



VETERINARY IRELAND

GUIDELINES ON USE OF ANIMALS IN EXPERIMENTAL RESEARCH

**RATIFIED BY
VETERINARY IRELAND NATIONAL COUNCIL
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Use of Animals in Experimental Research

Guidelines for Veterinary Practitioners who are charged with responsibility for animals used for scientific purposes under the Cruelty to Animals Act 1876, 39 & 40 Vict., Ch.77, 1876, as amended by the European Communities (Amendment of Cruelty to Animals Act 1876) Regulations 2002 (SI No. 566 of 2002)

Veterinary practitioners who are charged with the care of animals used for scientific purposes have professional, ethical and legal responsibilities.

Professional: A veterinary practitioner who is providing services in the area regulated by SI 566/ 2002 is commonly referred to as a 'Named Veterinary Surgeon' (NVS).

The NVS is advised to be familiar with the Guide to Professional Behaviour drawn up and amended from time to time by the Veterinary Council of Ireland. The Guide contains specific guidelines relating to this area.

Ethical: The NVS has a duty of care for all animals under his/her care. This includes using his/her influence to enhance the welfare of such animals and to ensure adherence to the principles embodied in the '3Rs' - Reduction, Refinement & Replacement.

Legal: as set down in:

- Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (Directive 86/609/EEC), as amended by Directive 2003/65/EC of the European Parliament and of the Council of 22 July 2003
- European Communities (Amendment of Cruelty to Animals Act 1876) Regulations 2002 (SI No. 566 of 2002) (hereafter referred to as 'SI 566/2002'). For all practical purposes, these Regulations amount almost to a complete re-writing and updating of the original Cruelty to Animals Act
- Protection of Animals Acts, 1911 and 1965
- Veterinary Practice Act 2005 (No. 22 of 2005)
- Animal Remedies Act 1993 (No. 23 of 1993) and Regulations made under that Act, most recently the Animal Remedies Regulations 2005 (SI No. 734 of 2005). Particular note should be taken of Regulations 17 and 20 of SI 734/2005

Contractual: The NVS will be obliged to enter into a business arrangement with the 'Operator' of the registered premises. It is imperative that he/she takes into account the diversity of the duties before agreeing a price.

The position is **not** similar to the normal service provided by a veterinary practitioner to his/her client. It may involve the assessment of the impact of procedures unfamiliar to the NVS, on species about which he/she is not routinely consulted. It will require the NVS to be involved in the ethical judgment of proposed scientific projects involving animals.

The following Guidelines are intended to help a Named Veterinary Surgeon (NVS) to fulfil his/her professional obligations as laid down within both the legislation and the Guide to Professional Behaviour. They will not cover all situations and the NVS is strongly advised to seek advice if in doubt about how to proceed.

Scope

The NVS should be aware of the scope of his/her responsibilities.

The position does not allow the NVS to undertake any primary research. He/she may not perform any procedure on an animal unless it is for the benefit of that animal or its companions, i.e. it must fall within the area of normal, ethical, veterinary practice. Any procedure performed for scientific purposes must be detailed in a current licence issued by the Dept. of Health & Children under SI 566/2002. The NVS has a responsibility to ensure that such permission exists. e.g. He/she may be asked to anaesthetise an animal using a Veterinary Practitioner Only (VPO) product, in order to perform or allow the performance of a licensed surgical procedure.

Clinical trials may prove to be an area of ambiguity. It may not be always clear if an experimental licence is needed. The NVS should be careful to ensure that he/she is acting within the law.

Training

The NVS will be expected to obtain and maintain the skills needed in this specialised area. This is likely to involve further training, as the undergraduate course does not provide the necessary knowledge in sufficient depth. It would be reasonable to expect the NVS to be a member of an organisation that would provide access to up to date information in Laboratory Animal Science (LAS) and Laboratory Animal Medicine (LAM)

There are NVS training courses run in the UK, which it would be useful to attend.

The training requirements for responsible persons working within the frame work of Directive 86/609/EEC and SI 566/2002 are defined in a guideline published by [FELASA](#)

Briefly, the categories are: -

- Category A: Animal care workers and technicians (subdivided into 4 subcategories)
- Category B: Licensed researchers
- Category C: Project leaders who design experiments
- Category D: Laboratory Animal Medicine specialists

Veterinarians who have accepted a responsibility under the SI 566/2002 may be regarded as Category D persons, depending on the level of specialisation achieved.

Certificate and Diploma qualifications are available.

The NVS would normally be expected to be involved in the training of new licensees and in ensuring, in conjunction with the 'Day to Day care person', that best practices of handling and welfare maintenance are adhered to. In particular, the NVS should be involved in training researchers in the areas of surgery, anaesthesia, analgesia and the use of controlled drugs.

Health Control

The NVS will be expected to establish and run appropriate health monitoring schemes and devise and run an appropriate quarantine scheme.

This will involve:

- ensuring regular monitoring by provision of specialised diagnostic techniques to help maintain SPF (Specific Pathogen Free) conditions.
- establishing or running a quarantine scheme that will complement disease control methods in place e.g. full SPF husbandry practices.

Cover

The NVS is obliged to provide a 24-hour full service cover in relation to health and welfare of animals. This will involve arranging for a suitably trained deputy to be available when the NVS is unavailable.

Medicines

The administration of medicines to animals for **any** purpose is subject to veterinary control. The inclusion of an animal remedy in a Department of Health Licence does not dispense with the NVS' obligations under the Animal Remedies Regulations.

Particular attention should be paid to products classified as Veterinary Practitioner Only (VPO). The control and supervision of these may require special provision or may be subject to conditions attached to a Licence issued under Regulation 17 of the Animal Remedies Regulations.

Advice (Ethical, Welfare, Health Programmes, Surgical, Anaesthesia & Analgesia, Husbandry & Breeding)

A specific mention should be made of the NVS' responsibilities to provide appropriate advice in the maintenance of an appropriate health standard for the animals under his/her care.

Ethical review

Ethical review committees are expected to have a veterinary practitioner among their members. The NVS is expected to have a major input into any discussion on the welfare impact of the proposed procedures on the animals under his/her care.

Certification

There are specific certification obligations provided for under the legislation regarding the welfare of animals on completion of an experimental procedure and in relation to transport of animals. The NVS is reminded of the certification principles in the Guide to Professional Behaviour.

Appendix 1

Example of an Ethical Review structure, adapted from Guidelines issued by the Health Research Board

RESEARCH USING ANIMALS: THE ROLE OF ETHICAL COMMITTEES

The purpose of this appendix is to provide background information and guidelines on the role and composition of ethical committees working at institutional level.

Background

Research using animals is controlled at present by the Department of Health and Children. Current legislation (SI 566/2002) requires that any person using an animal for scientific purposes is required to obtain a licence for the project from the Department of Health and Children and to perform the work in a designated premises using purpose-bred animals (except where the licence permits exceptions).

A goal shared by many scientists and people opposed to the use of animals in research is best summarised by reference to the proposals of Russell and Burch commonly known as the ‘3 Rs’. These stand for Reduction, Refinement and Replacement of animals in research.

These principles have been embodied in EU Directive 86/609/EEC ‘On the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes’, as amended by Directive 2003/65/EC of the European Parliament and of the Council of 22 July 2003, and have been incorporated in Irish legislation by SI 566/2002.

- Article 7(2) of the Directive requires that an experiment will not be performed if an alternative non-animal method is available.
- Article 23 (1) of the Directive requires that Member States should encourage research in the development of alternative methods.

Current processes

The criteria that are used to assess the acceptability of a specific animal research protocol fall into three categories:

1. Scientific validity
2. Welfare cost to the animals
3. Ethical considerations.

Currently, the scientific validity and welfare considerations are subject to assessment by the signatories to the licence and by the Inspectorate at the Department of Health and Children. Ethical considerations, on the other hand, are not formally assessed although, informally, several research institutions have internal ethical committees which comment on the ethical aspects of any research grant application.

Remit of ethical committees

The objective of an ethical committee or ethical review group for animal projects is to examine a proposal so as to determine, within the ethical parameters determined by that committee or group, whether or not the reasons put forward for the proposed study justify the use of animals.

The starting point of any consideration should be that the use of animals must be avoided unless there is no valid or practical alternative.

To this end the group should consider:

- The scientific validity of the procedure
- The welfare cost to the animals
- The proposed benefits that will be achieved
- The social / community acceptability of the procedures

Specific responsibilities of an ethical committee or ethical review group include:

- Ensuring compliance with the law
- Determining the acceptability of individual projects
- Establishing institutional policies that can be used to fast track non-contentious proposals
- Monitoring the use of animals in the institution and ensuring that appropriate standards and procedures are adhered to.

Composition of ethical committees

It is important that the people who make up the committee represent the various interests involved, including both those with animal research expertise and those without (some of whom should be independent of the research institution).

Where possible the following interests should be represented on a committee, although it is recognised that this may or may not be practical at a local level. The specific composition may vary from time to time depending on circumstances, but would be expected to include:

- The veterinary practitioner who is nominated for the health and welfare of the animals in the unit (the so-called NVS)
- The authorised person or persons responsible for the care of the animals and the functioning of the equipment in the establishment
- Representatives of the research community
- Persons independent of the establishment
- ‘Lay’ persons
- Persons with specific expertise, such as a statistician or ethicist
- Department of Health Inspector (as appropriate)

The Chairperson of the ethical committee or ethical review group should be a senior person in the institution.

Functions of specific committee members

Veterinary Practitioner

This person should be an individual with experience of laboratory animal medicine and, ideally, will have specialist training in the area. This person may be an employee of the institution or may be an outside person who is contracted to provide for the duties of the NVS as required by the legislation.

Representative of the research community

This will be one or more persons, not directly connected with the project under discussion, who can comment on the validity of the proposed protocol and attest to the proposed benefits which may accrue.

A public interest representative

This person's role is to give a public or non-scientific view of the proposal. It is important that the individual is appropriately trained to contribute to the committee and feels able to ask pertinent questions.

Persons with special expertise

It is becoming more accepted that statisticians should have an input into experimental design at an early stage. In the past it has been the practice to apply statistical assessment to data that have already been collected. However this can lead to a very wasteful use of animals. The design of the experiment may have been faulty, either using more animals than necessary or not using enough and thereby wasting the animals which have been used.

Other specialists such as ethicists may also be required from time to time to help develop policies.

Appendix 2

Guidance to Veterinary Practitioners undertaking Named Veterinary Surgeon (NVS) duties on a Part-Time or Consultancy basis

Establishing the Basis for a Contract

Introduction

These guidelines are intended to help an appointed veterinary practitioner formulate a contract structure. They have been adapted from a document produced by the 'Laboratory Animal Veterinary Association' (LAVA).

The scope, depth and volume of work undertaken by the Named Veterinary Surgeon (NVS) has increased significantly as a result of the increased complexity of the regulations and societal attitudes in this area. Typically, areas involved include the control of animal remedies, health monitoring, ethical review of projects and giving advice on anaesthesia, pain prevention and control.

In many cases part time and consultant NVS' contracts have failed to take account of this increased work load or have simply underestimated the level of involvement and responsibility required.

The best example of a recent and significant increase in workload comes from the introduction, of the Ethical Review Process (ERP). The NVS is one of only a few appointees who MUST have an integral role in the ERP. This frequently requires visits to the establishment to attend ERP meetings as well as reviewing and perhaps contributing to licences from outside the research establishment. It is hoped that this paper will highlight the areas to be considered when establishing an equitable charge for such work.

The Pricing Template

There are, essentially, five elements to be considered:

- Retainer Fee
- Hourly Rate
- Specific Services
- Travel (mileage and time)
- Frequency of visits

The Retainer Fee

The annual retainer fee is commonly deployed by a part-time NVS. The elements that a veterinary practitioner should consider when discussing a suitable retainer fee include:

- *Size and scope of the establishment.* This will vary from small individual units holding only small numbers of rodents to large, multi-unit research facilities conducting studies on a wide range of species (rodents, rabbits, dogs, cats, primates, farm animals).

- *The type and complexity of procedures conducted.* This will also vary from simply breeding to complex techniques including surgery. Clearly, large and complex facilities using large numbers of animals will require more frequent and time-consuming visits. These elements can be considered under the hourly rate.
- *The degree of expert or specialist knowledge expected of the attending NVS by the establishment.* Small units and perhaps small breeding units may demand little extra knowledge over and above that of a competent veterinary practitioner. However, even in such circumstances, every NVS must have a comprehensive knowledge and understanding of the legal framework as laid down in SI 566/2002.

The amount of "extra" knowledge and competency required is easily translated into a factor of "specialisation" required, which in turn relates to requirements for Continuing Professional Development (CPD).

The degree of specialisation required must reflect, not only the clinical expertise needed for the laboratory species, but also the knowledge and expertise that must be deployed in reading, reviewing and drafting many documents (NVS' reports, project licence reviews, ERP contributions). This requires a comprehensive and in-depth understanding of SI 566/2002 and Directive 86/609/EEC (as amended).

The question of funding of CPD to support the NVS' role, including mandatory training, specific training opportunities, refresher events and literature (textbooks and journals) may be addressed within the retainer fee.

- *Professional indemnity.* Most part-time and consultant NVS will have professional indemnity as part of their "practice insurance cover". In some cases the employing establishment may indemnify the work undertaken or exempt the NVS (in writing) from any liabilities resulting from his/her work. Whichever is the case, the NVS is well advised to establish how the indemnity is secured and if the liability cover is to fall upon the NVS then the retainer is best utilised to recover the expense.
- *24-hour cover and secondary (clinical) backup.* Provision of 24-hour, 365-day clinical cover is integral to accepting the responsibility of the role of NVS. This will normally require the basic training of at least one other veterinarian in the practice and the commitment to such a comprehensive service is generally accepted as attracting a premium. Expenses incurred through securing this service are generally best recuperated through the retainer and will be in addition to any hourly rates applied to out of hours call outs.
- *The risk factor.* The personal and property risk factor presented to those working in biomedical research, by individuals within extreme animal rights movements, cannot be ignored. Whilst ultimately everyone working with laboratory animals must accept some degree of personal risk from the activities of the extreme animal rights movements, it may be prudent for a part-time NVS to explore indemnity against loss of business and/or damage to personal/ business property as a result of such activities. Expenses incurred in such indemnity are best recouped through the retainer system.

Hourly Rates

Charging hourly rates appears to be the most common way of pricing for work directly undertaken as a NVS. There is wide variation in rates but it is not appropriate to consider rates / hour within this document. Likewise, while it is common practice to charge for both clinical and advisory services at the establishment, there is a wide variation in additional services charged for in such a way.

Additional services that may be charged at an hourly rate include:

- Attendance at meetings (e.g. management, ERP).
- Telephone time (using part of an hour as a "telephone unit").
- Licence application contributions and review (undertaken on the premises or at the home base).
- Writing other documents (e.g. NVS' reports to the Certificate Holder, visit reports, laboratory submissions and accompanying correspondence).
- Issuing of prescriptions for Prescription-Only Medicines (POMs).
- Attendance at CPD events (remember that there is a registration fee and time element to CPD events).
- Delivery and participation in the training of new licensees.

Specific Services

Whilst it is impossible in this document to cover all the "additional" services that may be provided to an establishment as part of the NVS' role, it is important to stress that these must be considered in pricing discussions. Otherwise, and all too often, they become integral with the overall role and then become difficult to identify clearly and to isolate for charging purposes.

Examples include:

- Laboratory work. This may be performed directly by the practice as a direct service, or the NVS may be involved in sending the samples to a third party for analysis. Be sure that the establishment is prepared to pay for laboratory investigations required as part of the role, or that such costs are adequately covered through the retainer fee. Also, consider time spent in discussing results with the investigating laboratory and / or time spent on direct interpretation.
- In some cases the NVS may be asked to undertake work as a Licensee, not as the NVS. This work can be charged at the hourly rate, or the vet may decide that it is worth a premium, especially if it is utilising personal skills and competencies (e.g. anaesthesia or surgery) not normally required in the execution of the NVS' role.
- Supply of Prescription-Only Medicines (POMs) to the establishment. It is best if the supply and charging of POMs to the establishment is considered at the outset and in the initial discussions. Again, for an establishment clearly requiring few or no POMs it may be appropriate to cover their supply through the retainer fee. Alternatively, establishments taking large quantities of POMs (e.g. vaccines) may be approached in a similar manner to a farm client for costing purposes.

Travel

There are clearly two dimensions to pricing travel:

- Direct and indirect vehicle running costs.
- Travel time.

The first, vehicle costs, is the simpler to consider. Almost universally a standard mileage charge will be made to the establishment on a rate / mile basis to cover the costs (direct and indirect) of the vehicle. Standard mileage charges for vehicles of various engine sizes are readily available from the motoring organisations (e.g. AA, RAC).

Travel time can be a contentious issue and charging is very much up to the individual NVS. Most charge travel time at the standard hourly rate. Alternatively, perhaps where the time for each journey is short, this could be covered under the retainer fee.

Frequency of Visits

How often to visit an establishment or animal unit is perhaps the most perplexing question for the new NVS. On the one hand he/she wishes to discharge his/her duties competently and conscientiously, but on the other is aware that many establishments, especially academic institutions, are running on very tight budgets.

As a general rule each establishment/animal unit should be inspected once every one to two months. In determining the exact frequency of visits, the following guiding principles should be considered carefully.

- Ensure that you are completely briefed on the size and scope of the units.
- Ensure that you are completely briefed on the species and animal numbers held.
- Ensure that you are completely briefed on the procedures undertaken (especially any recovery surgery and especially in the larger species [rabbits upwards]).
- Consider the attendance required for routine advisory visits, clinical attention, project licence work and the ERP and participation in any personnel training activities.
- Take into account the views of the licence holders, animal technicians and animal care staff.
- **CONSULT WITH THE INSPECTOR.**
- Be fully conversant with the contents of the VCI Code of Practice for Named Veterinary Surgeons.
- Finally, you must apply your professional judgment as to the time you believe will be required to discharge your responsibilities as the Named Veterinary Surgeon.
- Remember that visiting frequency can and should be reviewed on a regular basis and, most importantly, should adequately support the maintenance of the health and welfare of the animals under your care.

Conclusion

Appointment of a NVS to part-time or consultancy positions frequently takes place through a tendering process, often on very tight time lines. These two factors (process and timeline) often lead to the veterinarian underestimating the resources required or indeed an equitable remuneration for the provision of the services.

Alternatively veterinary practitioners frequently "inherit" a role as NVS with a pricing structure that no longer reflects the volume and complexity of work.

Once having won and signed a contract it is difficult to introduce new charges retrospectively, or to increase prices over the rate of inflation. The veterinary practitioner should ensure that he/she has adequate knowledge of what is required of him/her to ensure that both parties get a fair deal. It must be recommended that no tender submission is made without exhaustive enquiries into what the role entails and what commitments are necessary.

Finally the wise and knowledgeable veterinary practitioner will take the tendering process or pricing discussions as an opportunity to "market" the full breadth of the NVS' role. This ensures that not only is the 'Operator' satisfied with the fee structure presented, but is also comprehensively appraised of the full role that the NVS plays in the health and welfare of the animals within the establishment.

Appendix 3

Extract from the Guide to Professional Behaviour, Published by the Veterinary Council

The Use of Animals in Experimental Research

Veterinary surgeons involved in experimental research using animals shall ensure this research is conducted observing the terms and conditions of a licence issued pursuant to the European Communities (Amendment of Cruelty to Animals Act 1876) Regulations, 1994¹.

Named veterinary surgeons and veterinary surgeons involved in research are responsible for providing sound advice to their employers or co-workers on all animal welfare aspects of any procedure involving animals.

Veterinary surgeons should actively discourage research work which is unnecessarily repetitive or has ill-defined goals.

Veterinary surgeons should ensure that all research projects which involve the use of animals are well planned and include appropriate biometrical assessment of the number of animals to be used. The use of alternative research procedures which do not involve the use of live animals should be assessed during the planning of all research projects.

Veterinary surgeons involved in experimental surgery or other skilled procedures on animals must ensure that their own techniques and those of their co-workers are of high standard, and furthermore ensure best welfare practices for the animals concerned.

¹ Since the Guide to Professional Behaviour was last updated, the 1994 Regulations have been superseded by the European Communities (Amendment of Cruelty to Animals Act 1876) Regulations 2002 (SI No. 566 of 2002)

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EU Legislation

- Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes
http://europa.eu.int/comm/food/fs/aw/aw_legislation/scientific/86-609-eec_en.pdf
- Directive 2003/65/EC of the European Parliament and of the Council of 22 July 2003 amending Council Directive 86/609/EEC on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes
http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=2003&nu_doc=65

Irish Legislation

- Cruelty to Animals Act 1876, 39 & 40 Vict., Ch.77, 1876
- Animal Remedies Act 1993 (No. 23 of 1993) <http://www.irishstatutebook.ie/>
- Veterinary Practice Act 2005 (No. 22 of 2005)
<http://www.oireachtas.ie/documents/bills28/acts/2005/a2205.pdf>
- European Communities (Amendment of Cruelty to Animals Act 1876) Regulations 2002 (SI No. 566 of 2002) <http://www.irishstatutebook.ie/>
- Animal Remedies Regulations 2005 (SI No. 734 of 2005)
http://agriculture.gov.ie/areasofi/food_safety/SI_animalremediesRev3.pdf

International Conventions

- European Convention for the protection of vertebrate animals used for experimental and other scientific purposes (ETS No. 123)
<http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=123&CM=1&DF=06/12/2005&CL=ENG>

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- Veterinary Council (1998). *Guide to Professional Behaviour*. Veterinary Council of Ireland, Dublin. <http://www.vci.ie/Publications.htm>

Useful Organisations

- Veterinary Ireland <http://www.veterinaryireland.ie/>
- Laboratory Animal Veterinary Association (LAVA) <http://www.lavavet.org/>
- European Society of Laboratory Animal Veterinarians (ESLAV) <http://www.eslav.org/>
- Laboratory Animal Science Association (LASA) <http://www.lasa.co.uk/>