WASHINGTON STATE UNIVERSITY

Washington State University
Institutional Animal Care and Use Committee

Guideline #7: Using Novel Substances in Animals

Approval Date: 12/01/2022 (Replacing Version 12/19/2019)

A. Purpose

A novel substance is any chemical entity that has never been tested, is in the early stages of animal testing, or is a previously characterized substance administered in a novel way. This guideline provides guidance to WSU PIs and IACUC on the information that should be included in the Animal Subjects Approval Form (ASAF) to protect animal health and welfare and promote scientific rigor.

B. Guideline

If an investigator proposes to administer a novel substance to a particular species, the following information should be provided to the IACUC in the ASAF:

- By default, novel substance would be classified as non-pharmaceutical grade. Please refer to WSU IACUC Policy #29 for the definitions and preparation requirements.
- A synopsis of any available *in vitro* or *in vivo* data including pharmacological and toxicological actions of this or related compounds
- A brief description of the class of compound, including mechanism of action (if known)
- Information on the source of the novel substance (e.g., will it be created in the PI's laboratory, provided by a company, etc.?)
- A description of the grade/purity being proposed, the formulation of the final product, compatibility of components, and issues such as sterility, pyrogenicity, stability, pH, osmolality, storage, *shelf life, toxicity, pharmacokinetics, physiological compatibility, and quality control, if available.

  **If the shelf life is not pre-determined by the manufacturer, the PI is responsible for determining the expiration date of the compound once diluted; otherwise, the solution should be prepared each day that it is used.*

- A complete description of dosage, site and route of administration, how long compound will be administered, the intervals by which dosages will be

increased/decreased (if applicable), and the rationale for increasing/decreasing dosages

- The plan for monitoring of animals for side effects and adverse events after compound administration, including:
    - Frequency of monitoring should be:
        - more frequent if there is a potential for acute toxicity or unknown adverse effects
        - less frequent if there is previous data after administration to animals and no adverse effects were identified at the maximal dose
    - Identification of staff performing the monitoring
    - How monitoring will be documented
    - Behavioral signs of pain and distress that will be monitored
    - Objective monitoring parameters (e.g., biochemical or metabolic changes)
    - Plans for treating animals for toxicity, if indicated
- Specific humane endpoints, such as (but not limited to):
    - Impaired ambulation
    - Seizures
    - Rapid weight loss (usually due to dehydration)
    - Labored breathing
    - Impaired mentation
    - Anaphylaxis
- Study endpoints
- Potential occupational health and safety concerns for laboratory staff, animal caretakers, veterinarians, etc., during and after administration to animals, including handling of carcasses, bedding, and caging. Some compounds may require an IACUC- or IBC-approved SOP before work can begin.

If you have any questions or concerns regarding this guideline, please call the Animal Welfare Program Office at (509) 335-7951 or email iacuc@wsu.edu.

C. References

1. OLAW FAQ F(4)
2. Chemicals and Novel Compounds in Animals. Environmental Health and Safety. University of Florida.