



Animal Welfare Institute

900 PENNSYLVANIA AVENUE, SE, WASHINGTON, DC 20003 • 202-337-2332 • AWIONLINE.ORG

November 14, 2023

Re: FDA Guidance for Industry #282: Informed Consent Forms for Studies that Enroll Client-Owned Companion Animals

Dear FDA Staff:

The Animal Welfare Institute (AWI) supports the use of informed consent forms for any research involving client-owned animal patients, and believes a research model that employs animals as patients is a preferable alternative to research using laboratory animals. However, AWI believes that the use of informed consent forms should extend to all client-owned animals, not just to companion animals, as set forth below. In addition, AWI believes it is important to recognize that animals lack “the ability to adequately represent their own interests, which makes them vulnerable to exploitation and harm” (Ferdowsian, 2020) and that careful protection against undue influence must be built into study design and the informed consent process.

I. Background

AWI recognizes that animals often “overwhelmingly bear the burdens of research without accessing the benefits” (Ferdowsian, 2020) and that veterinary-focused research using a model that treats animals as patients, with informed consent by owners, can be an exception to that general rule. Therefore, AWI believes a research model focused on veterinary patients should be preferred over laboratory research using otherwise healthy animals unlikely to benefit, whenever possible. Indeed, “animal patients” who suffer from an illness or disease may be a better model for research intended to benefit both humans and animals than traditional laboratory animal studies. Similarly, client-owned animals may often be able to live at home and enjoy the companionship of their humans for the duration of a study, reducing stress. (Ferdowsian, 2020) “It has become widely recognized that animals may experience distress in a laboratory setting, and that this distress may interfere with the animal’s overall welfare, disrupt scientific experiments, and result in unforeseen behavioral and physical changes.” (The National Academies, 2007)

Scientifically sound, ethical studies are key to confirming safety and efficacy of medical treatment for use in humans, and the same can be said for treatments to be used in animals. If done ethically, “studies involving privately-owned pets can help fuel advances in both human and veterinary medicine.” (Bertout, 2021) Use of animals in laboratories is often scientifically justified by citing their similarities to humans, yet we rarely acknowledge their vulnerability and potential suffering and how that may impact ethical considerations. (Ferdowsian, 2020) No federal laws, including the Animal Welfare Act, currently regulate the gathering of informed consent and the ethical management of clinical studies using companion animals. (American Veterinary Medical Association, 2023)

While policies exist with regard to studies of humans and laboratory animals, companion animals represent a gap. (Bertout, 2021) **AWI fully supports beginning to close this gap by adding informed consent guidance to any study involving client-owned animals to help ensure ethical research practices** and to encourage trust between scientists and the animal-owning public. The requirement of informed consent does not prevent studies from happening, it simply helps ensure they are conducted ethically.

II. Scope

The draft guidance indicates it would be limited to “companion animals (dogs, cats, and horses).” (U.S. Department of Health and Human Services, 2023) **AWI strongly believes this does not go far enough and calls for the draft guidance to extend to all animals enrolled in a study by human owners**, including other companion animals and “food producing animals,” which are currently not covered by the guidance.

While dogs and cats are the most common pet in the United States, they are hardly the only species from which humans derive companionship. A survey by the American Pet Products Association indicates that there are over 11 million freshwater fish; over 6 million (each) birds, “small animals” and reptiles, and over 2 million saltwater fish living in US households. (Megna, 2023) There is no scientific basis for treating different companion animal species differently; owners of all pets, regardless of species, should be given complete information about the proposed treatment of their animals. All animals have an interest in humane and ethical treatment, and people may form close emotional attachments, as well as economic and other interests, in animals of many species, even those not traditionally considered “companion animals.” (Haddon, 2021) (Macauley, 2023)

Animals are considered property under the law (Francione, 1996) and in our legal system people have significant control over the right to “do with their property what they choose.” (Kenton, 2022) Under this premise, combined with the doctrine of informed consent, owners must “fully understand and agree” to the planned use of, and consequences for, their animals based on “enough information for the decision-maker to make an informed choice.” (Cleveland Clinic, 2022) The same rationale for giving human owners control over what happens to their companion animals also applies to “food producing” animals. The estimated \$2.57 trillion value

of agricultural animals, (Schrobbach, 2023) only strengthens the rationale for properly informed choice by owners of “food” animals. Therefore, informed consent should not be limited to companion animals only.

III. Basic Elements of an Informed Consent Form

AWI appreciates that the draft guidance starts by stating that Agency for Healthcare Research and Quality recommendations for human subjects should be “generally applicable to the owner or agent of client-owned” animals. (U.S. Department of Health and Human Services, 2023) **AWI endorses the application of standards applied to informed consent for human studies to studies using client-owned animals.** However, AWI feels that additional safeguards are necessary in a context in which the actual study participant cannot speak for him or herself. The Belmont Report, the cornerstone of ethical guidelines regarding informed consent for people, incorporates two moral requirements: “individuals should be treated as autonomous agents, and second, that persons with *diminished autonomy* are entitled to protection.” (*emphasis added*) (The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979) We believe that animals lack “the ability to adequately represent their own interests, which makes them vulnerable to exploitation and harm” (Ferdowsian, 2020), and thus need heightened protections before they are used in medical research. In other contexts, such as research involving very young children, research subjects are allowed to “dissent even if they are not deemed to have the capacity to provide informed consent” “unless perhaps the study promises direct benefits that are otherwise unavailable.” (Ferdowsian, 2020)

In the context of client-owned animals, a careful balance between respecting the animal’s wish not to participate and the owner’s ability to make choices in the animal’s best interest and the interests of society should be the goal. Therefore, ethical research using client-owned animals should consider not only the owner’s informed consent but also the minimization of risks and maximization of benefits. The balancing act would be relatively clear cut in a situation where the animal is ill and the proposed study offers potential benefits to that animal. In circumstances in which the animal is not ill and/or does not have the potential to benefit directly from the study, such an analysis should focus on the principle of beneficence, particularly the principle of maximizing possible benefits while minimizing possible harms. (Ferdowsian, 2020) Therefore, informed consent should involve helping the owner determine whether the animal will be injured or distressed, and if so whether that injury or distress is outweighed by potential benefits, with the owner making the final calculation. Potential benefits could include benefits to the animal, benefits to the animal’s species, benefits to the animal’s human family, or benefits to “society at large.” (Ferdowsian, 2020) The calculation should also consider whether the proposed benefits can only be achieved through the proposed research and/or whether alternative methods are available or are likely to be available in the future (Ferdowsian, 2020) – all of which should be communicated as part of the informed consent process.

Lastly, “although endpoints for ordinary research animals are generally set by researchers in consultations with Institutional Animal Care and Use Committees,” in a study using human-owned animals, any decision regarding euthanasia will ultimately belong to the client. (Rollin, 2005) As a result, special considerations must be made by the researcher regarding guidelines for the end of an animal’s study participation, including euthanasia, particularly where the potential for undue influence (intentional or inadvertent) exists. For example, researchers must commit – to themselves and the owner – that if at some point “saving the animal or even keeping it comfortable requires specialized knowledge or facilities” unavailable at their facility, they will disclose this to the owner. “By no means should this private clinician trade extra data for animal suffering.” (Rollin, 2005) The researcher should commit to remove the animal from the study if at any point the harm to the animal outweighs any potential benefits as determined by the researcher’s best judgment. Similarly, special attention should be paid to the potential for undue influence over the consenting owner where the researcher and his or her institution stands to benefit from the proposed research as animals belong to a particularly vulnerable population.

Thank you for your consideration.

Sincerely,

A handwritten signature in cursive script that reads "Lisa Hoover".

Lisa Hoover, JD, MA, MLS
Senior Policy Analyst
Animals in Laboratories Program

References

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