative or other difficulties encountered, including any notable observations of the testing facilities;

(d) Any matters that may affect Cochlear's ability to comply with the Australian Code.

Through annual performance evaluation, the AEC will strive for continuous improvement in processes and operations as well as maintain compliance with the relevant provisions of the Australian Code.

6. Definitions

Term	Description
Animals	Any vertebrate animal (e.g. laboratory animals, agricultural animals, wildlife and aquatic species) produced for or used in research, testing or teaching.
Animal use	The proper care, use, and humane treatment of laboratory animals produced for or used in research, testing or teaching.
Cochlear	Cochlear Limited and each of its related body corporates.
Humane care	Actions taken to ensure the animals are treated according to high ethical and scientific standards.
GLP	Good Laboratory Practice refers to a framework within which laboratory studies are planned, performed, monitored, recorded, reported, and archived.

7. Version Control

Policy application	Global
Policy approver	Board of Directors
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Policy delegate name	Vice President, Global Head of Biosciences and Hearing Drug Solutions
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