Determining if IRB Approval is Required for Surveys used in Veterinary Studies

Background: If a researcher intends to obtain identifiable pet owner information ("Owner Information") during a veterinary study, this activity may be considered Human Subjects Research and therefore subject to IRB approval. For purposes of this document, an Owner Survey is considered a tool (printed, written or verbal) used to acquire data and information during the course of a veterinary research study. Owner Information is considered personally identifiable information (see Exhibit A: "HIPAA Identifiers"), or sensitive personal information.

Purpose: This document provides general guidance for seeking approvals for Owner Surveys.

- 1. IRB Approval is **REQUIRED** if the Owner Survey meets any of the following conditions:
 - A. Collects Owner Information for the purpose of conducting research. Note: Owner Information contained in the patient charts or in the electronic medical record, but are not being used for the purpose of conducting research, would not require IRB approval.
 - B. Gathers information about the pet owner's attitudes or feelings.
 - a. Example: a question(s) asking how the pet's condition affects the owner's wellbeing, emotional status, purchasing habits, or behaviors.
 - C. Through an anonymous survey where the investigator obtains information, in the absence of a Veterinary-Client-Patient relationship, about:
 - a. A pet or the pet's environment, diagnosis, treatments, etc.
 - b. A pet owner, such as owner preferences, use of products, purchasing preferences, pet's environment, historical information about the pet, etc.

2. IRB Approval is **NOT REQUIRED** if the Owner Survey:

- A. Concerns the pet's condition (health status; treatment outcomes) during the course of a study. This includes gathering information for patient screening purposes to determine eligibility to enter a study.
 - a. Example: Asking a pet owner about their perceptions of their pet's disability or quality of life before or after receiving a therapeutic intervention.

3. UNCERTAINTY

A. If the PI is uncertain of the need for IRB approval of an Owner Survey, then the PI should inquire directly with the respective IRB.

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Exhibit A: HIPAA Identifiers

- 1. Names
- 2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geocodes, except for the initial three digits of the ZIP code if, according to the current publicly available data from the Bureau of the Census:
 - (1) The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and
 - (2) The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000
- 3. All elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
- 4. Telephone numbers
- 5. Vehicle identifiers and serial numbers, including license plate numbers
- 6. Fax numbers
- 7. Device identifiers and serial numbers
- 8. Email addresses
- 9. Web Universal Resource Locators (URLs)
- 10. Social security numbers
- 11. Internet Protocol (IP) addresses
- 12. Medical record numbers
- 13. Biometric identifiers, including finger and voice prints
- 14. Health plan beneficiary numbers
- 15. Full-face photographs and any comparable images
- 16. Account numbers
- 17. Any other unique identifying number, characteristic, or code, except as permitted by HHS (refer to HIPAA policies at HHS); and
- 18. Certificate/license numbers

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