



Dr Sally Robinson
Chair of the Animals in Science Committee
By email only: asc.secretariat@homeoffice.gov.uk

02 June 2026

Dear Sally,

Response to the Animal in Science Committee's Report on the use of Non-Human Primates Used in Service Licenses

Thank you for the Committee's report of October 2024 on the use of non-human primates (NHPs) in service licences. This work was undertaken following a commissioning letter from the Home Office in 2020, which set a programme of work for the Animals in Science Committee to provide strategic advice on the operation of the animals in science regulatory framework. In response, the Committee established a Task and Finish Group in 2021 to carry out a strategic review of project licences, with subsequent workstreams, including this review, examining the use of NHPs in service licences and the associated scientific, ethical and regulatory considerations under the Animals (Scientific Procedures) Act 1986

I am grateful to the Committee for its detailed assessment and constructive recommendations. The report provides valuable advice on how regulatory assurance and consistency can be strengthened in the context of service licences.

Since the publication of the report, officials have undertaken further work to consider the recommendations alongside ongoing regulatory reform activity and other activity across the animals in science portfolio. This has included engagement with the Animals in Science Regulation Unit (ASRU) and the National Centre for the 3Rs (NC3Rs) to ensure the proposed actions are proportionate, coherent, and focused on strengthening delivery within an already robust regulatory framework.

The Government fully accepts the Committee's recommendations and, working closely with ASRU, will implement them to strengthen assurance mechanisms and ensure there is clear and consistent justification for all use of NHPs.

Implementing these measures will help to ensure that the UK remains at the forefront of ethical and scientifically robust research practices.

Yours sincerely,

Lord Hanson of Flint

The Government's Response to the Animals in Science Committee's Recommendations on the Use of Non-Human Primates (NHPs) in Service Licences

Working closely with the Animals in Science Regulation Unit (ASRU) and taking account of related work across the animals in science portfolio, the Government will implement the ASC's recommendations to strengthen regulatory assurance, improve consistency and ensure clear justification for the use of non-human primates in service licences.

In summary, we will deliver the recommendations through a combination of strengthened scrutiny within the licensing process; clearer communication of expectations to establishments and licence holders; and targeted reviews of current processes, guidance and oversight arrangements. Where recommendations intersect with ongoing reviews, including work led by the NC3Rs and the ASC's review of AWERBs, action will be aligned to ensure a coherent and proportionate approach.

Taken together, these measures will help ensure that the UK continues to uphold high standards of animal welfare and protections while supporting scientifically justified research.

Implementation Plan

- 1. In accordance with ASPA, all licences involving the use of NHPs must provide a clear justification for the requirement to use NHPs and the type of NHP to be used and explain why no other species is appropriate. (PPL Applicant)**

The Government accepts this recommendation.

- The Animals in Science Regulation Unit (ASRU) will continue to assess rigorously the justification provided for the use of NHPs as part of the licencing process.
- ASRU will review current licencing processes for NHPs to explore whether assessment of the justification for NHP use could be strengthened, including for the assessment of expectations on scientific necessity and explanations of why no other species is appropriate.
- This action will be completed by the end of 2026.

- 2. If the licences are providing a service, they should include a description of what information the applicant obtains from the sponsor and how that information is assessed. (PPL Applicant)**

The Government accepts this recommendation.

- ASRU already requires project licence applicants to provide information obtained from sponsors and explain how that information is assessed to demonstrate that the work is necessary and scientifically justified.
- ASRU will continue to scrutinise applications for this information and will reinforce the expectation for the clear provision of sponsor-derived information within project licence applications by communicating this recommendation to establishments and licence holders.
- ASRU will also conduct an internal review to explore whether the assessment of sponsor-derived information as part of the licencing process can be enhanced for example, through strengthening assessment criteria, to ensure sponsor information is sufficient and systematically interrogated.
- These actions will be completed by the end of 2026.

- 3. ASRU should consider limiting safety assessment licences to cover a smaller number of species, and licences involving the use of NHPs could be confined to that**

species only. This would encourage more specific justification for the use of NHPs, more specific details on experimental design and more focused and detailed consideration of 3Rs initiatives that are in place. This consideration could also apply to other non-rodent animals that are used as a second species in safety and metabolism testing. (ASRU)

The Government accepts this recommendation.

- ASRU will review current processes to assure that new safety assessment project licences include separate protocols for NHPs where appropriate. Justification and design details, including considerations of the 3Rs, are currently required for each protocol. ASRU will ensure they are specific to NHPs to encourage more specific justification for the use of NHPs. This action will be completed by the end of 2026.
- The number of animals and species is dependent on the regulatory requirement which the testing is satisfying, which is set out in test guidelines. ASRU is only able to authorise the use of animals where the principles of the 3Rs have been fully applied, meaning that practicable non-animal alternative methods are not available, the fewest possible animals will be used to achieve the scientific outcome sought, and harms have been minimised through application of the most refined testing techniques.
- This recommendation aligns with the Government's published *Replacing animals in science* strategy, which includes two specific commitments relating to reducing and refining the use of non-human primates.

4. Licence applications should consider and reference (as a minimum) the resources available on the NC3Rs (UK) website and clearly outline how all aspects of the 3Rs will be incorporated into the programme of work. (PPL Applicant)

The Government accepts the recommendation.

- ASRU will communicate this recommendation to establishments and project licence holders to reinforce the expectation that applicants should regularly review the resources available on the NC3Rs website. This will be communicated by the end of July 2026.
- A review by the NC3Rs of the project licence application form and process is currently in progress. ASRU will consider this recommendation further in the context of the findings from this review to ensure a coherent, holistic approach which reduces duplication and potential rework. Any necessary changes will be embedded into the project licence template, within associated guidance, and in inspector training. The timeline for this action will be determined following the completion of the NC3Rs review.

5. Scientific and ethical justifications for re-use, and the humane endpoints to be used to ensure that overall cumulative severity remains within a moderate severity, should be clearly stated, considered as part of the evaluation process, and included in a final authorised licence as well as the non-technical summary. (PPL Applicant)

The Government accepts this recommendation. Work will be taken forward to implement its intent, and the specific details of delivery will be refined to achieve the best outcomes.

- Project licence applications must clearly justify any proposed re-use of a non-human primate and explain why such re-use is scientifically and ethically necessary.
- ASRU will review how re-use and humane endpoints are addressed within the application and evaluation process to assure sufficient clarity, detail and robust evidence. ASRU will begin the review in 2026.
- ASRU will communicate this recommendation to establishments and licence holders to highlight the importance of clearly stating the scientific and ethical justifications for re-

use and the humane endpoints to be used to limit overall cumulative harms. This recommendation will be communicated by the end of July 2026.

- ASRU will also review how re-use and humane endpoints are captured as part of the audit process for NHPs used in service licences to ensure robust assessment. This review will be completed alongside a wider consideration of the audit process which is due to follow from the ASC's upcoming recommendations on Animal Welfare and Ethical Review Bodies (AWERBs). Subject to the expected completion of the ASC's report on AWERBs in late 2026, this action will be complete by the end of 2027.

6. ASRU should review its operational practices, especially the audit process, to ensure that all relevant establishments are empowering their local AWERBs (or have an equivalent process) to challenge the need to use animals, prospectively. This would include:

- **an assessment of ethical justification on a substance-by-substance basis, which includes consideration of the societal value and utility of each substance to be tested, and**
- **ensuring that all opportunities for avoiding, replacing, reducing and refining animal use are being taken and shared.**

The Government accepts the recommendation.

- ASRU requires applicants to provide a clear scientific and ethical justification for the use of all animals in science, including providing assurance that the principles of the 3Rs have been applied so that animal use is replaced wherever there is a practicable alternative, the number of animals used is the lowest possible, and refined testing techniques are used to minimise harm.
- AWERBs have an important role in continually advising on the application of the 3Rs at establishments. The ASC is currently commissioned to review AWERBs, and ASRU will consider this recommendation alongside the wider findings from that review to help ensure there is a co-ordinated, unified approach to audit and AWERBs. The definition of "substance" in this context will also be considered. Subject to the expected completion of the ASC's report on AWERBs in late 2026, this action will be complete by end 2027.

7. All licence applications (including for service licences) should detail the experimental design processes that are being used to justify the number of animals required by species. Within licences that include regulatory testing this does not necessarily have to include power analysis. (PPL applicant)

The Government accepts the recommendation.

- Project licence applications must demonstrate that the number of animals proposed is necessary to meet the scientific objectives and explain the experimental design principles used to determine this.
- ASRU will communicate this recommendation to establishments and licence holders to reemphasise the importance of detailing the experimental design processes that are being used to justify the number of animals required by species, by the end of July 2026.
- ASRU will review current assessment practices to identify where there may be opportunities to strengthen the requirements or guidance for reviewing experimental design processes. This recommendation will be considered in the context of the NC3Rs review of the licence application form and process to ensure a coherent, joined-up approach. The timeline for consideration and implementation of recommendations from the NC3Rs review will be determined following the completion of the NC3Rs review.

8. For the provision of blood and tissue, adequate justification should be provided in project licence applications for the number of samples taken and the oversight processes associated with supplying blood or tissue. (PPL applicant)

The Government accepts the recommendation.

- ASRU will communicate this recommendation to licence holders by the end of July 2026 to reinforce the importance of robust justification for the samples to be taken and the oversight processes associated with supplying blood or tissue.
- ASRU will also review information requirements within licence applications relating to blood and tissue sampling, exploring where detail and justification could appropriately be strengthened. This action will be completed by end of 2026.

9. The ASPeL project licence template should be reviewed and updated to include questions to the applicant about how they determine that the experimental design and group sizes are appropriate for delivery of the required experimental outcome. This should be updated for studies that are conducted for regulatory purposes as well as for those that do not generate quantitative data. (ASRU)

The Government accepts this recommendation.

- As noted in recommendation 4, the NC3Rs are currently conducting a review of the project licence application form and process. ASRU will consider this recommendation in the context of this wider review to ensure a coherent, holistic approach to recommendations. Any necessary changes will be embedded into the project licence template, within associated guidance, and inspector training. The timelines for completion will be determined following the completion of the NC3Rs review.

10. Before proceeding with their own ethical review, service providers should receive formal confirmation that the regulatory necessity of the proposed work and its ethical justification have been fully considered by the commissioning organisation through a robust internal system. (Service provider / Commissioning organisation)

The Government accepts this recommendation.

- Commissioning organisations are responsible for determining whether proposed work is necessary and scientifically justified before it is commissioned to a service provider. Service providers are then responsible for undertaking their own ethical review.
- ASRU will communicate this recommendation to establishments and licence holders by the end of July 2026.
- ASRU will also assess whether guidance or oversight at project application stage could be strengthened to help ensure that decisions to commission work involving NHPs are clearly evidenced and subject to appropriate upstream scrutiny. This action will be completed by the end of 2026.

11. A common pro-forma should be developed for the collection of all the necessary preliminary information from a commissioning organisation, including formal confirmation that their own ethical review has been completed. (Service provider / PPL holder)

The Government accepts this recommendation.

- Applicants are required to provide sufficient evidence that ethical considerations have been explored and justified for the proposed work within the licence application.
- ASRU will communicate this recommendation to establishments by the end of July 2026.

12. There is a need for greater oversight on the part of both the AWERB and ASRU on the readability and quality of non-technical project summaries It is recommended that establishments have processes in place to assist the applicant with the help of lay members or non-technical staff. (AWERB / ASRU)

The Government accepts this recommendation.

- ASRU will reinforce the expectation of accessible, high quality non-technical summaries through communications with licence holders by the end of July 2026.
- In September 2025, the ASC provided further, detailed recommendations on strengthening non-technical project summaries, which encompass the intent of this recommendation. The Government published an initial response to these recommendations on 8 May 2026.