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**Clinical Trials: Client Information Sheet**

**{Insert Study Title}**

Your participation in this clinical trial evaluating {insert general purpose} is greatly appreciated. Your animal’s clinician will explain your animal’s condition as well as treatment options available. If you choose to enroll your animal in this study, this Information Sheet will explain the purpose of the study, your responsibilities, patient procedures, and possible outcomes.

**What are clinical trials?**

Clinical trials are research studies used in all specialties of human and veterinary medicine to evaluate new medical devices, vaccines, diagnostic tests and treatments. These trials may investigate new types of surgical or other procedures as well as novel medical therapies for diseases. Your animal’s clinician will discuss how your animal’s condition is typically treated, and will explain other options available through current clinical trials. Clinical trials allow clinicians to discover new and improved ways to prevent, diagnose or treat diseases.

**What is the purpose of this clinical trial?**

*State what the study is designed to assess or establish. Be aware that language used should be a grade 6 to 8 school level. Don’t assume the reader will understand technical terms or acronyms.*

The goal of this study is to determine {*list objectives*}.

**Which patients are eligible to participate in this study?**

Patients with a confirmed diagnosis of {*insert condition*} are eligible for enrollment in this trial. Other specific criteria required to be included in this study include {*state inclusion criteria*}

**What happens to my animal in this clinical trial?**

{Insert a brief summary of the procedures, timeframe, and commitment of owners enrolled in this study}

*Describe the procedures chronologically using simple language, short sentences and short paragraphs. The use of subheadings helps organize this section and increases readability. Medical and scientific terms should be defined and explained. Explicitly outline the procedures and/or drugs used in this study, and state whether they are experimental or vary from current standard of care.*

*Specify the length of time for participation in each procedure, total length of time for participation, frequency of procedures, location for the procedure, type of sample to be collected, etc. Provide details about any plan to contact the owners for follow-up sessions or subsequent related study.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of Procedure** | **Length of time** | **Frequency** **(time interval)** | **Location for Procedure** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

*If there are alternative treatments to those being provided as part of the Study, information on those alternatives should be provided in sufficient detail to permit the owner to make an informed choice.*

**How long will my animal be involved in this clinical trial?**

This study will be completed in {insert number} weeks/months. **OR** Your animal’s participation in this study depends on his/her response to treatment.

Your animal’s clinician will explain ongoing diagnostic and treatment options available after the clinical trial is completed.

*Specifically describe the exact time and nature of recheck examinations for the client and animal to continue to be enrolled in the study*

**Are there any side effects or risks for participating in this clinical trial?**

Your animal may experience side-effects from this clinical trial.

*Describe any reasonable foreseeable risks, potential side effects, discomforts and/or inconveniences related to the procedures and/or drugs and how these will be managed.*

*If there are any rare, but catastrophic effects that the participant may experience, these should be described and explained to the client.*

*If there are significant physical or psychological risks to participants that might cause the researcher to terminate the study, please describe them.*

**Can I withdraw my animal from this clinical trial?**

You are free to withdraw your animal from this clinical trial at any time, and this decision will not influence your animal’s medical care. Withdrawal will not result in penalty unless it is explicitly stated that completion of the study is required for eligibility for incentives *{State whether this applies to the current study}*. Please contact your animal’s clinician or the study contact person as soon as possible if you are considering withdrawing your animal from this trial, so that an alternative treatment plan can be created.

The clinician in charge of the study may withdraw your animal from the clinical trial at any time if your animal is adversely affected by the trial, or if you do not follow the study protocol.

**Are there any financial or other benefits to participating in this clinical trial?**

*{Outline study incentives here. State whether the owner will receive some form of compensation including the coverage of costs for services. If no, say so. Be specific, e.g., is the study covering the cost of a medication and for how long, are the appointment fees covered, etc.}*

*If the owner is expected to cover certain costs as a result of the Study, this should be specified. Indicate the costs unrelated to the study for which the client is responsible.*

**Are there any benefits to my animal, other animals and/or the veterinary community, society?***Describe benefits to participants expected from this research. If the participant will not benefit from participation, clearly state this fact.*

*State the potential benefits, if any, to science or society expected from the research.*

*Indicate that the results of the study will be published and made available for the benefit of the scientific community or society and that client confidentiality will be maintained in publications.*

**What are my responsibilities if I choose to participate in this clinical trial?**

You will be responsible for the costs of {*list diagnostic tests, expected costs to owner*}, and any other tests recommended by your animal’s clinician. Like any medication, the clinical trial treatment may have a low rate of side effects. This study does not cover the costs of hospitalization or other costs associated with illness related or unrelated to the clinical trial.

You are expected to return to the Ontario Veterinary College for follow-up appointments as outlined by your clinician and the clinical trial protocol.

**How is this study funded?**

The costs of this study are supported by {*insert granting agency*}.

**Who do I contact if I have further questions?**

Please feel free to contact your clinician or the study investigator(s) if you have any questions:

{*insert name, telephone, email of principal investigator*}

In case of emergency, contact the Ontario Veterinary College at (519) 823-8830 or your referring veterinarian immediately.