

Ethical Review for Practice-based Research
A report of a joint RCVS / BVA working party
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1. Summary

An increasing amount of clinical research is being conducted by veterinary surgeons based in private practice. Unlike those based in veterinary schools and institutes, private practitioners may not be so familiar with the regulations and best practice associated with research particularly with reference to ethical review. To facilitate practice-based research, to enable it to be conducted to best standards and to protect both practitioners, the public and the animals they own, a working group was established by the RCVS and the BVA. Involving representatives of relevant bodies and experts, its aim was to provide advice and guidance on the ethical review of practice-based research in the UK.

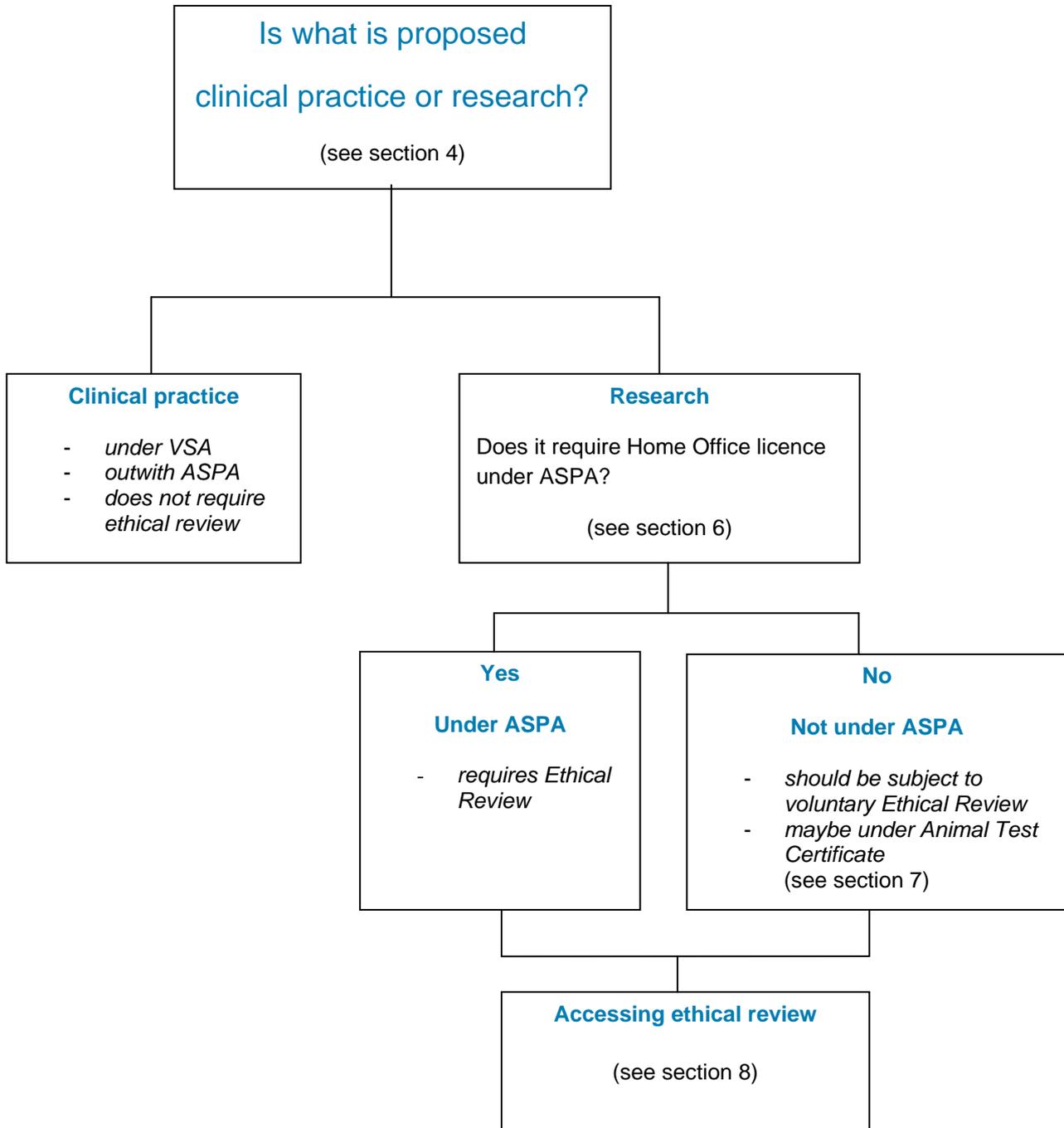
This report provides the group's advice with respect to ethical review for the veterinary surgeon planning clinical research. It discusses the distinction between clinical practice and clinical research and then considers under what circumstances research requires Home Office authorisation under the Animals Scientific Procedures Act 1986 (ASPA) and when it does not. All research requiring Home Office authority requires mandatory ethical review and arrangements and processes are embraced in the licence application.

This report concentrates particularly on clinical research outwith ASPA. Ethical review for all such research is advised. The reasons and issues are extensively discussed, not only for interventions directly with animals (including those under Animal Test Certificates) but also for research not involving clinical interventions (e.g. questionnaires, use of superfluous tissues, and environmental sampling).

Finally, guidance is given on accessing ethical review of research. Ideally, researchers are advised to develop a relationship with veterinary institutes so as to be able to submit research proposals to the ethical review committees of those institutes. We also recommend that the RCVS considers establishing an ethical review committee to consider research proposals from practitioners who may not have, or wish to have, links to existing institutions. To enhance advice to practitioners, we recommend that the RCVS standing committee on Recognised Veterinary Practice be enlarged and its existence better publicised.

It is hoped that this report will facilitate and encourage practice-based clinical research by giving practitioners constructive advice which will reassure both the profession and the public.

Ethical review – a flow chart to aid decision making and navigation of the report



2. Terms of Reference

- a) With reference to ethical review, to produce advice and guidelines for veterinarians conducting research from practice.
- b) To recommend means of access to ethical review processes for veterinarians wishing to do research in practice.

3. Background

Research 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. The role of practising veterinary surgeons in that process is important and has been recognised by, amongst others, the seminar at the RCVS in 2005 'Research into Practice – Practice into Research', the University of Cambridge initiative (Clinical Research Outreach Programme – see references, section 12) and the BSAVA (see Mellanby, 2011).

At the same time, more and more practices are operating at standards where research is feasible and clinical advances are validated. Those involved in research centres in institutions and universities are familiar with Home Office regulations, the Animals Scientific Procedures Act (ASPA) 1986, and the value of ethical review processes, but busy practitioners may not be so aware of these issues or may not be able to easily access advice on them. Recognising the positive effect advice and guidance in this area could have to ensure that practice-based research is conducted according to best practice, the BVA and the RCVS agreed to set up a Working Party to consider Ethical Review for Practice-based Research (ERPRB).

We were particularly mindful that prior ethical review of proposed procedures could provide important reassurance to practitioners considering research.

What the working party and this report do NOT consider are the wider ethical issues about the extent of treatment of individual animals which is the subject of widespread professional debate elsewhere. Nor does this report discuss in detail matters covered by ASPA – although for completeness we discuss the criteria by which research may or may not fall within the remit of ASPA. Particularly, **this report concerns itself with clarifying those many situations where it would be prudent to involve ethical review for research falling outwith ASPA.** This could be for such apparently innocuous procedures as sending out questionnaires. And we make recommendations about how ethical review might be obtained.

For the purposes of this report, we consider practice-based research as research involving client-owned animals and conducted by non institutionally-based veterinary practitioners who might not normally be involved with research.

We emphasise that this report seeks to provide guidance and help of practical benefit to veterinary practitioners and to provide re-assurance to the profession and public alike. It is not intended to impose unnecessary barriers to the pursuit of knowledge.

4. When does clinical practice become research?

- 4.1** Valuable advice about this is contained in the RCVS Code of Professional Conduct for Veterinary Surgeons: Supporting Guidance, Chapter 25, Recognised veterinary Practice <http://www.rcvs.org.uk/advice-and-guidance/code-of-professional-conduct-for-veterinary-surgeons/supporting-guidance/recognised-veterinary-practice/> and can be obtained from the Home Office Inspectorate, and from the RCVS through their standing committee on Recognised Veterinary Practice.
- 4.2** In essence, the **veterinary surgeon must decide whether an intervention is likely to be of direct benefit to the animal or its immediate group and / or is for a purpose of recognised agricultural or animal husbandry practice in the UK. If it is, it falls within clinical practice and under the Veterinary Surgeons Act (VSA) 1966. If it is not then it may be deemed research.** In all circumstances the individual has to consider the primary purpose and whether he or she is acting in a professional capacity as a veterinary surgeon or as a research scientist. Although the procedures and techniques may be identical, analysis of the purpose for which they are applied should help the veterinary surgeon to determine if the intervention is recognised veterinary practice or research. If it is research it would benefit from ethical review and might require a licence under ASPA. It is important to appreciate that **whilst all activities requiring a Home Office licence require ethical review, not all research which would benefit from ethical review requires a Home Office licence.** One such example is work undertaken under an Animal Test Certificate (ATC) of the VMD (see later), but also much other clinical research may fall into this category. **Do not assume that because work does not require a licence under ASPA that it does not need ethical review.** Note that for procedures outwith ASPA and outwith clinical practice there is no legal requirement for ethical review, but seeking it – and responding to its advice – will be a valuable assurance to the veterinary surgeon especially in the event of any subsequent dispute. Note too, that this advice pertains to each component of an investigation. Thus if a patient or series of patients underwent several procedures which might reasonably be regarded as part of normal clinical practice, but an additional procedure was carried out which might be argued was unnecessary for the direct clinical benefit of the animal / animals (but which contributed to the acquisition of knowledge), then the inclusion of the latter should prompt consideration of the requirement for ethical review and / or ASPA. Clearly there will be many instances where it is arguable to what extent a procedure is necessary, normal or beneficial to the patient. A number of examples are considered in this report and also in the RCVS Code of Professional Conduct, Supporting Guidance, Chapter 25. If in doubt, seek advice. Let us consider clinical research in more detail.

5. General considerations about clinical research and ethical review

- 5.1** Clinical research can arise from a continuum of activities that range from observational studies using data collected during routine veterinary practice to interventional studies where the treatment of patients is determined by their allocation to a particular intervention group. Any collection of clinical data where the intention is to communicate information about clinical practice may be described as clinical research.
- 5.2** All clinical research should be subject to some degree of ethical review, and many peer-reviewed journals now make such review a condition of publication. The extent and nature of any ethical review should be proportionate to the scale of any ethical risks that may be involved. Thus ethical review is a sequential or incremental process and should take the following steps:
- i. The investigator should review any potential ethical issues that may arise from the planned research in order to make a judgement on the need for further formal ethical review. If the investigator is relatively inexperienced, advice should be sought from more experienced colleagues who are familiar with clinical research and ethical review.
 - ii. If the process in (i) above indicates that formal ethical review might be needed the investigator should submit an outline of the proposed research to an official representative of an institutional ethical review committee for an opinion on the need to submit the proposed research for full ethical review by that committee.
 - iii. If the advice in (ii) is that full ethical review is needed the investigator should submit a detailed protocol of the proposed research to an institutional ethical review committee for a formal ethical review.

5.3 What features of clinical research raise ethical issues?

The following sections indicate areas that should be considered, but this is not an exhaustive list. Ethical issues may arise from many unanticipated areas:

- i. Any potential to cause harm or distress to a patient that may occur as a result of the animal's participation in the research.
- ii. Any potential to cause harm or distress to an owner or keeper of a research subject.
- iii. Breaching the confidentiality of the owner/client/keeper of an animal during the conduct of the research or its publication.
- iv. Ownership of data or clinical material.
- v. Obtaining informed consent.
- vi. Research involving children, or adults unable to provide full and informed consent.

5.4 The purpose of ethical review

- i. The overarching principle of ethical review is to ensure that the potential risks are balanced by the likely outcome of the research.
- ii. A formal ethical review considers the extent to which any hypothesis being tested or the aims of the research are credible and that the methodology is appropriate.
- iii. Ethical review may identify issues that have not been recognised by the investigators.
- iv. Feedback from an ethical review committee may suggest modifications to the research protocol that avoid or ameliorate ethical problems.
- v. Veterinary ethical review can be expected to consider the possibility that the proposed research may require a Home Office licence under the ASPA. While this is not an ethical issue *per se* it is an important legal consideration.
- vi. Going through a process of external ethical scrutiny provides assurance to the participants and to the publishers of research that ethical issues have been carefully assessed, and the design and conduct of the research meets agreed standards.
- vii. Formal ethical review is normally an iterative process and often improves the quality of the proposed clinical research.

5.5 At what stage should clinical researchers seek external formal ethical review?

- i. Formal ethical review can only be effectively carried out prior to the research being conducted or published.
- ii. Retrospective studies using data that have been collected in the normal course of veterinary clinical practice are less likely to raise ethical concerns. However, there are likely to be ethical issues relating to assimilation and storage of data. In addition, even the publication of a simple case report may cause a problem if the patient or its owner may be identified as a result of publication.

5.6 Publication of research

Conducting research without an intention to publicise the results more widely is difficult to justify ethically. The routes of publication need not be through refereed journals (although this is preferable) but they should try to reach the relevant audiences.

6. When does research fall within the Animals Scientific Procedures Act 1986 (ASPA) and when does it not?

- 6.1** Any research involving animals that has the potential to cause "pain, suffering, distress or lasting harm" falls under ASPA. The threshold of pain that is used is that of introducing a hypodermic needle through the skin. All research under ASPA requires ethical review.
- 6.2** For clinical research NOT to fall under ASPA it must either not cause pain, suffering, distress or lasting harm OR any potential to cause pain, suffering or lasting harm must result from an act of veterinary surgery as part of recognised veterinary practice (see 4.2 above). To reiterate, key considerations include the following -
- i. An act of veterinary surgery must be performed for the direct benefit of the animal (or group of animals, i.e. a pen, flock, or herd) under a veterinary surgeon's care.
 - ii. The primary motivation leading to the procedure is an important distinction. Where that motivation is entirely for research purposes that procedure would fall under ASPA. Where the motivation is for the treatment of an animal it would fall under 'recognised veterinary practice'.
 - iii. Any information obtained from a diagnostic intervention should have the potential to influence the treatment of the animal that has been subjected to that diagnostic test.
 - iv. Sampling for surveillance purposes, where the sampling involves pain e.g. blood sampling, requires ASPA unless it can be clearly shown to be of direct benefit to the animals under the veterinary surgeon's care.
- 6.3** Withholding treatment, when such a treatment has the potential to prevent "pain, suffering, distress or lasting harm", such as the use of a placebo, would fall under ASPA.
- 6.4** Practical considerations of the interface between clinical research and ASPA requirements:
- i. Surplus tissue samples, such as blood, taken in the course of veterinary treatment may be used for research purposes. Additional amounts of blood may be withdrawn without a licence under ASPA as long as they are not likely to cause "pain, suffering, distress or lasting harm" (i.e. from the single needle stick used to take the diagnostic sample, and usually less than 10% of blood volume withdrawn in total). See also Section 7.4.1.
 - ii. The use of novel surgical techniques on a patient may be performed when the primary intention is to treat the animal although there may be a secondary intention to publish the outcome. This is 'recognised veterinary practice' when the surgery is performed by a suitably experienced veterinary surgeon, and the procedure used has a reasonable expectation of a successful outcome appropriate for the condition being treated and supported by rational use of existing knowledge and literature.

7. Ethical review for research outwith ASPA

7.1 Research involving clinical intervention with animals

There are several categories of practice-based veterinary research which may be associated with clinical intervention and which require ethical review. Examples follow but this list is not exhaustive.

- i. Clinical trials of novel medicines with a view to product registration. Such research generally requires an Animal Test Certificate (ATC) issued by Veterinary Medicines Directorate - see section 7.2.
- ii. Novel uses of licensed medicines in prospective group or cohort studies. Such research may be justified with appropriate reference to the veterinary medicines cascade. Veterinary surgeons should carefully consider the clinical and scientific justification for such research. The circumstances under which such studies can be conducted without an ATC are quite specific (see VMD guidance – VMGN No. 6).
- iii. Novel surgical techniques. There is no regulation for this type of research but veterinary surgeons should carefully consider the scientific and clinical basis to undertake research on a novel surgical technique. One would expect existing literature or studies to support the proposal, and this might include *ex vivo* research, or translation of data from other species including human beings.
- iv. Novel medical devices or implants. Medical devices and implants are not regulated in veterinary medicine in UK. However, veterinary surgeons considering clinical research with a novel device or implant should carefully consider the existing knowledge on that particular device or implant. This may involve translation of data from other species, including human beings, but may also involve *ex vivo* testing, or materials testing.
- v. Any study where decision-making (e.g. diagnostic or therapeutic intervention) is determined by the study design e.g. a randomised study, rather than the attending veterinary surgeon, requires formal ethical review.
- vi. Any study where personal data (i.e. data that is not anonymous) may be passed to a third party who would not normally receive that data should be considered for formal ethical review.
- vii. Studies where additional clinical data, or larger clinical samples, are obtained as part of the research require formal ethical review.

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.

7.2 Animal Test Certificates - veterinary research which may require VMD Regulation

- 7.2.1 The Veterinary Medicines Directorate regulates clinical (field) trials using animals to demonstrate efficacy and/or safety of a Veterinary Medicinal Product in the intended target species under conditions of field use. Such trials may be carried out by individuals, organisations or companies. The VMD authorises such work through Animal Test Certificates (ATC).
Full details can be found in the Veterinary Medicines Guidance Notes 6 (VMGN6) and related guidance on the VMD website (www.vmd.defra.gov.uk). It is recommended that specific, case-by-case, advice be sought from the VMD Licensing team on 01932 338439 or 336911.
- 7.2.2 A Veterinary Medicinal product is defined as:
Substances or combinations of substances presented as having properties for treating or preventing disease in animals; or
Substances or combinations of substances that 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
- 7.2.3 An ATC is granted if the benefit to risk assessment is considered positive. Justification is required for the proposed trial. From the perspective of ethical use of the animals involved, the ATC provides appropriate safeguards for their safety. However, **all procedures applied to animals during the course of the trial must be consistent with “recognised veterinary practice”** and the investigating veterinary surgeon must act in accordance with the Veterinary Surgeon's Act, otherwise the study will also need to be regulated under the ASPA.
- 7.2.4 Authorities under ASPA may be required when animals may experience pain, suffering, distress or lasting harm. Particular consideration should be given to animals in placebo treated “control” groups. The ATC itself does not relieve the veterinary surgeon from providing normal veterinary care for the animal involved in a trial. Should this be prohibited by the protocol of the trial, or if trial procedures are not compliant with recognised veterinary practice, the Home Office should be consulted regarding the need for an ASPA licence. Further information is available from the Home Office website at:
<http://www.homeoffice.gov.uk/science-research/animal-research>.
- 7.2.5 The animals are usually client-owned animals rather than animals held at research establishments. Informed owner consent must be obtained.
- 7.2.6 In order to minimise the data requirements and time to approval, ATCs are divided into three types (A, B, and S) depending on their complexity. ATC's A or

B are usually awarded to pharmaceutical companies to provide data for marketing authorisations. In these cases the pharmaceutical companies will have their own ethical review processes which will be invoked as required. The veterinary surgeon involved in trials under ATCs A or B should satisfy themselves that suitable ethical review has been done. Note that ethical review is not part of the VMD's authorisation procedure.

7.2.7 The ATC-S is specifically intended for small scale research trials conducted by veterinary surgeons; these cases usually do not require the work to be conducted to Good Clinical Practice standards and involve only small numbers of animals (usually <50). **For Type S ATC**, as the protocol is not submitted, **the researcher/investigator and at least two other veterinary surgeons**, who are independent of the trial and have a further qualification in the discipline concerned, **should provide signed confirmation that they have reviewed the protocol and that they are satisfied that the study is ethical** and is to be conducted in accordance with these requirements.

7.2.8 **In summary**, the ethical considerations for the use of animals in these types of field trials include;

- Justification of the need for such a trial, which could not be addressed without using live animals.
- Provision for the safety and welfare of the animals involved.
- Confirmation that the procedures comply with the RCVS Guide to Professional conduct and be "recognised veterinary practice", unless additional licence authorities under ASPA have been obtained.
- Informed consent from the owners of the animals.
- For ATC-S independent *ad hoc* ethical review by two veterinary surgeons

7.3 Helpful hints for research involving clinical interventions

7.3.1 Study design

- i. There are various study designs that investigators may choose to use depending on the research question and the regulatory and ethical issues around the clinical intervention (e.g. retrospective, prospective, randomised, parallel group, cross-over, etc.). When considering study design, the investigator must consider the ethical issues around the clinical condition and the proposed intervention. The use of placebos in any trial must be very carefully considered. For example, placebo-controlled trials are not considered ethical in many types of cancer. In addition, studies of analgesics must be carefully planned such that animal welfare is carefully maintained and there are appropriate steps to use "rescue" analgesia, or withdraw the patient from the study. Surgical studies also have their own issues and

investigators are advised to seek professional help in choosing the most appropriate study design.

- ii. Investigators should strive for the most robust study design having considered the ethical, clinical and financial constraints. Dialogue with the research ethics reviewers may be necessary to evolve an acceptable study design.
- iii. Retrospective studies may also require ethical approval despite the fact that no prospective clinical interventions are planned. This is because patient and owner data will be collected; investigators must have ethical review for their data collection methods and appropriate data protection methods. Review may be required if stored data are to be used retrospectively for purposes other than those for which they were collected. Questionnaires to be sent to owners retrospectively must also have ethical approval (see non-interventional research).

7.3.2 Funding and potential conflicts of interest

The funding of the proposed research should be clearly identified. In addition, any relationship between the researchers and the funders should be declared, along with any other potential conflicts of interest.

7.3.3 Recruitment of animals

- i. The methods for animal recruitment should be described.
- ii. With respect to animal owners, researchers should describe how they would be identified, approached and recruited.
- iii. Any advertisements for recruitment should be drafted and enclosed with the research ethics application along with the type of advertisement to be used.
- iv. When involving animal owners, researchers should consider each owner's ability to give informed consent.

7.3.4 Human participants in animal studies

- i. Where humans are providing information or participating then the ethical review process should involve appropriate medical and / or social science research expertise.
- ii. The researchers should carefully consider the human participants (e.g. owners, farmers, jockeys, kennel assistants, etc.). In particular, the collection of any data regarding the human participants should be carefully considered and disclosed (e.g. discussion of sensitive topics which might cause embarrassment or distress).
- iii. If the study involves deliberately misleading the human participants, this should be declared and justified.
- iv. Any financial inducements to human participants must be declared.
- v. Human participants must provide full informed consent and must be informed that their participation is voluntary and that they can withdraw themselves and their animal(s) from the research at any time.

- vi. The collection of samples from humans as part of animal studies (e.g. in a study of zoonosis) is outwith the scope of this report and would require review by a suitable medical ethical review committee.

7.3.5 Good clinical practice

Studies regulated by the Veterinary Medicines Directorate, and performed under an Animal Test Certificate generally operate to Good Clinical Practice (GCP) guidelines. Staff engaged in GCP studies must be suitably trained.

7.3.6 Sample size estimates for research involving clinical intervention.

Researchers should make sample size estimates on the basis of sound statistical principles. They make use of existing literature and seek professional help in doing so if necessary.

7.3.7 Inclusion and exclusion criteria

Inclusion and exclusion criteria for human and animal participants should be listed separately.

7.3.8 Outcomes measures in research involving clinical intervention

- i. Outcomes measures should be clearly defined in the study protocol.
- ii. The chosen outcomes measure(s) should be ethical, reasonable and entirely appropriate for monitoring the clinical condition being studied. In a rapidly evolving diagnostic environment, outcomes measures may be novel but novelty *per se* should not be the reason for choosing a specific outcomes measure. There should be clearly justifiable grounds for choosing a specific outcomes measure and if at all possible, it should be non-invasive. Where it does involve some intervention, this should be the least invasive method for the condition or pathology being monitored.
- iii. A single primary clinical outcomes measure should be defined prospectively. The selection of this primary outcomes variable should be considered carefully. Generally, it will be the most relevant and robust measure collected. Some suitable examples include: somatic cell counts in milk in mastitis studies; objective measure of limb function in lameness studies; an echocardiographic parameter in cardiac studies; a hormonal assay in endocrine studies; a biochemical or haematological parameter in internal medicine studies; an animal owner questionnaire (clinical metrology instrument) which would preferably be previously validated for the clinical condition under research.
- iv. Secondary outcomes measures should also be defined prospectively and may be single or multiple. Such measures are often less robust or less directly relevant but are of sufficient relevance to be included

to provide additional dimensionality to the research. Examples might include: an owner questionnaire; a biomarker, or panel of biomarkers.

7.3.9 Risks and their management

- i. The potential risk to animal or human participants should be carefully considered. How the benefits of the research outweigh the risks should also be explained.
- ii. Any risks to the researchers should also be considered and explained.
- iii. The procedures for detection and reporting of unexpected outcomes or adverse events should be documented.
- iv. The conduct of the study should be monitored and adherence to the study plan documented.

7.3.10 Data access and storage

- i. When the research involves collection of personal data (including at the recruitment stage), researchers should put in place strategies to maintain confidentiality of personal data (e.g. encryption or anonymisation procedures).
- ii. Export and sharing of data, or transport of data away from the research facility, should be carefully monitored.
- iii. The custodian of the data and those who will have access to the data should be logged.
- iv. The length of time for which the data will be stored should be detailed.

7.4 Research not involving clinical interventions

This is an important area where, at first glance, it may be thought that ethical review is unnecessary but there may be many consequences of such research which raises ethical issues. We consider some examples here but this list is not exhaustive.

7.4.1 Use of tissues collected for clinical reasons

Guidance on this subject is given in Chapter 12 of the supporting guidance to the *RCVS Code of Professional Conduct for Veterinary Surgeons* - <http://www.rcvs.org.uk/advice-and-guidance/code-of-professional-conduct-for-veterinary-surgeons/supporting-guidance/use-and-re-use-of-samples-images-post-mortems-and-disposal/>

Superfluous tissue left after its clinical purpose has been fulfilled can be a valuable research resource. The commonest example is the use of archived sera collected primarily for diagnostic purposes and when, at the time of collection research was not envisaged, nor was consent given. Providing samples can be securely anonymised, subsequent use may not pose ethical questions. However,

this will depend on what the research tests seek to find. The tests may identify information of clinical relevance which should be disclosed to the owner. Consequently, **it is advisable to include in consent forms the agreement to the use of superfluous tissue or serum**, and acknowledge that any information subsequently deemed to be of clinical relevance would be disclosed to the owner.

The collection of either a significantly greater quantity of tissue, or additional types of tissue (say, during surgery) than is strictly required for diagnostic or treatment purposes requires ethical review. Licence authorities under ASPA may also be required if the additional intervention are such that, of themselves, they may cause pain, suffering, distress or lasting harm.

7.4.2 Environmental samples

The collection of samples from the environment may raise ethical issues. For example, if faecal samples of livestock and/or wild animals are being collected from farmland, the consequences of what may be found in those samples for the farmer or landowner need to be thought through. Maintaining anonymity will be a problem if, either findings require mandatory reporting, or for example, results are to be presented graphically at high resolution. Thus informed consent should be obtained for this type of sampling including the commitment to disclose any clinically relevant information to the owner.

7.4.3 Questionnaires

This is a popular type of research tool for student projects and lends itself very well to practice-based research since it is generally straightforward, relatively cheap and apparently free of restrictions. However, there are technical aspects to the design of questionnaires which should be incorporated to ensure they achieve meaningful and reliable results. This is beyond the remit of this report, but readers are advised to seek advice on the design of questions and questionnaires (see for example Holmes and Cockcroft, 2008).

There are also likely to be ethical issues involved with most if not all questionnaires and advice should be sought. Note that this is always required in NHS or medical research related to patients, students or human subjects. Matters for consideration include anonymity, self incrimination, data protection and unanticipated distress or psychological harm.

7.5 Fulfilling requirements of funders and publishers

Ethical review will almost certainly be required by both the funders and the publishers of the research. They will require statements confirming that the research has undergone ethical review. For example, many journals have adopted into their Instruction for Authors the ARRIVE guidelines of the National Centre for the Replacement, Refinement and Reduction of Animals in Research (see References – section 12). These guidelines particularly pertain to laboratory animal experiments but may be useful to consult.

7.6 Informed Consent

- 7.6.1 The requirement for informed consent and the procedure through which informed consent is obtained is an important consideration in ethical review.
- 7.6.2 Informed consent is an agreement to carry out specific actions, based on what those actions involve, and the likely consequences of those actions.
- 7.6.3 Obtaining informed consent is a process and goes beyond obtaining a signature on a consent form. A signature on a consent form provides some evidence that the process was complied with, but may be invalid if it was obtained without adhering to that process.
- 7.6.4 Requirements for an ethically acceptable informed consent process include:
- i. Providing relevant information accurately and in a way that the person providing informed consent can comprehend it.
 - ii. Any undesirable outcomes should be discussed, as well as any potential benefits. The relative likelihood of these events should be communicated as well as the degree of uncertainty involved, as far as is possible.
 - iii. People being asked for informed consent must be made aware of the alternatives (i.e. that they do not have to agree to participate in the research) and that the veterinary care of a patient will not be prejudiced if they decline to participate. They must also be informed that they may withdraw at any stage during the research.
 - iv. Those being asked for informed consent must be given an opportunity to ask questions and seek clarification about any information they have been given but do not understand fully. They should be asked to confirm that they understand before signing a consent form and confirm that they have been given the opportunity to raise any points of uncertainty. It is important that during the informed consent process, a veterinary surgeon familiar with the proposed research (or other suitably qualified person) is available to answer any questions that may arise. It may be helpful if the consent form is countersigned by the person administering the form to confirm that these requirements were fulfilled.

- v. It is good practice to offer participants giving consent an independent person or body who they may contact if they are unhappy with the conduct of the study or the persons involved in it.
- vi. All communications with owners/clients during the informed consent process should be impartial to avoid direct coercion or paternalistic intimidation.
- vii. The competence of the person from whom the informed consent is being obtained should be established. It is important to take all reasonable steps to ensure the person giving consent is the owner, or is genuinely acting on their behalf. Anyone providing informed consent must be capable of understanding the nature of the decision. This would exclude children, adults with learning difficulties, or people not fluent in the English language (unless translations are available).
- viii. It is good practice to offer subjects access to the research project's report and conclusions.
- ix. Further guidance is available from the RCVS Code of Professional Conduct for Veterinary Surgeons 2012, Supporting Guidance Chapter 11 - <http://www.rcvs.org.uk/advice-and-guidance/code-of-professional-conduct-for-veterinary-surgeons/supporting-guidance/communication-and-consent/>

7.6.5 What is required for the ethical review of the informed consent process?

- i. In order to review the mechanism by which informed consent is obtained final copies of all documents (e.g. consent forms, client information sheets, questionnaires etc.) will be required.
- ii. A protocol of the research clearly identifying the likely populations from which the research subjects (and their owners/keepers) will be recruited. This should state if any people likely to be less able to provide informed consent are likely to be approached, or how they are to be excluded.
- iii. A description of the process by which informed consent will be obtained.

8. Accessing ethical review

The working party considered four potential means of access to ethical review:

- i. Collaboration with colleagues in research institutions that already have ethical review committees.
- ii. Purchase of ethical review services from institutions that have ethical review committees and are prepared to provide these services.
- iii. The establishment, under the auspices of the RCVS, of a national independent body available to practitioners for ethical review of veterinary practice based research.
- iv. Setting up an *ad hoc* ethical review process (the “DIY” option).

8.1 Collaboration

8.1.1 The working party recognises that collaboration between veterinary practice and research institutions is potentially fruitful but has limitations. For example, the type of clinical work performed in practice based research may be unattractive to research institutions in terms of effort versus reward, or veterinary surgeons performing research in veterinary practice may not wish to share data with colleagues in research institutions unless there is a perceived benefit of the collaboration that goes beyond ethical review.

8.1.2 Notwithstanding the recognised limitations, **the working party wished to encourage collaboration between veterinary practice and veterinary research institutions** on as many levels as possible. The practice-based clinician can achieve this by identifying and collaborating with an existing member of staff of an institution which has an ethical review process. Alternatively, many institutions will also confer honorary staff status on persons working in practice or industry who are seen to be contributing to the institution's goals. Honorary staff would normally have access to the institutional ethical review process. Since existing institutional committees are dealing with ethical review on a relatively frequent and large scale, they are well placed to ensure expertise, consistency and fairness in the process (see also 8.2.2 below).

8.2 Purchase

8.2.1 The working party recognises ethical review committees as a valuable resource meeting a needed service. As such some research institutions may wish to make this resource available to individuals outside of the institution and the working party is already aware of instances of this. Some practitioners may wish to make use of this on an *ad hoc*, pay as needed basis.

8.2.2 All veterinary schools, veterinary research institutes and other biomedical research organisations will have ethical review committees and they may be willing to help. Practitioners are advised to approach the institution of their choice directly.

- 8.2.3 Should practitioners seek to purchase ethical review, we recommend that the ethical review of veterinary practice-based research is done by committees based in clinical veterinary research establishments and which comprise at least one veterinary qualified member. There may be other specialised aspects of the research (e.g. social science) where the researcher should satisfy themselves that the chosen ethical review committee have available appropriate expertise.
- 8.2.4 The working party believes that individual institutions will need to decide for themselves whether to charge for these services at a commercial rate or whether to provide them at reduced cost as a service to the greater good of building an evidence base for veterinary medicine and surgery.

8.3 A body or bodies under the auspices of the RCVS

- 8.3.1 To set up and service a “bespoke” ethical review committee to be available for *ad hoc* requests from practice-based researchers would demand considerable resources. Moreover, it might only be used intermittently and thus maintaining consistent standards and experience would be challenging. However, we are aware of increasing demand for such a body and we recognise that this could provide a valuable support to facilitate practice-based research. **Thus the working party recommends that the RCVS considers establishing a national standing committee for ethical review of practice based research.**
- 8.3.2 The working party agrees that there is currently not a role for the RCVS in overseeing other bodies providing ethical review of veterinary practice based research.
- 8.3.3 The working party agreed that the RCVS is, and should be, in a position to provide guidance to veterinary surgeons concerning what is and what is not recognised veterinary practice. The working party notes that there already exists for this purpose a Recognised Veterinary Practice Sub-Committee of the RCVS. The working party also agreed that the RCVS should be in a position to give advice to veterinary surgeons as to whether ethical review is required when an act of veterinary surgery includes an element of research and, if so, to guide veterinary surgeons to suitable resources. If the RCVS decides not to establish an ethical review of practice based research committee (contrary to the recommendation in 8.3.1 above), we recommend that the RCVS considers establishing a list of institutions in the UK which have ethical review committees and which are willing to either collaborate with practitioners or sell their services.
- 8.3.4 The working party agreed that the RCVS should be in a position to give advice to veterinary surgeons as to whether a proposed act potentially falls outside the Veterinary Surgeons Act 1966 and might be considered to fall under ASPA and, if so, to guide veterinary surgeons to suitable resources for clarification.

- 8.3.5 In respect of the above, the working party considered that **an extension of the membership, resource and remit of the existing Recognised Veterinary Practice Sub-Committee could serve this purpose.**
- 8.3.6 The working party urges the RCVS **to publicise the availability of the Recognised Veterinary Practice Sub-Committee to the profession at large.**

8.4 Setting up an *ad hoc* ethical review process

- 8.4.1 This may be an option favoured by practices which conduct, or plan to conduct, significant amounts of research. Guidance on setting up ethical review committees, their composition and processes is given in the LASA/RSPCA publication 'Guiding Principles on Good Practice for Ethical Review Processes' 2nd Edition 2012 (see references – section 12). This is written largely for institutionally-based research involving laboratory animals, but the general principles of setting up and running an ethical review committee are relevant.
- 8.4.2 Setting up an *ad hoc* committee requires a number of issues to be considered and resolved. It will be important to ensure true independence from the 'parent' practice to ensure credibility and meaningful review. Of course it is in the practice's own long term interests that any review is thorough, rigorous and independent. The quality of review and reviewers will partly depend on their experience. A group which is reviewing very few proposals, and from only one source, will be less able to comment authoritatively or to benchmark activities. This is why the use of pre existing ethical review processes handling scores of proposals a year is recommended above (see section 8.1.2). Nonetheless we recognise that some practices may wish to set up their own processes. In that case, the involvement of individuals who have past, and preferably current experience of ethical review is essential, as is the inclusion of suitable lay representation.

9. Meetings held

17th May 2011
20th September 2011
1st February 2012

10. Acknowledgements and list of others consulted

RCVS Advisory Committee, RCVS Research Sub-committee and RCVS Trust

- BVA and its divisions (BEVA, BCVA and BSAVA)
- Home Office
- Veterinary schools / HoVS
- Research institutes
- Funders:- Horse Trust / World Horse Welfare / BSAVA Petsavers / Petplan / RSPCA / UFAW / Wellcome Trust / DEFRA
- Boyd Group – (Sue Houlton)
- VDS
- VMD
- Peter Fordyce

11. List of acronyms

RCVS – Royal College of Veterinary Surgeons

BVA – British Veterinary Association

VSA – Veterinary Surgeons Act

ASPA – Animals Scientific Procedures Act

VMD – Veterinary Medicines Directorate

ATC – Animal Test Certificate

12. References and further information:

- Holmes, M.A. & Cockcroft. P.D., Handbook of Veterinary Clinical Research (2007) ISBN: 978-1-4051-4551-0, Wiley-Blackwell
- Mellanby, R J *Promoting Clinical Research in Practice* (2011) Journal of Small Animal Practice 52, 537 – 538.
- Cambridge Clinical Research Outreach Programme
<http://www.vet.cam.ac.uk/cidc/outreach.html>

- LASA/RSPCA publication '*Guiding Principles on Good Practice for Ethical Review Processes*' (2010) 2nd edition – from <http://content.www.rspca.org.uk/cmsprd/Satellite?blobcol=urldata&blobheader=application%2Fpdf&blobkey=id&blobnocache=false&blobtable=MungoBlobs&blobwhere=1232992110664&ssbinary=true>
Or
<http://www.lasa.co.uk/publications.html> (primarily concerned with ASPA procedures and research on lab animals in licenced premises; some useful general advice about ethical review)
- RCVS Code of Professional Conduct for Veterinary Surgeons 2012: Supporting Guidance.
<http://www.rcvs.org.uk/advice-and-guidance/code-of-professional-conduct-for-veterinary-surgeons/supporting-guidance>
- RCVS Seminar 2005 'Research into Practice ... Practice into Research'
<http://www.rcvs.org.uk/document-library/research-into-practice-bonner-report/>
(useful general discussion, but does not mention ethical review)
- VMD Guidance Note No 6 2009 Animal Test Certificates from
<http://www.vmd.defra.gov.uk/pdf/vmgn/VMGNote06.pdf>
(briefly refers to ethical review in paragraph 52)