

Animal Welfare Ethical Review Board Standard Operating Procedures

The Management and Review of Research and Teaching Activities Involving Animals – (Non ASPA)

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¹ http://www.sussex.ac.uk/staff/research/governance

Purpose

- 1.1 This Standard Operating Procedure (SOP) describes the process for gaining ethical approval from the Animal Welfare and Ethical Review Board (AWERB) to undertake research and engage in teaching activities with animals. This includes the monitoring of accessing animal tissue and products directly obtained from animal sources by the AWERB.
- 1.2 This SOP describes the process for gaining ethical approval for studies that are not covered by the Animal Special Procedures Act (ASPA).

1.0 Introduction

- 2.1 The University of Sussex (US) is committed to delivering 'transformative, high quality education and learning' and through its research seeks to 'nurture and develop research excellence wherever it is found'.
- 2.2 In the UK, research and teaching activities involving animals considered to be sentient are governed by a range of legislation, including the Animals (Scientific Procedures) Act (ASPA), 1986 and, in the case of teaching to veterinary students, the Veterinary Surgeons Act 1966. Compliance of research involving these species is monitored by University staff and by the Home Office through its inspectors.
- 2.3 Some animal research studies, are not covered by the Animals (Scientific Procedures) Act (as amended in 2012), for example because they involve types of animal whose use is not regulated or simple behavioural observations that are not expected to cause harm. In these cases, the Principal Investigator, or Supervisor (in the case of student projects) is still required to apply for approval through the University's AWERB, which considers study design, care and welfare and involves the same group of reviewers who review projects that are covered by the Animals (Scientific Procedures) Act (as amended in 2012).
- 2.3 The University is committed to the principles of reduction, refinement and replacement (the 3Rs); on each project it ensures that the number of animals used is minimised and that procedures, care routines and husbandry are refined to maximise welfare.
- 2.4 The University is committed to the Animal Research: Reporting of In-Vivo Experiments guidelines (ARRIVE), which are intended to improve the reporting of research using animals, to maximise information published and reduce the risk of duplication of studies. ARRIVE guidance is disseminated to staff and students through an online research integrity programme, directly to relevant schools and is blended into learning for postgraduate students.
- 2.5 The University of Sussex is committed to meeting all external ethical and regulatory requirements for research and is a signatory to the Concordat on Openness in Animal Research (COAR), which aims to ensure that the public understand how and why animals are used on its behalf in scientific, medical and veterinary research in the UK.
- 2.6 The requirement for review includes research with animals undertaken by research collaborators on behalf of Sussex led studies, whether in the UK or overseas. The level of ethical scrutiny needed will be considered on a case by case basis. The AWERB may accept review undertaken by another competent body where suitable.
- 2.7 The University is also committed to the development of a number of alternative methods such as computer modelling, tissue culture, cell and molecular biology, and human clinical research. Animal procedures are replaced with non-animal techniques wherever possible. Where the use of animals remains essential, the University of Sussex is committed to a culture of care and respect for animal welfare.

- 2.8 The University seeks to avoid duplicate ethics review by similar internal bodies. Studies that have both animal and human participants can be reviewed by a C-REC or the AWERB with coopted experienced on agreement of the AWERB and relevant C-REC Chair.
- 2.9 Whilst teaching at the University is conducted under a policy involving respect for all forms of life, the use of animal material is considered to be a necessary ingredient in the training of scientists and clinicians, and while this may be supplemented with videos, models and computer simulations, these cannot entirely replace the use of living or killed material. The University is concerned to ensure that any animals used for teaching purposes have been treated humanely, that stress and suffering are avoided, that a minimum number of animals is used, and that students are fully prepared, by previous study, to make the most of the opportunities involving the use of the animals.
- 2.10 Research and teaching also involves undertaking fieldwork, in the UK and overseas to study animals in their natural habitat. The University is committed to ensuring that such work occurs in a sustainable manner, respectful of the fair and equitable sharing of any benefits arising from accessing natural resources with local communities overseas or in the UK.
- 2.11 The University's Code of Practice for Research (CoP (R)) states that 'The University requires that all research involving non-human animals undergoes ethical review regardless of status in relation to the Animals (Scientific Procedures) Act.' (Paragraph 3.3) which serves to protect 'protected animals' which are defined as 'any living vertebrate other than man and any living cephalopod'. This principle also applies (by extension) to teaching activity. This is made explicit in the terms of reference of the AWERB which states that its role is to 'review all aspects of work by the University on animals, promoting best practice with respect to animal welfare and ethical review and ensuring compliance with the Animals (Scientific Procedures) Act 1986 and subsequent legislation.'

2.0 Roles and Responsibilities

2.1 Staff and Students

- Staff and students should treat all animals with respect and consideration and should fully consider the 3Rs when undertaking any animal related activity.
- Staff and students engaged in animal related activity are responsible for ensuring they have the necessary skills, experience and training to carry out this work. They should be aware of, and comply with, the appropriate legislation, codes of conduct and University policies and procedures.
- All animal related activity must be scrutinised through the University AWERB ethical
 and scientific review process before it can commence (as per section 4 below).
 Where licences are required, staff and students are responsible for securing them
 from the relevant authority before any activity is undertaken.

3.3 Establishment Licence Holder (Named Compliance Officer)

- Will ensure that all relevant animal related activities follow the principles of the 3Rs: Replacement, Reduction and Refinement.
- Will ensure that the Animal Welfare and Ethical Review Body (AWERB) is established and that it takes advice from the Named Veterinary Surgeon.
- Will ensure that a system is in place to enable ethics review and to prevent unauthorised procedures.
- Will ensure that those dealing with animals are adequately trained and supervised, that they receive appropriate ongoing training, and have access to any information they need in order to comply with this Policy.

3.4 Named Animal Care and Welfare Officer (NACWO)

• Is responsible for the day-to-day care of animals and ensuring that the highest standards of animal husbandry and care are followed.

3.5 Named Veterinary Surgeon (NVS)

• The Named Veterinary Surgeon Is responsible for advising AWERB on individual research projects, and for providing advice on animal health and welfare.

3.6 **Course module leads**

 Are responsible for ensuring that teaching staff are aware of processes for ethics review for their module

3.7 Animal Welfare and Ethical Review Body (AWERB)

 Ethically reviews applications for ASPA research involving animals including how the applicant implements the 3Rs

- Has oversight of non-ASPA studies
- Monitors annual returns relating to the sourcing of animal derived materials across the University
- Provides a forum for discussion and development of ethical advice on all matters related to animal welfare, care and use at their establishment;
- Supports named persons, and other staff dealing with animals, on animal welfare, ethical issues and provision of appropriate training;
- Helps promote a 'culture of care' within the establishment and, as appropriate, in the wider community

3.7 AWERB Research Group (ARG)

Undertakes review of applications for non-ASPA studies.

3.8 Research Ethics, Integrity and Governance Office (REIGO)

• The REIGO will service the AWERB, ARG and related processes

4.0 Procedure

4.1 Ethical review of research and teaching activity

- 4.1.1 All applications for Non-ASPA research and teaching activity will be reviewed by the NACWO and NVS in the first instance on behalf of the AWERB.
- 4.1.2 The AWERB delegates responsibility for the review of non-ASPA research to the NACWO and NVS. Studies with significant issues may be presented to the AWERB or the ARG for detailed scrutiny.
- 4.1.3 Applicants shall submit the AWERB non-ASPA Project Pro-Forma to the AWERB secretary (awerb@sussex.ac.uk)
- 4.1.4 The following (non-definitive list) indicates the types of teaching activities that should be indicated to the AWERB:
- Field trips involving interaction with or observation of animals (netting, ringing, trapping,
 GPS tracking etc.) or in a way that impacts directly on their habitat and environment
- The use of videos of animals from facilities or laboratories where animal research occurs
- Activities involving the use of animals brought onto campus
- Human-animal interactions off-campus
- Sourcing animals, animal parts (including tissue, blood etc.) for demonstrations or practicals
- 4.1.5 To ascertain the nature of the review required, some studies or activities will need to be outlined by the Principal Investigator of Module Leader through completion of the Non ASPA Pre-Application Form (see appendix C below).
- 4.1.6 The Non ASPA Pre-Application Form may be used to ensure ethical review and approval of similar or related activities across a module. The applicant may be asked to submit Protocols for activities within the module to which all researchers/students working under the Protocols are required to closely follow.

4.2 Oversight of sourcing of animal products for use in research or teaching

4.2.1 The AWERB shall annually review returns from across the University relating to the use of directly animal derived products or materials, reporting on findings to the Research Governance and Quality Assurance Committee.

5.0 Training

5.1 This is a 'read and understand' SOP. Please note that the Research Ethics, Integrity and Governance Team discourages the retention of hard copies of SOPs and can only guarantee that the most up-to-date version is on the University website.

6.0 Abbreviations

3Rs Replacement, reduction and refinement

ARRIVE Animal Research: Reporting of In-Vivo Experiments (guidelines)

ASPA Animals (Scientific Procedures) Act (
AWERB Animal Welfare and Ethical Review Body
COAR Concordat on Openness on Animal Research
C-REC Cross Schools Research Ethics Committee
NACWO Named Animal Care and Welfare Officer

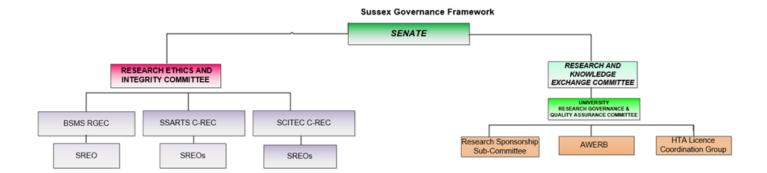
NVS Named Veterinary Surgeon

RSPCA Royal Society for the Prevention of Cruelty to Animals

SOP Standard Operating Procedure UAR Understanding Animal Research

URGQAC University Research Governance and Quality Assurance Committee

US University of Sussex



Key:

AWERB – Animal Welfare and Ethical Review Body BSMS RGEC – Brighton & Sussex Medical School Research Governance and Ethics Committee

C-REC – Cross Schools Research Ethics Committee HTA – Human Tissue Act

SCITEC – Sciences and Technology (Life Sciences; Psychology; Engineering & Informatics; Mathematical & Physical Sciences)
SSARTS – Social Sciences and Arts (Global Studies; The University of Sussex Business School; Education & Social Work; Law, Politics & Sociology; English; History, Art History &

Philosophy; Media, Film & Music

SREO - School Research Ethics Officer

7.0 References and sources of further guidance

RSPCA and LASA,2015,Guiding Principles on Good Practice for Animal Welfare and Ethical Review Bodies. A report by the RSPCA Research Animals Department and LASA Education, Training and Ethics Section. (M.Jennings ed.)

http://www.lasa.co.uk/PDF/AWERB Guiding Principles 2015 final.pdf

Appendix A

Animal Welfare and Ethical Review Body (AWERB)

Key Role

To review all aspects of work by the University on animals, promoting best practice with respect to animal welfare and ethical review and ensuring compliance with the Animals (Scientific Procedures) Act 1986 and subsequent legislation.

Terms of Reference:

- a) to consider all proposed new applications for Project Licences, focusing on the justifications given for the use of animals and the balance between the likely harms to the animals and the expected benefits of the research;
- b) to produce and annually review standard protocols for procedures and husbandry to offer assistance to researchers applying for new Personal and Project Licences;
- c) to approve amendments to existing Project Licences and additional availabilities which have been considered by the Applications Review Group (ARG)
- d) to advise staff on matters related to animal welfare, in relation to animal acquisition, accommodation, care and use;
- e) to promote awareness of animal welfare and the 3Rs (reduction, refinement, and replacement)
- to provide a forum for discussion and development of ethical advice to the establishment licence holder on all matters related to animal welfare, care and use at the University;
- g) to promote the development and uptake of the 3Rs and to ensure that appropriate and up-to-date guidance and information is available wherever necessary;
- to follow the development and outcome of projects carried out at the University, taking into account the effects on the animals used, considering interim and retrospective reviews and assessments of all Project Licences and to continue to apply the 3Rs;
- to ensure that general facilities within the Biomedical Research Facility are satisfactory and that good standards of care and accommodation are achieved;
- to establish and regularly review the Biomedical Research Facility's managerial systems, procedures and operational protocols for monitoring, reporting and followup where these bear on the proper use and welfare of animals;

- to support named persons, and other staff dealing with animals, on animal welfare, ethical issues; to advise on the training requirements of all relevant staff to ensure that they are fully aware of the need to implement the 3Rs and take into account ethical aspects of animal use;
- to advise on re-homing schemes, including appropriate socialisation of the animals to be re-homed;
- m) to review and approve the ethical aspects of research projects that involve animals but do not require a Project Licence under the Animals (Scientific Procedures) Act; the Applications Review Group (ARG) is authorised to approve Non-ASPA applications and to issue the applicant with an AWERB Certificate of Approval in consultation with the Chair of the AWERB;
- n) to help to promote a 'culture of care' within the establishment and, as appropriate, in the wider community, including considering any public relations issues relating to the use of animals by the University;
- o) to consider any matters raised by Project Licensees, or other persons whether internal or external to the University, regarding the use of animals by the University;
- p) to produce a report for each meeting of the University Research Governance and Quality Assurance Committee summarising the work of the Committee;
- q) to respond to enquiries, and consider advice received, from the Animals in Science Committee;
- r) Any annual reports should also be circulated for information to all Project Licence Holders (who should discuss the Report with their staff as appropriate), the Biomedical Research Facility Management Board and the Biomedical Research Facility User Group.
- s) The Committee may delegate to its Chair or any other member, for the purposes of implementing policy in accordance with Statute XVI.3, powers and functions which it is itself competent to perform.

AWERB Composition

Membership

- Establishment Licence Holder
- Named Veterinary Surgeon;
- Named Animal Care & Welfare Officer;
- Two lay members, at least one of whom should have no responsibility under the Act;

- One representative of the Project Licence Holders;
- One representative of the Personal Licence Holders;
- One representative of the Biomedical Research Facility User Forum;
- One representative from the School of Psychology;
- One representative from BSMS.

In attendance

- The local Home Office Inspector;
- Research Governance Officer.

Representative members shall be appointed by the Chair for three years (renewable). Additional members may be co-opted by the Committee for particular meetings or items to ensure an appropriate range of expertise. Project Licence applicants or holders may be invited to attend relevant meetings of the Committee to answer questions about their application or ongoing licence.

Reports to:

University Research Governance and Quality Assurance Committee

Appendix B

Animal Welfare and Ethical Review Body (AWERB) Applications Review Group (ARG)

Key Role

To assist in streamlining the process of considering applications for project licences. The Group comprises approximately two thirds the membership of the full Committee, however any AWERB member may attend an Applications Review Group meeting, should they wish to review licence applications or hear from academics about their work.

Terms of Reference

- a) to consider, by circulation wherever possible, all proposed new applications for Project Licences, significant amendments to Licences, focusing on the justifications given for the use of animals and the balance between the likely harms to the animals and the expected benefits of the research;
- b) The NACWO and NVS are authorised to consider all non-ASPA project applications on behalf of the AWERB ARG unless either the NACWO or NVS deem it necessary to request review and approval by the Group. All approved application to be circulated to the Group for information.
- c) to apply local perspectives, knowledge and expertise to applications, taking account of local policies, facilities, resources and good practices for procedures;
- d) to conduct Project Licence reviews;
- e) to recommend all licence applications, amendments and reviews to the Chair of the Animal Welfare and Ethical Review Body (AWERB) and Establishment Licence Holder
- f) the Applications Review Group is authorised to approve Non-ASPA applications and to issue the applicant with an AWERB Certificate of Approval. Where there are any disputes over the approval of a non-ASPA application, this should be referred to the AWERB for decision.

AWERB ARG Composition

Membership

- Biomedical Research Facility Manager (Chair);
- Named Veterinary Surgeon (AWERB member);
- Two Lay members, at least one of whom should have no responsibility under the Act (AWERB Members);
- One representative of the Personal Licence Holders (AWERB Member);
- One representative from the School of Psychology (AWERB Member);
- One representative from BSMS (AWERB Member);
- Research Governance Officer; (AWERB Member);
- Secretary of Animal Welfare and Ethical Review Body.

The Group shall be quorate if the Chair, a Lay member and either the Named Veterinary Surgeon or representative of the Personal Licence Holders are present. Project Licence applicants or holders may be invited to attend relevant meeting of the Group to answer questions about their application or ongoing licence.

Reports to

Animal Welfare and Ethical Review Body (AWERB)

Appendix C Non-ASPA Pre-Application Form

STRICTLY PRIVATE AND CONFIDENTIAL

NOT FOR FURTHER DISCLOSURE

ANIMAL WELFARE AND ETHICAL REVIEW BODY (AWERB)

PRE-APPLICATION TO DETERMINE FULL ETHICS APPROVAL OF A RESEARCH PROJECT INVOLVING ANIMALS BUT NOT REQUIRING A LICENCE UNDER THE ANIMALS (SCIENTIFIC PROCEDURES) ACT 1986

A core function of the AWERB is to assess the potential harm to animals and balance these against the likely benefits of the research for each project. The AWERB requires information on what will happen to the animals during all stages of the project and what the animals are likely to experience as a result.

This form will help us assess if the project you are intending to undertake is of low or high risk, both in terms of to the animals being used in the research and the regulatory compliance the University upholds.

Please complete this form to the best of your knowledge and send to AWERB (<u>awerb@sussex.ac.uk</u>) and we will reply shortly whether this form is enough for us to grant ethical approval or if a full application is required.

IF YOUR RESEARCH INVOLVES THE STUDY OF ANIMALS REGULATED BY THE ANIMALS (SCIENTIFIC PROCEDURES) ACT 1986 (ASPA) PLEASE DO NOT COMPLETE THIS FORM AND GO DIRECT TO A FULL AWERB APPLICATION

http://www.sussex.ac.uk/staff/research/governance/erp_overview/animals

Name(s) and role(s) of researcher(s):
School of Study:
(For student projects only) Name(s) and role(s) of supervisor(s):
Title of research project or class practical including module code:
Date of application (to be reviewed annually):
Proposed start date and duration of research:
Is the proposed activity for teaching □ or research □?*

(*tick as appropriate)
Is the activity exclusively lab based¹ □/ exclusively field based □/ both lab and field
based□?*
including greenhouses or indoor rooms not described as laboratories
(*tick as appropriate)
Does the activity involve birds □, invertebrates □, fish □, mammals □, reptiles and
amphibians □ ?*
Other (please specify) □:
(*tick as appropriate and go to relevant section)
Is the proposed activity UK based □ or Overseas □?*
(*tick as appropriate)
If working overseas please evidence awareness of relevant legislation or regulations:
Does the activity involve access to resources that fall under the Nagoya Protocol?
https://www.cbd.int/abs/about/
https://www.obd.mgabodg
Yes □ No □
Will the research involve human participants that is subject to C-REC/SREO ethical review
processes?
http://www.sussex.ac.uk/staff/research/governance/erp_overview
Yes □ No □
Activities involving the study of Birds
Activities involving the study of <u>birds</u>
Please list species involved:
Require a wildlife licence (UK research only) https://www.gov.uk/guidance/wildlife-licences
Observation □
Netting □
Ringing □
Radio / GPS tracking □
Other (please specify): □
Activities involving the study of Invertebrates
Please list species involved:
Require a wildlife licence (LIK research only), https://www.gov.uk/guidance/wildlife-licences

Observation □
Live capture and release □
Capture and kept in captivity □
Capture and death □
Other (please specify): □
Carlor (ploade aposity).
Activities involving the study of <u>Fish</u>
Please list species involved:
Require a wildlife licence (UK research only) https://www.gov.uk/guidance/wildlife-licences □
Observation □
Live capture and release □
Capture and kept in captivity □
Capture and death □
·
Other (please specify): □
Activities involving the study of <u>Mammals</u>
Please list species involved:
Require a wildlife licence (UK research only) https://www.gov.uk/guidance/wildlife-licences \square
Field observations □
Camera traps □
Radio / GPS tracking
Small Mammal Trapping □
Capture and kept in captivity □
Bat netting □
Bat ringing □
Other (please specify): □
Activities involving the study of Reptiles and Amphibians
Please list species involved:
Require a wildlife licence https://www.gov.uk/guidance/wildlife-licences □
Observation □
Radio / GPS tracking □
Live capture and release □
Capture and kept in captivity □
Capture and death □
Other (please specify): □

All applications should be completed giving consideration to the ARRIVE guidelines and the NC3Rs experimental design assistant:

https://nc3rs.org.uk/arrive-guidelines

https://www.nc3rs.org.uk/experimental-design-assistant-eda

Appendix D

Non-ASPA Project Application Form

STRICTLY PRIVATE AND CONFIDENTIAL NOT FOR FURTHER DISCLOSURE ANIMAL WELFARE AND ETHICAL REVIEW BODY (AWERB)

APPLICATION FOR THE APPROVAL OF A RESEARCH PROJECT INVOLVING ANIMALS BUT NOT REQUIRING A LICENCE UNDER THE ANIMALS (SCIENTIFIC PROCEDURES)

ACT 1986

Guidance Note.

The University has its own Animal Welfare and Ethical Review Body (AWERB), which is a requirement for all establishments that use animals in research regulated by the Animals (Scientific Procedures) Act 1986 (ASPA). The AWERB reviews all projects involving animals from a local perspective to ensure that animal use is carefully considered and justified, and that the Three Rs of Replacement, Reduction and Refinement are fully implemented.

The AWERB also reviews and approves any proposal for research involving animals that is not regulated by the ASPA. In such cases, the AWERB will need to satisfy itself that such projects are ethically acceptable to the University, that all relevant regulations are complied with (and no procedures are inadvertently conducted without an ASPA licence), and that all potential harms to animals, however mild, are reduced to a minimum.

A core function of the AWERB is to assess the potential harms to the animals and balance these against the likely benefits of the research for each project. To do this, the AWERB requires information on what will happen to the animals during all stages of the project and what the animals are likely to experience as a result. This form has been designed to take all of the above issues into account and facilitate effective communication with the AWERB.

Prior to submission, consultation must take place with the Named Animal Care and Welfare Officer (NACWO) and Named Veterinary Surgeon (NVS). Please contact a.cunningham@sussex.ac.uk

All applications should be completed giving consideration to the ARRIVE guidelines and the NC3Rs experimental design assistant:

https://nc3rs.org.uk/arrive-guidelines

https://www.nc3rs.org.uk/experimental-design-assistant-eda

Nome (a) and value (a) of vaccoushou(a)
Name(s) and role(s) of researcher(s)
(For student projects only) Name(s) and role(s) of supervisor(s)
(For student projects only) Name(s) and role(s) of supervisor(s)
Title of research project
Title of research project
Date of application
Date of application
Proposed start date and duration of research
Detail the grant awarding body and status of grant application
State which, if any, relevant guidelines on animal use you will be following (e.g. Association
for the Study of Animal Behaviour (ASAB), British Society of Animal Science (BSAS),
Canadian Council on Animal Care (CCAC), International Society for Applied Ethology
(ISAE)).
1. To enable us to judge the relevance and value of the aims and objectives of your project
we need to understand the current state of knowledge or product availability on which the
proposed project intends to build.
For research projects: Summarise the current position in your area of work and
explain how this project will help to advance knowledge or meet a clinical need.
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Where applicable, summarise your achievements and previous relevant research.			
Explain the extent to which you achieved the stated objectives of your previous project and list publications or other significant outputs.			
2. We have to carry out a harm-benefit analysis of the programme of work to assess whether			
the harm that would be caused is justified by the expected outcome, taking into account ethical considerations and the expected benefit to human beings, animals or the environment. Please set out the expected benefits of your programme of work; and explain why those benefits will be worthwhile.			
We need to understand:			
What data or product outputs will be generated by your programme of work			
 Who will use those outputs (e.g. your group, other researchers, the pharmaceutical industry, clinicians, patients) 			
 How the outputs will be used (NB benefit might be to screen out) 			
The short-term, medium-term and long-term benefits			
3. Please list the species and number of animals involved (and indicate if any of these species have any special protection / endangered status).			

4. Describe how your project has considered the 3Rs Replacement, Reduction and Refinement:
5. Where will the research be carried out?
6. If your project is to take place in the wild, will the procedures impact upon any other members of their social group, or other species? If so, how will you monitor this and what steps will you take to mitigate any impact?
7. If animals are to be removed from the field, please describe housing and care including diet, group size, composition and (where appropriate) environmental enrichment.
8. What kind of procedures will be involved? For example, simple observational studies, manipulation of the environment, training animals to perform tasks?
9. What physiological and behavioural effects (adverse effects) might these procedures have on the animals? Is there any potential to cause stress, change behaviour in the short or long term or otherwise compromise the animals' fitness or wellbeing?
10. How will you assess the animals' welfare when carrying out these procedures? What signs of anxiety, stress or distress will you be looking for and at what level of distress would you terminate a procedure? (humane end point) Do you have contingency plans in case animals need veterinary treatment or euthanasia?
11. If desired, please provide any closing remarks regarding the ethical aspects of your proposed project.

<i>(For student projects onl</i> y he application.	y) The supervisor	should provide a	brief statement in	support