Place Patient Identification Sticker Here

To complete the form please:

- complete the items **in blue** and convert to **normal black text**
- remove instructions **in blue**

Informed Owner Consent Form
Study Title

Note: The study title should be easy to understand, in lay language, and does not need to match the title on the AUP.

Name(s) and title(s) of the principal investigator(s)

Note: If an investigator is listed as a contact in this form, this investigator should also be listed on the header.

1. Purpose of the project

Note: Please state the primary purpose of the study in one or two sentences using easy-to-understand lay language. Please do not state non-specific long-term goals or general implications for veterinary or human medicine.

2. Eligibility for participation

Note: Please give a short statement of the criteria for eligibility for participation and describe any specific exclusions. Include any restrictions for age, breed, and weight (**i.e.,** *large blood draws may limit weight of the animal*).

3. Expected duration of participation

Note: Please state the maximum duration for which each animal will be enrolled in this project. Also state how long each direct participation period is, if multiple visits or procedures are performed (**e.g.**, *animal will participate for a total of 6 months… each visit will take approximately 1 hour*). Include the time that all activities required outside the clinic (**i.e.**, *at home by the owner*) will be performed for the study.

4. Description of procedure(s)

Note: Please describe all procedures unique to study participation that will be performed on the enrolled animal, whether the procedures are diagnostic or therapeutic. Procedures that would be performed even if the animal was not enrolled in the study should not be described. If special expertise is required, please indicate who will perform the procedure (**e.g.**, *licensed veterinarian, veterinary technician, or veterinary student*), but please remember that this will then limit who

can in fact administer these procedures. Note the collection of biological samples and the purpose of collection, if this is pertinent, but please do not describe the analyses in detail. If the study includes the collection of genetic material, please address long-term disposition of samples.

5. Possible discomforts and risks

Note: Please list all known risks and discomforts. If there is morbidity and/or mortality associated with any of the proposed procedures, such risks must be clearly stated in lay terms in this paragraph.

If applicable, please include instructions for the client on what to do in the event of a specific adverse reaction that could modify participation in the study or modify the study protocol. Steps to be taken in the event of an adverse reaction should be clear and explicit so that participants know what they are signing up for should such a reaction occur.
For suggested wording for possible discomforts and risks associated with commonly used procedures see below. Please copy and paste if applicable and only modify if there is a specific reason to deviate from the standard language.

Suggested Wording:

Cystocentesis: Urine is collected by inserting a needle through the abdominal wall into the bladder. This may cause irritation of the bladder and a need for the animal to urinate frequently for about a day after the procedure. Bladder infections can occur on occasion after this procedure. In rare instances, low blood pressure or loss of blood can occur, and may very rarely result in a tear of the bladder and possibly death.

Blood collection: A small amount of swelling and bruising may occur at the site of blood collection. If this were to occur, it would most likely resolve within 24 hours. Occasionally, a small amount of hair must be clipped. In very rare cases, the hair does not grow back or, if it does grow back, it has a different color.

Sedation: Sedation is the result of giving certain drugs to relax and calm the animal. Potential side effects of sedation are abnormal behavior, vomiting, decreased appetite, coughing, nausea, drowsiness, allergic reactions (including life-threatening), decreased heart rate, decreased blood pressure and possibly death.

General anesthesia: Anesthesia is the result of giving certain drugs that will result in the animal losing consciousness. Potential side effects of general anesthesia are abnormal behavior, vomiting, pneumonia, decreased appetite, sore throat, coughing, nausea, drowsiness, allergic reactions (including life-threatening), changes in body temperature, decreased heart rate, decreased blood pressure, decreased breathing rate and possibly death.

Skin punch biopsies: Possible risks associated with skin punch biopsies include slight bleeding, focal bruising, minimal scarring, and secondary infection.
Intradermal allergy testing: This testing may cause itching, persistent hive formation, or bruising at the site of testing. This is typically short-lived (1-2 days) and will be alleviated with the use of

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a topical steroid if necessary. Persistent scratching may lead to a secondary bacterial infection, which may require antibiotic medication to treat.

Allergic reactions: Typical signs of allergic reactions include swelling of the face (especially around the eyes) and body; swollen, pale red bumps on the skin; itchiness; generalized redness of the skin; agitation or restlessness; sneezing; and vomiting and/or diarrhea. In rare cases, anaphylaxis (a body-wide reaction) can occur. Signs of anaphylaxis include difficulty breathing, an elevated heart rate, apparent dizziness or weakness, collapse, and possibly death. If signs of anaphylaxis happen, call your veterinarian immediately.

If you have any questions or concerns related to potential side effects from this study, please contact the investigator (see section 11). {Replace with specific instructions if appropriate}

6. Possible benefits of study

Note: Please list direct and likely benefits to the enrolled patient only but avoid using coercive or misleading statements. Do not list benefits to the owner of the enrolled patient or any long-term benefits to the breed or species. Also, please do not list any potential benefits to human patients. If a diagnostic procedure is being performed that would usually not be performed on the patient (for example a blood culture on a healthy patient) then the result from such a procedure should not be considered a possible benefit. If it is not likely that there will be a benefit to the individual animal that is being enrolled, please state this clearly (see standard language below).
Option #1: Your animal will receive no direct benefits from participation in this study.
Option #2: Your animal may receive no direct benefits from participation in this study.

7. Alternative diagnostics, procedures, or treatments

Note: If the study treatment, procedure, or testing is available on a fee-for-service basis, please state this. If alternative diagnostics, procedures, or treatments are available for the pet owner if the animal is not enrolled in the study, please describe them here. If none are available, then "None" can be stated.
Example #1: *Echocardiography is available on a fee-for-service basis*.
Example #2: "*Curezol" is an experimental drug and is not available to animals not enrolled in this study; however, standard treatments for this condition, including antibiotics, steroids and sedatives, are available on a fee-for-service basis.*

8. Confidentiality

Owner and patient confidentiality will be maintained. No identification of individuals shall be made when reporting or publishing the data arising from this study.
Note: Or alternative text as appropriate for your study.

9. Conflict of interest

The investigators associated with this study declare no conflicts of interest.
OR
One or more investigators on this study has a financial interest in the development of this treatment. For this potential conflict of interest, a management plan has been implemented by the institution.

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*It is the responsibility of the Primary Investigator (PI) to retain the **signed** copies of all consent forms for a period of five (5) years, as is standard within the Texas A&M University System.*

10. Financial obligations
The owner will be responsible for all costs not directly associated with this study, such as the assessment, diagnosis, and/or treatment of the participating animal. However, there are no additional study-related financial obligations by the owner to Texas A&M University.
Note: Or alternative text as appropriate for your study.

11. Compensation or therapy for accidental injury or complications
In the event of complications or accidental injuries associated with this study, the owner of any participating animal is financially responsible.
Note: Or alternative text as appropriate for your study.

12. Primary contact person(s)
To obtain further information regarding this study contact:
Example:
Dr. John Smith
Department of Small Animal Clinical Sciences
College of Veterinary Medicine & Biomedical Sciences
Texas A&M University
4474 TAMU
College Station, Texas 77843-4474
979-845-xxxx
email address (optional)
Note: Please include the name and phone number contact information listed here at the bottom of the informed owner consent page, where indicated. Please take into consideration the expected duration of employment for any individual listed as the sole primary contact person. For example, interns that only have one-year employment contracts would not be the ideal contact persons to be listed in this section.

13. Participation and right to withdraw
Enrolling your animal for participation in this study is voluntary, and refusal to participate involves neither penalty nor loss of care to which your animal is otherwise entitled. You have the right to withdraw your animal from the study without penalty at any time and for any reason.
Note: Or alternative text as appropriate for your study.

14. Termination of participation by principal investigator(s)
The investigator(s) has/have the right to terminate the study for any or all participants at any time and for any reason.
Note: Or alternative text as appropriate for your study. Please make sure the language is appropriate for the number of contact persons.

15. Unforeseen complications
Unforeseen complications might arise at any time during the study. The investigator(s) will promptly inform you of any new information that may affect your willingness to continue to

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have your animal participate in the study. **Note:** Or alternative text as appropriate for your study. Please verify the language is appropriate for the number of contact persons.

INFORMED OWNER CONSENT

Study Title

Note: The title on this page should be identical to the title on page 1

Name(s) and title(s) of the principal investigator(s)

Note: Names and titles should be identical to the investigators listed on page 1

I, _____(name), of

_____ (address)

_____ (City, Zip)

hereby consent to the participation of the following animal in the study cited above. I certify that I am the legal owner (or agent of the owner) of and am responsible for this animal. I have read, received a copy of, and understand the Informed Owner Consent Form.

Animal Details

Name: _____

Breed: _____

Age: _____

Signature of Owner or Agent: _____ Date:_____

Signature of Investigator or authorized clinical trial personnel:

_____ Date: _____

Witness: (Optional) _____ Date: _____

I have received a copy of the consent form

_____

This consent form has been reviewed and approved by the Clinical Research Review Committee of the Texas A&M University College of Veterinary Medicine & Biomedical Sciences (VMBS).

For questions about this study, please contact Dr. John Smith, Dept. of Small Animal Clinical Sciences; VMBS; Texas A&M University; 4474 TAMU; College Station, TX 77843-4474; 979-845-xxxx;	**For questions regarding your rights as the owner of a participating animal**, please contact Dr. Michael Criscitiello, Associate Dean for Research and Graduate Studies; VMBS; Texas A&M University; 4461 TAMU; College Station, TX 77843-4461;

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xxxxx@cvm.tamu.edu	979-845-5092; crrc@cvm.tamu.edu

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