Trials in Non-University Owned Animals

Purpose
This statement clarifies the requirements for submission of an Animal Care and Use Protocol for trials in non-university owned animals.

Background
The University is frequently involved in types of animal research that do not fall under the traditional definition of laboratory research. For example, a veterinarian might develop a new method for treating skin cancer and apply that technique to several of his/her patients presenting with skin cancer. An animal scientist might recommend a change in diet to a commercial dairy and record the influence of that diet on the performance of the cattle. Either of these projects could be conducted by any practicing veterinarian or by any dairymen; outside the University neither of these projects would be regulated by any laws, regulations, or guidelines.

There are no laws governing such trials in animals. This is different from studies conducted in human beings, in which clinical trials are regulated. With respect to trials in non-university-owned animals, there is no equivalent to Human Subjects regulations.

Definition
A "trial in non-University owned animals" with respect to this policy, refers to a research project in which a treatment is applied to animals that are not actually experimental animals in the typical sense. The key factors that make a study a "trial in non-University owned animals" are:

1. The Animals are not owned by the University of California, nor are they client-owned Veterinary Medical Teaching Hospital (VMTH) patients.
2. No disease is being induced or health problem being created for the animals by the study. If the study is focused on a particular disease, the disease is spontaneously occurring in the animals.
3. The procedures performed on the animals are those that a practicing veterinarian, pet owner, or farmer/rancher would perform on their own animals or their clients’ animals and are being done for the health benefit of the animals.
4. The project is not being funded by a federal funding agency. Both USDA and OLAW require a protocol to be reviewed for animal research and teaching that is federally funded.

All of these conditions must apply for the study to be considered a trial in non-university-owned animals.
Policy

Trials in non-university-owned animals are not regulated by the Animal Welfare Act. As such, these trials are exempt from the requirement for submission of an Animal Care and Use Protocol. Submission of a protocol for Animal Care and Use for such studies is optional. Some funding agencies and certain publishers or manuscripts or reports may require review of such a trial by the Institutional Animal Care and Use Committee (IACUC). The IACUC will review such projects on request in order to satisfy the requirements of funding agencies or publishers.

For clinical research involving client-owned VMTH patients, an IACUC approved protocol is required. The veterinary Clinical Trial Review Board (CTRB) functions in an advisory fashion to the UC Davis IACUC and will pre-review all protocols involving client-owned VMTH patients. The primary responsibility of the CTRB is to determine whether clinical research projects place VMTH patients at increased risk. Protocols involving client-owned VMTH patients must also include an owner Informed Consent Form. Implementation of new technologies or procedures that are believed to be in the best interest of the patient, or that fall under compassionate use, do not constitute an investigation and thus do not fall under the definition of clinical research.

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Contact

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More information
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