

UNIVERSITY OF WISCONSIN-MADISON
RESEARCH ANIMAL RESOURCES CENTER
ALL CAMPUS ACUC POLICY

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POLICY REGARDING NOVEL SUBSTANCES TESTED IN LABORATORY ANIMALS

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 policy provides guidance to UW-Madison PIs and ACUCs on the information that must be included in animal use protocols in order to protect animal health and welfare and promote scientific rigor.

Policy: If a PI proposes to use a compound in animals that has never been tested in that species, the following information must be provided to the ACUC in the animal use protocol:

- 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)
- A complete description of dosage, 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 adverse events after compound administration, including:
 - Frequency of monitoring
 - More frequent especially if there is a potential for acute toxicity
 - Less frequent after animal responses are better known
 - 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

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Reference Minutes: 07/08/2005, 08/05/2005, 10/9/2009

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