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IACUC GUIDELINE: PROVISION OF ADEQUATE VETERINARY CARE AND REPORTING UNANTICIPATED ADVERSE EVENTS

DATE IMPLEMENTED: December 11, 2009

REVISION APPROVED: February 11, 2025

Background:

This guideline describes the IACUC's expectations specific to the prevention and management of study or protocol-associated pain, distress, disease, or disability. Furthermore, it describes the reporting of unanticipated adverse events to the IACUC.

Definitions:

Adverse events: Include unforeseen, unanticipated, inappropriately addressed, or inappropriately alleviated sources of pain, distress, and/or death of an animal that were NOT identified (specifically or generally) as potential risk factors or potential adverse complications in the approved IACUC protocol.

Procedure:

The Principal Investigator (PI) and research personnel are required to consult with the Attending Veterinarian (AV) and notify the AV, or notify the IACUC under the following circumstances:

1. The AV must be consulted when creating or amending any animal research protocol that includes procedures that may cause more than momentary or slight pain or distress to the animals, for example, a surgical procedure or a protocol-associated disease or disability. The AV will assist the PI to identify procedural guidelines, and training, as appropriate, for new or on-going experimental procedures.

2. The AV must be notified in a timely manner if during or following an experimental procedure an animal manifests unexpected or untoward behavior or clinical signs, or dies unexpectedly. Reportable clinical signs may include, but are not limited to, bleeding, open wounds, difficulty breathing, inability to ambulate or difficulty moving, unusual postures at rest, and abnormal neurological signs (head tilt, circling, ataxia).
    a. The Attending Veterinarian can be notified in any of the following ways:
        i. By phone – (805)451-5931 (cell phone)
        ii. By email – manuel.garcia@ucsb.edu

iii. By calling the Animal Resource Center (ARC) – 893-2333

b. In the event of an emergency, the AV, or trained ARC staff under the direction of the AV, may euthanize animals in severe pain or distress without consultation with the investigative group.
c. Protocol personnel or the PI must respond to requests (written or verbal) for treatment or euthanasia made by the AV, or by the ARC staff under the direction of the AV, within 24 hours to ensure timely resolution of clinical problems. After 24 hours, treatment or euthanasia may be initiated without consultation from the investigative group.
d. For animals housed at remote facilities off campus (e.g., SNARL), contact the AV for advice in an emergency until that animal can be seen by a local veterinarian and a Veterinarian-Client-Patient Relationship (VCPR) can be established. Most states and the AVMA's Principles of Veterinary Medical Ethics require a VCPR for a veterinarian to diagnose, prescribe medication or otherwise treat an animal. Without a VCPR, any advice provided through electronic means should be general and not specific to a patient, diagnosis or treatment.[2]

3. The IACUC must be notified of any serious, unanticipated adverse events or problems encountered while conducting work on an approved animal protocol, and if needed, the animal protocol should be amended in a timely manner.
    a. Examples of unanticipated adverse events include, but are not limited to:
        i. Complications during surgery or anesthesia, at a frequency higher or severity greater than expected or described in the approved protocol. A review of the surgical and postoperative records should be conducted at regular intervals to facilitate the identification of surgical complications at a higher-than-expected rate.
        ii. Unanticipated animal morbidity or mortality following an experimental procedure or manipulation (i.e., animal treatment or experiment), or animal morbidity or mortality occurring at increased severity or rate greater than the expected outcomes described in the protocol.
        iii. Euthanasia that did not result in the humane death of the animal.
        iv. Deviations, departures or mistakes made by the research team during the performance of an animal procedure that are inconsistent with the approved protocol and resulted in harm to the animal.
        v. Facility, weather-associated events, or environmental hazards (e.g., HVAC or power failure, flooding, fire, animal disease outbreaks) that negatively impact the welfare of an animal.
        vi. Unanticipated life threatening or debilitating phenotype discovered with transgenic animals that negatively impact animal welfare.
    b. Examples of adverse events that don't need to be reported to the IACUC:
        i. Adverse drug reactions, if specifically identified in the drug manufacturer's product label. For instance, injection site reactions are noted for SC injections with certain analgesics (e.g., meloxicam, extended-release buprenorphine) or antibiotics (e.g., enrofloxacin). Pica is an identified adverse drug reaction for extended-release buprenorphine treatment. Gastrointestinal ulceration is recognized as a post-approval adverse drug reaction for parenteral administration of NSAIDs (e.g., carprofen).
        ii. Adverse events that are specifically identified in the approved IACUC protocol. For example, rodents approved for treatment with non-pharmaceutical grade (NPG) drugs (e.g., tamoxifen, thioglycolate) that develop abnormal clinical symptoms following treatment (e.g., lethargy,

weight loss, hunched posture). Please note that for many NPG treatments, humane endpoint monitoring plans are included in the IACUC protocol to identify and alleviate potential adverse events. These plans must be strictly followed by the research team. Failure to do so would constitute an instance of protocol non-compliance.

References:

1. DoD Guidance on Adverse Event Reporting: https://mrdc.health.mil/assets/docs/orp/acuro/ACURO_Reporting_Guidance.pdf

2. American Veterinary Medical Association (AVMA): https://www.avma.org/resources-tools/avma-policies/telemedicine