

**BRC-BIO-001 CAMPUS USE OF ANIMALS IN RESEARCH
POLICY**

Policy managed by the Babraham Institute

Document reference

Policy number:	BRC-BIO-001		
Policy Owner:	Len Stephens, Establishment Licence Holder		
Date:	13 October 2021		
Version:	1.1		
Status:	Active		
EIA number:	BRC-BIO-001-EIA		
Review period:	3 years		
Last reviewed:	31 August 2022	Next review:	August 2025

Version control

Date	Version	Status	Summary of Changes
01 December 2020	1.0	Active	Updated in the 2020 Policy Review
13 October 2021	1.1	Archived	Removal of civil proceedings wording in Further Information (all policies); addition of 3.3 & 5.5; change of Owner

Document approval

Define the approval authorities for the document

Document version	Document approved by	Position	Date
1.0	Policy Review Working Group	N/A	01 December 2020
1.1	Karen Vincent	Head of Governance	13 October 2021

Distribution

Name or Group	Date of issue	Version
Babraham Research Campus	18 January 2021	1.0
Babraham Research Campus	13 October 2021	1.1

Associated policies, procedures and guidance

This policy should be read in conjunction with:

BRC-BIO-002 Campus Use of Animal Tissues in Research Policy

~~BRC-HAS-001~~[BI-HAS-015](#) Biosafety Policy
BRC-BIO-003 BSU Barrier Integrity Policy
Animal Use Codes of Practice on the BSU Hub pages
Animal Use Standard Operating Procedures (SOPs) on the BSU Hub pages

Contents

1.	Definitions.....	4
2.	Commitment statement	4
3.	Purpose.....	4
4.	Scope	4
5.	The Babraham Institute & the Babraham Research Campus	5
6.	Establishment Licence	5
7.	Exclusions.....	6
8.	Project Licences & the Animal Welfare & Ethical Review Body	6
9.	Import & export of live animals & cryopreserved germplasm	7
	9.1. Overview	7
	9.2. Imports.....	7
	9.3. Exports	7
10.	Standard Operating Procedures for research using animals.....	7
11.	Further information.....	8

1. Definitions

“Employee” Institute employees on Institute or Babraham Institute Enterprise Ltd (BIE) terms and conditions, Institute employees on BBSRC or other terms and conditions, and Research Fellows on Institute terms and conditions.

2. Commitment statement

- 2.1. At the Babraham Research Campus, our mission is to be one of the UK’s leading campuses supporting early-stage bioscience enterprise, bringing together world class research and business to promote innovation and strengthen links between academia and the commercial world. The Babraham Research Campus is distinctive in its co-location of bioscience companies with the Babraham Institute.
- 2.2. Research and operational excellence are essential to meeting our vision of being at the forefront of research that improves lives. The [Institute Values](#) set out our approach to how we operate across all Institute activities, both at an individual level and together as the Babraham Institute. The expectation of the Institute is that each staff member looks to represent and reflect the Institute Values within their own contributions and function, and to support and not hinder the expression of these Values in the work of others.
- 2.3. We are committed to openness and transparency in research using animals, in line with best practice in the UK.

3. Purpose

- 3.1. This policy outlines the approach to research involving animals on the Babraham Research Campus, including how the requirements of the UK Government Home Office under the Animals (Scientific Procedures) Act 1986 (ASPA) are met.
- 3.2. The Institute is a signatory to the Concordat on Openness on Animal Research in the UK. This policy aligns with the principles outlined in the Concordat.
- 3.3. This policy and its associated policies align with the principles in the [UK Research Integrity Office’s \(UKRIO’s\) Code of Practice for Research](#)¹.

4. Scope

- 4.1. This policy applies to all those on the Babraham Research Campus (the Campus) associated with research using animals.
- 4.2. For avoidance of doubt, companies on the Campus must abide by this policy. The exception to this is MRC ARES, which holds its own Establishment Licence and is excluded from this policy.
- 4.3. This policy is public-facing on the Institute’s website.
- 4.4. The following policies are supplementary to this policy:
 - Campus Use of Animal Tissues in Research Policy (BRC-BIO-002).

¹ <https://ukrio.org/publications/code-of-practice-for-research/>

- BSU Barrier Integrity Policy (BRC-BIO-003).
- Biosafety Policy (~~BI-HAS-015~~~~RC-HAS-004~~).

5. The Babraham Institute & the Babraham Research Campus

- 5.1. The Babraham Institute is part of the Babraham Research Campus (the Campus), with a research remit to underpin the overall healthcare responsibility of the Biotechnology and Biological Sciences Research Council (UKRI-BBSRC). The research carried out by the Institute aims to advance knowledge in important biological systems, and in their ageing-related changes, leading to health and economic benefit. It seeks to identify novel targets for the development of therapies and diagnostics applicable to autoimmune diseases, cancers, diseases of neurological decline such as Alzheimer's, reproductive disorders and many others. Findings are published in scientific journals and the Institute continues to maintain and develop its programme of activities to provide public access to research and other advances in the biosciences.
- 5.2. The Campus is home to other academic and commercial organisations working in the biomedical and biotechnology sectors. Additionally, some work is undertaken with external collaborators.
- 5.3. The Institute is the Establishment Licence holder for the Campus and, as such, all animal research on the Campus is required to comply with the Institute's policy on animal usage, as outlined below. See exception above in 4.2.
- 5.4. The research conducted on the Campus falls into four broad categories:
 - Research that does not require living tissue, such as computer modelling or molecular analysis such as the study of DNA.
 - Research that uses the culture of tissues or cells originally sourced from live animals, including human donors.
 - Research using non-vertebrate species such as yeast, nematode worms and fruit flies when it is necessary to study or utilise biological responses that cannot be reproduced in tissue culture.
 - Where there are no other alternatives, research involving live vertebrate animals (exclusively rodents), which are classified as protected species under the Animals (Scientific Procedures) Act in UK law.
- 5.5. If researchers consider that animals involved in research are subject to unreasonable risk or harm, they must report their concerns through the Institute's Whistleblowing Policy (BI-COR-010), which is available on the Institute's website.

6. Establishment Licence

- 6.1. Work that falls under the fourth category in 5.4 is carried out under a single Establishment Licence, issued by the UK Government Home Office under the Animals (Scientific Procedures) Act 1986 (ASPA). A named Institute employee (the Policy Owner) holds the Establishment Licence on behalf of the Campus. Compliance with the requirements of UK and EU legislation is maintained through visits by Home Office inspectors.

- 6.2. Other Institute employees hold responsibility for different areas of animal care under the Establishment Licence. Their contact details are available on The Hub. These are:
- Named Veterinary Surgeon(s) (NVS)
 - Named Animal Care and Welfare Officer(s) (NACWO)
 - Named Information Officer (NIO)
 - Named Training and Competency Officer(s) (NTCO)
 - Home Office Liaison Contact (HOLC)

7. Exclusions

- 7.1. Facilities on the Babraham Research Campus are not used to perform animal research involving statutory testing of substances for their safety. Investigations of the efficacy or quality of substances may form part of specific, approved programmes of research and development work.
- 7.2. The main species used in the live animal research at the Campus are laboratory strains of rodents.
- 7.3. No cats, dogs, horses or primate species (Home Office sensitive species) are housed on the Campus for research purposes.

8. Project Licences & the Animal Welfare & Ethical Review Body

- 8.1. All applications from the Campus for Home Office Project Licences to use living animals under ASPA are subjected to ethical review and must be approved by an [Animal Welfare and Ethical Review Body](#)² (AWERB) in advance of submission to the Home Office. The AWERB compares potential benefits to human or animal health and welfare arising from the research with possible harms that may result to the animals used. The membership of the Campus' AWERB includes Institute and non-Institute scientists, veterinary surgeons, and animal care staff. Lay members and observers are invited to AWERB meetings by arrangement.
- 8.2. A commitment to reduce, refine and replace animal experiments, where possible, underpins the work of AWERB. The Home Office Inspector has an open invitation to attend AWERB meetings, and receives Project Licence applications that have been given local approval.
- 8.3. All Project Licence applications and renewals should be submitted to the HOLC. Details are available on The Hub.
- 8.4. AWERB decisions on the manner in which procedures may be conducted apply to this Establishment Licence but should also inform studies undertaken at other academic establishments as part of a collaboration. Limitations on Project Licence applications imposed during AWERB scrutiny should not be circumvented by exporting such procedures to another jurisdiction, so called "ethics dumping". The AWERB may at its discretion seek reassurances from collaborating laboratories in regards to animal welfare and humane endpoints.

² <https://www.babraham.ac.uk/our-research/animal-research/ethical-review>

9. Import & export of live animals & cryopreserved germplasm

9.1. Overview

- 9.1.1. All imports and exports of live animals or frozen germplasm are co-ordinated by the Biological Services Unit (BSU).
- 9.1.2. All live animal / germplasm imports and exports from academic collaborators will require Material Transfer Agreements to be in place prior to shipment.
- 9.1.3. Colonies purchased initially from commercial suppliers (including wild type colonies) are subject to terms of use. Supply of these animals to any external collaborators will require justification and a letter of permission from the original supplier.

9.2. Imports

- 9.2.1. Requests to import new genetically modified (GM) strains will require a GM risk assessment and approval from the Chair of the AWERB.
- 9.2.2. A cumulative health report for the preceding eighteen months is requested from the sending establishment for approval by the NVS in advance of any live animal import.
- 9.2.3. The Campus uses courier companies who specialise in shipment of laboratory animals to ensure animal welfare and integrity of animal health barriers during transport.

9.3. Exports

- 9.3.1. For export to countries outside of the UK and EU, information on ethical oversight and standards of care is required from the receiving facility. This information is subject to AWERB scrutiny and approval prior to any shipment of live animals / germplasm.
- 9.3.2. Exports within the UK or to EU member states will usually be permitted without further checks on standards at the receiving establishment.
- 9.3.3. Exports outside of the EU may require export health certificates signed by an Official Veterinarian. Any such arrangements will be coordinated by the BSU.
- 9.3.4. Receiving facilities will be encouraged to use Campus-preferred courier companies to transport live animals.

10. Standard Operating Procedures for research using animals

- 10.1. It is required that all animal use at the Campus conforms to the Campus Codes of Practice and Standard Operating Procedures (SOPs) governing animal use for scientific purposes. These documents have been reviewed and approved by AWERB. Documents may be amended by agreement with AWERB or in response to changes in legislation. Failure to comply with these documents may lead to disciplinary action by your employer.

- 10.2. In addition to adherence to severity limits outlined in the documents listed above, the actual severity experienced by every animal used in experiments must be categorised. Discussions with animal care staff are an important part of this process.
- 10.3. The requirements for, and provision of, appropriate training and assessment (for Schedule 1 killing; Home Office modules in specific procedures) will continue, as will the need for periodic reassessment of skills.
- 10.4. In situations where procedures are specified on a Project Licence that are at variance from the Codes of Practice and SOPs (outlined in 10.1), the Project Licence authority takes precedence. Nonetheless, AWERB reserves the right to apply local constraints to research conducted locally on campus or exceed the local Codes of Practice and SOPs on a case-by-case basis.

11. Further information

11.1. Further information can be found:

- [On the Institute's website](#)³

- 11.2. This policy will be reviewed regularly to incorporate any changes, legislative or otherwise. The next review date is specified on the cover sheet.
- 11.3. Associated policies, procedures and guidance are listed on the cover sheet. The Policy Owner named on the cover sheet can be contacted with any queries.
- 11.4. This policy may be varied, withdrawn or replaced at any time by the Institute at its absolute discretion.

³ <https://www.babraham.ac.uk/our-research/animal-research/ethical-review>