

Clinical Study Protocol Review Committee

Guidelines for Submission of Protocol for Review

The charter of the Clinical Protocol Review Committee is to evaluate protocols for study on client-owned animals for humane and appropriate use of these animals.

Protocol submission

- A protocol must be submitted for any study that requires an additional procedure(s) than would normally be performed, any study where there is allocation of a procedure or treatment, or any study that involves a treatment being withheld.
- Any study requiring funding from any in-house or external funding source must be submitted.
- Observational studies which involve **only** extraction of recorded data from medical records are exempt from review.
- If there is question on whether submission is required, please consult with the chair of the committee

The material submitted to the committee should include

- 1) Objectives
 - Clearly state the objectives or goals of the study. Point form is suggested.
- 2) Hypothesis
 - Clearly state the hypothesis of the study. Point form is suggested.
- 3) Study design
 - Clearly describe the design of the study. This should include
 - ... the criteria for inclusion or exclusion of animals
 - ... the number of animals to be included
 - ... how treatment or intervention procedures are allocated. This must include a true randomization process to allow meaningful results and ethical protection that each animal has an equal chance of receiving either treatment.
 - ... list drugs (doses/frequency) that will be administered
 - ... list amount/frequency of any body fluid sample collection
 - ... list frequency of any invasive procedure
 - Do not reference procedures that will be performed on the animals. These should be explained in detail
- 4) Personnel
 - Please list personnel (and their qualifications) that will be performing the procedures described in the protocol.
- 5) Justification
 - Provide justification for the number of animals included in the study
 - If two treatments are being compared, you must assure the committee there is no convincing evidence that one treatment is better than the other
 - Explain or justify the procedure(s) or treatment and the frequency of performing these in the study
- 6) Expected results
 - Please explain what you are expecting the results to be. This should agree with your hypothesis and should not conflict with the justification of the study
- 7) Evaluation of results
 - Please include how the data will be collated, summarized, evaluated and presented
- 8) Expected time line/duration of study
- 9) Appropriate references
- 10) Please include an **OWNER INFORMATION FORM** that consists of a 1 page description of the justification and value of the study with a clear statement as to the owner's commitment and exactly what they are consenting to have done to their pet. Write this form in layman's terms. Include a line for the owner's signature, a witness signature, and the date of signing at the bottom.

Owner information and consent

- The committee will determine whether owner consent is required for the study.
- **The committee will generate a consent form for use in the study.** This will be returned to you with notification of your study's approval.
- No animal can be enrolled in a clinical study that requires owner consent without a signed consent form.
- Upon enrollment of an animal into the study, have the **owner sign the information and consent forms**. The PI should keep the signed information and consent forms on file. A copy of the signed owner information form and the consent form should be given to the owner and a copy of the consent form should be placed in the animal's record.

Approval

- Submitted studies will be evaluated on a “as submitted” basis and you will be notified within a week of submission.
- Submissions that do not provide the information described above to prohibit complete evaluation will be returned to the investigator for modification.
- There will be no time limit for the approval period.
- The study design will not be critiqued unless it is inherently flawed such that the results would be meaningless and hence the use of the animals is inappropriate. Suggestions for modification of the design will be made and resubmission encouraged.