Home Office

NON-TECHNICAL SUMMARY

Training in advanced or complex procedures or devices

Project duration

5 years 0 months

Project purpose

- (f) Higher education and training

Key words

Training, Endoscopy, Laparoscopy, Robotic, Endovascular

Animal types	Life stages
Pigs	adult

Retrospective assessment

> The Secretary of State has determined that a retrospective assessment of this licence is required, and should be submitted within 6 months of the licence's revocation date.

Reason for retrospective assessment

This may include reasons from previous versions of this licence.

- Education and training licence

Objectives and benefits

Description of the projects objectives, for example the scientific unknowns or clinical or scientific needs it's addressing.

What's the aim of this project?

Education and training of practising surgeons in specific, novel/complex techniques, procedures and devices.

A retrospective assessment of these aims will be due by 20 February 2027

The PPL holder will be required to disclose:

- Is there a plan for this work to continue under another licence?
- Did the project achieve it's aims and if not, why not?

Potential benefits likely to derive from the project, for example how science might be advanced or how humans, animals or the environment might benefit - these could be short-term benefits within the duration of the project or long-term benefits that accrue after the project has finished.

Why is it important to undertake this work?

In a recent report by the UK Shape of Training steering group (https://www.gmc-uk.org/-/media/documents/report-from-the-uk-shape-of-training-steering-group_pdf-79105880.pdf) they acknowledge that:

"...such is the rate of change that elements of the information gained during undergraduate training have been superseded by the time doctors commence work..."

and that "...In the future doctors must be able to adapt to this rate of change by having the flexibility to acquire new skills, change careers and participate in career long learning..."

Also, the second key point in the recent GMC 'shape of training' review states that "We will continue to need doctors who are trained in more specialised areas to meet local patient and workforce needs."

This is particularly true with the continuing development of increasingly complex surgical devices in both the laparoscopic and endoscopic fields and the expansion of the use of robotics in surgical procedures. Given this complexity there is the need for high fidelity training which is currently not possible by simulation alone hence the need for live training prior to use in patients.

How will course attendees use their knowledge or skills in their future careers?

Course attendees will all be currently practising surgeons with an interest in using the devices/ techniques. Upon completion of the course they should be immediately able to transfer the skills gained into human clinical practice.

What are the principal learning outcomes from the course?

To understand how to safely and effectively use novel endoscopic and/or laparoscopic devices and novel methods of energy delivery for cutting, coagulation (stopping bleeding) and/or ablation (destruction of tissue e.g. tumours).

To understand how to safely and effectively use novel endovascular devices (devices designed to navigate and treat the vascular system).

How are these learning outcomes important to the people on the course?

The course will enable the attendees to safely and effectively utilise the new devices/techniques and provide the confidence required for incorporation into their current clinical practice. This in turn could lead to significant cost savings as well as allowing more procedures being carried out minimally invasively and safely.

Who or what will benefit from the transfer of knowledge, or acquisition of skills that this course will deliver?

The skills developed through these training courses should directly benefit patients through improved surgical outcomes, reduced surgery times, reduced recovery times and, in some cases, allow the use of new, less invasive, treatments that may not have been available before.

How will you look to maximise the outputs of this work?

This training programme in the UK are part of the company's developing global training programme. Training under this licence will also form part of the internal 'train the trainers' programme. Training locations at other sites around the world will benefit from refinements and improvements made in UK.

Species and numbers of animals expected to be used

- Pigs: 380

Predicted harms

Typical procedures done to animals, for example injections or surgical procedures, including duration of the experiment and number of procedures.

Explain why you are using these types of animals and your choice of life stages.

Adult pig stomach, colon and abdomen, in terms of the anatomy and size and because of their omnivorous nature, is closest to that of human, making the pig the most appropriate animal to use for laparoscopy and endoscopy.

Whilst the adult pig vasculature is the model of choice for central, abdominal, thoracic and neuro endovascular training.

The pig is also easily induced to, and maintained in, deep general anaesthesia for long durations.

Typically, what will be done to an animal used in your project?

The animals will undergo deep anaesthesia from which the animal is not allowed to recover and will remain insentient throughout.

Then some, or all, of the following techniques will be taught during the live phase of the course, as these have been identified as the most common areas where complications occur during human surgery.

For each animal this will involve inserting instruments through one, or more, of the appropriate routes (e.g. through the abdominal wall, via the anus or the mouth, or through the skin directly into the vascular system.)

For laparoscopic courses this may include stomach, kidney, liver and/or bowel surgery, gall bladder removal, hysterectomy or similar procedures.

For colorectal endoscopic courses, procedures may include a range of new surgical bowel procedures.

For upper GI endoscopic courses procedures may include tonsillectomy, oesophageal, stomach, duodenal or pancreatic surgery, or other new, appropriate procedures.

For Endovascular procedures, vascular access will be gained and a port placed, students will then practice a variety of procedures within the vasculature.

What are the expected impacts and/or adverse effects for the animals during your project?

All procedures under this licence are non-recovery (i.e. the pig is anaesthetised and is not allowed to recover). Therefore, no other impacts or adverse effects are anticipated. In addition, throughout the procedure animals will be provided with fluids (I.V.) and their temperature monitored with warming or cooling applied if/when required.

Where possible/appropriate, procedures will be carried out in accordance with the LASA Guiding principles for preparing for and undertaking aseptic surgery. However, it is not possible to carry out the majority of endoscopic procedures aseptically.

Another potential adverse effect that can occur during endoscopy training is increased intra-abdominal pressure but this can usually be controlled using needle decompression, combined with endoscopic suction.

Expected severity categories and the proportion of animals in each category, per species.

What are the expected severities and the proportion of animals in each category (per animal type)?

Pigs- non-recovery - 100%

What will happen to animals at the end of this project?

- Killed

A retrospective assessment of these predicted harms will be due by 20 February 2027

The PPL holder will be required to disclose:

- What harms were caused to the animals, how severe were those harms and how many animals were affected?

Replacement

State what non-animal alternatives are available in this field, which alternatives you have considered and why they cannot be used for this purpose.

Why do you need to use animals to achieve the aim of your project?

Whilst there have been many improvements in non-animal models and simulations for basic endoscopy and laparoscopy they are still not similar enough to the real experience (working with live tissue). For this reason, training in advanced techniques is especially important when using some of the advanced devices for cutting, removing tissue and stopping bleeding. Temperature, blood flow, tissue reaction and movement are all significant factors that can affect how advanced devices, especially those using energy (e.g. Microwave, radio frequency), are used. None of these factors are currently sufficiently, reproducible in an non-living/simulated model, therefore it is not possible to only use cadavers (either human or animal) for training with such devices.

It is not currently possible to simulate a complete vascular system with enough accuracy to carry out endovascular training.

Why can’t your aim be met by observing or by participating in ongoing research or clinical procedures?

Current clinical/ surgical training is moving away from the current standard of see one, do one, teach one. This is especially true for advanced procedures, where there is still no substitute for actually performing the procedure multiple times under supervision. Also, this is rarely possible in a clinical setting and even when it is, is not often advisable, on the grounds of patient safety.

A retrospective assessment of replacement will be due by 20 February 2027

The PPL holder will be required to disclose:

- What, if any, non-animal alternatives were used or explored after the project started, and is there anything others can learn from your experience?

Reduction

Explain how the numbers of animals for this project were determined. Describe steps that have been taken to reduce animal numbers, and principles used to design studies. Describe practices that are used throughout the project to minimise numbers consistent with scientific objectives, if any. These may include e.g. pilot studies, computer modelling, sharing of tissue and reuse.

How have you estimated the numbers of animals you will use?

The estimate is based on one 2-day course per month using 4-6 animals per course (depending upon the number of students) for 5 years for the endoscopy/laparoscopy.

Plus a series of four, 1-day courses per year using 2 animals per course (depending upon the number of students) for 4 years for the endovascular courses. With the option for more similar courses from other companies as requested.

What in silico or ex vivo techniques will you use during training?

Theory training should be carried out before delegates attend this course. However, there are also endoscopic training boxes/simulators available on the training days that allow individual students, and/or their assistants, to practise on non-living tissue. These can also be used for demonstration purposes.

Will these techniques reduce animal numbers? If so, how?

The training boxes will be an adjunct to the primary, endoscopic training but are not sufficient to replace live animal training and therefore are unlikely to reduce the total number of animals used, however multiple students/ surgical teams use the same animal in order to reduce total animals used.

What other measures will you use to minimise the number of animals you plan to use in your project?

Where possible we will use both the upper and lower gastro-intestinal tract (Colon, Stomach and Oesophagus) and on occasion the abdominal cavity, and maximise the number of procedures carried out in each animal. By doing so, it should reduce overall animal usage.

For endovascular training, by starting at the periphery (i.e. further from the centre where the vessels are smaller), where possible and working back to the central vessels enables more of the vasculature to be used. Also, by getting clinicians to work together: one acting as primary surgeon and another as assistant, with others (if present) observing, and then alternating these roles, students get maximum time on the animal and gain maximum exposure, from different perspectives, of the procedure as a whole.

A retrospective assessment of reduction will be due by 20 February 2027

The PPL holder will be required to disclose:

- How did you minimise the numbers of animals used on your project and is there anything others can learn from your experience?

Refinement

Give examples of the specific measures (e.g., increased monitoring, post-operative care, pain management, training of animals) to be taken, in relation to the procedures, to minimise welfare costs (harms) to the animals. Describe the mechanisms in place to take up emerging refinement techniques during the lifetime of the project.

Which animal models and methods will you use during this project? Explain why these models and methods cause the least pain, suffering, distress, or lasting harm to the animals.

All training will be carried out as a non-recovery procedure under deep terminal anaesthesia and, as such, beyond the initial induction of anaesthesia the animal should not experience any suffering or distress.

Why can’t you use animals that are less sentient?

The pig has been chosen for these courses because surgeons will need to work on an animal that is the same size and general anatomy, and has the same reaction to surgery, as humans and there are no less sentient animals of the same size. However, as the animals are terminally anaesthetised for the duration of the procedure and do not regain consciousness afterwards, their awareness/suffering is reduced as low as possible.

How will you refine the procedures you're using to minimise the welfare costs (harms) for the animals?

All procedures carried out under this licence are non-recovery.

Ensuring good induction, monitoring and maintenance of deep anaesthesia, reducing, as much as possible, any stress prior to the procedure (through acclimatisation, training, etc.), administering fluids (I.V.) and temperature monitoring with warming or cooling applied if/when required, will all help to minimise the suffering the animal is exposed to. Also, any increased intra-abdominal pressure resulting from insufflation can usually be controlled using needle decompression/ venting, combined with endoscopic suction.

At the end of the training the animals will be killed without regaining consciousness.

What published best practice guidance will you follow to ensure experiments are conducted in the most refined way?

Reviews of the current literature and any revisions to the relevant guidelines.

By maintaining contacts with other training centres nationally and internationally and incorporating any appropriate improvements they make to these and similar courses.

I have also been referred to standard, established, well regarded reference books, for up to date anaesthesia advice/techniques.

How will you stay informed about advances in the 3Rs, and implement these advances effectively, during the project?

We will review the current literature. We will have discussions with and input from the local Named Information Officer (NIO), Named Animal Care Welfare Officer (NACWO), Named Veterinary Surgeon (NVS) and other local animal care staff. We will check the Norecopa, NC3Rs and LASA (Laboratory Animal Science Association) and similar animal research and welfare websites. Also by maintaining contacts with other training centres, nationally and internationally, and incorporating any appropriate improvements they make to these and similar courses.

A retrospective assessment of refinement will be due by 20 February 2027

The PPL holder will be required to disclose:

- With the knowledge you have now, could the choice of animals or model(s) used be improved for future work of this kind? During the project, how did you minimise harm to the animals?