

Owner Informed Consent Form

Study Title for Study Participants:

Official Title:

What is a clinical trial?

Clinical trials are research studies that evaluate new types of treatment. Clinical trials may be designed to determine the effectiveness and side effects of new drugs or treatments, new surgical procedures, new diagnostic procedures, or novel approaches to treatment (such as gene therapy or immunotherapy). It is your decision whether or not you want your pet to participate in a clinical trial. You may discuss your pet's participation with your family and your pet's veterinarian. If you have any questions, please ask your pet's veterinarian for additional information.

Why is this clinical trial being done?

The purpose of this study is to _____. There will be about [INSERT NUMBER OF ANIMALS] pets taking part in this study.

What is the usual approach for [DISEASE/CONDITION OF INTEREST]?

We invite your pet to take part in this clinical trial because _____. Pets that are not in a study are usually treated by _____.

What are my other choices if my pet does not take part in this study or stops taking part in this study?

Participation in any clinical trial is voluntary. If you decide that you do not want your pet to participate in the study, your choice will not affect your pet's future medical care. In the event that you decide not to take part in this study, you have other choices, including:

- Pursuing the usual treatment approach described above
- Taking part in a different study, if one is available
- Not having your pet treated for [DISEASE/CONDITION OF INTEREST] but instead providing comfort care to help reduce or relieve symptoms.
- [OTHER?]

If I enroll my pet, can my pet stop taking part in this study?

Yes. You can decide to stop at any time and it will not be affect the medical care of your pet. The study veterinarian will tell you about new information or changes in the study that may affect your pet's health or your willingness to have your pet participate in the study.

Please note that the study veterinarian can remove your pet from the study:

- If your pet's health changes and the study is no longer in his/her best interest
- If new information becomes available
- If you do not follow the study protocols and rules
- If the study is stopped by the sponsor, the Institutional Animal Care and Use Committee (IACUC) or a regulatory agency (e.g., FDA).

If you decide to remove your pet for any reason, it is important to let the study veterinarian know as soon as possible so that treatment can be discontinued safely. Additionally, please note that we will not remove any data that has already been collected from the trial database.

What are the study groups?

What tests and procedures are required to determine if my pet can take part in this study?

Before your pet begins the study, your pet will need to have the following (***INSERT APPROPRIATE WORD, E.G., EXAMS, TESTS, AND/OR PROCEDURES***) to find out if he/she can be in the study:

What tests and procedures will my pet have if my pet takes part in this study?

If the exams, tests, and procedures show that your pet can take part in the study, and you choose to enroll them, then the following will happen as part of the study:

How long will my pet be in this study?

What possible benefits can I expect from my pet taking part in this study?

We cannot promise any benefits to your pet or other animals from your taking part in this clinical trial; however, possible benefits include _____.

What possible risks can I expect from my pet taking part in this study?

What happens if my pet experiences adverse event(s) because he/she took part in this study?

If your pet experiences adverse event(s) as a result of taking part in this study and is in need of medical treatment, please tell your study veterinarian. The study sponsors (**WILL/WILL NOT**) offer to pay for medical treatment for injury up to a specified monetary amount (**PLEASE SPECIFY**).

What are my responsibilities if my pet participates?

If you wish to have your pet participate in this study, you will be responsible for _____

What are the costs of my pet taking part in this study?

For more information about possible costs, please contact the investigator. The results of this study, including specimens collected, may have commercial value to the sponsors, the hospital, and/or the researchers. You will have no legal or financial interest in any commercial development resulting from the research or from the information or materials collected.

What happens to the information collected for the clinical trial?

Your privacy is very important to us. Our researchers will make every effort to protect it. All client and animal details, and information obtained from the study will be considered confidential and will be used for research purposes. We will limit the use and/or disclosure of your information or that of your pet to

people who have a need to review this information, including the study sponsor, the drug company or funding agency supporting the study and/or regulatory agencies (e.g., FDA). In addition to standard electronic medical records at the hospital, some of your pet's health information, and/or information about his/her specimen, from this study may be kept in a central database for research. Your name or contact information will not be put in the database. We may publish the results of this research but we will keep your name, the name of your pet, and other identifying information confidential.

Is there anything else I should know?

Who can answer questions about this study?

For specific questions about the study in which your pet is enrolled, concerns, complaints, or if you believe that the study has negatively affected your pet (e.g., an adverse event due to participating in the study), please contact the study veterinarian:

- ***Study Veterinarian(s):***
- ***Contact Information:*** For questions or reporting of a trial-related adverse event, please contact.

This research has been reviewed and approved by an Institutional Animal Care and Use Committee (IACUC) or Hospital Executive Committee. You may contact _____ if you cannot reach the investigator.

By signing below I agree to permit my pet _____ (insert name) to participate in this clinical study and undergo the procedures described to me above.

By signing below, I have read through this informed consent document and that a signed and dated copy of the consent form will be given to me.

Signature of Owner

Date

Printed Name of Owner

Signature of Person Obtaining Consent

Date

Printed Name of Person Obtaining Consent