



## Commission of policy advice from the Animals in Science Committee

### Animal Welfare and Ethical Review Bodies and the Named Information Officer

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| <b>DATE:</b>           | 22 January 2025   |
| <b>POLICY SUMMARY:</b> | <p><b>Recommendations sought for strengthening the functioning of Animal Welfare and Ethical Review Bodies (AWERBs) and the Named Information Officer (NIO) role. Advice is sought in the following specific areas:</b></p> <ul style="list-style-type: none"><li>- Best practice guidance for AWERBs, particularly relating to their duties regarding the 3Rs (replacement, refinement, and reduction) and training;</li><li>- The questions that AWERBs should ask project applicants to check that replacement methodologies have been fully considered;</li><li>- A review of the ASC AWERB network model to assure dissemination of leading practice; and</li><li>- Leading practice to ensure that the NIO role functions effectively at establishments, where required.</li></ul> <p>The Committee may also wish to provide advice on any other relevant areas it finds salient in the context of strengthening the functioning of AWERBs and NIO role.</p> <p>The Committee's advice will inform the expected standards of practice for AWERBs established within the regulated sector, Home Office guidance and effective audit practices by the Regulator.</p> <p>This request for advice is intended to build upon the findings of the NC3Rs-commissioned report into regulatory review mechanisms published in February 2023.</p> |

## 1. Policy issue

The effective functioning of the Animal Welfare and Ethical Review Bodies (AWERBs) and Named Persons (NPs) are crucial to the effective delivery of establishments' responsibilities under the Animals (Scientific Procedures) Act 1986 (ASPA).

There is evidence of variability in how AWERBs function, and evidence that AWERBs could be better enabled to deliver their functions under ASPA. In addition, there is evidence that the Named Information Officer (NIO) role is not always enabled to deliver effectively. Improvement in both areas has the potential to enhance animal protections.

ASPA sets out at a high level the duties of AWERBs and outlines the need for NPs (Section 2C (5) of ASPA). Guidance on the operation of ASPA, published by the Home Office, under the requirements of ASPA, sets out more detail on the expectations of NPs and summarises the requirements for AWERBs.

Guidance has been produced by the animals in science sector providing more detail on how AWERBs and NPs should operate. However, beyond the high-level requirements of the Guidance on the operation of ASPA, there are no consolidated standards provided or formally endorsed by the Government.

Advice from the Committee is requested to help clarify and drive improved standards from AWERBs and the Named Information Officer Role. The intention is for these standards to inform audits carried out by ASRU.

## 2. Context

### What is an AWERB and what are Named Persons?

All establishments that use, breed or supply animals for scientific procedures under ASPA are required to establish an AWERB. The role of the AWERB is to promote welfare and the uptake of the 3Rs of animal research (Replacement, Reduction, Refinement), to provide advice on project proposals and to approve all project licence applications prior to their submission to the Establishment Licence Holder and ASRU.

In addition, all project licences must specify named individuals responsible for the roles defined in ASPA. These are the Named Veterinary Surgeon (NVS), the Named Animal Care and Welfare Officer (NACWO), the Named Training and Competency Officer (NTCO), the Named Information Officer (NIO) and the Named Person Responsible for Compliance.

### What is the legal requirement under ASPA?

ASPA sets out the requirement for applicants to establish an AWERB and Named Persons prior to being granted a licence. Further detail on the Named Person's roles can be found in sections 3.8, 3.13 and 8 of the Guidance on the Operation of the Animals (Scientific Procedures) Act 1986.<sup>1</sup>

Schedule 2C of ASPA states, in relation to the AWERB, that a section 2C licence requires the holder to "to establish and maintain a body (to be known as an "Animal Welfare and Ethical Review Body") which:

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<sup>1</sup> [Guidance on the operation of ASPA - December 2023.pdf \(publishing.service.gov.uk\)](#)

- Consists of the persons mentioned in sub-paragraph (2) and such other persons as are determined in accordance with the licence; and
- Carries out the tasks mentioned in paragraphs (a) to (e) of Article 27.1 of the Animals Directive and such other advisory and reviewing tasks as are specified in the licence.

The legal requirements of AWERBs as listed in Article 27.1 are to:

- Advise the staff dealing with animals on matters related to the welfare of animals, in relation to their acquisition, accommodation, care and use;
- Advise the staff on the application of the requirement of replacement, reduction and refinement, and keep it informed of technical and scientific developments concerning the application of that requirement;
- Establish and review internal operational processes as regards monitoring, reporting and follow-up in relation to the welfare of animals housed or used in the establishment;
- Follow the development and outcome of projects, taking into account the effect on the animals used, and identify and advise as regards elements that further contribute to replacement, reduction, and refinement; and
- Advise on rehoming schemes, including the appropriate socialisation of the animals to be rehomed.

With regards to the Named Persons, Section 2C (5) of ASPA states that all project licences granted by the Animals in Science Regulation Unit (ASRU) must specify:

- A person to be responsible for overseeing the welfare and care of the animals kept at the place specified in the licence (Named Animal Care and Welfare Officers);
- A veterinary surgeon with expertise in laboratory animal medicine, or other suitably qualified person, to provide advice on the welfare and treatment of those animals (Named Veterinary Surgeon);
- A person to be responsible for ensuring that the persons dealing with those animals have access to any information they need about the species concerned (Named Information Officer);
- A person to be responsible for ensuring that the persons dealing with those animals are adequately educated and trained and are supervised until they have demonstrated the requisite competence (Named Training and Competency Officer); and
- A person to be responsible for ensuring that the conditions of the licence are complied with (Named Person Responsible for Compliance).

### 3. Evidence

The role of review and regulatory approvals processes for animal research in supporting implementation of the 3Rs (Rawle report)

The Rawle report<sup>2</sup>, published in February 2023 (commissioned by the National Centre for the 3Rs (NC3Rs)), assessed the review mechanisms in place for the 3Rs across the landscape of animals in science. It aimed to detail the review processes in place to ensure compliance with 3Rs principles and promote adoption of 3Rs advances; to identify variations and gaps; and explore opportunities for adjusting current processes and responsibility to cover gaps and promote adoption of 3Rs advances.

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<sup>2</sup> The role of review and regulatory approvals processes for animal research in supporting implementation of the 3Rs (2023), NC3Rs

In relation to the AWERB and NPs, the report indicates several potential issues. These included:

- **AWERB tasks in ASPA are not always fully fulfilled.** High workloads from reviewing project licence applications can result in a lack of time for other functions related to promoting the 3Rs. AWERBs rarely suggest the use of replacements due to knowledge gaps and difficultly challenging work once funding is agreed.
- **A lack of clarity/guidance in certain areas of AWERB delivery.** For example, the report suggests that AWERBs may benefit from guidance on which questions to ask to check that replacements have been fully considered. In addition, it recommends that “AWERBs should be clear on the expectations for their role in promoting the 3Rs on a facility-wide basis outside the process of PPL review, including the importance of spending enough time and attention on this part of their role and what constitutes good practice”. This suggests that AWERBs could benefit from clarity on their roles and responsibilities surrounding 3Rs advances.
- **Potential gaps in training and expertise of AWERB members.** There appear to be particular gaps in knowledge of biostatistics, experimental design and replacement methodologies.
- **Potential difficulty recruiting independent members** on account of high workload.
- **The NIO role may not always be enabled to performed effectively.** This is due to resourcing, lack of training or unclear role definition at establishment level. This results in a reduced ability to search efficiently for information to support licence applications in 3Rs implementation.

The Rawle report provides recommendations to the Home Office that the Regulator (ASRU) “should cover the effectiveness of the NIO role in their audits; and, ASRU has the opportunity to clarify expectations for training of AWERB members and to confirm via audit that these are being followed”.

### RSPCA Article & Report

The RSPCA is a significant contributor of learning materials to the animals in science sector, having published guidance for AWERBs amongst other leading practice resources. The Home Office regularly engages with the RSPCA as well as other animal protection and welfare groups about the regulation of animals in scientific procedures.

The RSPCA has published material which highlights several concerns with the way in which some AWERBs are functioning within the UK, based on their engagement with AWERBs and related animals in science bodies. Issues highlighted include: some AWERB tasks may be neglected; lack of awareness of the AWERB and its role in some establishments; not all AWERBs setting out annual action plans with objectives; resources allocated to AWERBs are not always sufficient; and many members reporting that they do not receive sufficient training or induction. The RSPCA published a report<sup>3</sup> in April 2024 from a survey conducted of AWERB members; this survey found that 14% of members received no induction or training at the start of their role, and many felt they had significant knowledge gaps in areas such as experimental design and non-animal alternative methods. More detail can be found on the RSPCA website<sup>4</sup>.

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<sup>3</sup> [AWERB training survey report \(rspca.org.uk\)](https://www.rspca.org.uk/awerb-training-survey-report)

<sup>4</sup> [Issues with the AWERB | rspca.org.uk](https://www.rspca.org.uk/issues-with-the-awerb)

## 4. Advice sought from the Animals in Science Committee

The Government wishes to receive advice from the Committee to strengthen the functioning of AWERBs. Specifically, advice is sought on the below areas.

1. Best practice guidance for AWERBs, particularly relating to their duties regarding the 3Rs (replacement, refinement, and reduction) and training.

The Rawle report recommends that “AWERBs should be clear on the expectations for their role in promoting the 3Rs on a facility-wide basis outside the process of PPL review, including the importance of spending enough time and attention on this part of their role and what constitutes good practice”. The report also cites a view that there is variation in practice among AWERBs since responsibilities are not set out in detail in law. We note that more detailed guidance exists for AWERBs from other forums such as the RSPCA – the ASC may wish to engage the RSPCA to support advice for the regulatory framework.

The Rawle report highlights that it would be beneficial to clarify training expectations for AWERBs and states that best practice for induction for AWERB members should include training in the 3Rs and the principles of experimental design. “All AWERBs and funder review panels should have access to expertise in statistics and experimental design”.

The ASC may wish to advise on the standards of verifiable evidence that could be provided to the Home Office to demonstrate effective, compliant AWERB functioning.

2. The questions that AWERBs should ask project applicants to check that replacement methodologies have been fully considered.

The Rawle report states that “Establishments should ensure that their processes allow the use of animals to be challenged early in the research planning process. AWERBs should ask questions about whether/how an applicant has searched for information on possible replacements or reduction strategies. They should expect a clear explanation of what replacements have been considered and why they are not suitable, and whether approaches to get more information from a group of animals have been considered. This could be facilitated by guidance to AWERBs on questions to ask and what should reasonably be expected of applicants.”

3. A review of the ASC AWERB network model to assure dissemination of leading practice

The ASC run AWERB network fulfils an important role in regard of AWERB practice that is effective. The Committee is asked for a brief appraisal of the current effectiveness of the network and if there are options for strengthening the approach.

4. Leading practice to ensure that the NIO functions effectively at establishments (where required).

The Rawle report recommended the following which ASRU intends to take account of as part of future audit processes: “The expectations of the NIO role should be set out clearly at each establishment in line with ASPA and LASA/IAT guidance.

Establishments must ensure that NIOs have the expertise, time and appropriate resources and training to effectively support researchers, AWERB members and animal facility staff in accessing information on 3Rs advances. They should be well

trained in approaches to search for information and have time to support researchers to fulfil their responsibility to look for alternative approaches. ASRU should cover the effectiveness of the NIO role in their audit.”

The committee is therefore asked to provide advice on best practice to ensure that the Named Information Officer role functions effectively at establishments, where insights are available beyond those provided from the Rawle report.

Advice from the Committee would allow the sector to achieve greater clarity on the roles and responsibilities of the AWERB and the Regulator, and thus drive a more consistent and strengthened approach in how these duties are carried out and assessed.

The Committee may wish to make other recommendations as it sees appropriate, and may combine advice to the above questions as it sees fit.

The Committee is asked to provide written advice on the topics set out above by September 2025.

## 4. Process

### How will the Committee provide advice?

The Committee will provide written advice to the UK Government in line with its statutory remit, as set out in ASPA Section 20:

*(1) The Committee must provide advice to the Secretary of State and the Animal Welfare and Ethical Review Bodies on such matters relating to the acquisition, breeding, accommodation, care and use of protected animals as the Committee may determine or as may be referred to the Committee by the Secretary of State.*

*(2) In its consideration of any matter the Committee shall have regard both to the legitimate requirements of science and industry and to the protection of animals against avoidable suffering and unnecessary use in scientific procedures.*

*(3) The Committee must take such steps as it considers appropriate to **ensure the sharing of best practice** in relation to the acquisition, breeding, accommodation, care and use of protected animals.*

In developing advice, the Committee will wish to gather relevant evidence by engaging with relevant stakeholders concerned with science and industry, animal protection, and regulated establishments.