RCVS Ethics Review Panel for practice-based clinical research

Guidance for practice-based veterinary surgeons and veterinary nurses applying for ethics review of clinical research proposals

This guidance is intended to assist veterinary surgeons and veterinary nurses applying for ethics review of clinical research proposals outside the scope of a university and/or industry context and not covered by Home Office licensing under the Animals (Scientific Procedures) Act 1986 (as amended). Please note that formal ethics review should be carried out prior to the research being conducted and is necessary for publication.

1. Practice-based clinical research versus experimental research

1.1 Practice based clinical research can advance knowledge of conditions affecting animals and is essential to provide the evidence base for veterinary science in order to improve the health and welfare of animals and to improve public health. This can result in changes to the way that conditions and diseases are diagnosed, managed and treated. Research must however be conducted to best standards in order to protect animals, researchers and clients, and to maintain public confidence in the profession.

1.2 Experimental research involving animals that has the potential to cause "pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by inserting a hypodermic needle according to good veterinary practice" falls under ASPA and is considered under a separate ethical process. All research requiring Home Office authority requires mandatory ethics review and arrangements and processes are embraced in the licence application. The RCVS ERP Panel will not consider applications involving research covered by a licence from the Home Office as this will be subject to a separate ethics review process. The Home Office provides further guidance on ethics review within the ASPA process here: https://www.gov.uk/guidance/research-and-testing-using-animals

1.3 Clinical research conducted as part of recognised veterinary practice does not require Home Office authority. Recognised veterinary practice is interpreted as ‘procedures and techniques performed on animals by veterinary surgeons in the course of their professional duties, which ensure the health and welfare of animals committed to their care’. For more detailed information on the meaning of recognised veterinary practice, please see Chapter 25 of the Supporting Guidance to the Code of Professional Conduct (www.rcvs.org.uk/recognised)

1.4 Clinical research conducted as part of recognised veterinary practice should however be subject to some degree of ethics review. The RCVS / BVA joint Working Group on Ethical Review for Practice-Based Research found that “a pragmatic threshold for the need for formal ethical review is any study where a reasonable person would expect to obtain permission from the owners or keepers of an animal before including that animal in that study” (Section 7.1, page 11 of 24).

1.5 The extent and nature of any ethics review should be proportionate to the scale of any risks that may be involved to animals or their owners/keepers. What will be proportionate will vary from case to case.
2. Ethical issues in practice-based clinical research

2.1 Practice-based clinical research may involve client-owned animals, or data pertaining to them, and may be conducted by non institutionally-based veterinary surgeons and veterinary nurses, who might not normally be involved with research, or who may have experience of research, but have now moved to a practice-based environment.

2.2 There are several different categories of practice-based veterinary research which may be associated with clinical interventions and which require ethics review. Research not involving clinical interventions may also require ethics review. Some examples include collection of superfluous or extra tissues, or the use of questionnaires.

2.3 Ethics review helps to ensure that important ethical issues are addressed. For example, where live animals are involved, has written informed consent for the procedure been obtained from the animal owner? Or, where tissue or samples derived from animals during normal post-mortem examination are collected, has the owner given informed written consent for their use in research?

2.4 In order for research to result in benefit and minimise the risk of harm to animal or client (i.e. be conducted in accordance with a veterinary surgeon or veterinary nurse’s responsibilities under the RCVS Codes of Professional Conduct, and other legal responsibilities) it must be conducted ethically. Obtaining ethics approval from the RCVS ERP (or another such panel) will ensure that a researcher can be confident in their compliance with the Code and defend any allegations of poor research practices robustly.

2.5 Ethics approval also helps in protecting the researcher and enables them to demonstrate that they have adhered to the accepted ethical standards of a research study. Many publications will no longer accept for publication research or articles which have not had ethics approval; for example, the Journal of Small Animal Practice (JSAP) states that all authors applying for publication must "certify that all relevant legal and ethical requirements have been met with regards to the humane treatment of animals described in the study". Peer-review is important in ensuring the integrity of veterinary science and development, and ethics review forms an important part of that.

2.6 Animal owners have the right to know who has access to their data and how it is being used, and the right for their participation to remain confidential in that only the researcher(s) will be aware of their identity. Researchers should put in place strategies to maintain confidentiality of personal data (e.g. anonymisation and pseudo-anonymisation procedures).

2.7 There is detailed advice on the categories of research requiring ethics review in the report by a joint RCVS / BVA Working Party (see related documents). This includes advice on the features of clinical research that may raise ethical issues. Applicants are encouraged to read this report.

3. Applying to the RCVS ERP for ethics review

3.1 You can apply to the ERP by completing the application form attached to this guidance. You should complete the application form in simple prose, understandable to all members of the ERP (including lay members) and all abbreviations should be explained at the time of their first use.

3.2 The completed form should contain sufficient information for a thorough ethics review to take
place. If a project is deemed to be poorly planned, or may cause unjustifiable harm/inconvenience/risk to participants without any likelihood of producing worthwhile information or results, it will be rejected or referred back to the applicant for substantial amendment.

3.3 If you consider that a section of the form is irrelevant to your study, please do not leave it blank - please write "N/A" and explain why. All relevant documents, such as information sheets, consent forms, questionnaires and/or risk assessments, should be included with the form and submitted.

3.4 You should submit your proposal by email to ethics@rcvs.org.uk or by post to:

Laura McClintock (Standards and Advisory Manager / Solicitor)

or

Natalie Heppenstall (Standards & Advisory Officer)

Royal College of Veterinary Surgeons, Belgravia House, 62-64 Horseferry Road, London SW1P 2AF.

3.5 Once you have submitted your proposal, you may be contacted to clarify or modify aspects of it before it can formally be considered by the full ERP.

4. Details to be included on the application form

4.1 Your application should be suitably detailed so as to allow for rigorous ethics review. Whilst every study will be different, there are a number of elements which will be common to all applications and the minimum of information expected by the ERP is set out below.

a. Details about the purpose and aims of the study and, if appropriate, the hypothesis being tested.

b. Background to the study, including why you are interested in answering the research question and what is already known and not known in peer-reviewed literature.

c. Description of the study, including a defined subject group and any inclusion and exclusion criteria as appropriate to the study. The sample size should be large enough to produce a statistically valid conclusion, but no larger than absolutely necessary to avoid unnecessary harms or risk. If you are unsure as to an appropriate sample size for your project, you should obtain appropriate advice from a fellow researcher or statistician.

d. Methods of recruitment for proposed subjects and evidence that fully informed consent can be obtained. Sample consent forms should be attached to the form and should be sufficiently detailed to ensure informed consent, including information about risks, benefits, what the study will involve (perhaps as part of an information sheet) and a declaration of voluntariness as a minimum.

e. Potential benefits arising from the study and to other animals in the future.

f. Potential ethical issues and how these will be addressed (e.g. consent, confidentiality, animal restraint, issues for human participants).
g. Any harms likely to occur, how they have been mitigated and assessment of any animal welfare issues that may arise.

h. Potential risks to the project’s success, including any potential risk to subjects arising from their participation and any risk to researchers or staff working with the subjects in any way, and evidence of any precautionary measures that have been taken to safeguard against these. Any risk assessments should also be included.

i. Outcomes being assessed, including who will be assessing them, which methods and at which time points.

j. Details of any medications to be administered, including proposed dosages, details and legal/regulatory status as well as any procedures to be carried out / samples taken.

k. Details of information to be collected e.g. copies of draft / outline questionnaires.

l. Access to data, including any measures taken to maintain anonymity.

m. Details about how the study will be funded, any payments or incentives given to the owners and whether there has been any support and/or guidance from any other group when formulating the study.

Please note that this is not an exhaustive list and there may be many more elements to consider depending on the nature of your proposal. Generally, the more relevant detail you are able to provide, the less likely it is that the ERP will need clarification and so, potentially, speed up the process.

5. The decision-making process

5.1 We will aim to acknowledge receipt of your application within 2 working days.

5.2 The decision-making process will be carried out in 2 stages:

Stage 1: Your application will be considered by the Recognised Veterinary Practice Sub Committee to confirm that the proposal falls within ‘recognised veterinary practice’ and does not need to be regulated under ASPA. The RVP Sub Committee aims to make a decision within 3 weeks of the application being submitted, subject to any requests for clarification or further information. In some cases it may be necessary for the RCVS to discuss aspects of your application with the Home Office or with the Veterinary Medicines Directorate.

Stage 2: If the proposal falls within ‘recognised veterinary practice’ it will be referred to the ERP for consideration. We anticipate that a decision will be made within 10 weeks of the application being submitted.

5.3 The ERP may make one of the following decisions:

| Approved                  | The application is ethically sound and needs no amendment or correction. |
Approved in principle | The application is essentially ethically sound but requires minor amendments before definitive approval can be given. Once such amendments have been made and confirmation of this has been received, the Chair of the ERP will generally action approval.
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Deferred | The ERP could not reach a decision and needs to seek further advice either from the applicant or from other sources.
Not approved | The application is seriously flawed and requires major revision before it can be reconsidered.
Rejected | The study is deemed unethical and cannot be approved.

5.4 Ethics approval is generally given for the duration of the project and therefore the proposal you submit should be intended to be final. Any amendments not requested by the ERP can only be made after approval has been granted and would need to be reassessed by the ERP for ethics approval.

5.5 Please note that in obtaining ethics approval from the ERP, you agree to provide the ERP with feedback on the results of your study, which will be sought by the ERP after the study's completion.

6. Other sources of advice and guidance

6.1 Please note that the ERP will not provide assistance in designing clinical research proposals. If you are seeking help with study design, you may wish to consider sources such as the Clinical Research Assessment and Guidance (CRAG) initiative which has been developed by JSAP. According to the website, the goal of the CRAG panel is to provide assistance in designing, running and analysing clinical research projects. Applicants should be able to work with the CRAG panel to refine the methodology so that the project will be feasible. Further information is available here: [http://www.ed.ac.uk/vet/services/small-animals/services/internal-medicine/news/crag](http://www.ed.ac.uk/vet/services/small-animals/services/internal-medicine/news/crag)

6.2 Grants may also be available through organisations such as Pet Savers, which supports veterinary surgeons to advance clinical investigations into the problems associated with pet animal medicine and surgery to the knowledge acquired for the benefit of patient, owner and the profession. Pet Savers awards grants to researchers in universities, practices and research organisations following a selection process and there is more information available here: [http://www.petsavers.org.uk/Home.aspx](http://www.petsavers.org.uk/Home.aspx)

Standards and Advice Team, August 2016