Chapter 1
Education and Training for the Personal Licence Holder

Introduction

The use of animals in research in the UK and Europe is controlled by several pieces of legislation, namely Council of Europe Convention ETS 123, EU Directive 2010/63 and the UK Animals (Scientific Procedures) Act 1986. These require that institutions where such research is carried out must have sufficient numbers of suitably trained staff. EU Directive 2010/63 specifies training requirements for four categories of personnel: those carrying out procedures on animals, those designing procedures and projects, those taking care of animals and those killing animals. The framework places clear responsibilities on persons in these roles. These are key functions, and it is imperative that people carrying out these duties are competent, to ensure that animal welfare and scientific integrity are maintained. People intending to carry out these roles must complete appropriate training prior to starting work. In addition, the framework requires that persons carrying out procedures, taking care of animals or killing animals must be supervised until they are competent. The supervisor retains this responsibility until training is completed and the requisite competence demonstrated.

Any person wishing to embark on a career in biomedical research must appreciate that they will become primarily responsible for the welfare of the animals on which they have performed scientific procedures. It is an important part of that responsibility that the procedures are performed competently, causing the least amount of trauma to the animals. It follows that those who are carrying out procedures need to understand the legal and ethical framework under which experiments may be performed, how to handle and take care of animals and how to carry out the procedures. It is important for animal welfare and for good science that procedures are carried out to the highest standards, using the best techniques and equipment available, to minimise animal suffering and maximise scientific output. This is usually achieved by a period of fundamental education and training, followed by a period of practice under supervision, in order to acquire the requisite knowledge, skills and attitudes to become competent.

Those who take responsibility for the direction and control of a programme of work must be able to manage such a programme, taking all opportunities for Reduction, Refinement and Replacement (the three Rs) and encouraging and promoting an appropriate attitude in those working in the programme. Again, specific training may be required for this role, for example in experimental design and project planning, in communication and in team building. They may also be required to communicate
with lay audiences to promote public understanding of science, and training for this may be necessary.

Those who have responsibility for the care of animals must understand the needs of the species they are working with, and know how best to provide for these needs in a laboratory environment.

Those who are just killing animals for tissues must be able to perform the chosen methods of killing swiftly and competently, causing a minimum of distress to the animal and maintaining the carcass such that it is appropriate for use in the subsequent experiment.

In addition, those personnel with responsibility for overall management of facilities must be in a position to maintain the fabric of the establishment and ensure adequate staffing, and put management systems in place for the prevention of unauthorised procedures. They need to develop a culture of care in the institution and must ensure that appropriate training is available for all staff. These people need to be aware of the legal and ethical issues surrounding the use of animals in scientific procedures, and also have training needs. Those acting as named veterinary surgeons or named animal care and welfare officers may also need to undergo specific training for the role.

Education involves the acquisition of relevant knowledge and development of a suitable attitude, whereas training involves the acquisition of manual skills. Both of these are important in the training of those about to embark in a career in biomedical research.

EU Directive 2010/63 states that EU member states should publish guidelines on training requirements based on the following key areas.

(1) National legislation in force relevant to the acquisition, husbandry, care and use of animals for scientific purposes.
(2) Ethics in relation to the human–animal relationship, intrinsic value of life and arguments for and against the use of animals for scientific purposes.
(3) Basic and appropriate species-specific biology in relation to anatomy, physiological features, breeding, genetics and genetic alteration.
(4) Animal behaviour, husbandry and enrichment.
(5) Species-specific methods of handling and procedures, where appropriate.
(6) Animal health management and hygiene.
(7) Recognition of species-specific distress, pain and suffering of most common laboratory species.
(8) Anaesthesia, pain-relieving methods and killing.
(9) Use of humane end points.
(10) Requirement of Replacement, Reduction and Refinement.
(11) Design of procedures and projects, where appropriate.

This list is not exhaustive: additional training in other areas may also be required, and those working with animals in research have a responsibility to determine their individual training needs and ensure that these are met.

Framework for Education and Training of Licence Holders

In 2012 an Expert Working Group (EWG) was set up by the European Commission to develop a common education and training framework for the EU to fulfil the requirements under Directive 2010/63/EU. The EWG defined the fundamental principles, set
the common framework and identified output-driven quality standards for contents. The framework should be implemented through accreditation of training modules, assessment of competence, oversight of the delivery of training and identification of additional training needs. The framework is not binding, and each Member State can interpret whether and how this general guidance is to be implemented. At the time of writing this guidance is under development. The Federation of European Laboratory Animal Science Associations (FELASA)\(^2\) and the Animal Procedures Committee\(^3\) have also published reports detailing recommendations for the education and training of persons involved in animal experiments. The core competencies of these persons have been defined as follows:\(^2\)

- To be aware of European and national laws and guidelines relating to the conduct of experimental or other scientific procedures on animals.
- To be aware of and to respect societal ethics in relation to animal research.
- To understand and respect the general rules of the animal facility, where procedures are carried out.
- To understand the theoretical background of tasks one is expected to do, so as to safeguard animal well-being and ensure the relevance of scientific findings.
- To be competent in handling and other techniques one is expected to carry out.
- To be able to recognise pain and discomfort and to assess the welfare status of animals with which one is working.
- To be aware of the need for, and capable of taking, appropriate action when adverse outcomes occur during or following procedures.
- To be knowledgeable concerning the uses of laboratory animals and be competent to take appropriate measures to minimize interfering factors when a procedure is conducted.

These can be considered to be the core competencies required by those undertaking experiments on animals, and any training programme should address these areas. The reports describe a suitable curriculum for such training, and suggest ways in which competence can be achieved. Learning can be achieved through the provision of a variety of learning opportunities, including lectures, tutorials, discussions, videos and reading, but practical experience is particularly important.

The EWG has identified that the training framework should be flexible, available and accessible, affordable and of agreed quality to ensure competence of staff and facilitate free movement of personnel. Training is divided into individual modules, some of which (termed core modules) are required for staff in all four categories, and others of which are required only for specific functions (termed prerequisite and additional modules). There may be other modules developed to cover issues of national relevance, such as other legislation relevant to the use of animals for scientific purposes, or specialised skills. It is also expected that there will be ongoing lifelong learning, and researchers will be expected to keep up to date with new developments, such as new techniques, and advances in the three Rs. Institutions will be expected to have a training officer, whose role will be to ensure that staff are educated, competent and continuously trained.

For each module, the framework details the desired learning outcomes, and the theoretical knowledge and practical skills to be obtained, define how the module should be assessed and identify pass/fail criteria. The focus for training will be the development of competence: passing the required modules for a task should indicate that the individual has attained a level of learning appropriate for the performance of the task, but competence will be attained only after a period of supervision following initial training.
Some of the training modules are specific to a species or group of species, and initial training may need to be completed fully for one or more species or groups. Extension of training to add further species will require demonstration of attainment of learning outcomes for the new species, but may not always require all the elements of the initial training module for the new species to be completed, as there may be common elements which do not need to be repeated. Full details of the requirements can be found on the UK Home Office website (www.homeoffice.gov.uk).

Core modules

Modules to be completed by personnel in all four categories include:

- national legislation relevant to animal care and use,
- ethics, animal welfare and the three Rs,
- basic species-specific biology (including routine animal husbandry and enrichment practices),
- animal care, health and management,
- recognition of species-specific pain, suffering and distress including humane end points,
- humane methods of killing (theory).

Prerequisite and additional modules

Modules to be completed by personnel according to their function and individual needs include:

- more detailed consideration of ethics, animal welfare and the three Rs,
- detailed animal husbandry, care and enrichment practices,
- animal handling methods,
- minor procedures,
- anaesthesia and analgesia,
- humane methods of killing (skills),
- invasive techniques including surgery,
- design of procedures and projects.

Education and training in the UK

Since 1994 in the UK, applicants for personal licences allowing them to carry out scientific procedures on animals have been required to complete a training programme, accredited by a recognised body according to a syllabus set by the Home Office. The Society of Biology, the Scottish Accreditation Board and the Universities Accreditation Scheme are currently recognised by the Home Office for this purpose.

Aims of Accredited Training

When learning any new skill there is an initial period of unconscious incompetence, during which the person is not aware of the skills required to carry out the new task, and may not be aware that they have a deficiency in this area. This is followed by conscious incompetence, when the person becomes aware of their deficiency and makes a commitment to learn and practise the new skill. They then move to the
consciously competence stage, when they can perform it reliably at will but need to concentrate and think in order to perform the skill. Finally, they reach the stage of unconscious competence, when the skill becomes so practised that it becomes second nature. The person might then be able to supervise and teach others.

It is not expected that anyone completing accredited training will immediately demonstrate a high level of competence in the skill areas identified above. The person must become conscious of their incompetence before development of the new skill or learning can begin, and the aim of accredited training is simply to move the person into the conscious incompetence stage, so that they become aware of the range of skills they need to develop to become competent. The object of mandatory training courses is therefore to establish a sound foundation upon which competence can be effectively built, and a period of on-the-job training under the supervision of someone already expert and up to date in the field will be required subsequently until practical competence is achieved. New researchers should take an active role in their training, and liaise closely with their supervisors to devise a personal development plan, to ensure that they receive the support required to become competent.

Continuing Professional Development and Reflective Practice

New researchers are ‘loaded up’ with the requisite knowledge regarding the biological and behavioural needs of animals. It is impressed upon them that they have a personal responsibility to implement the three Rs. They are shown how to carry out procedures correctly and told where to seek guidance. However, techniques and methods are constantly improving and, in order to keep up to date, the experimenter needs to reflect on their own actions and actively seek improved methods. Training is often approached like a battery—charging students up with knowledge, which they discharge when they enter the world of practice—it yet this is quite inappropriate in a fast-changing world. EU Directive 2010/63 requires that personnel are ‘educated, competent and continuously trained’, introducing a requirement for personnel to undergo continuing professional development (CPD). Experimenters may leave their training sessions with the latest information, but unless this is accompanied by an acceptance that this knowledge is likely to be superseded, and the drive to seek actively for up-to-date information, they will not identify and implement refinements as they develop.

Training programmes should encourage participants to reflect on their actions, and to consider how they can improve their techniques to improve both animal welfare and the quality of science. CPD is now a requirement for biomedical scientists. New researchers therefore need to be trained in factual knowledge and practical skills at the start of their careers, but then need to implement reflective practice, where they become self-critical and actively seek the advice of others, to determine their own ongoing CPD needs. Supporting this reflective practice is an important role for the supervisor.

Summary

Becoming a biomedical researcher carries with it a responsibility for learning a set of new skills. This is accomplished by foundation training followed by period of supervision until competence is achieved. This needs to be backed up by a commitment
to ongoing reflective practice and CPD to ensure that skills continue to develop, to maintain animal welfare. A person should only become a researcher if they are prepared to accept the responsibilities that come with the job.

References