

Ethics training for licensees under the Animals (Scientific Procedures) Act 1986

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Summary

This is a report of the first year of a project designed to develop resources to support ethics training for personal and project licensees under the Animals (Scientific Procedures) Act 1986 (ASPA), and, in particular, to take forward the recommendations of a Laboratory Animals Science Association (LASA) workshop held in December 1997. The Workshop concluded that there are needs:

- (i) to develop syllabuses for ethics training for licensees, incorporating lists of topics and an indication of their priorities;
- (ii) to collate existing resources for ethics training, where necessary develop new ones, and make all these resources widely available; and
- (iii) to consider the expected outcomes of ethics training and how best to assess whether these have been achieved.

(See report by Jennings and Hawkins 1998).

Before any such resources could be developed or evaluated, it was important to establish a clear idea of what ethics training has to achieve. To do this, information was needed about the 'starting points' of licensees when coming for training. In addition, more information was needed about how trainers currently tackle ethics in Modules 1 and 5, and what kinds of additional support might be helpful.

This report, therefore, addresses the following questions:

- (i) what relevant experiences, attitudes, knowledge and understanding of ethics do potential licensees bring with them to Module 1 and Module 5 training, and what, therefore, are the gaps or needs that the ethics component of training has to address?
- (ii) what currently is provided on ethics in Module 1 and 5 courses accredited by the Institute of Biology (IOB) and/or the Universities Accreditation Scheme, and how far does current provision meet the needs identified?

Information in the report is based on the findings of two surveys regarding these questions, together with discussions with trainers and others with an interest (both informally and at LASA workshops held in 1994, 1997 and 1999). The report makes practical recommendations on strategic issues to be considered in developing guidance on ethics training for licensees. Although the focus is on the ethics component, some, at least, of these recommendations apply to licensee training more generally. The report's conclusions have been developed through continuing discussions with, and between, trainers themselves. Moreover, ideas on ethics training are likely to continue to evolve, in particular because

people's needs for training may change as a result of experience with the Ethical Review Process (ERP), and as successive 'generations' of licensees participate in training.

Key points from the report are that:

1. There is widespread agreement amongst trainers on what ethics training should aim to achieve for potential licensees, i.e. that, broadly speaking, ethics training should:
 - a) **Impart knowledge** - so that licensees gain some understanding of what ethics means; of the ethical framework of ASPA; and of the ERP; as well as of alternative positions and perspectives on animal use.
 - b) **Raise awareness** - to enable licensees to identify ethical questions and issues arising in their work, and to think as widely as possible about these issues, recognising that they are not simply matters of personal opinion.
 - c) **Help thinking** - so as to begin to develop licensees' skills in applying the ethical framework of ASPA, helping them to make and constructively criticise ethical decisions about their own and others' work.
 - d) **Influence practice** - so that licensees are encouraged to
 - show positive, proactive concern for animal welfare, as well as for science;
 - engage in continuous, on-going ethical review of projects and procedures;
 - accept individual responsibility and accountability for animal use; and
 - have sufficient confidence to raise concerns with others, such as project licence holders, Named people and/or Certificate Holders as appropriate, and take action where necessary.
2. The surveys of prospective licensees' backgrounds and understanding of ethics in relation to animal use support these conclusions, showing clear needs for ethics training to:
 - include clear, factual information on ASPA's ethical framework and the ethical duties and responsibilities it demands of licensees;
 - cover the requirements of the ethical review process, particularly with respect to *local* arrangements;

- expose potential licensees to a range of different ethical perspectives on laboratory animal use, and encourage them to consider seriously arguments which challenge their own thinking - recognising that there is more to contemporary debate on animal use than a clash of irreconcilable, polarised positions; and
 - assist participants in adopting a critical perspective on *their own* use of animals - to think more widely about their own research and how far the use of animals is justified.
3. To achieve these practical goals, ethics training needs to be practically orientated. Whilst course participants seem to find the ethics component of training interesting, they can find it hard to relate ethical theory to their own work in practice (see also point 4). Course organisers agree that licensees need practical tools to enable them to identify, think through and take action on ethical aspects of their own work. But philosophical lectures on ethics *per se*, for example, will not address such practical ethical issues; and debates on how to ‘counter’ anti-vivisectionist claims encourage a defensive position. In contrast, many trainers are using brief scene-setting talks, along with structured discussions (stimulated by questionnaires, and/or case material for example) to explore how licensees personally will respond to the ethical issues raised in the course of their work (see also point 5). The latter approach should be encouraged by the accreditation bodies and Home Office.
 4. The ethics component should encourage licensees to focus on the issues *they themselves* will have to deal with. In providing training, it is important to have at least basic information about the backgrounds and future work of people coming to courses, and then to ensure that, as far as possible, sessions draw on individual experiences, and raise issues relevant to participants’ own work.
 5. The ethics component of modular training offers licensees an important, and, for some apparently unique, opportunity to meet with others to explore different perspectives and consider practical responses to ethical issues in animal use. To be productive, such discussion requires adequate time. In practice, opportunities for discussion, and time allocated to the ethics component vary considerably from course to course, and there may be a need for more prescription on these aspects from the accreditation bodies.
 6. In ethics, as in other aspects of the Modules, there is a need for training to be geared to *local* practice, since arrangements (e.g. for the ERP) can vary widely between establishments. Where licensees attend training away from their places of work, there

remains a need for 'home' establishments to ensure that potential licence holders fully understand local procedures.

7. Consideration should be given to amending Home Office guidance, to promote more in-depth treatment of the topic in *all* Module 1 courses - including consideration of different perspectives and sensitive treatment of views which might influence or challenge licensees' own thinking. By Module 5, potential project licence holders feel that they need to get a licence and get on with the work, and tend to see ethics training mainly as a means of achieving this end. In contrast, Module 1 participants hope more that the ethics component will make a practical difference in their day-to-day work - and, perhaps, are more likely to be influenced by training. Furthermore, Module 5 is attended only by people sufficiently senior to manage projects, whereas Module 1 should be attended by *all* licensees - including the project licence holders of the future.
8. Acknowledging that gaining a licence is a major motivation of people attending Module 5 training could lead to a radical re-working of the philosophy and design of the module. This need not involve any compromise in achieving the goals identified for (ethics) training, but should be geared towards making (ethics) training feel more *practically* useful for potential licensees. In particular, there is a need for more integration of ethics with other aspects of training, particularly in Module 5, and also, perhaps, in Module 1.
9. A possible approach is to tie together all the different components of training, including ethics, into a common practical theme (such as preparing a project licence application, and/or considering the workings of the ERP), and having specialists in ethics, as well as other aspects (such as alternatives, statistics, veterinary advice) on hand *throughout* the course to address issues as they arise. This is done to good effect in one current Module 5 course. It is possible that the approach could be adapted with small groups of participants, to focus on applicants' own work, and to provide a series of individual 'clinics' with the specialists throughout the day.
10. Consideration should be given to developing means of more formally assessing the ethics component of Module 1 as well as Module 5. Competence in recognising and responding appropriately to ethical issues is an important part of the overall competence of licensees, and should be open to formal assessment. Medical ethics trainers have validated methods for assessing medical students' 'ethics competence', and similar methods may be appropriate in licensee training.

11. Participants at the 1999 LASA workshop agreed that they would like to pool their ideas, share resources and perhaps visit one another's courses in order to learn more about possible approaches. With the support of trainers, we are now gathering together resources currently used in ethics training, and will make these more widely available; and we are also considering possibilities for developing new resources, as required.



1. Introduction

This is a report of the first year of a project designed to develop resources to support ethics training for personal and project licensees under ASPA and, in particular, to take forward the recommendations of a LASA workshop held in December 1997.

2. Background to the project

Home Office guidance requires that mandatory training for prospective personal licensees and project licence holders under ASPA includes consideration of ‘ethical aspects’ of the use of living animals.

It is agreed amongst trainers and others with an interest that ethics is an essential part of licensee training, and that it pervades all aspects of training. This is because:

- (i) ethics concerns the essential spirit of the legislation - the moral assumptions, or ethical framework, from which all the legislative provisions follow; and
- (ii) almost all aspects of licensee training require participants to consider ethical questions about how animals ought and ought not to be treated.

Nevertheless, in spite of broad agreement on the importance of ethics training for licensees, there is still little published guidance on how this component of training should be tackled in practice. The Home Office statement of policy on licensee training (Home Office 1993) states merely that ethical aspects must be addressed, and the two licensee training accreditation bodies provide only brief advice on this subject for course organisers (Box 1).

The broad goals of ethics training were discussed, and agreed, at LASA workshops held in 1994 and 1997, but debate continues about the best means of achieving these goals. The 1994 workshop resulted in a series of brief statements on aims and methods in ethics teaching (LASA 1995). The 1997 workshop agreed more detailed goals of ethics training, looked at the range of potential ‘audiences’ for such training, suggested possible elements of a syllabus, and considered practical aspects of delivery (e.g. position of ethics in the course, speakers, facilities, resources and means of assessment of the ethics component). However, a number of important aspects remained unclear or in need of further work, and the following series of actions points was suggested (Jennings and Hawkins, 1998):

BOX 1: Home Office and accreditation body advice on ethics training for licensees

Home Office Statement of Policy (1993):

Module 1 should include “an introduction to ethical aspects of the use of live animals in scientific procedures”; and

Module 5 should include consideration of “ethical aspects of the use of live animals”.

Since 1 April 1994, all applicants for **personal licences** must successfully complete Module 1 (and also Modules 2 and 3); and

since 1 April 1995, all new applicants for **project licences** must successfully complete Modules 1 and 5 (also Modules 2, 3 and 4 where appropriate).

Institute of Biology Accreditation Scheme (1998)

“The specialised skills and responsibilities of individuals working under the Act vary considerably. The IOB does not therefore publish a standard syllabus and it is the course organiser’s responsibility to ensure that the training programme meets the needs of individual participants, as well as fulfilling the requirements of the Act.”

Module 1: There “should be discussion on the historical background of the use of animals in research, the legislation and attitudes to animals and animal welfare in the UK. Trainers should aim to instil a sense of personal responsibility, as well as a working knowledge of relevant legislation.... There should be some discussion on the ethical debate on the use of animals for scientific purposes, including Reduction, Refinement and Replacement. Course organisers should attempt to present the debate from more than one perspective, recognise that the selective use of information is not limited to one side only, and encourage respect for differing opinions. Participants should be introduced to the concept of good experimental design as an efficient, scientifically valid and ethical approach to research...”

Module 5: “How the ethical aspects are covered will depend on what exposure the trainees have already had to the ethical debate. Module 1 should have presented to trainees the foundations of ethical debate and an opportunity to discuss the issues. Therefore it is recommended that module five should be more concerned with the practical application of ethics.” (e.g. the rationale for studies, cost-benefit analysis, appraisal of the 3Rs, estimation of severity, assessment of pain, suffering and distress). “Attitudes in other countries towards the use of animals should also be discussed, particularly if licensees will be working with visiting foreign researchers.”

Universities Accreditation Scheme

Requires ‘due consideration’ to be given to the ethics component, but nothing is laid down on how ethics should be taught, and course organisers are allowed flexibility in their approach to the subject.

Nevertheless, organisers of courses accredited by the Universities Scheme have regular discussion meetings, and have used at least one of these to explore approaches to ethics training.

- (i) develop detailed syllabuses for ethics training in Modules 1 and 5, incorporating lists of topics and an indication of their priorities;
- (ii) collate existing resources for ethics training, where necessary develop new ones, and make all these resources widely available;
- (iii) consider the expected outcomes of ethics training and how best to assess whether these have been achieved; and
- (iv) consider the extension of formal ethics training to Certificate Holders, Named Veterinary Surgeons (NVS), Named Animal Care and Welfare Officers (NACWO), and those working under Schedule 1, as well as other participants in the ethical review process.

The last recommendation is currently being progressed, for all groups, in a variety of other forums and is therefore not considered further here.

The aim of the present project is to take forward recommendations (i) to (iii), working together with key people and organisations already involved in each area. A complementary aim of the full project is to consider and develop resources to support the work of lay members of ERPs, but this aspect is not reported here.

3. Objectives and methods in the first year of the project

As we began to think about the action points listed above, we realised that we could not begin work on syllabuses or resources for ethics training until we had a clear idea of what this aspect of training needs to achieve. What, if any, changes in potential licensees' knowledge, understanding, thinking and practice, for example, should ethics training attempt to bring about? The answer to this question depends on potential licensees' starting points when coming for training. What relevant experiences, attitudes, knowledge and understanding do participants bring with them to training, and what, therefore, are the particular gaps or needs that ethics training has to address? These questions needed to be considered before the LASA workshop recommendations could be progressed. Furthermore, in order to evaluate whether and how such training needs are being met at present, more information was needed about what is currently provided on ethics in Modules 1 and 5.

The first year of the project, therefore, was devoted mainly to gathering information, and then considering broad strategy in delivering the ethics component of training. In particular, we:

- (i) contacted Module 1 and Module 5 course organisers, and visited a variety of Module 5 courses, to gather information on what is actually provided in the ethics components of Modules 1 and 5, whether and how assessments are made, and trainers' comments on what currently is done. The findings are reported in Appendix 1;
- (ii) attempted to assess prospective licensees' knowledge and attitudes towards ethical issues in laboratory animal use, and their views on ethics training, by means of questionnaires. The surveys themselves are described in Box 2, and licensees' responses are reported below; and
- (iii) organised a LASA Workshop in December 1999, to discuss these findings with course organisers and other interested people.

BOX 2: Surveys of potential licensees

- 120 participants on Module 1 courses and 130 participants on Module 5 courses responded to our questionnaires, prior to starting their courses.
- Questions were asked about potential licensees' notions of their future ethical responsibilities, their previous opportunities for consideration of the ethics of animal use, how important they considered ethics training, and what they hoped to gain from it.
- The courses took place between late 1998 and autumn 1999. They were mainly those of the two major commercial providers (which take on a wide range of potential licensees) but also included two courses in universities, and two in industry.

- Respondents came from the following kinds of establishment:

	MODULE 5		MODULE 1	
	N	%	N	%
Universities	72	55	52	43
Research institutes	29	22	42	35
Commercial organisations	27	21	23	19
Other (mainly hospitals)	2	2	3	2
TOTAL	130		120	

- 33% of the Module 5 delegates were already project licence holders or deputies; and (of a sub-sample questioned) 78% had held personal licensees for between 2 and '33' years. 11% of the Module 1 delegates were already personal licensees.
- In both surveys participants were working on a wide range of projects, mainly, though not exclusively, related to human health, and were using (or intending to use) a wide range of species.

The aims in what follows are to:

- (i) describe the findings of our surveys, which have influenced our thinking on how the ethics component of training in the courses might be approached;
- (ii) make the findings available to course organisers, the accreditation bodies, the Animal Procedures Committee (APC) sub-committee on education and training, and others with an interest; and
- (iii) recommend strategic points in developing further guidance on ethics training for licensees.

Our future objectives, to complete the project, are to:

- (i) further consider syllabuses and means of assessment of the ethics component of licensee training, and
- (ii) collate, develop and disseminate resources to support ethics training.

4. Findings and conclusions

As suggested above, the conclusions drawn here are not ours alone, but have been developed through continuing discussions with, and between, trainers themselves. Moreover, ideas on ethics training are likely to continue to evolve, in particular because people's needs for training may change as a result of experience with the ERP, and as successive generations of licensees participate in training.

4.1 Trainers' views on the aims and importance of ethics training for licensees

Aims of ethics training for licensees have been agreed by trainers in a variety of different forums (see for example, LASA 1994; Smith and Jennings 1998; and Jennings and Hawkins 1998; also Hynes *pers. comm*). The aims are similar to those widely agreed for medical ethics training (see Boyd 1987, Hope and Fulford 1994, for example), and can be expressed in similar style to the goals described for medical ethics education by Hope *et al.* (1996):

- (i) **Impart knowledge** - so that licensees gain some understanding of what ethics means; of the ethical framework of ASPA; and of the ERP; as well as of alternative positions and perspectives on animal use.

- (ii) **Raise awareness** - to enable licensees to identify ethical questions and issues arising in their work, and to think as widely as possible about these issues, recognising that they are not simply matters of personal opinion.
- (iii) **Help thinking** - so as to begin to develop licensees' skills in applying the ethical framework of ASPA, helping them to make and constructively criticise ethical decisions about their own and others' work.
- (iv) **Influence practice** - so that licensees are encouraged to
 - show positive, proactive concern for animal welfare, as well as for science;
 - engage in continuous, on-going ethical review of projects and procedures;
 - accept individual responsibility and accountability for animal use; and
 - have sufficient confidence to raise concerns with others, such as project licence holders, Named people and/or Certificate Holders as appropriate, and take action where necessary.

All four of these aims could apply to many other aspects of licensee training, though the details under each general heading will differ.

The course organisers we asked all regarded ethics as a very important, or essential, part of their courses. Furthermore, ethical aspects will be important throughout licensee training and consideration of them need not be confined to a discrete ethics slot (see also point 4.7 below).

4.2 Participants' views on the aims and importance of ethics training

Like the course organisers, people coming for training considered ethical aspects to be an important part of both Module 1 and Module 5. Ninety-two per cent of participants in both Modules thought that training in ethics would be 'important' or 'very important'. In common with trainers, course participants said that the value of ethics education lay in:

- broadening perspectives, raising awareness, making or helping people think; and/or
- ensuring good outcomes, e.g. promoting animal welfare, ensuring that harms to animals are 'weighed' against benefits.

These two aspects were mentioned roughly equally, with some people mentioning both. See Appendix 2 for examples of comments. Interestingly, however, when people attending modular courses were asked what they, *personally*, hoped to gain from ethics training, they expressed somewhat different perspectives (Box 3 overleaf):

- The most frequent hoped-for gain from ethics training was *factual knowledge* - of legal and/or ethical responsibilities, and associated rules and guidelines.
- For potential project licence holders the drive to gain a licence was clearly evident in a majority of the replies. One third of Module 5 participants specifically mentioned that, for them, the main hoped-for gain from the ethics component would be their licence. Where gains in knowledge were mentioned, these were also often in the context of writing a licence application. In contrast, potential personal licensees only rarely mentioned that training would help them to gain a licence. Far more prospective personal licensees than prospective project licence holders expressed a hope that ethics training would help them in practical animal management and improving animal welfare. Given the different roles of project and personal licensees, these responses would not be particularly surprising as perspectives on training *generally*, but the contrast between the responses seems more noteworthy given that they are what the different groups said they hoped to gain from *ethics* training.
- In both groups around a quarter of replies hoped for greater awareness of the issues, including alternative perspectives, other ideas, public/societal perceptions and similar.
- 10% of Module 1 and 20% of Module 5 participants replied that they hoped that the ethics section would help them in their own thinking about ethical issues and/or challenge them in some way; and around 1 in 8 of the replies were very general - wanting, for example, an ‘overview’, or an ‘update’ on ethical issues.

4.3 Variation in provision of ethics training for licensees

The way in which ethical issues are addressed during licensee training varies considerably between courses (Appendix 1). For example, both Module 1 and Module 5 courses vary in:

BOX 3: What participants in Modules 1 and 5 said they hoped to gain from ethics training

	% Module 5 replies	% Module 1 replies
General ‘overview’/ ‘update’ on issues	13	12
Knowledge/understanding of responsibilities/rules/ guidelines etc	39	43
Greater awareness of/ broader perspective on issues	25	24
Help in my own thinking	20	10
Practical benefits for animal welfare	6	29
‘A licence’	33	6

- the time allocated to the ethics component;
- provision of opportunities for discussion;
- resources used, and type of speaker;
- broadness of perspective offered;
- encouragement for licensees to question their own work;
- degree of integration of ethics with the rest of the course; and
- whether and, if so, how the ethics component is assessed.

This variation is not surprising, since courses take place in diverse kinds of establishment, and are aimed at a variety of different kinds of potential licensee. Establishments vary in size, in the kinds of work they are involved in, and in their management structures; and licensees vary in seniority and experience, the type of work they are proposing or carrying out, and their roles within the establishments (e.g.

postdoctoral personal licensee, NACWO personal licensee, professorial project licence holder, contract testing study director project licence holder, etc.)

As a result, there is unlikely to be a single blue-print for success in providing ethics training. But, nevertheless, it is clear that there are practical, strategic considerations that can impact on the success of ethics training and which are likely to be generally applicable. These considerations are explored below.

4.4 Licensees' backgrounds and possible needs for information and ideas on ethical aspects

It is clear that achieving the goals of raising awareness of ethical issues, helping licensees to think about the issues, and, hopefully, influencing practice, requires that potential licensees share certain key knowledge and understanding, on which to base their thinking. However, this is not to say that ethics education should be prescriptive. Moreover, such information can be gained through interactive discussion with, and between, course participants, and need not be imparted in didactic fashion.

In our surveys of people coming for training, we enquired about participants' knowledge of their future ethical responsibilities and any previous opportunities they had had for considering ethical issues. The findings provide evidence to support the conclusions of the 1997 LASA workshop, and our previous paper, on what broad aspects should be covered in the ethics component of training (Jennings and Hawkins 1998, pp. 447 and 453; Smith and Jennings 1998).

4.4.1 *Potential licensees' knowledge of future ethical responsibilities, prior to attending training*

In our surveys, less than half (40%) of the sample of people coming to Module 5 courses expressed a comprehensive grasp of their future ethical responsibilities (including ideas relating both to animal harm and to human benefits) prior to undertaking training. Although many of the answers were impressively comprehensive and thoughtful, there was wide variation in expressed knowledge and understanding of ethical responsibilities. Furthermore, whilst over two-thirds (70%) of Module 1 respondents emphasised their responsibilities towards animal welfare, far fewer mentioned broader ideas relating to the need to use animals at all. (See Box 4 below; and also Appendix 3 for further details and examples).

BOX 4: Module 1 and Module 5 participants' ideas on their future ethical responsibilities

Module 5

40% of those replying to this question said that they would have duties both to animals and to science, whilst 29% mentioned duties towards animal welfare, but not in relation to the benefits or necessity of their work. 6% noted duties only towards the science - to ensure there were benefits from animal use. A quarter of all respondents described a responsibility to consider replacement, reduction or refinement alternatives (not necessarily using this particular terminology).

Module 1

70% of people replying to this question mentioned responsibilities to care for the animals' welfare. Far fewer (16%) said that they should consider the benefits/necessity of the work itself, and fewer still (6%) mentioned consideration of alternatives (again, broadly defined)

As already noted, in both groups, around 40% specifically listed knowledge of their ethical responsibilities, and/or of ASPA's ethical rules and guidelines, as something they hoped to gain from training in ethics (Box 3). However, surveys of the training currently provided suggest variation in how directly, and in how much depth, the utilitarian framework of ASPA, and the broad ethical responsibilities following from this, are explored (Appendix 1).

Project licence holders and personal licensees need to function as a team in ensuring ethical animal use, with good communication between them. Thus, whilst their practical roles in managing and carrying out projects might differ, both categories of licensee need to understand fully the ethical framework of ASPA, and be aware of the questions and issues the framework raises. The survey findings emphasise the need to ensure **that ethics training includes clear, factual information on the ASPA's ethical framework and the ethical duties and responsibilities it demands.**

4.4.2 Potential licensees' awareness of their establishment's ERP

Sixty per cent of potential project licence holders, and 21% of potential personal licensees said they were aware of their establishment's ERP - though far fewer were able to give details. Our surveys were carried out early in the development of ERPs, so this situation is likely to improve, but it is interesting to note that there was no trend towards increasing awareness as sampling continued through the year. For Module 5, participants from commercial companies and research institutes expressed more awareness of the ERP than participants from universities; and, in Module 1, a

much greater proportion of participants from commercial companies were aware of their ERPs compared with people from either research institutes or universities.

There is clearly a need for ethics training to cover the requirements of the ethical review process - and for this to include information on *local* arrangements.

4.4.3 *Prior opportunities for consideration of ethical issues by potential licensees*

a) Previous modular training

Only a few potential personal licensees had already attended Home Office Modules (mainly Modules 3 and 4, or Module 5). Forty five per cent of those attending Module 5 courses had *no* previous Home Office-mandated training and only around half (51%) had attended Module 1. Very few potential project licence holders claimed that their prior training (undertaken on a wide variety of courses) had included significant consideration of ethical aspects (Box 5). (Note that this was not because respondents were uncertain what the phrase ‘ethical aspects’ meant - their responses elsewhere in the questionnaire showed that they knew.)

BOX 5: *Module 5 participants’ recollections of the content of Module 1*

- 15% of those who had attended Module 1 said that this did not include consideration of ethical issues, and 4 people could not remember. The recollection of the majority of the remainder seemed to be that consideration of ethics was brief or very brief in Module 1.
- When specific topics were mentioned by respondents these were mainly about reducing harms to animals - the 3Rs/alternatives/animal welfare (23% of those who had attended Module 1) - with fewer respondents (15%) mentioning something to do with necessity/justification /need to use animals.
- Only 15% of those who had attended Module 1 said that it had enabled them to discuss the issues and be introduced to at least some different perspectives.

b) Other prior opportunities for considering ethical issues

Around a third of potential licensees claimed that they had had no other experience of considering ethical issues in animal use prior to attending either Module 1 or Module 5 training (Box 6).

- For potential project licence holders, the most frequent means of considering the ethical issues prior to attending Module 5 was through reading. 58% of respondents noted that they had read about ethical issues in animal use, of which nearly half said that this was mainly or exclusively in newspapers or other general media (although what was actually covered in the newspaper articles is uncertain). Twenty-two per cent of potential personal licensees said that they had read about ethical issues, of which 22% said this was via the popular press, or in leaflets and, occasionally, books.
- Just under a quarter of Module 1 and Module 5 respondents said they had attended seminars/presentations on ethics of animal use - though the details given suggested that only around one in ten had been involved in something akin to the on-going programme of in-house awareness raising sessions that local ethical review processes will be promoting. All except two of the Module 1 participants who had attended in-house presentations said that this was as part of a Company induction course. Other participants mentioned diverse experiences - mainly as part of undergraduate science, veterinary or medical training, and/or discussions during postgraduate training, as well as LASA workshops (5 people had attended such workshops).
- 40% of Module 5, and 35% of Module 1 participants said they had taken advantage of other opportunities to consider ethical issues. These were mainly informal discussions with scientific colleagues and animal house staff in the workplace, for example: “discussions with my supervisor”; “dealings with colleagues and following the advice of visiting Home Office Inspectors”; “discussions with friends and scientists”.

Interestingly, people attending Module 5 courses said they had rather similar, and apparently not much greater, experience compared with those attending Module 1. Module 1 participants are expected to be relatively inexperienced (the majority will be applying for licences for the first time); but people coming to Module 5 are intending to be project licence holders or deputies and, in the main, should be experienced personal licensees, capable of managing projects. It seems surprising, therefore, that around one in three people coming for Module 5 training claimed they had had no other previous opportunities for consideration of ethical issues (or, at least, had not taken

advantage of any opportunities), and relatively few others had read about the issues except in the popular press - which is often critical of animal use, but rather rarely offers more than superficial, journalistic analyses of such perspectives.

c) Implications of these findings

Proper application of the ethical framework of ASPA (weighing harm and benefit) requires licensees to adopt a self-critical perspective - continually to ask questions about whether they have minimised harm to animals, maximised the benefits of their work - and always to try to ensure that the likely benefits are sufficiently significant given the harms. Since rather few potential licensees seem to have had formal opportunities to examine and discuss with others the ethical issues arising in animal use, and, in particular, to consider seriously alternative perspectives on animal use, it seems particularly important that ethics education should provide tools to support licensees in such critical reflection.

Notably, around a third of all potential licensees specifically asked that ethics training should give them a broader perspective and/or an update on the issues; and one in five potential project licence holders wanted ethics training to help them in their own thinking on ethical questions.

These findings lend support to views previously expressed, that, in addition to providing factual information on licensees' ethical responsibilities, **ethics training should:**

- (i) **expose potential licensees to a range of different ethical perspectives on laboratory animal use, and encourage them to consider seriously arguments which challenge their own thinking** - recognising that there is more to contemporary debate on animal use than a clash of irreconcilable, polarised positions; and
- (ii) **assist participants in adopting a critical perspective on their own use of animals** - to think more widely about their own research and how far the use of animals is justified.

Such aspects will become increasingly important, as licensees' justification for their work becomes open to broader, more public scrutiny. For example, licensees now have to justify their work and make details of it accessible to a diversity of people

involved in the local ERP, and in future, could have information about their work disclosed more widely. Licensees need to be aware of the range of perspectives that might be brought to bear - not necessarily all sympathetic.

BOX 6: Trainees' previous experience of considering of ethical issues

	% Module 5 participants	% Module 1 participants
Seminars/other presentations:	23	24
<i>Of which:</i>		
Seminars/other presentations at participants' place of work	47	42
Previous undergraduate or postgraduate training	23	45
LASA workshops	10	10
Reading:	58	39
<i>Of which:</i>		
Newspapers/general media	47	22
Popular scientific press	15	14
Scientific journals/professional guidelines	15	16
Leaflets/ books (mostly unspecified)	3	22
Documents relating to ASPA	15	8
Other opportunities:	40	35
<i>Of which:</i>		
Informal in-house discussions with colleagues	65	69
No such opportunities:	29	34

4.5 General strategic considerations in providing ethics training

There is unlikely to be a single best approach in achieving the goals suggested above, but some important factors can impact on the success of ethics training and current courses vary widely in relation to these factors.

- (i) To achieve the practical goals described in section 4 above, **ethics training needs to be practically orientated**. This point has been emphasised in

previous reports from trainers' meetings, and replies to our questionnaires indicate that, in both Module 1 and 5, potential licensees themselves hoped that the ethics section would provide them with practical assistance in considering the issues and working within ethical guidelines. Presentations and discussions by course organisers at the 1999 LASA workshop indicate that course participants tend to find the ethics component of training interesting, but they can find it hard to relate ethical theory to their own work in practice, particularly in Module 5 (see point 4.7 for further discussion).

The question of how to enhance the practical value of ethics training for potential licensees, whilst achieving the goals listed in point 1 above, is difficult and seems to be at the heart of debates on what should be provided. Philosophical lectures, whilst interesting and potentially useful in awareness-raising, are unlikely to address key practical aspects of ethics for licensees. Nor will discussions exploring how to counter anti-vivisectionist claims serve this purpose. Whilst such sessions can introduce potential licensees to the issues, they encourage a defensive, rather than constructively critical, position.

In contrast, many trainers are using brief scene-setting talks to raise the ethical issues, along with structured discussions to explore how licensees' will respond in practice. These discussions sometimes use questionnaires on licensees' attitudes to animal use to provoke debate, questions to encourage licensees to explore the issues arising in their own work, and/or case material to help participants in identifying and working through ethical aspects of projects. Similar approaches are used in medical ethics training, and are widely agreed to be constructive means of helping trainees to think about the issues they will encounter in practice (see for example, Hope *et al.* 1996).

- (ii) All previous reports emphasise that **the ethics component of training should include discussion between course participants**. Yet, despite this, provision of opportunities for discussion varies considerably between courses (Appendix 1). Our surveys show that, other than in training, potential licensees rarely have, or, at least, take advantage of formal opportunities for consideration of such issues within establishments. Thus, the ethics component of modular training offers licensees an important, and for some apparently unique, opportunity to meet with others who use animals (or have an interest in this area) to consider the different ethical perspectives, exchange views and experiences, and consider how they will make concern for ethics and welfare an integral part of their work.

- (iii) **Productive discussion requires adequate time**, yet, again, there is considerable variation in the time allocated to the ethics component of training (from 30 minutes to a whole morning - Appendix 1). It seems unlikely that much can be achieved when consideration of ethics is allocated only an hour or less.
- (iv) Having a particular session within a course dedicated to ethics need not be the sole means of approaching the topic, and **there are strong arguments in favour of more integration of ethics with other aspects in Module 1, and particularly Module 5, courses** (see point 4.7).
- (v) **Course organisers agree that ethics training should encourage licensees to focus on the issues *they themselves* will have to deal with**, and for this reason it may be better to debate issues raised by licensees' own work, rather than ask them to criticise fictional cases, or the work of others. Trainers are agreed that course participants are usually more happy to tear into others' work, than to criticise their own! If case material is used, a wide variety will be needed, to cope with the diversity of work carried out by licensees - it would be difficult to find generic material to raise issues pertinent for all potential licensees.

Ensuring that ethics training, and courses generally, raise issues relevant to the work of all participants is challenging - particularly where commercial and in-house courses take on people engaged in a wide range of different kinds of work. In providing training, it is important to have at least basic information about the backgrounds and future work of people coming to courses, and then to ensure that, as far as possible, sessions draw on individual experiences, and raise issues relevant to participants. At one of the Module 5 courses we visited, for example, two people using non-human primates were present in a small group of participants, yet the course had no discussion of the *particular* ethical issues raised by use of primates.

- (vi) On a similar theme, **consideration of ethics needs to be geared to *local practice*, as arrangements (e.g. procedures for the ERP) can differ widely between establishments**. This need for local information, which also arises in other aspects of the course (e.g. with regard to animal house procedures, personnel and resources available to assist licensees), presents particular difficulty when potential licensees attend training away from their own establishments. Not only might course participants fail to gain important

information, but, as noted in visits to Module 5 courses, they can also pass on to other participants misconceptions (or even mischievous thoughts!) about what happens in their establishments, which course organisers outside those establishments are not in a position to counter. Where licensees attend training away from their places of work, there is a need for 'home' establishments also to ensure that potential licence holders fully understand local procedures. Further than this, some in-house courses capitalise on local experience, explaining how the establishment itself, and senior licensees within it, take ethical issues seriously, and illustrating what this means in practice. Two cases illustrate this:

A pharmaceutical research company brings in a senior scientist to explain to Module 1 delegates the ways in which the Company responds to ethical issues raised by use of animals. Examples of changing thinking on the 3Rs and means of promoting animal welfare - including changes in scientific approaches - are given, and likely future developments (e.g. the ethical implications of increased use of transgenic animals) are discussed.

A university Module 5 course brings in experienced project licence holders to describe their work, and the ways in which they respond to ethical issues, negotiate the ERP, and manage their projects ethically.

- (vii) **Participants at the 1999 LASA workshop agreed that they would like to pool their ideas, share resources and perhaps visit one another's courses in order to learn more about possible approaches.** With the support of trainers, we are gathering together resources currently used in ethics training, and will make these widely available. Regarding preparation of new resources, the trainers we surveyed also suggested particular needs for practical resources - including good case material and lists of questions, as well as a user-friendly background document, drawing together information and ideas on ethical aspects of animal use, which they could use in preparing their courses. At the Workshop it was also suggested that a 'mini-syllabus' would be useful.

So far, these comments have not distinguished between approaches in Modules 1 and 5, on the grounds that most strategic considerations will be common to both Modules. However, two Module-specific issues are highlighted in our surveys and were debated at the 1999 LASA workshop. They are considered below.

4.6 Should there be more ethics in Module 1?

Present Home Office guidance suggests that consideration of ethics in Module 1 can be limited to a brief introduction to the issues, and that Module 5 is the place for more in-depth, extended discussion. Our results challenge this assumption.

Our surveys suggest that Module 1 ethics training had not been a ‘significant experience’ for people attending Module 5. Of those people that had previously attended Module 1, in a wide variety of courses, few remembered the ethics component as enabling them to explore the issues and consider different perspectives. In fact few remembered it at all. This is interesting, particularly given IOB Accreditation Board guidance that, in Module 5:

“How the ethical aspects are covered will depend on what exposure trainees have already had to the ethical debate. Module one should have presented to trainees the foundations of ethical debate and an opportunity to discuss the issues”.

Some Module 1 courses already devote considerable time and effort to consideration of ethical aspects, whereas others give ethics relatively little time, and there is little discussion. Given that Module 1 is supposed to provide a foundation for Module 5, **consideration should be given to amending Home Office guidance to promote more in-depth treatment of the topic in Module 1 courses.**

Course participants’ perspectives on what they hoped to gain from ethics training, and discussions with trainers at the 1999 LASA workshop, also suggest a need for this. Our surveys showed that, by Module 5, potential project licence holders felt that they needed to get a licence and get on with their work, and that the majority saw the training course mainly as a means of achieving this end. Nearly one in three noted this explicitly, but the drive to obtain a licence was also evident in many other replies. Module 1 participants, in contrast, hoped that the ethics component would be of real use in their day-to-day work. They saw ethics training as making a practical difference in their dealings with animals - including helping them to fulfil their responsibilities to promote the animals’ welfare. More subjectively, Module 1 participants seemed to express greater eagerness to learn, as might be expected in people just starting work in a new field and so, perhaps, might be more open to influence from ethics training.

At the 1999 LASA workshop, a description of the in-depth consideration of ethics provided in one Module 1 course included the following comment:

“Personal licensees are the ones at the coal face. It is essential that they have an opportunity early on to address the issues and concerns that they will need to face throughout their career.We actively encourage honest exchange and aim to provide an environment where this can be done freely, to help them form their thoughts on what they do and why and to feel confident to begin to question issues. And, yes, we really do need to get to them early in their careers - some of them will become senior scientists managing the research projects of tomorrow.” (Marie Wilson)

It would make sense, therefore, to make Module 1 more of a focus for ethics education, including consideration of different perspectives and sensitive treatment of views which might influence and/or challenge licensees’ own thinking. Module 1, after all, should be the course attended by *all* potential licensees, whereas Module 5 catches only those who are sufficiently senior to manage projects.

4.7 Module 5 and the drive to obtain a licence: making ethics practically useful

Perhaps the drive to get a licence should be acknowledged as a major motivation of potential project licence holders attending training, and taken into account when designing the ethics component of Module 5 and, in fact, Module 5 training generally? Even for those Module 5 participants kindly disposed to consideration of ethical issues, the hoped-for ultimate outcome will be gaining a licence. Course organisers’ experience shows that many potential project licence holders see training as yet another hoop to jump through - indeed, a few of the more negative replies to our surveys made this feeling explicit! And some trainers are wary of too much overt challenge in the ethics component of Module 5, which they feel could be counter-productive – switching participants off, and making them less receptive to the important practical considerations developed elsewhere in the course.

With increased emphasis on ethics in Module 1 (and assuming that, in time, all potential project licence holders¹ will have attended Module1), **Module 5 could focus more on *practical implementation of the ethical framework of ASPA***. This is suggested in IOB guidance, but is not always what happens.

A possible approach is to tie together all the different components of training, including ethics, into a common practical theme, such as preparing a project licence application, and/or considering the workings of the ERP. Such an approach is used in one current Module 5 course, where participants are asked to consider the issues they will need to address in writing, and eventually managing, a project licence to study

¹ With very few exceptions – e.g. for experienced people coming from abroad.

the efficacy of a possible herbal remedy for flu. Specialists in each of the different parts of Module 5 training (e.g. statistics, information services, alternatives, management, as well as ethics) are brought in to make presentations and then facilitate small group discussions, all related to this single practical example. A few pertinent published research papers are used to provide background information to assist participants in considering whether and how the work might be justified in terms of likely benefits, possible plans of work, methodologies and the application of the 3Rs - and the papers are critically reviewed for animal welfare concerns and statistical issues. Whilst each particular component of training still has its own special slot in the day, the specialists' input is not confined to that slot. They stay with the course for the whole day, facilitating discussion, and picking up on relevant issues as they arise. It is possible that this approach could be adapted with small groups of participants, to focus on applicants' *own* work, and providing 'clinics' with the specialists. It is possible to envisage similar integration in Module 1 courses.

4.8 Assessment

Few trainers say that they attempt to assess the ethics component of Module 1 (Appendix 1). The Universities Scheme provides a bank of multiple choice questions (MCQ) which trainers can use to devise assessments for Module 1, but it is difficult to assess ethics using multiple choice questions, and none of the MCQs in the bank could really be said to assess the ethics component. Module 5 assessment is most frequently via a 'flawed' project licence application, which might provide an indication of participants' approaches to ethical issues.

Around half of the Module 1 course organisers assess participants' attitude informally, as do most Module 5 trainers - and some commented that they had taken action in cases of poor attitude. Several Module 1 trainers felt that the ethics component could not be assessed meaningfully. In contrast, medical ethics trainers argue that assessment of ethics is both possible and important, because amongst other things, they believe that:

- (i) there is a need to evaluate the ethics competence of practitioners (competence in this area, increasingly, is being seen as an essential part of clinical competence generally);
- (ii) assessment can help to evaluate the effectiveness of different educational approaches in achieving the objective of promoting ethics competence and
- (iii) examination focuses the minds of students!

See, for example, Hope *et al.* 1996 and Savulescu *et al.* 1999. These points also apply in licensee training.

Brief cases are frequently used in assessment of medical ethics competence, and students are required to give short answers to demonstrate that they can:

- (i) identify the ethical issues involved in the cases; and
- (ii) reason about the issues and come to a justifiable resolution about what should be done.

Such methods have been evaluated for relevance, reliability and validity as assessments (Savulescu *et al.* 1999). It is possible that similar techniques could be used in licensee training, and we are investigating the possibilities.

We therefore believe that **consideration should be given to developing means of more formally assessing the ethics component of Module 1 as well as Module 5.**

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Appendix I

Current provision on ethics in Modules 1 and 5

Questionnaires were sent to all Module 1 course organisers, five Module 5 courses were visited, and information was received from a further four out of the remaining Module 5 course organisers. In each case, the following questions were asked:

1. How long does the whole course last, and, on average, how many participants are on the course?
2. What kinds of potential licensees come to the course? Are they engaged in similar areas of work, or do they tend to be a more heterogeneous group? Is the course open to people outside the particular establishment?
3. Is there a discrete ethics section within the course, or are ethics considered as part of a variety of other sections - or both? If there is a separate ethics section, how much time is devoted to this?
4. Is an outside speaker/leader used for the ethics part of the course, or someone in-house? What sort of background/expertise has the speaker/leader?
5. What kinds of knowledge/issues/questions are considered under the 'ethics' heading?
6. Are opportunities for discussion provided as part of ethics training?
If so, how is discussion stimulated, and how much time is devoted to discussion?
7. Is the ethics component assessed? If so, how?
8. What importance is attached to consideration of ethics within the particular course?
9. Have any difficulties been encountered in providing ethics training?
10. Would any further resources to support the training be useful? If so, what kinds of resources?

The findings are as follows:

Samples

- Twenty Module 1 course organisers responded to our questions, thus providing information on around two-thirds of the twenty-nine Module 1 courses currently accredited.
- In addition, information was obtained from nine out of the ten Module 5 courses currently accredited, five of which courses were visited.
- The courses on which information was received take place in the following kinds of establishments:

Type of establishment	No. Module 1 courses	No. Module 5 courses
Universities*	11	5
Research institutes	2	-
Commercial organisations	5	2

‘Commercial’ course providers - participants come from a wide range of different establishments	2	2

Total	20	9

* of which two are ‘consortia’ of universities

Module 1 courses are commonly put on at the same time as Modules 2 and 3, with the three Modules taking two to three days to complete. The elements of Module 1 are most often completed in half a day, although four course organisers specifically said that their Module 1 courses last a full day, and one said a day and a half.

Module 5 courses last between one and two days. Five courses are completed in a day, two in a day and a half, and two take a full two days.

Apart from the courses put on by the two commercial providers, both Module 1 and Module 5 courses cater mainly for participants from within the particular establishments concerned, though most sometimes also take on external participants.

Almost all the courses surveyed have to deal with very heterogeneous participants - differing in the kind of work they carry out, and/or in their experience, role and/or seniority within

their establishment. One commercial establishment reported that their Module 1 participants tend to be more homogenous - at least in the kind of work they are engaged in.

Results

Summary

- Practice in delivery of the ethics component varies between courses. For example, courses vary in:
 - the time allocated to the ethics component;
 - provision of opportunities for discussion;
 - resources used, and type of speaker;
 - broadness of perspective offered;
 - encouragement for licensees to question their own work;
 - degree of integration of ethics with the rest of the course; and
 - assessment employed.
- A number of the trainers said they would find general resources (e.g. a good video to promote discussion, general guidance on relevant ideas, case studies, etc) useful.
- Formal assessment of this component is generally regarded as difficult.

More details

(i) *Time allocated to ethics session*

The majority of Module 1 courses and all the Module 5 courses have a separate session devoted to consideration of ethical issues - though one Module 1 course calls this 'historical background'. The time allocated to the session varies as follows:

	No. Module 1 courses	No. Module 5 courses
<i>No separate session</i>	2	0
<i>< 1 hour</i>	3	1*
<i>1 hour</i>	7	<i>1.25 hours</i> 2
<i>1.5 hours</i>	3	4
<i>> 1.5 hours</i>	5	2

*although, here, the ethics session leader remains with the course throughout the day, and joins in discussion of ethical issues as they arise.

(ii) *Opportunities for discussion*

- Three Module 1 courses provide little or no opportunity for delegates to discuss the ethical issues.
- Six Module 1 and two Module 5 courses provide discussion as part of a ‘lecturing-style’ presentation - in which participants interact with a speaker, asking questions and/or responding to points and issues raised by the speaker.
- Eleven Module 1 and seven Module 5 courses have ‘separate’ opportunities for discussion - in which participants have more chance to discuss between themselves, with the support of a speaker/facilitator.

In the last case, discussion is stimulated in a variety of ways:

	No. courses*
Module 1	
• <i>Responses of participants to (sometimes pre-circulated) statements and/or questions on animal use, to promote discussions of different perspectives & issues</i>	4
• <i>Video (e.g. ‘Choices’, or a Channel 4 documentary or ‘animal rights’ group video)</i>	3
• <i>A scientific paper as platform to structure discussion around the 3Rs</i>	1
• <i>Setting up a debate</i>	1
• <i>Case study to encourage identification and discussion of ethical issues</i>	1

* One the Module 1 course organisers who provides for group discussion did not indicate how this is stimulated.

Module 5

• <i>Case studies (in one course, written up as a fictitious project licence) to encourage identification and discussion of ethical issues</i>	2
• <i>A biased newspaper report of work carried out at the establishment - participants discuss how they would advise the Certificate Holder to respond</i>	1
• <i>Specific questions on ‘costs’ and ‘benefits’, ethical review, and ‘ethical limits’ in animal research for participants to discuss, with particular reference to their own work</i>	3
• <i>By getting participants to talk about their own work</i>	1
• <i>Scientific papers to critically appraise for practical ethical issues (mainly 3Rs)#</i>	2

N.B. this last is in addition to other methods (i.e. in addition to the newspaper article in one case, and in addition to specific questions in the other).

Courses vary in the number of participants per course, and this is likely to influence the opportunity for, and intimacy, of discussion. Number of participants per course varies as follows:

MODULE 1*		MODULE 5	
No. participants	No. courses	No. participants	No. courses
<i>12 or fewer</i>	10	<i>5 to 10</i>	2
<i>15 to 20</i>	3	<i>circa 10</i>	3
<i>20 to 40</i>	3	<i>5 to 20</i>	1
<i>more than 40</i>	3	<i>circa 15</i>	1
	<i>(maximum 170)</i>	<i>up to circa 25</i>	2
*one Module 1 course organiser did not answer this question			

Of the Module 1 courses with twenty plus participants, two course organisers specifically mentioned that they divide into groups for discussions; as do two of the three largest Module 5 courses.

(iii) Choice of speaker

- In nine Module 1 courses the course organisers themselves tackle the ethics component. Of these people, four are vets, whilst the others are senior animal technicians, or people involved in Home Office Liaison.
- Three Module 5 course organisers deliver the ethics component themselves - two of these are vets, and one a research scientist and University Training Manager.
- Two Module 1 courses and the remaining six Module 5 courses bring in people who have made particular studies of the ethical issues. One of these has a degree in Divinity and also has been an animal technician, one is a clergyman who also teaches medical ethics, and one is a lecturer in medical ethics.
- Four Module 1 courses bring in scientists from within the establishment to address ethics. Two of these have a ‘special interest in ethics’, one, it was noted, is a spokesperson for the Research Defence Society, and the other is usually a senior project licence holder or a member of the local ERP.
- One Module 1 course uses an ex Home Office inspector (also a vet); one has tried various different speakers; and one, in which ethics is not allocated a special section, uses the various speakers within the course.

(iv) Content under ethics heading

All course organisers regard ethics as a ‘very important’ or ‘essential’ part of their courses.

Module 1

Nine course organisers specifically mentioned that they include exploration of alternative perspectives, public opinion and similar.

Eight said that they cover licensees' ethical responsibilities.

Five noted that they explore the 'logical' justification for using laboratory animals, and

Four specifically mention the ethical framework of ASPA.

Four reported that they consider the different uses of animals in science, and three compare use in science with other uses of animals in society.

Four give a historical perspective.

Three said that they encourage licensees to question their own positions, and one to consider their ethical 'boundaries'.

One considers security issues under the ethics heading.

The ten courses which include discussion between participants all seem to encourage consideration of alternative perspectives, and deepening/extending licensees' own thinking.

One course organiser (working in a field of research particularly open to public scrutiny) noted that 'there is a fine balance between raising their [licensees'] awareness of the ethical issues and making them overanxious'.

Module 5

Approaches to ethics training differ between the nine Module 5 courses surveyed:

- a) In the majority (seven out of nine courses surveyed) a leader/facilitator begins to generate discussion amongst course participants using brief scene-setting and/or information giving talks, which raise issues for consideration and, in four courses, cover a range of philosophical positions. One course ranges very widely, bringing in a mix of medical ethics, veterinary, environmental and agricultural ethics comparisons, as well as looking at public opinion and a broad span of philosophical opinion. Case material (two courses), a biased newspaper report (one course), scientific papers (two courses) participants' own work (one course) and/or specific questions (four courses) are used as platforms for discussion, and further details have been given in (i), above.

Discussion of the newspaper report could tend towards 'countering anti-vivisectionist claims', perhaps at the expense of more in-depth thought about the ethical issues raised by participants' own work - but in this course, a pertinent take-home message is explored, that "people outside the establishment are concerned about what is done

to animals, and researchers have a responsibility to respond to the concerns and take these on board in what they do”.

One of the seven courses using a discursive approach ties together all the different elements of Module 5 into a common practical theme - preparing a project licence application. As well as leading a general discussion on ethical aspects, the ethics specialist (along with specialists on other aspects) is on-hand throughout the day, helping to facilitate discussion on other issues, and picking up on ethical issues as they arise (see also Section 8 in the main report).

One course leader, using a discussion-based approach, commented that he wants the ethics part of Module 5 training to influence participants’ attitudes, so that feedback forms say something like, “That really made me think”. Another said that it is wrong to label the ethics component as training; the aim is to “encourage reflection by participants on their ethical stance” and “to develop an understanding of their own and society’s views on use of animals in research”.

b) In the remaining two Module 5 courses surveyed, the ethics component involves less interaction amongst course participants. In one course, the speaker explores key practical and philosophical aspects in dialogue with participants, including discussion of:

- the areas of work that the participants use animals for, and their experience of ethical debate or challenge in relation to that;
- ethical reasons for having statutory regulation of animal experimentation (i.e. it matters that we treat animals well);
- philosophical elements of the debate over the moral status of animals and their use in science, including utilitarian approaches (Peter Singer) and Rights based approaches (Tom Regan), and the differences and similarities between them; and
- ethical review processes as the main way in which ethical discussion will impinge on licence applicants, the reasons for welcoming rather than resisting the opportunity to justify work to those from other disciplines, and the necessity of doing this if the debate over animals and their use is to be moved forward.

This speaker commented that ideas for discussion formats/topics/examples would also be useful.

In the other course, there is a more philosophical lecture, primarily concerned with explaining what ethics, more generally, means, with occasional interruptions for

questions and discussion with the speaker. Key points in practical application of ASPA's ethical framework are also raised, but are not the major substance of the talk. There is also a discussion on involvement of lay members in the ERP, at the end of the course.

Taking the responses in the round, the replies suggest that, in both Modules 1 and 5, there is variation in information given about licensees' ethical duties in relation to the ethical framework of ASPA, variation in coverage of alternative perspectives, and variation in the provision of challenging discussion. However, it should be noted that it is possible that course organisers did not report in the questionnaire all that they do in relation to ethics - especially since ethical aspects can be raised in sections of the course other than the one specifically devoted to ethics.

(v) *Assessment*

- Only three Module 1 course organisers said that they attempt to assess the ethics component formally. Two said that they include background questions in their multiple choice assessments, and one assesses ethics as part of the oral course exam. The Universities Scheme provides a bank of multiple choice questions (MCQs) which trainers can draw on to devise assessments for Module 1, but it is difficult to assess ethics using multiple choice questions, and none of the MCQs in the bank could really be said to assess the ethics component.
- Eight of the remaining sixteen Module 1 course organisers said that they assess 'attitude' informally, and four said that they have taken action in cases of poor attitude. Several felt that the ethics component cannot be assessed meaningfully.
- Four of the eight Module 5 courses use flawed project licence applications to assess the Module generally, and these assessments encourage participants to identify and comment on ethical issues. One trainer asks participants to write a justification of their own work, rather like a project licence application, and this, again, will assess participants' abilities to recognise and reflect on ethical aspects. The remaining course organisers do not attempt to assess the ethics component formally - although, like the Module 1 course organisers, some assess participants' contributions in discussion, or lack of them, informally, and find that these observations can be useful in spotting people whose attitude seems inappropriate.

(vi) *Difficulties and future needs*

Where Module 1 course organisers noted difficulties in providing ethics training, these were mostly in deciding what to include, and finding good ways of generating discussion. Course participants can sometimes be reluctant to express their own thoughts and views. Several trainers commented on the difficulty of planning a course which would be useful for a rather heterogeneous group of people, and one mentioned that assessment is an issue - particularly where cultural differences in attitude are apparent.

Three quarters of the Module 1 course organisers felt that further resources might be helpful. One commented that new resources are always useful - to keep things fresh. One asked for more time - in order to train people to think. Three suggested that a good video might be useful; others asked for a synthesis of relevant literature, a good reference list, ideas of what others do - and two suggested a web-based resource. One suggested that “to ensure all new PILs are given food for thought, a basic presentation framework could be used within all establishments, put together by acknowledged experts in the field”; others suggested a user-friendly background document, drawing together a range of information and ideas, which course organisers could use in preparing their courses.

In Module 5, course organisers sometimes have difficulties because participants think that the ethics component is not important, and/or fail to see its practical relevance to their work. Several Module 5 course organisers suggested that resources to help generate discussion would be useful - and some, in particular, hoped for a bank of cases (or fictitious project licence applications) that would raise practical ethical issues. These cases, it was further suggested, would need to cover a diversity of different kinds of research and testing applications, so that course organisers could select examples that raise issues relevant to participants’ own work.

One Module 5 course organiser suggested that a reading list would be helpful, or perhaps documents on disc.

Appendix 2

Participants' views on the importance of ethics training

	% Module 5 participants	% Module 1 participants
Importance:		
Very important	46	41
Important	45	52
Not particularly important	5	6
Irrelevant	1	1
Don't know	2	1

Examples of comments which suggested that the importance lay in broadening perspectives/raising awareness/making people think:

Potential Project licence holders

“It is very important that people are aware of ethics. It is too easy for researchers to be driven by desire for knowledge without considering their ethical duties.”

“It is not possible to detach animal experiments from wider social/ethical attitudes to life in general”.

“I feel that, although in all probability, most people in this field will have addressed these issues frequently, both as a practical consideration and as a matter of conscience, it is necessary to formally make potential Project licence holders confront these issues - through discussion at this forum”.

Ethics training should “encourage everyone to think anew”.

“There is a need to appreciate the broader feelings of the public/non-scientists as well as scientists with regard to animal usage/ethics. Hopefully these points - both for and against - will be discussed in some detail”.

Potential Personal licensees

“Ethical and moral awareness are important for anyone who keeps animals, so are especially important to us who use them in testing”.

“One should be made aware of the issues if not already”.

Ethics training “gives a context for the rest of the course”.

Examples of responses which looked at the potential outcomes of ethics training - e.g. the importance for animal welfare, ensuring cost-benefit analysis and similar:

Potential Project licence holders

“Ethical consideration is important in the work that is going to be carried out so that suffering and severity is limited as well as usage of animals. The end result being that the benefits outweigh the adverse effects”.

“Too often the balance of value of work against suffering is fudged...”.

Potential Personal licensees

Ethics training is important “to help you decide whether experiments are essential, and to stop you causing unnecessary pain and distress - to realise animals have worth and shouldn’t be abused”. And “to treat animals with respect... and maintain decent conditions in laboratories”.

Examples of more negative comments:

“This is important from the point of view of the legislation, however, I feel that much of this is irrelevant to mouse work and that all of us would rather not work on animals and are obliged to do so. However, the prevailing attitude appears to be that we need to be restrained by law”.

“Hopefully [ethics training will provide] more guidance on what is required of my organisation in terms of ethics so that productivity does not suffer as a result of more red-tape. We are already a very ‘ethical’ organisation so I'm not sure I'll learn anything new about the actual ethical mechanics”.

The “importance depends on type and severity of experiments planned”.

“People doing my kind of research [ecology and conservation of wild bird populations] already practice high ethical standards”.

Ethics training “won’t change my position”.

One Module 1 participant expressed a particularly concerned perspective:

Ethics training is very important “because I find it difficult to live with the idea that I’m going to work with animals”.

Appendix 3

Participants' ideas on their future ethical responsibilities as licence holders

- *One hundred and six participants in Module 1 and 124 in Module 5 responded here.*
- *Fifty potential project licence holders (40% of the respondents) gave answers which expressed responsibilities to consider the 'complete utilitarian framework'. Many of these answers were impressively thoughtful and comprehensive.*

For example: The responsibilities are “to ensure that you have carefully considered the necessity of the work and can fully justify the numbers of animals used and the procedures which will be used”... Project licence holders “must also feel comfortable with the moral issues involved”. “I see ethics in terms of balancing the potential outcome of the scientific work covered by the project against the potential suffering of the animals involved. The key duties of the Project licence holder are to: minimise animal suffering; weigh up the benefits of the procedures; and review the direction and outcome of the work of the project.”

- *Thirty six (29%) of Module 5 respondents mentioned responsibilities for the welfare of the animals involved, but did not note duties to ensure the necessity of the animal use. Seven respondents noted the 'benefits side' only.*
- *Potential personal licensees focused mainly on ethical duties to ensure the well-being of the animals used, and to minimise pain, distress and other suffering. Seventy four (70% of respondents) explicitly mentioned these duties.*

For example: “Always maintain respect for non-human species, avoid unnecessary pain etc, and maintain animal health”. “Look after animals well and kill them humanely”. “Care about animal welfare; express sensitivity when handling animals and performing procedures”. “The welfare of the animals is paramount”.

- *Only 16% of potential Personal licensees who replied noted a need to consider the 'benefits side' - saying either that they needed to 'understand' or be able to question/think through the need to use animals.*
- *Thirteen (10%) of potential Project licence holders referred mainly to their role as project managers - they deferred to the law, emphasising the following of 'rules' - they did not mention their own ethical duties towards the animals.*

For example: the duties are to “respect the regulation of the Animal protection act (sic) - that already includes, I think, all the necessary issues”.

- *Seven Module 5 participants, and five Module 1 participants said merely that they had duties to be 'ethical', but did not describe what this meant.*

For example: "Work under ethical guidelines". "... ensure ethical practice".

- *26% of Module 5 respondents, compared with only 5% of Module 1 respondents mentioned the need to consider alternatives. 23% of potential Project licence holders who replied mentioned supervision; 6% of potential personal licensees noted competence.*

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The work reported here is from the first year of a three-year project funded by the RSPCA. The RSPCA as a matter of policy is opposed to all experiments or procedures that cause pain, suffering or distress to animals. As in other areas of its work, the Society adopts a constructive, practical approach to the laboratory animals issue, supporting and promoting the development and adoption of techniques that will result in the replacement, reduction or refinement of animal experiments (the 3Rs) and/or that will lead to improvements in laboratory animal welfare. Training is seen to play a vital role in promoting and implementing the 3Rs and the importance of training in ethics and welfare is actively promoted as part of the Society's work in this area. It is hoped that this project will make a useful contribution to the further development of such training.