

RCVS Ethics Review Panel guidance on ethical considerations in the funding of clinical veterinary research

Background

1. Clinical veterinary research¹ (CVR) is vital for providing an evidence base for treatment selections, and we rely on the good will of the animal's owners to participate. However, the research may carry additional financial costs compared with the conventional treatment. These costs may be directly borne by pharma, charity grant awarding organisations, funding awards from government, practices running the research, pet insurance companies, professional organisations, or directly by pet owners (either crowd funding or owners of pets enrolled in trials). It should, however, be recognised that the animal owning public fund each of the aforementioned organisations and so ultimately they will usually pay for some or all of this clinical research directly or indirectly whether they choose to participate or not.
2. It is important to bear in mind that the evidence base for many (even routinely used) veterinary treatments is limited and often in need of further development; and that grant funding for CVR is scarce in most veterinary sectors.
3. Taking these issues together, consideration must be given to whether it is reasonable for owners to have the option to participate in a project in which they pay some of the direct costs, or (in some cases) the research not taking place at all. However, the view of the ERP is that **in principle, any clinical veterinary research should be cost neutral for the client.**

Ethical considerations around research costs and clients

4. Many issues may arise when trying to mitigate the actual costs of conducting a CVR project and include the following.
 - a. Applicants for RCVS approval/advice should consider both the direct and consequential costs of participation for the clients. The latter costs could be those associated with attending clinics specifically for study follow-up purposes or as a consequence of the research and, therefore, the Principal Researcher should consider the purpose and the necessity for each visit.
 - b. It is expected that researchers will seek grant funding (either internal or external) to cover any research costs. When researchers have sought such funding, but have been unsuccessful the possibility of sourcing funds directly from participating clients can be considered as a last resort.

- c. Whilst funding may be limited for CVR, care should be taken by applicants to maintain objectivity in proposed methods and funding constraints should not be used as a justification for methods that could bias results, such as insufficient sample size.
- d. Applicants must be able to demonstrate a balanced and clear informed consent process (see RCVS ERP Guidelines).
- e. If researchers are seeking some of the research costs from owners then these costs must represent a small proportion of the total treatment cost; and the practice must not seek to profit from client's decision to participate. For example, any specific extra costs over conventional treatment, such as medicines, should be charged at cost price to the vet and dispensing fees should be waived.
- f. Costs incurred through unexpected side effects or complications due to the research (i.e. those not explained in the Participant Information Sheet) should not be a financial liability for the client.
- g. In some cases funding may be available to provide an inducement such as free or reduced cost veterinary care. The risk of coercion due to the value of such care will need to be carefully considered in any application. Any such payment, in kind or other inducement, must be proportionate.
- h. Clients participating in CVR should be explicitly informed:
 - i. who is funding the trial;
 - ii. whether the scientific data will be shared with funders (it is important that no personal data will be shared without specific consent);
 - iii. the duration for which subsidised treatment will be made available;
 - iv. any potential conflicts of interest affecting the researchers;
 - v. that they should check with their pet insurance policy to determine if participation will affect their cover; and
 - vi. whether the results are likely to benefit other animals.
- i. It will be a requirement for ethics approval that applicants agree to publish all the results in full, including the name of the funder(s) and that funders will have no undue influence on publication or dissemination of the results (other than providing financial support).

¹ CVR is research carried out on client owned animals and not to be confused with experimental research carried out on naïve animals usually in a research laboratory.