

Version Date
Applicant to complete version date

PPL No.



APPLICATION FOR A PROJECT LICENCE
UNDER THE ANIMALS (SCIENTIFIC PROCEDURES) ACT 1986

PROJECT TITLE Section 1 (<50 characters including spaces)

A. PROJECT LICENCE HOLDER

Under ASPA 5(2), project licences are granted to the person who has overall responsibility for the programme of work specified in the licence

a. Title (e.g. Professor, Dr, Mr)	<input type="text"/>
b. Surname	<input type="text"/>
c. Forename(s)	<input type="text"/>
d. Qualifications	<input type="text"/>
e. Position or appointment	<input type="text"/>
If you have previously been known by another name, give that name:	
a. Surname	<input type="text"/>
b. Forenames	<input type="text"/>
	<input type="text"/>

CONTACT DETAILS	
a. Address for correspondence <i>This will normally be the address of the establishment where you are working and must be within the UK</i> Post Code	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
b. Telephone number and extension	<input type="text"/>
c. Mobile phone number (optional)	<input type="text"/>
d. Fax number	<input type="text"/>
e. E-mail address	<input type="text"/>

DATE OF BIRTH (dd, mm, yyyy):	<input type="text"/>
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Your relevant knowledge, skills and experience

Give brief details of your knowledge, skills and experience. Indicate your position within your organisation which makes you a suitable person to take responsibility for this programme of work.

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Unless you hold/have held a project licence within the last 5 years, list the relevant modular training (Modules 1, 2, 5) you have completed successfully within the last five years, with dates and enclose copies of the certificates with your application.

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Funding, expertise and other resources

What resources do you have for this project? What expertise, staffing, facilities, equipment and funding are available to you? Has the proposed work been peer-reviewed? If so, by whom?

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Personal licences

Provide the number of your current or previously held ASPA personal licence.

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Project licences

Provide the number(s) and expiry date(s) of your current or previously held (in the last 5 years) ASPA project licence(s).

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Continuation of work

If you are seeking authority in this application to continue work under one or more current ASPA project licences, provide the number of the relevant expiring project licence(s) and expiry date(s).

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Duration of project

Under ASPA 5(7), the maximum allowable duration of a project licence is five years

Specify the duration of licence you require if less than five years

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LIAISON CONTACT (if you have one; this must be someone at your establishment)

a. Name	
b. Telephone number and extension	
c. Fax number	
d. E-mail address	

In your absence, who may we contact if we have any questions about the management of your project?

a. Name	
b. Position held	
c. Telephone number and extension	
d. E-mail address	

B. PLACE(S)

Under ASPA 5(1), a project licence must specify a place or places (so-called 'availabilities') where the regulated procedures will be carried out.

Primary availability

a. PCD number:	
b. Name of designated establishment:	

Additional availability (if any)

If you intend carrying out regulated work at more than one additional designated establishment paste in a copy of this section for each establishment. **You should note that the relevant parts of this application must complete the ethical review process at each additional establishment and that the Certificate Holder at each of these must complete a declaration in Part F (3) of this application.**

a. PCD number:	
b. Name of designated establishment:	

Why do you need this additional availability? Please indicate whether you intend to move animals between establishments during the course of a series of regulated procedures and if so describe the reasons for such transfers.

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Who will be responsible for supervising the work at this additional establishment?

a. Title (e.g. Professor, Dr, Mr, Ms)	
b. Surname	
c. Forename(s)	
d. Address for correspondence <i>This will normally be the address of the establishment where the supervisor is working and must be within the UK</i>	
Post Code	
e. Telephone number and extension	
f. Mobile phone number (optional)	
g. Fax number	
h. E-mail address	

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Places other than a designated establishment (PODEs) (if any)

List any place(s) that is not a designated establishment and where you intend to carry out regulated procedures

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Why do you need to undertake regulated work at this PODE?

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C. SCIENTIFIC BACKGROUND Section 17

Once the licence is granted, you should only need to amend Part C if you are significantly changing your project's purpose.

The total response to this Part must not exceed **2000 words**

Background

<ul style="list-style-type: none">• For research projects: What is the current position in your area of work and how will this project help to advance knowledge or meet a clinical need?• For testing or screening projects: What are the relevant statutory requirements or regulatory guidelines?• For service or production projects: What are the likely demands for the service or product in the lifetime of the licence?• Where applicable, summarise relevant progress under any previous project licence.

Benefits

Under ASPA 5(4), the Department is required to weigh the likely adverse effects on the animals to be used in the programme against the benefit likely to result from the programme to be specified in the licence.

What are the likely benefits of this project? Why are they worthwhile?

TOTAL NUMBER OF WORDS (PART C):
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References

List up to 10 key references and/or regulatory guidelines supporting the need for the work and/or benefits set out above and relevant references for any specific models proposed in your programme of work.

D. PLAN OF WORK Section 18

The total response to this Part must not exceed **2000 words**

For the purposes of this application, a “plan of work” is defined as a series of steps designed to achieve specified scientific purposes.

Purpose

What are you aiming to achieve, find out, establish, or produce by undertaking this project? Express this either as a single programme purpose, or as an overall aim with one or more key elements. The purpose should be specific to this project, unambiguous, realistic and achievable.

Project plan

<ul style="list-style-type: none">• Provide an outline of the stages of the plan of work and indicate clearly, by using the protocol numbers, how each protocol will be used to achieve your objectives. Where it would aid clarity, illustrate the steps of the programme using an annotated flow diagram or process map.• Indicate how in vitro and ex vivo work integrates with the in vivo work, the relationship between each component of the project and the sequence of the work.• In broad terms, what data or products are needed to achieve the purpose of the project?• How will those data or products be generated?

THE 3Rs

Under ASPA 5(5)(a), the Department cannot grant a project licence unless it is satisfied that the purpose of the programme to be specified in the licence cannot be achieved satisfactorily by any other reasonably practicable method not entailing the use of protected animals.

Under ASPA 5(5)(b), the Department cannot grant a project licence unless it is satisfied that the regulated procedures to be used are those which use the minimum number of animals, involve animals with the lowest degree of neurophysiological sensitivity, cause the least pain, suffering, distress or lasting harm, and are most likely to produce satisfactory results.

Replacement <ul style="list-style-type: none">• Why is it not possible to achieve the objectives of your project without using animals?• What alternatives have you considered and why are they not suitable? What alternatives will be used in achieving your objectives?

Reduction

- What measures have been or will be taken to ensure that the minimum number of animals will be used in this project?
- Explain the principles of experimental design you will use and any sources of advice you will consult e.g. on statistics

Refinement

- Explain your choice of species, model(s) and method(s). Explain why they are the most refined for the intended purpose.
- How will you minimise animal suffering in order to achieve your objectives?
- Provide specific justification for any substantial severity protocols

SPECIAL SPECIES

Cats, dogs, primates and equidae

Under ASPA 5(6), a licence cannot authorise the use of cats, dogs, primates or equidae unless no other species is suitable or it is not practicable to obtain animals of another suitable species.

If you intend using cats, dogs, primates or equidae, explain why no other species is either suitable for the purpose or practicably available

Endangered species

Under ASPA 10(3)(c), no vertebrate of an endangered species may be used unless the Department considers an exception justified.

If you intend using an endangered species, explain why no other species is either suitable for the purpose or available

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Animals taken from the wild

Under ASPA 10(3)(d), no protected animal taken from the wild may be used unless the Department considers an exception justified. *Note that animals undergoing work in the wild are not regarded as having been taken from the wild.*

If you intend using wild-caught animals, explain why no other animals are available or suitable for the purpose

USE OF NEUROMUSCULAR BLOCKING AGENTS

Under ASPA 17, neuromuscular blocking agents may only be used if expressly authorised by the personal and project licences under which the relevant regulated procedure is carried out and may not be used instead of an anaesthetic.

If you intend using neuromuscular blocking agents in any part of this project give details of how they will be used and provide justification for their use.

TOTAL NUMBER OF WORDS (PART D):

TRANSFER OF ANIMALS – the following gives authority to transfer animals from a previous project to this project, and/or to export / import rodents, normal and genetically altered, genetically altered zebra fish and genetically altered Xenopus sp. Provided these conditions can be met there is no need to seek prior authorisation for such transfers from the Department of Health, Social Services and Public Safety (DHSSPS)

Authority is hereby given to acquire rodents (including genetically altered animals), genetically altered zebra fish and genetically altered Xenopus sp. from non-designated establishments and transfer animals undergoing regulated procedures under the licence(s) specified at 'Continuation of Work' in part A to this project for continued use in the relevant protocols.

Export of genetically altered rodents, genetically altered zebra fish and genetically altered Xenopus sp
Genetically altered rodents, genetically altered zebra fish and genetically altered Xenopus sp. bred and/or maintained under the authority of this project may be transferred to scientific establishments outside the United Kingdom only if:

1. The transfer will be made to a recognised scientific research establishment with a scientific requirement for genetically altered animals (or their controls) of that type; and where appropriate veterinary care can be provided as necessary; and
2. Sending tissue, gametes or embryos is not practicable or carries a higher potential welfare cost than moving live animals; and
3. Animals will be transported in accordance with all relevant regulations regarding welfare of animals in transit or the import or export of animals; and
4. Animals will be inspected by a competent person before transfer; and
5. A veterinary surgeon will confirm that he/she is not aware of any reason why these animals might suffer by virtue of the fact of being moved to another recognised scientific establishment.
6. Any transport related problems with the welfare of the animals will be notified to the DHSSPS promptly.

Acquisition of rodents (including genetically altered animals) genetically altered zebra fish and genetically altered Xenopus sp. from non-designated establishments

Rodents (including genetically altered animals), genetically altered zebra fish and genetically altered Xenopus sp. may be obtained from recognised scientific and breeding establishments outside the United Kingdom for use under this project licence only if:

1. The purpose for which animals are imported is consistent with the programme of work specified on the schedule; and
2. Attempts have been made to obtain the animals from Designated Sources in the UK but they are not available or animals from Designated Sources in the UK are not suitable for the purpose; and
3. Receiving tissue, gametes or embryos is not practicable or carries a higher potential welfare cost than moving live animals; and
4. Animals are transported in accordance with all relevant regulations regarding welfare of animals in transit or the import or export of animals; and
5. Animals will be inspected by a competent person after transfer
6. Any transport related problems with the welfare of the animals will be notified to the DHSSPS promptly.

Details of each transfer shall be recorded and made available to the DHSSPS on request. These records should contain the information set out in paragraph 4.30 of the DHSSPS guidance, and include the reasons for obtaining animals from non-designated sources.

E. PROTOCOLS Section 19

Under ASPA 5(1), a project licence must authorise the application of specified regulated procedures to animals of specified descriptions.

The term “protocol” is used to describe a single or a series of regulated techniques applied for a particular experimental or other scientific purpose to a protected animal. In most cases a protocol will involve all regulated procedures applied to the animal until the animal is killed or released from the controls of ASPA. Depending on the complexity of your work you may need one or several protocols. Different protocols are usually needed where different types of experimental procedures are to be used to achieve your objective(s). For example a project licence may have a protocol for the breeding and maintenance of genetically altered animals. These animals may then be transferred to another protocol in which, for example, treatments are evaluated in disease models.

ASPA 5(5)b states that: The Department shall not grant a project licence unless it is satisfied that the regulated procedures to be used are those which use the minimum number of animals, involve animals with the lowest degree of neurophysiological sensitivity, cause the least pain, suffering, distress or lasting harm, and are most likely to produce satisfactory results.

To add extra lines to the Summary place the cursor at the end of the line and press ENTER

To add extra protocols copy and paste new protocol sheets into the application. Each protocol should start on a new page.

Summary. Section 19a

Protocol no.	Short title	Species of animals	Estimated numbers over the duration of the project	Severity limit

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PROTOCOL NUMBER. Section 19b :

Title:	
Species of animals (state if genetically altered):	
Severity limit:	

If the animals have been used, bred or surgically prepared under the authority of this or any other project licence, briefly describe what has been done to them and indicate whether the use now proposed represents 'continued-use' or 're-use' - refer to the Home Office Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 and Home Office guidance on Use, Continued Use and Re-use of Animals.

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List each of the steps in this protocol. Note: It is accepted that the order of steps may be varied according to scientific need. Indicate which steps are optional and for each give the anaesthetic code. If appropriate indicate the method of killing, Schedule 1 or non-Schedule 1. Give brief details of non-Schedule 1 methods e.g. perfusion fixation (AC).

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Fate of animals not killed at the end of the protocol

Indicate the proposed fate of animals which are not killed at the end of the protocol.

Continued use in another protocol under this or another project licence - give details below and ensure that you give an appropriate cross reference in the protocol sheet under which the continued use will occur.

Kept alive at the designated establishment. Note that any subsequent re-use must be authorised in the relevant project licence.

Discharge from the controls of the Act at a PODE site – e.g. setting free in the wild.

Other – give details below

Adverse effects

List the likely adverse effects of each of the regulated procedures described above. Indicate how you will manage these effects to minimise severity. There is no need to list uncommon or unlikely adverse effects or effects from procedures that cause no more than transient discomfort and no lasting harm, for example intravenous injection. For each adverse effect indicate:

- the likely incidence
- how the adverse effect will be recognised
- the measures you will take to prevent or control occurrence and severity
- practicable and realistic humane end-points.

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F. DECLARATIONS

1. Declaration by the applicant

I hereby apply for a project licence in respect of the studies described in this application form. To the best of my knowledge and belief all the information I have provided in this application form is correct and complete.

Signature of applicant:

Date:

2. Declaration by the certificate holder at the primary availability

I confirm that this application has completed my establishment's ethical review process.

If licensed, I accept responsibility for ensuring that suitable facilities will be available in accordance with the 'Code of Practice for the Housing and Care of Animals Used in Scientific Procedures'. I am aware of, and will carry out, my responsibilities as set out in the published 'Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 (HC321)'.

Name of PCD holder:

Signature of PCD holder:

Date:

3. Declaration by the certificate holder at the additional availability

I confirm that the relevant parts of this application have completed my establishment's ethical review process.

If licensed, I accept responsibility for ensuring that suitable facilities will be available in accordance with the 'Code of Practice for the Housing and Care of Animals Used in Scientific Procedures'. I am aware of, and will carry out, my responsibilities as set out in the published 'Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 (HC321)'.

Name of PCD holder:

Signature of PCD holder:

Date:

Make further copies of box 3 if you have more than one additional availability. Each additional availability must have a declaration signed by the relevant Certificate Holder.

G: PROJECT ABSTRACT

NOTE: This abstract will not form any part of the licensed programme of work. However, the Department considers the project abstract an essential step towards greater openness and expects them to be provided in every case. Use lay terms and avoid confidential material or anything that would identify you or your place of work. This abstract will be placed on the Home Office website at <http://scienceandresearch.homeoffice.gov.uk/animal-research/>. Examples of other abstracts can be viewed on this site.

NAME OF APPLICANT

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DESIGNATED ESTABLISHMENT

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PROJECT TITLE (Section 1) (<50 characters including spaces)

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In no more than 500 words:

- Summarise your project (1-2 sentences)
- Explain why you are doing this project. Describe the scientific unknown(s) or clinical or service need you are addressing. Give a brief scientific background or other explanation of why the work is needed.
- Outline the general project plan.
- State why you have to use animals and cannot use non-animal alternatives. Where appropriate, say how you will use non-animal studies in parallel with the project.
- Explain how you will ensure that you use the minimum number of animals. Indicate approximately how many animals of each species you propose to use.
- Explain why the protocols and the way they are carried out should involve the least suffering.
- Explain why you chose the particular species of animal.
- Give a brief description of the procedures to be applied to the animals used in this project and describe the expected adverse effects.
- Outline in a few sentences how science will advance, or people or animals will benefit from this project.

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