GUIDELINES FOR USING NOVEL SUBSTANCES IN 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 guidance to WSU PIs and IACUC on the information that must be included in animal use protocols in order to protect animal health and welfare and promote scientific rigor.

GUIDELINE: If an investigator proposes to use a compound in animals that has never been tested in that species, the following information should be provided to the IACUC 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. Some compounds may require an IACUC approved SOP before work can begin.

If you have any questions or concerns regarding this guideline, please call IACUC office at 335-7951 or email iacuc@wsu.edu.

Posted November 2016