to allow their pet to be assessed for enrolment on the study.

The animal will generally experience normal veterinary work-up and interventions for the treatment of their disease. Then a new therapy, supplement or device may be administered in conjunction with the gold standard treatment, with the aim of improving animal recovery/ outcomes. Only those studies approved by the Veterinary Medicines Directorate will allow a new therapeutic treatment to replace current licensed therapies.

Typically, the regulated procedures performed under this PPL will be the extra sampling required to show efficacy of the product or device being tested eg a series of blood samples collected for monitoring drug levels or a follow-up imaging session performed under general anaesthesia to assess the effectiveness of a new product.

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The primary purpose of this Licence is to improve the health of client-owned animals with spontaneously occurring diseases. Effectiveness of a new treatments require robust testing under controlled conditions in the target animal showing symptoms of the relevant disease prior to acceptance/ approval as a new veterinary treatment.

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Effectiveness of a new treatments require robust testing under controlled conditions in the target animal showing symptoms of the relevant disease prior to acceptance/ approval as a new veterinary treatment. Whilst non-animal alternatives may be used during product development this cannot replace the use of animals for efficacy testing in the target animal.

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There is a need to perform controlled veterinary clinical trials for novel therapies / techniques for treatment of animals in the target animal.

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The PPL holder will be required to disclose:

- What, if any, non-animal alternatives were used or explored after the project started, and is there anything others can learn from your experience?

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Each study is individually assessed and predicted animal numbers indicated on the relevant project protocol.

Client owned animals with defined specific spontaneous diseases will be used in these studies with the primary aim of conducting clinical trials of drugs/devices/techniques of these disease in these species. An alternative is therefore not an option.

A thorough review of all known adverse events of all drugs/devices/techniques to be tested will be conducted prior to commencement of studies to facilitate specific close monitoring for any expected adverse events.

If the specific target disease progresses despite study procedures, or other co-morbidities occur that are likely to compromise the study, then animals may be withdrawn from ASPA and returned to the care of the Owner and Veterinary Surgeon so that an appropriate treatment plan can be agreed under the Veterinary Surgeons Act.

All animals will remain under the care of their owners while enrolled on the study: their emotional and welfare needs will be taken care of in their own home. Regulated procedures will take place at the Veterinary Clinic to the highest standards of welfare and patient care and supported by 24/7 dedicated veterinary professional support.

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There is a need to perform clinical trials of novel treatments / techniques in animals of the same status for which the product/ techniques is intended.

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This PPL is performed within a world class veterinary teaching hospital where veterinary and veterinary technical support staff are required to keep up to date with CPD to advance their knowledge. Advice will be sought from these people when designing the study plan.

Any relevant post procedure care and monitoring will be performed by veterinary professionals until the animal is deemed fit to be released from the Act by the attending veterinary surgeon.

Where appropriate sedation, and/or local or general anaesthesia will be used to minimise stress or pain during procedures.

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Veterinary surgeons and veterinary nurses involved in these studies are all required to perform regular CPD to maintain the highest standards to maintain their professional registration.

Best veterinary practice will be employed at all times.

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NC3R website will be used as a source of information of advances in 3Rs, as well as review of the regular updates received from the designated establishment. Any advance considered appropriate in this PPL will be incorporated into the in-vivo experiments where possible.

Regular updates from the NC3R website are circulated by the establishment's AWERB.

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The PPL holder will be required to disclose:

- With the knowledge you have now, could the choice of animals or model(s) used be improved for future work of this kind? During the project, how did you minimise harm to the animals?