NON-TECHNICAL SUMMARY (NTS)

Project Title	Clinical veterinary studies of naturally occurring disease in animals
Key Words	Companion animals, Clinical trials, Pain killers, Heart disease, Diabetes
Expected duration of the project	5 year(s) 0 months

Purpose of the project (as in ASPA section 5C(3))

Purpose	
No	(a) basic research;
	(b) translational or applied research with one of the following aims:
Yes	(i) avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality, or their effects, in man, animals or plants;
No	(ii) assessment, detection, regulation or modification of physiological conditions in man, animals or plants;
No	(iii) improvement of the welfare of animals or of the production conditions for animals reared for agricultural purposes.
Yes	(c) development, manufacture or testing of the quality, effectiveness and safety of drugs, foodstuffs and feedstuffs or any other substances or products, with one of the aims mentioned in paragraph (b);
No	(d) protection of the natural environment in the interests of the health or welfare of man or animals;
No	(e) research aimed at preserving the species of animal subjected to regulated procedures as part of the programme of work;
No	(f) higher education or training for the acquisition, maintenance or improvement of vocational skills;
No	(g) forensic inquiries.

Describe the aims and objectives of the project (e.g. the scientific unknowns or scientific/clinical needs being addressed):

As in humans, there are many diseases that occur in dogs and cats, which are kept as pets, about which we do not fully understand and for which we do not have effective treatments.

The aims of our studies are to investigate new ways of treating and managing diseases in companion animals, similar to clinical trials in humans with diseases.

What are the potential benefits likely to derive from this project (how science could be advanced or humans or animals could benefit from the project)?

Every animal included in our studies will have a disease which has occurred spontaneously. Their disease will be investigated thoroughly to work out the exact nature of their disease and they will be monitored closely to see whether they are getting better whilst on our studies: every animal will therefore benefit. The information gained from our studies will hopefully result in more effective treatments and better diagnostic tests being available for vets to use for the treatment of companion animals.

What types and approximate numbers of animals do you expect to use and over what period of time?

Up to 300 pet dogs and cats per year

In the context of what you propose to do to the animals, what are the expected adverse effects and the likely/expected levels of severity? What will happen to the animals at the end?

Every treatment or diagnostic test that will be studied will have undergone rigorous testing before our studies. This means that they will have been proven to be safe and we will be able to predict the type of adverse effects which might occur, so that we can detect and treat them early. Adverse effects are therefore predicted to be mild in severity. Non-specific adverse events can be seen with any clinical trial. These are usually mild and self-limiting including nausea, temporary loss of appetite, diarrhoea, constipation, lethargy and allergic reaction. Specific adverse effects related to the proposed clinical trials will also be predominantly mild and self-limiting and may include effects such as sedation, weakness and low blood sugar. If unexpected adverse events occur that are not mild, not self-limiting or require specific treatment, the animal will be withdrawn from the study, so that they can be cared for by a vet. We will not trial any treatment or test that, to the best of our knowledge, may worsen an animal's disease and if any animal's disease deteriorates while on study, we will immediately withdraw them from the study, so that they can be cared for by their vet. Procedures to monitor the animals on clinical trials are expected to be associated with only transient, mild adverse effects including the transient, mild discomfort related to taking a blood sample. All animals enrolled to our studies will be pets. When the study is complete, we will make sure they have not been affected by the study and then return them to their homes.

Application of the 3Rs

Replacement

State why you need to use animals and why you cannot use non-protected animal alternatives

Replacement

The aim of the studies is to find new treatments for spontaneously occurring diseased in companion animals. Once these treatments have been shown to be safe and are likely to be effective, the only way to know for sure if they will work is to conduct a trial in companion animals.

Reduction

Explain how you will ensure the use of minimum numbers of animals

Reduction

The numbers of animals used in our studies will always be the smallest number required to show a true result.

Refinement

Explain the choice of animals and why the animal model(s) you will use are the most refined, having regard to the objectives. Explain the general measures you will take to minimise welfare costs (harms) to the animals.

Refinement

All animals will be closely monitored at all times by vets and vet nurses: if any problems are seen, they will be immediately withdrawn from the study to be cared for by a vet.