Informed Consent Form Guidelines for Studies Enrolling Client-Owned Animals

GENERAL CONSIDERATIONS

- **Use Lay Language**
  - Consent form should be written in clear, simple language that is easily understood by someone without expertise in the field. Aim for a Flesch Reading Ease Score of 70-100. Paste your document into this free readability checker to verify the reading level.
  - Avoid use of technical or medical jargon and define if used (for example say chest X-rays instead of thoracic radiographs).
  - Break up text into manageable sections using headings and subheadings or bullet points (Ex: What is the purpose of the study; What procedures or treatments will my animal experience as part of this study?)
- **Avoid Coercion or Undue Influence**
  - Avoid false or misleading statements
  - Don't give overly optimistic expectations regarding outcome, risks, prognosis, safety, or effectiveness
- **Consent Should Be Continual**
  - Make it clear that clients may remove their animals from the study at any time
  - Provide clear information and instructions for withdrawal from study

COMPONENTS OF A GOOD INFORMED CONSENT FORM

1) Purpose of the Study: State the objective or goals of the clinical investigation
2) Duration of the Study: What is the duration of the study and what procedures/treatments will the animal experience?
   - What are the owner's responsibilities to comply with the study (administration of medications, completion of surveys, recheck visits, etc.)?
   - Include description of the treatment groups and the likelihood of the animal being assigned to the control group (if applicable).
   - A study calendar provides a visual guide of how frequently the animal will need to come in, how long study will take, and which procedures are conducted at each visit.
3) What alternative, non-study options are available?
   - What procedures or treatments would animals with the condition(s) likely receive if they choose not to participate in the study?
4) What are potential benefits to the animal for participating?
   - Include a statement that the study may not improve the animal's outcome or disease status.

5) What are the potential risks or discomforts to the animal?
    - Note if there are any human or environmental safety concerns.
6) What are the financial costs and/or benefits for owners for enrolling?
    - Study incentives or compensation
    - List all specific procedures and costs covered by the study, and financial support for adverse events if available.
7) Statements Regarding Voluntary Participation and Withdrawal
    - Participation is voluntary; Owner may refuse to participate or withdraw their animal at any time and neither action will impact the care of their animal.
    - Anticipated circumstances under which the animal may be removed from the study at the discretion of the investigator(s). Ex: The study team reserves the right to remove my animal from this study if it is not in the best interests of my animal (he/she is not responding to therapy, experiences significant side effects or there is a failure to meet study requirements).
    - What happens upon withdrawal from the study?
        i. Inform the owner of the requirement for study animal medical record retention after withdrawal.
        ii. Inform the owner of any potential consequences (additional costs not compensated, etc.).
8) Statements on Confidentiality and Anonymity: Describe the extent, if any, to which confidentiality and/or anonymity of patient data will be maintained.
9) How are the outputs of study handled?
    - Excess body fluid or tissue samples
    - Data and/or image storage
    - Are results communicated to owner?
    - Any possible follow-up after study completion
10) Signatures and Dates: Acknowledgement that the owner has been provided the information discussed in the form.
    - Include confirmation that the signee is the owner of the animal.
    - Consider having a neutral witness present who also signs the form.
11) List of Contacts: Note if contact is different for general study questions versus possible study-related adverse effects.

TIPS FOR GAINING CONSENT EFFECTIVELY

1. Give owner adequate time to peruse the consent form.
2. Try to overcome any barriers to understanding (literacy, language barriers).
3. Discuss with owners in a private location – review the study protocol and consent form.
4. Allow time for questions
5. Signature denoting voluntary consent and discussion of consent form.