ANIMAL EYE CONSULTANTS OF IOWA

Animal Eye Consultants of Iowa

Institutional Animal Care and Use Committee

IACUC Policy #41: IACUC Standard Operating Procedures (SOPs) for Hazardous Agents

Approval Date: 05/08/2024 (Replacing Version 7/19/2021)

A. Purpose

The purpose of this guideline is to define the procedures for developing and reviewing Standard Operating Procedures (SOPs) for hazardous material use in Institutional Animal Care and Use Committee (IACUC) protocols. The SOPs created under this guideline are intended to describe the requirements for safe use and handling of hazardous materials when used within animal facilities. This includes handling animals, bedding, or cages contaminated with a hazardous material.

The PIs/research laboratories are still required to have their own SOPs for use of the raw materials in the laboratory consistent with their AEC Chemical Hygiene Plan or other applicable documents (e.g. Biosafety Approval Form).

B. Summary

SOPs are written when the hazard is defined as having statistically significant evidence conducted in accordance with established scientific principles that acute or chronic health effects may occur in exposed employees, per Environmental Health and Safety (EHS) definition (See Reference 1b.). Additional considerations are given to dose (whether it approaches a hazardous exposure), carcinogenicity, reproductive hazards, and others that are suspected to be hazardous but lacking scientific support.

SOPs are intended to provide guidance for use and to protect human and/or environmental exposure to agents defined as potentially hazardous by the drug safety data sheets (SDS), Occupational Safety and Health Administration (OSHA) or the Environmental Protection Agency (EPA). The SOPs created under this guidance serve to provide information to the animal care staff and others in the animal facility about any hazards present, proper procedures and PPE for animal handling, and proper bedding and carcass disposal.

C. Guideline/Policy

All Animal Subjects Approval Forms (ASAFs) that contain potentially hazardous agents that may be used within animal facilities must clearly identify the type of hazardous material being used, where it is being used and if the agent poses a potential risk to individuals or other animals in the facility. Each ASAF

involving hazardous material must have an attached Research Safety Program-reviewed SOP for each unique material. Materials with similar risk and handling requirements may be combined in a single SOP.

Animal Care and Use Protocols that involve the use of biohazardous material and/or radioisotopes will be reviewed by the appropriate unit in Research Safety to ensure that the necessary authorizations are in place and that there is an established plan for working safely with the material within the animal facility. All applicable "use authorizations" must be in place prior to initiating work with the material.

It is the Principal Investigator's (PI's) and research staff's responsibility to notify the animal facility manager when a project with hazardous material will begin. This notification is part of the hazard communication process and must occur prior to the hazardous materials being used both within the facility space or with the animals. This will help to ensure that the necessary signage is in place, animal care staff are notified, personal protective equipment (PPE) is available, and any special husbandry requirements (e.g., bedding disposal) are in place.

In general, hazardous materials for the research projects should not be stored in the animal facility. Any storage request would first need to be approved by the facility manager and storage must be in a manner consistent with EH&S requirements.

D. Procedures

Initial review (please view Figure 1 for flow chart)

1. Upon submission of a new ASAF or amendment, the Animal Welfare Program (AWP) Office will review the protocol to determine if it contains potentially hazardous materials (e.g. chemicals, toxins, radiation, biological, etc.).
2. If the AWP Staff believe the ASAF may require an SOP, the information will be sent to Research Safety Program staff (e.g., Biosafety, Radiation Safety), who will work with the Principal Investigator (PI), facility manager, veterinarian, research staff, and other subject matter experts (e.g., EH&S) to develop the SOP, as needed (see below flow chart).
3. Once the SOP is finalized and approved by both the Research Safety Program, and the PI, it will be attached to the ASAF. Approval of a new ASAF may be held up until any needed SOPs are finalized.
4. SOPs are subject to re-review every three years during the ASAFs three-year de novo review or when the biohazard use is significantly amended.

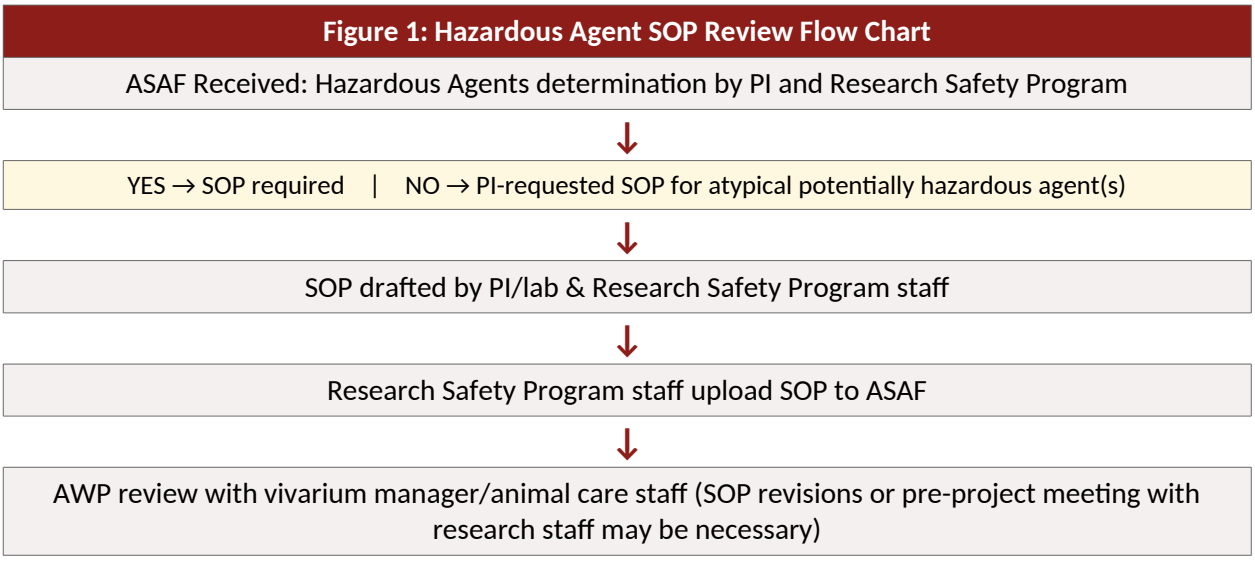
After Approval

1. Following protocol approval by the IACUC, the protocol with the relevant SOP will be available to the PI and Facility Manager via the MyResearch system.
2. The PI or research staff will notify the facility manager prior to initiating the component of the project with the hazardous material. They will also make sure to label cage cards/cages (as applicable according to SOP) with the date, agent, dose, route, and clearance date if applicable.
3. The facility managers will ensure appropriate animal room door posting and ensure staff have access to the SOP/safety information and are provided training if they will be handling the animals, housing/cages and disposal of waste.

Any needed changes to an SOP can be submitted to the AWP Staff via an administrative amendment. Please contact the AWP Office at IACUC@animal-eye-iowa.com to request an SOP amendment.

Compliance with the SOP(s) may be reviewed by numerous parties, such as the Office of the AEC Veterinary Staff (AEC), EHS, AWP office, PAR, IACUC site visits, during inspections by regulatory agencies and/or biosafety facility inspections.

Figure 1: Hazardous Agent SOP Review Flow Chart



E. References

1. AEC Environmental Health and Safety https://ehs.animal-eye-iowa.com
    a. Online AEC EH&S SOP template examples https://ehs.animal-eye-iowa.com/soptemplates/
    b. Laboratory Safety Manual - https://ehs.animal-eye-iowa.com/laboratory-safety-manual/
    c. Chemical Hygiene Plan https://ehs.animal-eye-iowa.com/documents/2020/05/chemicalhygiene-plan-guide.pdf/
2. AEC Research Safety
    a. Institutional Biosafety Committee - https://biosafety.animal-eye-iowa.com/
    b. Radiation Safety Program - https://rso.animal-eye-iowa.com/
3. For Hazardous Agent Information:
    a. https://www.osha.gov/carcinogens
    b. https://www.epa.gov/
    c. https://www.osha.gov/sites/default/files/publications/OSHA3491QuickCardPictogram.pdf