

PPL Application Process

Step 1:

Consider currency of module 5 training and ASPA knowledge (have you completed the training recently or have you actively managed a recent PPL?). If not discuss with NTCO (emma.kerr@qub.ac.uk) or AWERB chair (awerbchair@qub.ac.uk)

Review current best practice in animal research at <https://www.nc3rs.org.uk/>

Step 2:

Book a slot for review at AWERB meeting by emailing awerbchair@qub.ac.uk. There are six meetings per year in mid October, December, February, April, June and August. Slots are given on a first come first served basis so book early but be realistic about the time commitment required to write a PPL application and do not commit to a meeting that you will not be able to deliver for. It will prevent others from using this slot.

Step 3:

It is **essential** that you have an **early conversation** with NVS re plans (nvs@qub.ac.uk). Your documents will not be reviewed at AWERB unless you have been in touch with the NVS. In preparation for meeting the NVS you should provide a one page document with the research objectives and a list of the procedures to be undertaken sent in advance of the meeting.

Step 4:

Conversation with DoH Inspector (kathy.ryder@health-ni.gov.uk). The Inspector is available to discuss project and licence plans in broad terms and to provide advice. This does not constitute a review of the PPL application. Where diaries allow, it is recommended to meet with Inspector and NVS at the same time. The same document and information is required for both.

Step 5:

Review current SOP list. All procedures should be covered by a valid unit SOP. Review the list of current valid unit SOPs in relation to your work. If an SOP does not exist for any procedures proposed on your licence you should submit a draft SOP for approval by AWERB with your PPL application. For further information contact the Named Information Officer (BSUNamedInformationOfficer@qub.ac.uk)

Step 6:

Review guidance document for preparing PPL (annotated form)

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/670687/Annotated_PPL_v2.0_171221.pdf

It is **really important** that you follow the guidance given in the annotated form linked above so please review each section as you proceed. Key things to look out for:

- a. Objectives should align with the protocols and it should be clear which protocols address which objectives

- b. Plan of work section should describe the basis on which decisions will be taken where several options are available (e.g. delivery method, time points, doses etc)
- c. With the exception of breeding protocols, each protocol should relate to an overall experiment or objective rather than a single procedure, therefore an animal should usually only be subjected to the steps in a single protocol.
- d. Protocols should describe the sequence of steps in an experiment, clearly indicating where they are optional, and not specific details of individual procedures which should instead be in an SOP
- e. Include a single statement to confirm compliance with LASA guidelines and unit SOPs- do not include these as appendices
- f. If there are a range of optional steps- clearly indicate what a typical animal would expect to receive and what the maximum would be
- g. Adverse events should only be those that can reasonably be expected to happen and directly related to the procedures concerned. Assume competence of researchers and indicate the expected frequency of adverse events

Additional resources are available on the DoH website <https://www.health-ni.gov.uk/articles/animal-scientific-procedures-guidance-documents> the Home Office website (including example breeding protocols) <https://www.gov.uk/government/publications/animal-testing-and-research-improve-your-project-licence-application> and <https://nc3rs.org.uk/3rs-advice-project-licence-applicants> including links for advice on experimental design etc.

Step 7:

Submission to AWERB for review with supporting documentation (document submission for AWERB meetings close **3 calendar weeks before the meeting** date).

Supporting documentation required:

- a. If your licence contains procedures not currently performed within QUB please provide details of who the training will be provided by in Part A of application and provide evidence of trainer's credentials and competency
- b. SOPs for any procedures not currently covered in BSU SOP Portfolio

Step 8:

Attendance at AWERB meeting required.

Step 9:

Make changes to PPL required by AWERB and resubmit

Step 10:

AWERB Chair will approve changes and submit application to DoH

Step 11:

DoH will reply within 60 working days of submission. If changes are required a resubmission to DoH will be necessary and this will then take a further period to review.