**NOTES:**

1. **Items in red should be replaced with the appropriate information and changed to black text.**
2. **All parts of this document may be amended as appropriate to fit the specific circumstances of your study.**

***Don’t forget to delete these notes and each of the examples below!***

**Informed Client Consent Document**

“[Full Title of Study]”

We would like to include your [species of animal] in an on-going research study funded by [list funding source/agency]. This study is designed to [short version of study purpose]. This form is intended to provide information to help you decide whether you want your [species of animal] to participate in this clinical study. **Please read this form carefully.**

**Feel free to ask questions** about the purpose of this clinical study, the possible risks and benefits, and anything else about this form that is not clear. When we have answered all your questions you can decide whether you want your [species of animal] to be enrolled in the study.

1. **Principal Investigator:** [Name, Title, Service, Department], Washington State University, [email address], 509-335-0711.
2. **Purpose of Research:** [Background, what makes this important, what you hope to learn] Example: *Veterinary neurologists see a significant number of suspected brain tumor cases every year. Magnetic resonance imaging (MRI) has increased the sophistication for identifying lesions in the brain, but tumor diagnosis is only presumptive with imaging alone. Our ability to obtain a definitive diagnosis has been one of our biggest challenges because open brain surgery is costly and can carry a significant amount of risks. The purpose of this clinical trial is to evaluate the effectiveness of a MRI-compatible stereotactic brain biopsy system, a potentially less invasive method for obtaining definitive diagnoses in dogs with brain lesions. If this stereotactic system proves to be clinically safe and beneficial, this diagnostic modality can then be routinely made available to patients with brain lesions. Knowing the diagnosis will help clinicians gauge treatment protocols, provide owners with a more accurate prognosis, and help scientists establish research programs to better understand brain tumors in veterinary patients. This stereotactic system could also be the first frameless, MRI-compatible system made available for diagnosing brain lesions in veterinary patients.*
3. **Expected Duration of Participation:** [Length of procedure(s), length of stay at WSU-VTH, required rechecks, necropsy at end of life--if required for study]
4. **Description of the [Name of Procedure] Procedure:** [Description of what will occur for the procedure, from the time animal checks in to the time it leaves] Example: *Your pet will be anesthetized for the biopsy procedure. Anesthesia will be routinely monitored and be under the supervision of a board-certified anesthesiologist. We will first attach some important markers (fiducial markers) to your pet using a dental mold. Once attached, a 20 minute MRI scan is necessary to relocate the lesion in the brain. For preparation for the biopsy procedure, the skin on top of your pet’s head will be clipped and cleaned. In the neurosurgical suite, skin incisions will be made on your pet’s head to attach a surgical headclamp to the skull. With the stereotactic system and the neuronavigation software, we can plan the trajectory path to the brain lesion in real time. Once a trajectory path is chosen, a 5mm burr hole will be made in the skull at the biopsy needle entry point. A biopsy needle will be lowered to the brain lesion using the digital depth guide based on the predetermined trajectory and depth. With gentle aspiration using a syringe system connected to the biopsy needle, multiple biopsy samples will be taken. Routine closure of the incision will be performed. All stereotactic biopsy procedures will be performed by the principal investigator.*
5. **Potential Adverse Side Effects, Complications or Risks:** [Any possible risks or adverse side effects associated with the procedure(s)] Example: *This clinical trial involves inserting a biopsy needle into the brain which can create potential complications. Although this procedure is theoretically less invasive then open brain surgery, the risks associated with this procedure are not yet determined in dogs. Potential risks include hemorrhage, infection, neurologic deterioration, seizures, or death. Anesthetic complications can also occur like with any surgical procedure and can lead to death.*
6. **Possible Benefits:** [Benefit to enrolled animal and future benefits for other animals or humans]
7. **Alternative to Participation:** [Options, other than the study, for the animal to receive treatment] Example: *An alternative way for obtaining a diagnosis for your pet’s brain lesion would be with open brain surgery. This can be costly and carry a significant amount of risks depending on the location of the brain lesion. There are also some brain lesions that are not reachable with surgery.*
8. **Extent of Confidentiality of Records:** Your [species of animal]’s veterinary care team and the research investigators will have access to the medical records of patients enrolled in this clinical study.  Additionally, federal, state and university compliance entities may audit or review the medical records and the clinic must release records when required by law.
9. **Compensation or Therapy for Injuries:** [This will be unique to each study as some studies will cover possible secondary injuries and some may not. Please edit wording accordingly.] ***Example:*** *In the unlikely event that an injury occurs secondary to this clinical study, the patient’s owners may be monetarily responsible for any additional therapy for injuries.*
10. **Contact Person for the Study:** Should questions or concerns arise, you may contact the Principal Investigator: [Name, title, service], Washington State University, [email address], 509-335-0711
11. **Voluntary Participation and Right to Withdraw:** Participation in this clinical study is voluntary. You have the right to withdraw your [species of animal] from the clinical study before the [\_\_\_\_\_\_] procedure. Your [species of animal] will not be treated differently if you decline to participate in this study. Your decision to participate, not participate, or withdraw from this study will not affect your relationship with WSU or any other treatment your [species of animal] is receiving.
12. **Termination of Participation by the Principal Investigator:** It is unlikely that participation of a patient will require termination; however, the investigators retain the right to terminate any participant in the clinical study at any time.
13. **Financial Obligations:** This clinical study will cover the cost for [list of things covered by study and the approximate value]. Costs associated with [list of things not covered] are not covered by this clinical study.
14. **IACUC Review:** This clinical study has been reviewed and approved by the WSU Institutional Animal Care and Use Committee (IACUC). If you have concerns please contact them at (509) 335-7951.

**Informed Client Consent Form for [short name of study]**

“[Full Title of Study]”

I have read the Client Consent Document for this study and I agree that my [species of animal]can take part in this clinical study. I understand and agree to the information and requirements presented on this consent form. All my questions have been answered to my satisfaction, and I understand that the participation of my [species of animal] in this clinical study is voluntary. I will receive a copy of this consent form.

**I certify that I am the legal owner or custodian of this** [species of animal] **and have the authority to consent medical treatment for this** [species of animal]**.**

[Species of animal] **Name (print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Owner Name (print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Investigator Name (print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Patient Sticker goes here:

Case number, patient name, patient breed, patient sex, patient birth date, owner name and contact