

# NEWCASTLE UNIVERSITY

## **ANIMAL WELFARE & ETHICAL REVIEW BODY**

### **CONSTITUTION AND TERMS OF REFERENCE**

#### **Background**

Animal experiments in the UK are regulated by the Animals (Scientific Procedures) Act 1986 (A(SP)A). This is implemented by the Home Office Animals in Science Regulation Unit (ASRU), which has formal responsibility for project authorisation, including ethical review.

All establishments that use, breed, or supply animals for scientific procedures must have an institutional Animal Welfare and Ethical Review Body (AWERB). The AWERB fulfils all the functions of the Institutional Animal Welfare Body required by most countries which have equivalent legislation to A(SP)A, but the AWERB tends to have a broader membership and a wider range of tasks

Importantly, UK AWERB's review project licence applications, advising the Establishment Licence Holder whether to support these from a local institutional perspective, before they are formally reviewed by the Home Office.

In compliance with the University Research Ethics Policy, the University has determined that NU AWERB will also evaluate all research, teaching and wellbeing/engagement activities, involving the use of protected animals (including the use of animal tissues and/or data), both outside the UK and within the UK where the research does not reach the threshold for A(SP)A regulation. This also includes species not protected by A(SP)A but included in the Animal Welfare (Sentience) Act 2022.

Newcastle University applies the principle that, where UK-funded animal research involves procedures that can be conducted in the UK, it should be conducted in the UK. Exceptions to this will be considered when scientifically justified, for example, involving overseas-funded research collaborations or where the requisite infrastructure only exists overseas.

The main points of the University Research Ethics Policy are:

1. All procedures as described in the Animal (Scientific Procedures) Act 1986 conducted by staff or students at the University, whether taking place under a Home Office licence in the UK or outside the UK, will require ethical approval from the Animal Welfare and Ethical Review Body.
2. The Ethical review will be based on the principles of the Animals (Scientific Procedures) Act, 1986 and its associated codes of practice and guidelines, regardless of the location of the activity (i.e. within the UK or outside). The intention is to ensure that UK standards of care are applied no matter where the research may be carried out.
3. The University will comply with the expectations set out in the "Responsibility in the use of animals in bioscience research: expectations of the major research council and charitable funding bodies", statement.

## Procedure at Newcastle

1. The Committee for the ethical review process (Animal Welfare & Ethical Review Body) shall be:

|                                                                    |
|--------------------------------------------------------------------|
| Chairperson*                                                       |
| Deputy Chairperson                                                 |
| Director of Comparative Biology Centre (or deputy)                 |
| Named Veterinary Surgeon (or deputy)                               |
| Representative of the Researcher Group                             |
| Member of GM Committee                                             |
| Named Animal Care & Welfare Officer                                |
| Training and Competency Officer (or deputy)                        |
| Named Information Officer                                          |
| Colony Manager                                                     |
| Statistician                                                       |
| Lay Member***                                                      |
| Lay Member***                                                      |
| Lay Member***                                                      |
| Lay Member***                                                      |
| Lay Member***                                                      |
| Personal Licence Holder***                                         |
| Personal Licence Holder***                                         |
| Personal Licence Holder***                                         |
| Personal Licence Holder***                                         |
| Project Licence Holder***                                          |
| Project Licence Holder***                                          |
| Project Licence Holder***                                          |
| Project Licence Holder***                                          |
| Secretary to the Committee/Home Office Liaison Contact (or deputy) |
| Home Office Liaison Contact                                        |
| Research Application and 3Rs Advisor                               |

2. The quorum shall be 7 members, and shall include at least the following:

- a) Chairperson
  - b) One Named Veterinary Surgeon (NVS)
  - c) One Training and Competency Officer
  - d) Two Researchers (Personal or Project Licence Holder)
  - e) One Lay Person
  - f) One NACWO\*\*
3. Terms of membership would be 5 years for the Chairperson and 3 years for other members. The Establishment Licence holder will review the Chairperson's position at the end of the term and either extend for another term or source a replacement. Other members' terms would be reviewed by the Chairperson, and any extended term would be recommended to and approved by the AWERB.
4. A member of the Animal Welfare & Ethical Review Body shall also sit on the University Research Ethics Committee.

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\* The Chairperson will be either a lay person or a researcher, if directly involved in research using animals a suitable statement covering any potential conflict of interests will be put in place. A Chairperson from within the University must be a senior member of staff.

\*\* The appropriate Named Animal Care & Welfare Officer would attend a meeting, depending on the animals involved when possible, however a NACWO must be present.

\*\*\* Appointed by Establishment Licence Holder, for the purposes of this Committee the term 'Lay' refers to a person who is not currently involved in research using animals nor has been involved in research using animals for more than 10 years.

5. The following members can nominate a Deputy to attend in their place:
  - a) The Chairperson
  - b) Named Vet
  - c) NACWO
  - d) NTCO
  - e) HOLC
  - f) CBC Director
6. The Animal Welfare and Ethical Review Body shall normally meet once a month.
7. New project licence applications and major amendments to existing licences will be subject to review and guidance from the Research Application and 3Rs advisor before being tabled at a full AWERB meeting.
8. Minor amendments to existing Project Licences may be approved by the Chairperson or nominee plus one other AWERB Member. Where any doubt exists as to the degree of amendment required, the proposal will be brought to a full AWERB Meeting. A document detailing the amendments which can be approved by Chair's Action is appended as Appendix 1.
9. The Terms of Reference of the AWERB shall be as follows:
  - 9.1 To examine proposed applications for new Project Licences and amendments to existing licences, accounting for the extent and nature of benefits related to the cost of projects in terms of animal welfare, and to identify and advise on the 3Rs.
  - 9.2 To promote the appropriate use of animals, including adherence to the principles of the 3Rs (Replacement, Reduction and Refinement), use of alternatives, acquisition of animals, and animal accommodation, care and use.
  - 9.3 To promote the education and training of staff and users in best practice and relevant legislation.
  - 9.4 To review projects throughout their duration and retrospectively to identify and advise on the 3Rs.
  - 9.5 To review care and accommodation standards for all animals.
  - 9.6 To monitor the management and reporting systems relating to the proper use of animals and suggest improvements where necessary.
  - 9.7 To advise on re-homing schemes and appropriate socialisation prior to re-homing.
  - 9.8 To approve all animal work and activities undertaken by Newcastle University staff and students, whether licensed or unlicensed (including that undertaken outside of the UK).
  - 9.9 To be responsible for the formal ethical consideration of activities conducted by university staff/students that involve animals (Aligning with the University Research Ethics Policy; July 2023)
  - 9.10 To provide support, guidance and oversight for any non-research University business which involves animals (e.g., teaching activities, engagement activities, etc.).
10. The Animal Welfare and Ethical Review Body shall report to the Registrar as the Establishment Licence Holder and to the University Research Ethics Committee.
11. The Research Application and 3Rs Advisor will provide guidance to applicants producing applications for consideration by the AWERB

12. Animal Welfare and Ethical Review Body members will receive training to cover:
  - a) Legislation
  - b) Guidance as to what they should be looking for in regulated projects and non-regulated ethics applications
  - c) Explanation of a recent project licence application, including discussion of the cost-benefit analysis
  - d) Requirements for non-technical summaries and retrospective assessments
13. All forms will be provided electronically either through the Home Office Animals in Science Procedures e-Licensing (ASPeL) or via local systems. Completed forms are to be submitted to the AWERB electronically or via ASPeL.
14. The operation of the Animal Welfare and Ethical Review Body will be reviewed regularly (at a minimum of 2-yearly intervals) at the request of the Establishment Licence Holder.
15. Any decisions will be based on a majority decision. In the event of a tied decision, the Chairperson will have the casting vote.
16. If the Animal Welfare and Ethical Review Body is not satisfied with a licence or ethical application, it will be returned to the applicant together with any amendments and queries marked on the form. The AWERB will then either reconvene to consider the answers/amendments or, if they are classed as minor amendments, the Chairperson or their nominee will approve amendments by Chairpersons' Action. There will be no appeal against the final decision of the Animal Welfare and Ethical Review Body.
17. Users of the University's registered premises are informed of the Ethical Review process by means of the [CBC](#) and [AWERB](#) intranet sites
18. If problems are identified during a project, initial discussions will be held with the Project Licence holder, and recommendations for change will be made. The Home Office and/or Registrar (Establishment Licence Holder) may be informed, and the Animal Welfare and Ethical Review Body will monitor the situation regularly. If no improvement is made, the Registrar, as the Establishment Licence Holder, will be notified.
19. To retain records of advice given and decisions reached for 3 years after the completion of the project.
20. To make records available to the Home Office upon request.

## APPENDIX 1

### Project licence amendments

The Committee is also required to consider amendments to existing project licences. **Minor amendments may be approved by the Chairperson and one Committee member.** Examples of minor amendments include variations in the frequency and volume of blood samples or frequency of injections, which are not anticipated to have a significant effect on the welfare of the animals. Amendments which involve a significant expansion of the aims of the project, use of additional animals (e.g. a greater than 10% increase on initial estimates) or additional procedures that involve more than a mild severity banding will be dealt with during a full AWERB Meeting

### Certain classes of minor amendments to project licences can be “fast-tracked” by way of the Chair's Action.

Examples of the type of amendments that would be processed in this way are:

1. Transgenic mouse strains: At present, all applications to create or breed new transgenic mouse strains are considered by the main committee. If the proposed new strain is not considered likely to show clinical signs of ill-health associated with the genetic modification, then it will be fast-tracked. If the strain could show clinically apparent adverse effects, but steps will be taken to prevent these from occurring (e.g., if all studies are carried out on embryos and fetuses), then these amendments will also be fast-tracked.
2. Changes to the injection and blood sampling protocols: When a variation in the frequency, volume or route of injection or sampling is proposed, and the protocol either falls within the Home Office “minimal” severity guidelines or is considered by the NACWO and NVS not to differ significantly from that already approved in the project licence, then the amendment will be fast-tracked.
3. Changes in the duration of a study: When animals are required to be maintained for a longer period than originally specified on the project licence. This will be fast-tracked provided the humane endpoints originally authorised are either not varied or made more humane. The procedure/s **must** be classified as mild or moderate.
4. Changes to protocols that are intended as refinements to the procedure. Since it is important to introduce refinements as rapidly as possible, these amendments should be fast-tracked. However, when they represent a major change to a procedure, they will be tabled for discussion by the main committee.
5. Addition of other rodent species or strains to a licence. If approval has been given to carry out procedures with one rodent species (e.g. rats) or strain (e.g. a transgenic mouse), then an amendment to add an additional similar species (e.g. mice) or strain will be fast-tracked when it is considered that the adverse effects of the procedure on the new species or strain would be the same, or less than, those in the original species or strain. The amendment will be reviewed by the main committee if the use of additional animals would increase the overall number of animals used by more than 10%.
6. Minor surgical procedures not involving invasion of a body cavity

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