

## STUDY PROTOCOL BASICS

Linda Rhodes, VMD, PhD  
ACCD Board Member

### Introduction

The point of a study protocol is to describe the study in such a way that the study could be reproduced by anyone, just by reading the protocol. This level of detail then serves as a discipline for specifying exactly what is to take place during the study. A detailed protocol is essential when multiple sites are involved in a study, or when a study runs over a long time period, where multiple people may be involved.

For a study to be conducted and submitted as pivotal to satisfy regulatory requirements, it must be conducted under Good Clinical Practices (GCP). The details of GCP are beyond the scope of this brief guideline, and GCP also requires a detailed protocol be followed.

### Points to include when writing a protocol for a field study in cats or dogs:

1. A detailed list of the study personnel that will oversee the study, handle any samples, and conduct the statistical analysis, including contact information.
2. Objectives, background and justification for the study.
3. A study schedule, specifying all study events that will happen to the animals. Generally Day 0 is the first day of treatment – events to list in the schedule include day of randomization, days of baseline data collection, dates of any blood samples or treatments, etc.
4. Study design
  - a. Specification of treatment groups to be included and approximate number of animals in each group.
  - b. Randomization procedures
  - c. Masking (blinding) procedures
5. Description (in detail) of the test articles – that is, the vaccine, drug or treatment to be used, and how they will be identified (lot or batch numbers, etc.) including a description of the packaging, and the specification that the lot and batch numbers, including expiration dates, will be listed in the final study report. How the drug will be stored, and how drug will be accounted for should be specified.
6. A description of the test animals
  - a. Species, sex, age, weight, physiological status, etc.
  - b. Identification methods
  - c. Inclusion and exclusion criteria

- d. How animals will be removed from the study and accounted for (death, disease, lost to follow up, etc.)
7. Animal management including food and water, if animals confined, and any concomitant treatments allowed.
8. What will be assessed and how and when. At a minimum, the following should be included:
  - a. Physical exams at the start and end of the treatment
  - b. Any blood work
  - c. Whatever parameter is needed to evaluate the treatment
  - d. Specify what time periods each assessment will be completed
9. Adverse events should be recorded in all groups. An adverse event is any unwanted or unexpected observation, experience or reaction, whether or not related to treatment that happens to animals while enrolled in the study.
10. What specifically will be done if an animal dies in the study (necropsy, follow up, etc.).
11. How changes will be made to the study (via amendments) and how deviations from the protocol will be recorded.
12. How the statistical analysis will be conducted.
13. Who will be responsible for collecting and overseeing the data, where it will be stored, etc.
14. Who will write the final study report and generally what will be included in that report.
15. If samples have to be sent somewhere for analysis, a detailed description of how they will be handled, tracked, and who will do what analysis.
16. For every parameter of data, a form should be created to record those data on and a copy of the blank forms (numbered) should be included with the protocol. Forms should always include, at a minimum:
  - a. Date the data were recorded
  - b. Animal ID
  - c. Number of the protocol
  - d. Signature of the person recording the data