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 in order 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 welfare of animals is not compromised. 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. In cases where animal testing is deemed necessary, we use the minimum number of animals required to obtain scientifically valid results.

(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. We will also ensure that our experiments are designed and conducted in a way that minimises animal suffering and stress.

(c) **Refinement** – We take all reasonable steps to ensure that our animal experiments are as humane as possible. Our experiments are designed to minimise stress and discomfort to the animals, and all personnel involved in animal experiments receive 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 CROs (such as NAMSA) that have their own independent research ethics committee and procedures and are governed by local laws (such as Animal Welfare Act in the USA, EU directive 2010/63/EU and the Australian Code for the Care and Use of Animals for Scientific Purposes. These contract research organisations should be accredited with ISO 17025 or follow GLP (e.g. 21 CFR Part 58), and are audited 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. Where GLP toxicology studies are required involving drug candidates for integration into a combination device, Cochlear will engage with contract research organisations, however existing drug candidates may have sufficient toxicity data available, negating the need for these 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 primary responsibility of the Cochlear AEC is to ensure that 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, and the 3R principles of Replacement, Reduction, and Refinement are incorporated and adhered to.

4.1 RESPONSIBILITIES

The Cochlear AEC will:

(a) Review all proposals that utilise animals and assess whether animal use is appropriate and justified.

(b) Confirm that alternative methods and models have been considered and are not suitable.

(c) Determine whether the proposal is ethically acceptable.

(d) Research involving animal use will not proceed without AEC review and approval of facilities, procedures, technical qualifications, and research protocols.

(e) Receipt and review of progress reports involving conduct during study and action as appropriate concerning non-compliance.

(f) Ensure members review guidelines on the care, and use of animals, and standard operating procedures and provide review and approval where applicable.

(g) Advise the organisation on measures required for ongoing compliance with the Australian Code.

(h) Provide input on decisions and policies related to the care and use of animals.

4.2 MEMBERSHIP

The Cochlear AEC will be comprised of internal staff as well as external partners with a chairperson and at least one person from each of four categories of membership:

Category	Description
A	A person with qualifications in veterinary science and with experience relevant to the proposed activities or the ability to acquire relevant knowledge.
B	A suitably qualified researcher with recent and relevant experience in the use of animals for scientific purposes.
C	A person with demonstrable commitment and established experience in progressing animal welfare. This person is not actively involved in animal research and must not be employed by or otherwise associated with Cochlear.
D	A person that is not employed by or otherwise associated with Cochlear and has no prior involvement with the use of animals for scientific or teaching activities.

Additional to members fulfilling the criteria of the four categories, members with skills, background and project-specific expertise of value to the AEC may be appointed to provide input and advice, as required.

Policy for the appointment, reappointment and retirement of AEC members:

- AEC members are appointed for a term of no more than three years following nomination.
- All conflicts of interest must be declared by any incoming member prior to appointment.
- Incoming AEC members must acknowledge in writing their acceptance of the terms of reference of the AEC prior to appointment and any requirements for confidentiality required by Cochlear.
- Upon expiry of the term, the Chair will review the appointment and a further term may be offered at the discretion of the Chair, bearing in mind the need for a turnover of members over a period of time.
- The appointment of any member may be terminated by the Chair in writing at any time.

4.3 ROLES AND RESPONSIBILITIES

Role (R, A, C, I)	Responsibility
Responsible: Those who are assigned to do the work. **Initiators of animal research are responsible for following the policy.** **External partners require to follow policy**	Initiators of Animal research, including Cochlear Clinical and Medical Affairs, Cochlear R&D External research partners and Contract research organisations (CROs)
Accountable: The person who makes the final decision and has the ultimate ownership.	Cochlear Medical Science Committee
To be Consulted: Those who must be consulted before a decision or action is taken.	Clinical Research Ethics Committee
To be Informed: Those who must be informed of a decision or action that has been taken.	Legal, Investor Relations, Group Risk & Assurance, Regulatory Affairs, Medical Affairs

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) The physical facilities for the care and use of animals by external CRO partners;

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

(d) Outcomes of project reviews including any administrative or other difficulties encountered;

(e) 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
Policy owner name	Chief Technology Officer
Policy delegate name	Director Pharmaceutical Approaches
Policy version number	2.0
Policy version date	24th July 2025
Policy review cycle	Annually

8. Change History

Version	Changes
1.0	Initial version
2.0	Add examples of applicable laws to Section 3.1 Replace 'Test House' with 'Contract Research Organisation' at request of AEC Update Policy Delegate name, Accountability and annual reporting committee