Animal Research Policy

Version Control

1. Full Document Number:	LSTMGroupRGEPOL18
2. Version number:	6
3. Superseded version number:	5
4. Document owner job title:	Chair AWERB
5. Department / function:	AWERB
6. Approved by:	AWERB, RIG-C
7. Date of approval:	01-08-2023 (RIG-C)
8. Next review date:	01-08-2025
9. Date of Equality Impact Assessment (assessment enclosed):	This policy did not require an Equality Impact Assessment
10. Accessibility checked: Yes/no	Yes
11. Does this policy apply to LSTM Group (LSTM and subsidiaries?) Yes / no	Yes
12. All policies will be added to the LSTM website unless an exception is provided here	None
13. If this policy has been reviewed, has this resulted in a minor or major changes?	Minor
14. Does this policy ensure that there is no modern slavery or human trafficking in our supply chains or in any part of our business?	na

Modifications from previous version of document

Version	Date of issue	Details of modification
Draft v2	04-MAY-2023	Addition of standard policy template and minor edits based on initial RIGC review
Draft v3	18 JUL 2023	Addition of minor clarifications on policy of animal research overseas post-AWERB review
V4	01 AUG 2023	Accepted version following final RIG-C review
V5	18 SEP 2023	Proof-read version, minor edits, typos and section citation errors amended post AWERB meeting 18/09/23.
V6	11 Oct 2023	Amendments post Executive Group feedback (MJD, GB, SA)

1. Introduction & context: Use of animals in our research

1.1. LSTM is at the forefront of translational biomedical science to improve health outcomes in disadvantaged populations globally, through partnership in research and education. Research conducted at LSTM is focussed on the innovation of new products, tools, diagnostics, therapeutics & vaccines which can be developed and implemented into affordable solutions within low-resource health care settings. We focus our research on tropical diseases with high risk of mortality such as: TB, malaria, multi-drug resistant bacteria and emerging viral pathogens. We also prioritise research in Neglected Tropical Diseases with the capacity to cause permanently disfiguring morbidities (including worm infections and snakebite). This research may require the use of animal testing, the sampling of biological fluids or tissues from live animals and/or other experimental procedures on live animals.

1.2. The use of animals in our research takes place only when it is necessary to replicate the complex physiology of a whole living body and there is no practical alternative. In some instances, this research is a fundamental requirement by medicines regulators before a candidate treatment or vaccine can ethically enter human testing. The majority of the animal research undertaken by LSTM researchers, either at our premises or at other sites in the UK, will constitute a 'regulated procedure' which is legislated within the **Animals (Scientific Procedures) Act 1986**, or 'ASPA'[1].

2 Equality and Diversity

2.1 LSTM is committed to promoting equality of opportunity, combatting unlawful discrimination, and promoting good community relations. We will not tolerate any form of unlawful discrimination or behaviour that undermines this commitment and is contrary to our equality policy.

3 Safeguarding

3.1 In line with our Safeguarding policy and procedures, LSTM's processes reflect our organisational commitment to keeping children and vulnerable adults safe.

[1] https://www.legislation.gov.uk/ukpga/1986/14/contents

4 Scope

This policy applies to:

4.1 all post-graduate students conducting animal experimentation and/or animal sampling either at LSTM, other sites in the UK or at international collaborative partner sites.

4.2 all research staff conducting animal experiments and/or animal sampling either at LSTM, other sites in the UK or international collaborative partner sites.

4.3 all supervisors and line managers of students or staff directly involved in animal research activities.

5 Definitions

5.1 acronyms which require interpretation:

ASPA:	Animals in Scientific Procedures Act
ASRU:	Animals in Science Regulatory Unit
ARRIVE:	Animal Research Reporting of *in vivo* Experiments
AWERB:	Animal Welfare and Ethics Review Board
NACWO:	Named Animal Care and Welfare Officer
NC3Rs:	National Centre for the Replacement, Refinement and Reduction of Animals in Research
NVS:	Named Veterinary Surgeon
PGR:	Post-Graduate Research (student)
PGT:	Post-Graduate Taught (student)
PREPARE:	Planning Research & Experimental Procedures on Animals: Recommendations for Excellence
RIGC:	Research Integrity Group Committee

6 Responsibilities

6.1 It is the responsibility of managers, research staff and PGR / PGT students who directly use animals in their research, whether conducted at LSTM, at other UK sites or by international collaborators, to be compliant with the LSTM Animal Research policy, UK ASPA legislation and all AWERB review processes.

7 Related documents and resources

7.1 Animals in Scientific Procedures Act 1986

https://www.legislation.gov.uk/ukpga/1986/14/contents

7.2 NC3Rs mission

https://www.nc3rs.org.uk/who-we-are/our-mission

7.3 NC3Rs guidance on choosing contractors for animal research

https://www.nc3rs.org.uk/sites/default/files/documents/Choosing%20contractors%20for%20animal%20research%20-%20expectations%20of%20the%20major%20UK%20public%20funders.pdf

7.4 ASRU guidance for project licence applications

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1107608/Guidance_Notes_for_Project_Licence_Applications.pdf

7.5 Prepare guidelines

https://norecopa.no/prepare

7.6 ARRIVE guidelines

https://arriveguidelines.org/

7.7 AWERB Terms of Reference

https://lstmed.sharepoint.com/committees/AWERB/Pages/Terms-of-Reference.aspx

7.8 Concordat on Openness of Animal Research in the UK

https://concordatopenness.org.uk

7.9 LSTM Research Governance, Integrity & Misconduct Policies

https://lstmed.sharepoint.com/policies/Pages/Dept-Policies.aspx?dept=RGE

8. Regulatory framework for experimental animal use in the UK

8.1 A definition of a regulated procedure which is legislated by ASPA is one undertaken on a protected animal which may cause a level of pain, suffering, distress, or lasting harm equivalent to, or higher than, that caused by inserting a hypodermic needle according to good veterinary practice.

8.2 The legislation describes in detail what animal species and life-stages fall within the act, what is required to undertake research procedures on living animal species, and includes guidance on housing, care, and welfare of the animals, as well as the strict licensing, training and monitoring processes involved in research itself.

8.3 ASPA has a three-level licensing system (for the person, the project and the place):

- Those carrying out regulated procedures must hold a 'personal licence', which authorises them to apply those procedures to specified animals, initially under supervision until they have demonstrated competence.
- The regulated procedures to be carried out must be authorised by a 'project licence' which specifies the programme of work within which the procedures are being performed.
- The place at which the work is carried out must normally be specified in an 'establishment licence'.

8.4 Licences are issued by the UK Home Office, via the Animals in Science Regulatory Unit (ASRU). This legislation requires our institute to allow access to our facilities and our practitioners for audit by Government-appointed ASRU inspectors.

8.5 Certain research activities that our institute may be engaged in which involve animals will fall outside of the ASPA regulatory framework. Examples include tracking, observing, capture and release, and a range of associated studies in domesticated livestock, bred in captivity or wild-caught animal species. Such research is regulated by a wide range of separate legislation including the Animals Act, the Wildlife and Countryside Act, and others. LSTM requires the same standard of welfare and ethics in these projects as expected in experimental laboratory animal biomedical research projects compliant with ASPA.

9. Animal procedures undertaken at international sites

9.1 As opportunities for LSTM-based researchers to partner with international researchers undertaking animal studies have increased, so too has the importance of ensuring that for all LSTM-funded research at international sites, animal welfare standards are appropriate and equivalent to those performed at LSTM or other UK licenced sites.

9.2 International sites include those of contract research organisation (CRO) facilities. LSTM investigators should always select UK-based contractors for full national regulatory alignment, wherever possible. Selection of contractors at international sites should be fully justified and will require our scrutiny of regulatory and welfare standards, as advised by NC3Rs[2] and UK funding agencies.

9.3 LSTM researchers must fully justify the necessity of specific protected species at international sites and be able to provide sufficient details on welfare aligned with UK standards to funding bodies.

9.4 For LSTM-funded research at an international location, following a successful grant award outcome, LSTM will require investigators to submit projects and evidence of 'in country' ethical review and protocols to AWERB to evaluate compliance with our policy.

10. LSTM commitment to Replacement, Refinement and Reduction of animal in research

10.1 LSTM will seek to minimise the use of animals in research whilst continuing to facilitate advances in science, research, and medical knowledge to achieve our mission. Our animal research will apply the principles of the '3Rs' as outlined by the National Centre for 3Rs in Animal Research[3].

11. How LSTM will achieve and monitor expected standards in animal research in the UK and at international sites

[2] https://www.nc3rs.org.uk/sites/default/files/documents/Choosing%20contractors%20for%20animal%20research%20-%20expectations%20of%20the%20major%20UK%20public%20funders.pdf
[3] https://www.nc3rs.org.uk/who-we-are/our-mission

11.1 Our institute will require staff and students involved in animal-based research to treat animals with respect and consideration and to be suitably trained. Obligatory training for UK-based animal research will comprise the ASRU Home Office Personal Individual Licence Course and will be followed by observations and competency training by named experienced practitioners. Our experienced designated trainers will also be supported to gain further vocational level qualifications in animal care and welfare. All staff and students will be required to take a proactive interest in the welfare of animals in their charge, and to ensure that all aspects of their work comply with the regulations set out by ASPA and the Home Office licensing authority.

11.2 Where animal procedures are undertaken in collaboration with international partnering organisations receiving funding from LSTM, we expect similar high standards, sufficient training and alignment with UK regulatory compliance as outlined in (11.1). AWERB will review local ethical permissions and protocols for LSTM-funded research undertaken at international sites. We expect LSTM investigatory teams to undertake further due diligence of standards and compliance of animal welfare aligned to UK legislation once ethical approvals have been granted, including site visits and local training where necessary.

11.3 AWERB will maintain up to date record of projects at international sites where procedural experiments are being undertaken and collate animal use that would otherwise not be captured in UK ASPA metrics.

11.4 LSTM is committed to reduction, replacement, and refinement (3Rs) in all animal-based research; to promoting knowledge of the moral and legal requirements for animal research; and to promoting a culture of care in all aspects of research. We will engage with NC3Rs activities, initiatives and knowledge exchange through workshops, seminars and dissemination via our networks.

11.5 All prospective animal research will be designed to rigorous statistically valid standards aligned with national guidelines including: ASRU project licence guidance documentation[4] and Planning Research & Experimental Procedures on Animals: Recommendations for Excellence (PREPARE)[5] Unless a legitimate reason is ratified

[4] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1107608/Guidance_Notes_for_Project_Licence_Applications.pdf
[5] https://norecopa.no/prepare

with AWERB, we will always use balanced sex ratios in our animal research and test for differences in outcomes between males and females.

11.6 We will encourage engagement and proactively foster 'replacement technologies' via collaboration with acknowledged experts in non-animal technologies, through an exchange of views and promoting the sharing of new ideas and techniques.

11.7 We will similarly actively pursue innovations and promote immediate incorporation of refinements to our animal experiments which avoid, or reduce, substantial or moderately severe levels of pain and suffering

11.8 We will require our researchers to provide accurate and transparent reporting of the use of animals in research, by following national Animal Research Reporting of In Vivo Experiments (ARRIVE 2.0) guidance[6]. Further we will encourage the open access publication of negative data sets and will be transparent on our total institutional animal use.

12. The LSTM Ethical Review Process

12.1 Our internal review process, led by the LSTM Animal Welfare & Ethics Review Board (AWERB)[7], will ensure our institutional animal research policy standards are being upheld.

12.2 The continued role of the LSTM AWERB is to provide strategic direction and leadership to promote awareness of animal welfare issues and to offer advice and guidance on ethical, legal and practical issues concerning the use of protected animals for scientific purposes for LSTM-led research.

12.3 A major responsibility of the AWERB is to evaluate, request amendments or refuse new licensed procedures to be undertaken within the framework of ASPA. The AWERB also has responsibility for the ethical review of new animal procedures of LSTM-funded research to be undertaken at international establishments.

12.4 The LSTM AWERB is chaired and deputy-chaired by experienced academics and also includes a named veterinary surgeon (NVS), experienced senior scientists

[6] https://arriveguidelines.org/
[7] https://lstmed.sharepoint.com/committees/AWERB/Pages/Terms-of-Reference.aspx

who are experts in different fields, a biostatistician (or person with suitable knowledge of biostatistics), a lay person (who has no links to LSTM), named animal care and welfare officers (NACWOs) and any other person the Chair might ask to provide advice.

13. Concordat on Openness on Animal Research

13.1 LSTM agrees to abide with the commitments of the Concordat on Openness on Animal Research in the UK, which has been developed by Understanding Animal Research in collaboration with leading research institutes[8]. The concordat aims to broaden understanding and acceptance of humane animal use in biomedical research, and calls for research institutes to be transparent with the public about all aspects of research conducted using animals.

13.2 As part of The Concordat, LSTM commits to:

- be clear about when, how and why we use animals in research;
- to enhance our communications with the media and the public about our research using animals;
- to be proactive in providing opportunities for the public to find out about research using animals;
- to report on progress annually and share our experiences.

13.3 In enhancing our communications, we will always do so in a sensitive way to protect the anonymity of our researchers who may feel at risk of targeting by animal rights activists. Communications will always be ratified by AWERB and External Relations for sensitive disclosures.

14. Raising Concerns & Escalation Routes when Research Conduct Standards are not met in animal research

14.1 LSTM will uphold the highest standards of research integrity and good research conduct relating to our animal research. Any reported failures by LSTM staff or partnering organisations funded by LSTM to apply ethically approved welfare

[8] https://concordatopenness.org.uk

standards and humane endpoints in animal research will always be taken seriously and appropriately investigated.

14.2 Breaches of approved thresholds of animal welfare and suffering during an animal procedure must be communicated to AWERB and, for UK-based research, will be escalated to ASRU regulator via formal reporting process for independent Inspectorate review.

14.3 We will always be fully compliant with ASRU Inspectors and be responsive to their recommendations following reports of welfare breaches to minimise re-occurrence. This may involve mandated amendments to animal procedure protocols, revocation of specific protocols / licences or re-training of staff to improve competencies.

14.4 With international partner sites, reporting of welfare standards falling below agreed criteria in the ethical review process by local or LSTM personnel will be taken seriously and acted upon by AWERB. Actions may include pausing or revoking ethical approvals of projects pending investigation and reporting to and working with the partnering institute and LSTM investigatory team to make necessary improvements and re-training of specific staff.

14.3 negligence in following ethically acceptable procedures, or gross failure to exercise due care in carrying out responsibilities for animals used in research may be deemed as research misconduct. In such instances, we will follow processes as outlined in our Research Governance, Research Conduct & Integrity Mis-conduct, and Investigations of Allegations of Research Misconduct policies[9].

14.4 Any students under investigation for animal research misconduct will be subject to procedures as set out in the LSTM Quality Manual.

14.5 LSTM seeks to provide a supportive environment for those with research misconduct concerns. Concerns about research misconduct relating to animal research may initially be raised informally in confidence with the Chair of AWERB, the Dean of Research Culture & Integrity or the Research Governance & Integrity Manager. They may also be raised formally as set out in the procedures for the

[9] https://lstmed.sharepoint.com/policies/Pages/Dept-Policies.aspx?dept=RGE

investigation of research misconduct as per LSTM Investigating Allegations of Research Misconduct Policy. Advice about how to raise concerns can be sought from LSTM Research Integrity Champions.

14.6 Colleagues and students also have the option of anonymously raising concerns via LSTM Freedom To Speak Up.

Equality Impact Assessment (EIA) template

(Please refer to the EIA guidance document)

Equality Impact Assessment: Section 1 (to be completed for all Policies)

Title of policy/process:	*Animal Research Policy*
Policy owner job title:	*Chair, AWERB*
Date of EIA:	*15/06/23*
Policy relevant to: Staff / students / visitors etc:	*Staff* *PGR students*
Summary of any consultation with stakeholders (e.g. date and type of consultation):	*RIGC review 31st May 2023*
This policy has been checked for accessibility on: (date)	*15th June 2023*

I confirm that this policy does/does not impact people, and therefore does not require an EIA (delete as appropriate)	**Does not** impact people *(you have finished the exercise, copy this table into your policy and review in line with your policy review cycle)*