VETERINARY IRELAND

GUIDELINES FOR VETS ON THE USE OF ANIMALS IN SCIENTIFIC PROCEDURES 2018

AS RATIFIED BY
VETERINARY IRELAND NATIONAL COUNCIL
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CONTENTS

The Role of the "Designated Veterinarian" in the Use of Animals in Research or Teaching

Guidelines for Veterinary Practitioners who are undertaking duties as a Designated Veterinarian under the European Union (Protection of Animals used for Scientific Purposes) Regulations 2012 (SI No 543 of 2012)

Note: The services provided by a Designated Veterinarian are **not** the same as those normally provided by a Private Veterinary Practitioner to his/her clients. The requirement in SI 543 of 2012 is for the Designated Veterinarian to be "*a veterinarian with expertise in laboratory animal medicine […] charged with advisory duties in relation to the well-being and treatment of the animals*".

A veterinary practitioner may be involved in animal-based research in a role other than that of Designated Veterinarian, e.g. as an authorised researcher, or as an authorised project manager. Similarly, veterinary practitioners involved in teaching activities may come under the scope of the legislation. These roles are subject to separate authorisation by the Health Products Regulatory Authority (HPRA), the Competent Authority under SI 543 of 2012, and are not the subject of this guideline.

Introduction

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

Professional: A veterinary practitioner may be appointed as a "Designated Veterinarian" (DV) under the European Union (Protection of Animals used for Scientific Purposes) Regulations 2012 (SI No 543 of 2012). The provisions of the Veterinary Council of Ireland's "Code of Professional Conduct (Veterinary Practitioners)" apply to all veterinary practitioners, regardless of the nature of their employment. The DV is advised that the Code contains specific sections relevant to a veterinary practitioner's involvement in animal research. It should be noted that, depending on the circumstances, a breach of the Code might amount to "professional misconduct". As the Code is amended from time to time by the Veterinary Council of Ireland, the DV should ensure that he/she keeps abreast of any changes to the current Code. The Code can be found on the Veterinary Council of Ireland's website at www.vci.ie.

Ethical: The DV 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 (Russell and Burch, 1959). Additionally, the DV should set a culture of care in the establishment and work to ensure that all researchers treat animals with empathy and act in a responsible manner at all times.

Legal, as set down in:

- Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (hereafter referred to as "the Directive").
- European Union (Protection of Animals used for Scientific Purposes) Regulations 2012 (SI No 543 of 2012) (hereafter referred to as SI 543).
- European Union (Protection of Animals used for Scientific Purposes) (Amendment) Regulations, 2016 (SI No 552 of 2016)
- Animal Health and Welfare Act, 2013 (No 15 of 2013).
- Veterinary Practice Act 2005 (No 22 of 2005), as amended by the Veterinary Practice (Amendment) Act 2012 (No 25 of 2012). Note that the amended Act contains a revised definition of "professional misconduct".
- Animal Remedies Act 1993 (No 23 of 1993) and Regulations made under that Act, most recently the European Communities (Animal Remedies) (No 2) Regulations 2007 (SI No 786 of 2007), as amended by the European Communities (Animal Remedies) (Amendment) Regulations 2009 (SI No 182 of 2009). Particular note should be taken of Regulations 17 and 19 of SI 786 of 2007.
- Misuse of Drugs Act 1977 (No 12 of 1977), as amended by the Misuse of Drugs Act 1984 (No 18 of 1984), the Misuse of Drugs (Safe Custody) Regulations 1982 (SI No 321 of 1982), the Misuse of Drugs (Exemption) Order 1988 (SI No 326 of 1988), the Misuse of Drugs Regulations 1988 (SI No 328 of 1988), the Misuse of Drugs Regulations 1993 (SI No 338 of 1993), the Misuse of Drugs (Scheduled Substances) (Exemption) Order 1993 (SI No 341 of 1993), the Misuse of Drugs (Amendment) Regulations 1993 (SI No 342 of 1993), the Misuse of Drugs (Designation) Order 1998 (SI No 69 of 1998), the Misuse of Drugs Act 1977 (Controlled Drugs) (Declaration) Order 2010 (SI No 199 of 2010), and the Misuse of Drugs (Amendment) Regulations 2010 (SI No 200 of 2010).

Contractual: SI 543 requires authorisation at three levels:

1. Breeders, suppliers and users (sometimes referred to collectively as "establishments");
2. Projects;
3. Individuals (three sub-types: procedures, project manager, and killing).

The operator of an establishment must appoint a DV, who will then be named on the establishment authorisation issued by the Health Products Regulatory Authority (HPRA). The DV should enter into a business arrangement with the operator of the establishment.

The following Guidelines are intended to help a Designated Veterinarian to fulfil his/her professional obligations as laid down within both the legislation and the Veterinary Council of Ireland's "Code of Professional Conduct (Veterinary Practitioners)". These Guidelines will not cover all situations, or all legal or business elements, and the DV is strongly advised to seek relevant professional advice if in doubt about how to proceed on any aspects of his/her duties.

Scope

The DV is "*charged with advisory duties in relation to the well-being and treatment of the animals*".

Under SI 543, every establishment must also have an animal welfare body (AWB), and the DV is required to "*assist the animal welfare body in its tasks*". The tasks of the AWB are to: -

(a) advise the staff dealing with animals on matters related to the welfare of animals, in relation to their acquisition, accommodation, care and use;

(b) advise the staff on the application of the requirement of replacement, reduction and refinement, and keep it informed of technical and scientific developments concerning the application of that requirement;

(c) establish and review internal operational processes as regards monitoring, reporting and follow-up in relation to the welfare of animals housed or used in the establishment;

(d) follow the development and outcome of projects, taking into account the effect on the animals used, and identify and advise as regards elements that further contribute to replacement, reduction and refinement;

(e) advise on rehoming schemes, including the appropriate socialization of the animals to be rehome; and

(f) facilitate, where appropriate, the establishment of programmes for the sharing of organs and tissues of animals killed.

The AWB is required to "*receive input from the designated veterinarian*", so the DV must ensure that he/she has the skills, knowledge and experience necessary to provide that input.

Appointment as a DV **does not** authorise the appointee 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 authorised separately and will require individual and project authorisations. Where a veterinary practitioner is called upon to participate in or to facilitate a scientific procedure involving the use of animals, he/she must ensure that the relevant authorisations are in place. Likewise, the DV may euthanise an animal for animal welfare reasons but may not kill animals as part of a research project; such activities require a separate Individual Authorisation.

Clinical trials are specifically excluded from the scope of SI 543 of 2012. However, veterinary practitioners are advised to exercise care and to ensure, by reference to the legislation, that any such trial that they are involved in does not require HPRA authorisation. If in any doubt, they are advised to consult the Scientific Animal Protection team in the HPRA for advice (or, if working in an authorised Establishment, the Compliance Officer).

Training of the DV

The DV will be expected to obtain and maintain the skills needed in this specialised area. This is likely to involve further training, as the basic veterinary degree course does not provide the necessary knowledge in sufficient depth. It is prudent for the DV to be a member of an organisation that provides access to up-to-date information in Laboratory Animal Science (LAS) and Laboratory Animal Medicine (LAM).

In the UK, the nearest equivalent to a DV is a "Named Veterinary Surgeon" (NVS). Although the duties and responsibilities of a DV are not identical to those of an NVS, there is a significant overlap in the skills and expertise required, so NVS training is likely to be of benefit to a DV. There are NVS training courses run in the UK, which it would be useful to attend.

In Ireland, there are HPRA approved courses for individuals conducting research that requires the use of animals. Though they are not particularly designed for veterinary practitioners, any veterinary practitioner considering working as a DV should participate in one of these courses as a first step.

Training by the DV

Under SI 543 of 2012, each establishment "*shall designate one or more persons as training officer, who shall be responsible for ensuring that the staff are adequately educated, competent and continuously trained and that they are supervised until they have demonstrated the requisite competence*". The training officer need not be a veterinary practitioner but may delegate training to an appropriately qualified person. It seems reasonable to expect that a DV might be asked to provide training for researchers in the areas of surgery, anaesthesia, analgesia, the handling and administration of medicines and the use of controlled drugs, as drugs used in procedures are prescribed by the DV and supervision in their use may be required. The DV might also be called upon to provide training in the handling and welfare of animals.

Health Control

The DV, through the Establishment's Animal Welfare Body (AWB) will be expected to: -

(a) Have primary responsibility for animal welfare;

(b) Ensure correct severity banding of procedures and post-procedural monitoring;

(c) Make determinations on analgesia and euthanasia;

(d) Establish and run appropriate health monitoring schemes;

(e) Devise and run an appropriate quarantine scheme;

(f) Develop plans for dealing with health breakdowns.

Cover

The DV is often required to provide 24-hour full service cover, but SI 543 says that he/she "*may delegate any of his or her respective functions to other persons who shall be qualified by appropriate training and experience to perform them*". It is important to note that "*Where a person delegates functions […], he or she shall remain accountable for the performance of those functions*".

In the case of holiday-cover the DV should take particular care to inform the animal care and welfare officer and staff of the provisions made for veterinary cover during that period. In this instance the covering veterinary practitioner will be accountable for the assumed responsibilities which might be restricted to welfare issues / animal health issues and might not include training of researchers, participation in ethical review committees, or routine administrative duties.

Medicines

The administration of medicines to animals for any purpose is subject to veterinary control. The inclusion of an animal remedy in a research authorisation does not dispense with the DV's 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. Likewise, controlled drugs require very special attention.

All relevant records should be filed and be available for inspection for a minimum of five years.

Ethical Review

Before granting a project authorisation, the HPRA is required to conduct a project evaluation. The criteria for that evaluation are laid out in SI 543 of 2012, and many of them correspond to criteria that should be considered by an ethical review committee in the establishment. It is normal practice that the DV be among the members of the ethics committee.

The HPRA provides a guideline for ethics committees. This details best practice, to ensure that the committee's assessment is acceptable to the HPRA as being thorough, expert, robust and independent. Where the HPRA is satisfied that a robust ethical review has been conducted and has been given a detailed written report from the ethical review committee, the HPRA will endeavour to assess applications for project authorisations in a shorter timeframe than the 40 working days allowed by SI 543.

Certification

In the event that the DV is required to certify anything, he/she is reminded of the certification principles in the Code of Professional Conduct (Veterinary Practitioners).

Examples of such certification are as follows:

- Certify that it is acceptable to re-use animals taking into account the life experience of the animal, in accordance with Regulation 21 of SI 543.
- Examination of animals that may be injured or sick, when included in a project authorisation.
- Certifying the health status of an animal prior to advising on setting an animal free or rehoming it, subject to the granting of the HPRA authorisation.
- Certifying the health status of animals supplied to other establishments.

Appendix 1

Guidance to Private Veterinary Practitioners (PVP) undertaking Designated Veterinarian (DV) duties on a Part-Time or Consultancy basis

Introduction

Due to the small scale of operations of many Irish research establishments, it is often the case that the role of the DV will be undertaken on a part-time or consultancy basis by a Private Veterinary Practitioner (PVP).

The scope, depth and volume of work undertaken by the DV has increased significantly as a result of the increased complexity of the regulations and societal attitudes in this area. As well as the legal obligations laid down in SI 543 of 2012, other areas that are often involved include the control and administration of animal remedies, health monitoring, ethical review of projects and giving advice on anaesthesia, pain prevention & control, and surgery.

These Guidelines are intended to assist a PVP in considering an appointment as a DV, in order to take account of this increased workload, and to adequately estimate the level and responsibility required in the role.

Ethical Considerations

One example of the increase in workload comes from the introduction, in many establishments, of the Ethical Review Process (ERP). Before it will grant funding the Health Research Board (HRB) (which funds much of the medical research in Ireland) requires ethical approval for all research using either animals or human subjects. The HRB states that the membership of an Ethical Committee should include "*The veterinary surgeon who is nominated for the health and welfare of the animals in the unit*", i.e. the DV. This frequently requires visits to the establishment to attend ERP meetings, as well as reviewing and perhaps contributing to applications for authorisations from outside the research establishment.

Practical Considerations

- *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, farm animals).
- *The type and complexity of procedures conducted.* This will also vary from simply breeding animals to complex techniques including surgery. Clearly, large and complex facilities using large numbers of animals will require more frequent and time-consuming visits.
- *The degree of expert or specialist knowledge expected of the attending DV by the establishment.* Small units and perhaps small breeding units may demand little extra knowledge over and above that of a competent Private Veterinary Practitioner who has additional training and/or experience in the relevant species. However, even in such circumstances, **every** DV must have a comprehensive knowledge and understanding of the legal framework as laid down in SI 543 of 2012 and of all species used within the Establishment.

The amount of "extra" knowledge and competency required is easily translated into a factor of "specialisation" required, which in turn relates to requirements for relevant Continuing Veterinary Education (CVE) to support the DV's role, including mandatory training, specific training opportunities, refresher events and literature (textbooks and journals), and liaison with the HPRA.

The degree of specialisation required must reflect, not only the clinical expertise needed for the laboratory species concerned, but also the knowledge and expertise that must be deployed in reading, reviewing and drafting many documents (DV's reports, project licence reviews, ERP contributions). This requires a comprehensive and in-depth understanding of the Directive, SI 543 of 2012, and various guidelines that the HPRA may publish from time to time.

- *Professional indemnity.* Most part-time and consultant DVs 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 DV (in writing) from any liabilities resulting from his/her work. Whichever is the case, the DV is well advised to establish how the indemnity is secured and whether or not any liability extends personally to the DV.
- *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 DV. This will normally require the basic training of at least one other veterinary practitioner, on whom the DV can rely to provide relevant commitment and cover.
- *The risk factors.* The potential for a personal and property risk factor presented to those working in biomedical research, from extremist movements in society cannot be ignored. Whilst ultimately everyone working with laboratory animals must accept some degree of personal risk from any potential activities of extremist animal rights activists, it may be prudent for a part-time DV to explore indemnity against loss of business and/or damage to personal/business property as a result of such activities.

Specific Services

While it is impossible for this document to cover all the services which may be covered in the duties of a DV, the following give some indication as to the level of service which would be provided by a DV to a research establishment.

- Attendance at meetings (e.g. management, ERP).
- Telephone conferences and consults.
- Contributions to, and review of, applications for authorisations (undertaken on the premises or at the home base).
- Writing other documents (e.g. DV's reports to the authorisation holder, visit reports, laboratory submissions and accompanying correspondence).
- Liaison with the HPRA.
- Issuing of prescriptions for Prescription Only Medicines (POMs) and Controlled Drugs, and/or supply of Prescription Only Medicines (POM) to the Establishment.
- Attendance at relevant CVE events to maintain level of knowledge and service.

- Delivery and participation in the training of new Individual Authorisation Holders.
- Laboratory work. This may be performed directly by the practice as a direct service, or the DV may be involved in sending the samples to a third party for analysis.
- In some cases, the DV may be asked to undertake work as a participant in a project, not as the DV, and may require the utilisation of personal skills and competencies (e.g. anaesthesia or surgery) not normally required in the execution of the DV's role. Great care must be taken to ensure that the project authorisation allows such participation, and that the appropriate Individual Authorisation is in place. Additionally, the veterinary practitioner should acknowledge the possible conflict of interest and, where possible, should arrange for another veterinarian to act as DV for animals that he or she has conducted procedural work on.

Frequency of Visits

"*How often to visit an establishment or animal unit*" is perhaps the most perplexing question for the new DV.

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 authorisation holders, animal technicians and animal care staff.
- If in doubt, consult with the HPRA.
- Be fully conversant with the Code of Professional Conduct (Veterinary Practitioners), published by the Veterinary Council of Ireland.
- You must apply your professional judgment as to the time you believe will be required to discharge your responsibilities as the Designated Veterinarian.
- Finally, 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

Before applying for or accepting the role of a part-time or consulting DV, it is imperative for the PVP to ensure that he/she is professionally qualified for the specific role, conversant with the ethical and legal frameworks within which the DV must operate, as well as being aware of the practical elements and requirements being placed upon them.

When considering such elements initially, and before accepting any DV engagement, it is prudent for the PVP to seek relevant professional advice on these various aspects.

Appendix 2 - Code of Professional Conduct (Veterinary Practitioners)

Extract from the Code of Professional Conduct (Veterinary Practitioners), published by the Veterinary Council of Ireland

Animals Used in Research
Veterinary practitioners involved in experimental research using live 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 1994[1]. Veterinary practitioners should note that they should not engage in research on live animals unless they themselves possess such a licence[2] permitting them to conduct this research.

Responsibilities to Co-Workers in Animal Research
Named veterinary practitioners[3] and veterinary practitioners involved in research are responsible for providing sound advice to their employees or co-workers on all animal welfare aspects of any procedure involving animals.

Planning of Animal Research
Veterinary practitioners should ensure that all research projects that 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 that do not involve the use of live animals should be assessed during the planning of all research projects.

Responsibilities Regarding Skills and Techniques
Veterinary practitioners involved in experimental surgery or other skilled procedures on animals must ensure that they are competent in these procedures and furthermore ensure best welfare practices for the animals concerned. Veterinary Ireland has produced a useful reference document for veterinary practitioners involved in experimental research.

(NB: This extract was taken in November 2018 from Issue 12 (13.09.18) of the Code. At any time, the contemporary Code of Professional Conduct (Veterinary Practitioners) can be found on the Veterinary Council of Ireland's website – www.vci.ie.)

[1] These Regulations have been repealed and, for all practical purposes, replaced by the European Union (Protection of Animals Used for Scientific Purposes) Regulations 2012 (SI No 543 of 2012). At the time of writing the Code of Professional Conduct (Veterinary Practitioners), which is regularly reviewed and updated, had not yet been updated to reflect this change.
[2] This needs to be updated to "*the requisite authorisations*".
[3] The reference to "*Named veterinary practitioners*" would apply equally to Designated Veterinarians.

Primary References (essential reading)

Irish Legislation & Codes of Practice

- European Union (Protection of Animals used for Scientific Purposes) Regulations 2012 (SI No 543 of 2012) http://www.HPRA.ie/images/uploaded/documents/S I No 543 of 2012.pdf
- Veterinary Council of Ireland 2018. *Code of Professional Conduct (Veterinary Practitioners)*. The Code is updated periodically, and the URL changes accordingly. Search the Council's website for the most recent version. http://www.vci.ie

EU Legislation

- Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:en:PDF

Other Primary References

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- Institute of Laboratory Animal Research (ILAR) 2011. *Guide for the Care and Use of Laboratory Animals*, 8th edition. Published by The National Academies Press on behalf of the National Research Council. http://www.aaalac.org/resources/Guide_2011.pdf
- Wolfensohn, S. and Lloyd, M. 2003. *Handbook of Laboratory Animal Management and Welfare,* 3rd Edition. Published by Blackwell Press.

Secondary References

Irish Legislation

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- European Communities (Animal Remedies) (No. 2) Regulations 2007 (SI No 786 of 2007) http://www.irishstatutebook.ie/2007/en/si/0786.html
- European Communities (Animal Remedies) (Amendment) Regulations 2009 (SI No 182 0f 2009) http://www.irishstatutebook.ie/2009/en/si/0182.html
- European Union (Protection of Animals used for Scientific Purposes) Regulations 2012 (SI No 543 of 2012) http://www.HPRA.ie/images/uploaded/documents/S I No 543 of 2012.pdf
- Veterinary Practice Act 2005 (No 22 of 2005), as amended by the Veterinary Practice (Amendment) Act 2012 (No 25 of 2012). Note that the amended Act contains a revised definition of "professional misconduct".

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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- Australian and New Zealand Council for the Care of Animals in Research and Teaching (ANZCCART) Ethics Documentation http://www.adelaide.edu.au/ANZCCART/
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- Russell, W.M.S. and Burch, R.L., 1959. The Principles of Humane Experimental Technique (Special Edition, 1992) http://altweb.jhsph.edu/pubs/books/humane_exp/het-toc
- Smith, J.A. and Boyd, K.M. (Eds.), 1991. Lives in the Balance: The ethics of using animals in Biomedical Research. Oxford University Press, New York

Useful Organisations & Websites

- **Health Products Regulatory Authority - Scientific Animal Protection unit** http://www.HPRA.ie/EN/Veterinary/Scientific-Animal-Protection.aspx
- **Veterinary Ireland** http://www.veterinaryireland.ie
- **Veterinary Council of Ireland** (VCI) http://www.vci.ie
- AAALAC International - Association for Assessment and Accreditation of Laboratory Animal Care http://www.aaalac.org/accreditation/resources.cfm
- European Society of Laboratory Animal Veterinarians (ESLAV) http://www.eslav.org
- European Union Reference Laboratory on Alternatives to Animal Testing (EURL ECVAM) http://ecvam.jrc.ec.europa.eu
- Federation for Laboratory Animal Science Associations (FELASA) http://www.felasa.eu
- Fund for the Replacement of Animals in Medical Experiments (FRAME) http://www.frame.org.uk
- Institute for Laboratory Animal Research (ILAR) http://dels.nas.edu/ilar
- Irish Laboratory Animal Science Association (ILASA) http://ilasa.last-ireland.org
- Laboratory Animal Science Association (LASA) http://www.lasa.co.uk
- Laboratory Animal Science and Training (LAST-Ireland) http://www.last-ireland.ie
- Laboratory Animals Limited - Education and Training in Laboratory Animal Science & Welfare (LAL) http://www.lal.org.uk
- Laboratory Animals Veterinary Association (LAVA) http://www.lava.uk.net
- National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs) http://www.nc3rs.org.uk

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