A. Purpose

The purpose of this guideline is to define the preparation process of Standard Operating Procedures (SOPs) for hazardous agent use in Institutional Animal Care and Use Committee (IACUC) protocols.

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 2a). Additional considerations are given to dose (whether it approaches the LD50), carcinogenicity, reproductive hazards, and others that may 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).

C. Guideline

All Animal Subjects Approval Forms (ASAFs) that contain potentially hazardous agents are required to have an attached Biosafety-reviewed SOP for each unique agent. The process described below will be used to determine if an ASAF requires an SOP.

1. Upon submission of a new Animal Subjects Approval Form (ASAF) or amendment, the Animal Welfare Program (AWP) Office will review the protocol to determine if it contains potentially hazardous drugs, chemicals, or agents.
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), vivarium manager, research staff, and other subject matter experts (e.g., EH&S) to develop the SOP, as needed.

3. Once the SOP is finalized and approved by both Biosafety 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.

Any needed changes to an SOP can be submitted to the AWP Staff via an administrative amendment. Please contact the AWP Office at iacuc@wsu.edu to request an SOP amendment.

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

1. For templates:
   a. https://ehs.wsu.edu/soptemplates/

2. For SOP information:

3. For Hazardous Agent Information:
   b. https://www.epa.gov/