RCVS Ethical Review Panel (ERP): Applicant guidelines for practice-based veterinary surgeons and veterinary nurses applying to the RCVS ERP

These guidelines are 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 or other appropriate review bodies e.g. NHS Human Research Ethics Committees.
It is important that a formal ethics approval be obtained **prior** to any research being conducted.

1. Background: Practice-based clinical veterinary research versus experimental research

1.1 Practice based clinical veterinary research is an integral part of veterinary practice. It is essential in providing the evidence base for veterinary science 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 within a recognised legal and ethical framework and to best standards to protect animals, researchers and clients, and to maintain public confidence in the profession. Occasionally the object of the research may involve the health and wellbeing of veterinary surgeons, veterinary nurses, or seeking their views on various aspects of veterinary practice.

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 A(SP)A and will need to be considered under a separate ethics review process undertaken by the Home Office during the licensing processes. The RCVS ERP will not consider applications involving research requiring an A(SP)A licence and will only consider applications where the study is considered to be clinical veterinary research, but will be happy to provide guidance on whether or not an application needs an A(SP)A licence.

1.3 Clinical veterinary research conducted as part of routine veterinary practice does not require Home Office approval. Routine veterinary practice is interpreted as 'procedures and techniques performed on animals by veterinary surgeons [or veterinary nurses under their direction] 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 clinical veterinary research in this context, please see Chapter 25 of the Supporting Guidance to the Code of Professional Conduct. If the research involves randomisation or a placebo group, the applicant may need to obtain an 'Animal Test Certificate' for the work from the Veterinary Medicines Directorate in order to carry out a veterinary field trial of a veterinary medicine (https://www.gov.uk/guidance/animal-test-certificates). Applicants should also contact the VMD to discuss any prospective study evaluating a veterinary medicinal product to determine if an ATC is required.

1.4 Clinical veterinary research conducted as part of routine veterinary practice should however be subject to ethics review. The RCVS/BVA joint Working Group on Ethical Review for Practice-Based Research in 2013 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. It may also involve novel treatments particularly in medicine and surgery, or use of the cascade for novel non-veterinary medicines or dosages.

2. Ethical issues in practice-based clinical research

2.1 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's 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 other such panel) will ensure that a researcher can be confident in their compliance with the *Code* and be able to defend any allegations of poor research practice robustly.

2.2 Practice-based clinical veterinary research usually involves client-owned animals, or data pertaining to them, or veterinary personnel, and may be conducted by veterinary surgeons and veterinary nurses not normally involved with research.

2.3 There are several different categories of practice-based veterinary research which may be associated with clinical interventions that require ethics review. Research not involving clinical interventions may also require ethics review. Some examples include collection of surplus/unneeded tissues or extra tissues, the use of questionnaires for clients or peers, the collection and retention of personal or scientific data, or retrospective analyses of collected clinical data.

2.4 Ethics review helps to ensure that important ethical and scientific issues are addressed. For example, when live animals are involved, has informed consent for the procedure been obtained from the animal owner or keeper? Or, where tissue or samples collected from animals during diagnostic evaluation, surgery or post-mortem examination , has the owner given informed consent for their use in research? Have the attendant risks and novelty of the research been made quite clear to the owners in an understandable way to obtain 'informed' consent?

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, including a robust experimental design. Peer-review is important in ensuring the integrity of veterinary science and development, and ethics review forms an important part of that. In addition, most journals will no longer accept for publication manuscripts that describe research which has 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"*. The same legal and ethical requirements pertain when the research (medical or social science) involves humans.

2.6 Human participants (for example clients, animal owners, and veterinary professionals) have the right to know who has access to their personal data and how it is being used and have 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 pseudonymisation procedures), and to ensure that owners have consented to the use of their data in that context in line with current data protection legislation (i.e. the General Data Protection Regulation). Anonymised clinical data can be used without client consent however, it is preferable to obtain consent to the use of the data at the time of client enrolment. Applicants are encouraged to review the Information Commissioners Office website regarding processing of personal data and record the legal basis for processing any personal data (per ICO recommendations).

2.7 There is detailed advice on the categories of research requiring ethics review in the report by the RCVS/BVA joint Working Group 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 these guidelines if you are a 'UK practicing' member of RCVS or a Registered Veterinary Nurse (RVN). You should complete the application form using lay terminology where indicated, understandable to all members of the ERP, which includes lay members unfamiliar with some veterinary terminology. Similarly, you should explain all abbreviations at the time of their first use.

3.2 The completed application 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 deferred and sent back to the applicant for revision.

3.3 If you consider that a section of the form is irrelevant to your study, please do not leave it blank; instead, please write "N/A" and explain why. All relevant documents, such as consent forms, information sheets, questionnaires and/or risk assessments, should be submitted with the form. Proposals for a study will not be considered by the ERP until the relevant client/owner consent forms and information sheets are provided.

3.4 Please note that the ERP will also look at the experimental design of the study as well as the ethics as a poorly designed study may cause suffering with no compensatory benefits.

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

The Ethics Review Panel
Royal College of Veterinary Surgeons
3 Waterhouse Square
138 - 142 Holborn
London EC1N 2SW

3.6 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 detailed enough to allow rigorous ethics review. The minimum information expected by the ERP is set out below in a copy of the application form. Please ensure that you use the latest version of the form.

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

Study details		
1.	*Purpose and aims of study*	*Including the research question or hypothesis that is to be tested.*
2.	Short summary of the proposed study **using lay terms and simple prose.** Max 500 words. Please explain:	

	• What you are intending to do (species, number procedure or review of clinical records). • What question you are intending to address. • What is already known about this subject and what your research will add to this. • How you will collect and analyse the data. • What benefits this study will bring. For an example of a short summary, please see the 'RCVS ERP Guidance on writing lay summaries' document on the RCVS ERP webpage. Lay summaries will be made available to the public on the RCVS website after 12 months: please do not include any identifying information in this section.	
3.	Outline of the proposed study While this should still be written for a non-clinical audience, please provide sufficient information to enable the Panel to understand what you will be doing. Please also provide a list of references. The following information should be provided for all studies: I. Background to the proposed research including current knowledge and how the research will add to the knowledge base. II. Details of the study design and methodology. III. Inclusion and exclusion criteria and participant recruitment. IV. Sample size (which should be justified) and the methods that will be used to analyse data. This applies to both quantitative and qualitative data analysis. V. If it is a multicentre study, details	*The following details should be included here:* • *The background to the study, including why you are interested in answering the research question, and what is already known and what is not known from the peer-reviewed literature. This is likely to be similar to an 'Introduction' to a paper that you may ultimately submit for publication.* • *The description of the proposed study, including defining the subject group and inclusion and exclusion criteria as appropriate to the study. In effect, this will be a precis of what will be your 'Materials and Methods' section when publishing. The sample size should be large enough to produce a statistically valid conclusion, but no larger than necessary to avoid unnecessary harm or risk and should be justified using a sample size calculation with defined parameters. If you are unsure as to*

	relating to where the study will be undertaken and how the data will be recorded. If your research involves collecting and analysing qualitative data e.g., from questionnaires, interviews or online surveys, please describe the methodology and attach a copy of the instruments to be used.	*an appropriate sample size for your project, you should obtain appropriate advice from a fellow researcher or statistician before applying. Similar principles apply to studies that involve collecting qualitative data for analysis.* • *Details of where the study will be conducted, including names of any additional practices that may be involved in multi-centre studies and the local person responsible. The form that will be used to collect data at all of the participating sites should be included alongside the information about the study that will be provided to each participating centre.* • *Provide the research outcome measures being assessed, including who will be assessing them, any necessary training, which methods and at what time points.* • *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 and when those samples will be taken.* • *Details of information to be collected e.g. copies of draft / outline questionnaires and an assurance that the information being collected is specifically required for the research.* • *Methods of recruitment for proposed subjects and evidence that fully informed consent can be obtained.*

4.	*Please justify why your research falls outside of the remit of the Animals (Scientific Procedures) Act 1986, i.e. why a Home Office Project Licence is not required and, therefore, can be considered Routine Veterinary Practice ('RVP').*	*For more information on RVP, please see the RCVS supporting guidance: Chapter 25 – Routine veterinary practice and clinical veterinary research.*
5.	*Please confirm whether an Animal Test Certificate is required for your research. If so, has one has been obtained from the VMD?* Please note, if this is a prospective study involving randomisation of administration of a veterinary medicinal product, a placebo group or off-licence administration of medication, it will require an ATC-S. If in doubt, please contact the VMD for clarification and attach a copy of your ATC or confirmation that one is not required.	• *Details of any (a) any substance or combination of substances presented as having properties for treating or preventing disease in animals; or (b) any substance or combination of substances which may be used in or administered to animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis may require an ATC or ATCS.* • *Information should include substances to be administered, including proposed dosages, details and legal/regulatory status as well as any procedures to be carried out/samples taken and when those samples will be taken. If approved registered products are to be used in an off-licence way, advice from the VMD regarding an ATCS or ATC should be sought. For more information on Animal Test Certificates, please see the VMD: https://www.gov.uk/guidance/animal-test-certificates*
6.	*If the study involves collecting data from or about animals, what are the potential benefits to individual animals involved in the study, and to other animals in the future?*	*Most studies should benefit the subject as well as similar cases in the future.*

7.	*Please advise whether there are any alternative treatments, if applicable.*	*Consideration of alternative treatments forms part of informed consent (see 3(a)(i)), which should always include euthanasia.*
8.	*If the study involves **human participants e.g., veterinary professionals or animal owners**, what ethical issues could arise as a result of the study and how will these be addressed?*	
9.	*What ethical issues **relating to client/owner consent** could arise as a result of the study and how will these be addressed?*	*Note that there may be potential to cause distress to owners through follow-up for data-collection for example, if their pet has died and there should be consideration of how this distress will be mitigated/minimised.*
10.	*What ethical issues **relating to confidentiality** could arise as a result of the study and how will these be addressed?*	*Could there be inappropriate linking of data after publication?*
11.	*What ethical issues **relating to minimising the risk** of harm to animals could arise as a result of the study and how will these be addressed?*	*Many veterinary procedures cause some distress or harm to the animals, but these should be minimised and always kept proportional to potential benefits.*
12.	*Are there any other animal welfare or other ethical issues that may arise?*	*For example, if there is potential for pain and/or distress to escalate then a suitably effective rescue plan should be in place.*
13.	*What are the main risks to the project's success?*	• *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.* • *Risks to the number of cases may arise through recruitment difficulties and any*

		contingency planning (see 2(b)(ii))
		• *Please explain whether these risks are to:*
		  ○ *animals involved in the study;*
		  ○ *benefits not being achieved;*
		  ○ *issues with study design*

14.	*How will you assess success or failure of the study?*	*For example, could quality of life of the subject animals be used, or some other form of benefit or reduced incapacity?*
15.	*What steps are in place to deal with any unintended outcomes or welfare issues?*	• *What you will do in the case of incidental findings e.g. unrelated finding on imaging, or blood tests.* • *Information about how inadvertently discovered clinical findings may need to be reported and discussed with the client (and insurer, as it potentially might affect future claims).*
16.	*How do you intend to assess scientific success, or withdrawal end points if it fails, for the animals involved in this study?*	• *Information about how scientific success or scientific end points will be assessed.*
17.	*What measures are in place to ensure that animals are withdrawn from the study if it becomes clear that the study has failed?*	• *Consider that the study may not work out as planned and so the experiment may have to be stopped early and animals withdrawn from the study group.*
18.	*If your research involves collecting and analysing qualitative data e.g. from questionnaires or online surveys, please include the methodology and instruments to be used.*	• *Qualitative research has an important place in the early stages of some types of research or for the whole of a study. Please include details of the proposed methodology as well as any instruments to be used (e.g. questionnaires, online surveys). Make sure that all questions relate to the study and avoid 'phishing' using borderline relevant questions with poor justification.* • *A useful summary: Ethical Issues in Web-*

		based Research Using the Internet for Research. Dr Alice Temple (Research Ethics Senior Training & Development Officer, University of Leeds; See other articles here.
19.	How will the results of the study be disseminated/published? Will the data be made available within a public repository upon publication?	• *Provide details of where you intend to publish the results of the study and other methods that will be used to disseminate the findings to the appropriate audience.* • *Many journals require the anonymised raw scientific data to be made available in a suitable online repository for wider dissemination and reuse once the project is complete and published. Provide details as to how this might be achieved.*
Practicalities		
20.	*How will consent be obtained for participation in the study?* ***For prospective studies, please attach copies of BOTH the proposed client/participant consent form AND the separate information sheet for all centres involved in the study. These are mandatory.*** *In certain circumstances, an agent acts on behalf of the owner (e.g. horse racing trainer) and it is acceptable for them to provide consent.*	• *For prospective studies, sample owner's consent forms AND information sheets **must** be submitted alongside the application form and should be sufficiently detailed to ensure informed consent, e.g. in plain English. This would normally include information about alternative treatments, the potential harms and other risks, the anticipated benefits, what the study will involve, and a declaration of voluntariness as a minimum. This is best achieved with a relatively simple consent form with an accompanying owner information sheet which contains enough information to allow clients to give informed consent. A YES/NO consent to individual statements format is recommended as it can clarify the issues being addressed.* • *The Panel will also expect to see the following within the owner consent form:* ○ *Consent to the use of their animal in the*

		proposed research that has been duly explained to them and that they have been able to have any questions answered to their satisfaction. This should include any procedures to be carried out over and above what can be considered routine veterinary practice. ○ *Consent should include how clients can access the primary investigator, or someone else familiar with the study, who can answer their questions.* ○ *Separate consent to the use and storage of their personal data in the proposed research (see (v) below,).* ○ *A statement explaining to the owner that non-participation or withdrawal of their animal or their personal data from the study is voluntary and will not be detrimental to the animal or the owner or the owner's other animals either now or in the future.* ○ *A statement explaining to the owner that if their animal becomes unduly stressed during the procedure then it will be stopped immediately, and the animal withdrawn from the study.* ○ *A statement explaining to the owner that if their animal suffers unexpected pain during the procedure then it will be stopped immediately, pain relief administered and the animal withdrawn from the study.* ○ *It is preferable that a statement is included explaining to the owner that results of the whole study when completed will be reported back to them, or information about how results can be accessed.* ○ *A statement that the owner consent is limited exclusively to the study as*

		described in the information sheet. ○ *For retrospective studies using data already collected consent may already have been obtained to use it at the time of collection. Such historic data can still be used providing any personal details of any human (owner) involved are anonymised.*
21.	*How will your study be funded? How will any potential conflicts of interest be addressed?*	*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 (see separate guidance). It is preferable that the study is cost neutral for the client.*
22.	*Is the success of the project contingent on obtaining funding?*	
23.	*Will any payment or other incentive be given to the owners of the animals in the research group? If so, please specify.*	*Incentives should be sufficient to cover expenses but not be coercive. Assurance should be given that there will be adequate funds to cover the study. Clear information should be included regarding which treatments are to be paid for by the owner and which are covered by the researchers. A greatly reduced fee compared with conventional treatment could be considered coercive. The costs involved when unexpected reactions occur should be explicitly covered and should not involve extra costs for the client unless previously agreed.*
24.	*How are you going to store your data? Who will have access to these data?* *Please state any measures you will take to maintain anonymity or pseudoanonymity (with details of the linkage and security between case records and the owner's personal*	• *Information about controlling access to data, including any measures taken to maintain anonymity in line with the GDPR* • *If the study design involves more than one centre, please indicate how data will be anonymously collected and securely transferred to the lead investigator. The person assuming responsibility at the*

	information), to ensure compliance with the General Data Protection Regulation. *Include details of how data will be handled across multiple centres, if applicable.*	*secondary centre must be named.* • *The following wording may be used on the client consent form:* *"I consent to my personal data (INSERT WHAT DETAILS YOU WILL USE) being used to select my animal into the study. After selection, I understand that my personal details will be anonymised and unlinked from the study and will be erased. Only anonymised details will be used for publication and for any subsequent studies."*
25.	*How long are you going to store the personal data, and when will it be destroyed?*	*How long personal data will be stored and when it will be destroyed: it would not be sufficient to say that such data will be destroyed or only stored until the date of publication, as the applicant may choose not to publish the results. The applicant should also consider what they will do, if a journal asks for the raw data to be available for analysis. NB this refers only to personal data, not to any scientific data that is not linked to personal data.*
26.	*To the best of your knowledge, will the intended group of animal subjects be involved in any other research project?*	*It is unlikely but possible that clients may be enrolled in more than one study that may compromise the results or welfare.*
27.	*Have you received support and/or guidance from any group e.g. BSAVA or BVNA, in formulating your study design?*	*It may be helpful to consult other websites on research design.*
28.	*Have you completed all relevant documentation in preparation for your study, i.e. insurance, COSHH risk assessment forms, etc? (Please attach copies of documents if so)*	
29.	*Has the study been previously, or simultaneously, submitted to another organisation for ethics review?* *If so, what was the outcome?*	*Applications to multiple ethics review boards are potentially confusing and should be avoided without good reason. Multi-centre trials may require multicentre ethics approvals, and this should be stated and discussed. Copies of*

		approvals at the other centres should be provided. The ERP will still require amendments to be made even if the study has been approved by another ethics review board.

5. The decision-making process

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

5.2 The application will be checked for completeness and if any mandatory documents are missing, (e.g. consent form, information sheet), or the lay summary is not written using appropriate language, the application will be returned to the applicant.

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

Stage 1: Your application will be considered by the Routine Veterinary Practice Subcommittee to confirm that the proposal is clinical veterinary research or that the study needs to be regulated under ASPA. The RVP Subcommittee aims to decide within 12 working days 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 proposal with the Home Office or with the Veterinary Medicines Directorate.

Stage 2: If the proposal is considered to be clinical veterinary research, it will be referred to the ERP for consideration. We anticipate that a decision will be made within 27 working days of the application being submitted. A letter will be sent to the applicant outlining the decision and highlighting any areas for amendment/clarification within 32 working days of the application being submitted.

5.4 The ERP may make one of the following decisions:

Approved	The application is ethically sound and needs no amendment or correction.
Deferred	The application is returned to the applicant for amendments.
Refused	The study, or parts of it, is ethically sub-optimal and cannot be approved.

5.5 Ethics approval is given specifically for the proposal as described in your submission. Any amendments not requested by the ERP made after approval has been granted would need to be reassessed by the ERP using the specific amendment form.

5.6 If unexpected issues arise during the project that may impact on the ethics approval given, the applicant is expected to notify the ERP as soon as possible for further guidance. It is also good practice to plan an interim ethics review to be carried out by the applicant/researcher for long-term studies.

5.7 Please note that in obtaining ethics approval from the ERP, you agree to provide the ERP with feedback by completing a form, which will be sought by the ERP after the study's completion. Please answer the questions upon it fully and honestly, as relevant to your research project. All feedback will remain confidential and will not be published outside the RCVS unless you specifically agree otherwise. You are of course welcome to supply the Panel with copies of proposed journal articles or similar as part of your feedback if you wish.

6. Other sources of advice and guidance

6.1 Please note that the ERP will not provide assistance in designing or analysing clinical research proposals prior to submission. 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: https://www.bsavalibrary.com/researchers

6.2 Grants may also be available through organisations such as PetSavers (for small animals), Horse Trust and Petplan Charitable Trust (amongst many others), each of which support veterinary surgeons to advance clinical research into problems associated with their respective species of interest.