Safety In Research and Vivarium Environments (SIRVE) Program

1. Program Description

The purpose of the Safety In Research and Vivarium Environments (SIRVE) program is to prevent injuries and exposures from the use of hazardous materials and hazardous operations related to animal research. This will be accomplished by:

1. Reviewing Institutional Animal Care and Use Committee (IACUC) protocol submissions including new protocols, resubmissions, renewals, and modifications.
2. Performing a risk assessment of the agent(s) and procedure(s) proposed in each submitted protocol.
3. Initiating safety considerations meetings with University Lab Animal Resources (ULAR) representatives and research groups.
4. Providing hazard communication to all parties involved.
5. Providing support for ULAR and research staff in developing and complying with effective risk management strategies.

2. Scope

This document applies to all UC Irvine research and staff support personnel where potential exposure to research animals or their materials may exist.

The SIRVE program addresses:

1. Risk Identification
2. Hazard Assessment
3. Hazard Communication
4. Engineering Controls
5. Administrative Controls/Work Practice Controls
6. Personal Protective Equipment

3. Definitions

3.1 ULAR: University Laboratory Animal Research: Office of Research department responsible for maintaining animal research on campus including housing, maintenance, and oversight of laboratory animals.

3.2 IACUC: Institutional Animal Care and Use Committee: Committee composed of research faculty, veterinarians, representatives from the public and Environmental Health and Safety representatives. The IACUC committee is charged with ensuring the welfare of animals, personnel and the environment in which animal research is conducted.

3.3 Vivarium: A facility for keeping and raising living animals and plants under natural conditions for observation or research.
3.4 SOP: Standard Operating Procedures, a document outlining best practices regarding the safe use of an agent or procedure. It includes identifying appropriate engineering controls, administrative controls and personal protective equipment.

3.5 Vivarium Safety Officer: Environmental Health and Safety personnel responsible for vivarium safety and laboratory biosafety.

3.6 Animal Research Technicians: Personnel charged with the daily care and maintenance of laboratory animals.

3.7 Safety Considerations Meeting: A meeting intended to communicate risk and mediate the distribution of responsibilities for risk management for all stakeholders involved.

4. Responsibilities

4.1 Vivarium Safety Officer is responsible for:
   4.1.1 Reviewing IACUC protocols
   4.1.2 Identifying biological, chemical, and radiological agents and procedures
   4.2.3 Initiating and facilitate meeting with research staff and vivarium staff
   4.2.4 Providing hazard communication, training, and consultation
   4.2.5 Developing SOPs

4.2 Animal/Research Technicians are responsible for:
   4.2.1 Performing Animal room inspections
   4.2.2 Providing food and water for animals
   4.2.3 Changing cages and bedding
   4.2.4 Cleaning cages
   4.2.5 Following established SOPs

4.3 Faculty/Principal Investigators (PI) are responsible for:
   4.3.1 Designing research projects
   4.3.2 Submitting protocols
   4.3.3 Directing supervision of research project and research personnel
   4.3.4 Complying with federal, state and other regulations as applicable to the research project.

4.4 ULAR Veterinarians are responsible for:
   4.4.1 Providing routine and specialized medical care of animals used in research
   4.4.2 Ensuring compliance with all research projects to IACUC policies
   4.4.3 Performing periodic inspections of laboratories and animal holding rooms
   4.4.4 Reviewing IACUC protocols and serving as voting members of the Committee

4.5 IACUC: The IACUC is a faculty committee responsible for:
   4.5.1 Reviewing all animal use protocols
   4.5.2 Ensuring compliance with federal regulations
   4.5.3 Inspecting animal facilities and laboratories

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4.5.4 Overseeing training and educational programs

4.6 IACUC Administrator Responsibilities
   4.6.1 Managing all administrative responsibilities of the IACUC
   4.6.2 Analyzing, interpreting and applying regulations and policy
   4.6.3 Organizing/conducting semi-annual evaluations and inspections
   4.6.4 Assisting with resolution of noncompliance allegations
   4.6.5 Coordinating/performing post-approval monitoring and outreach services
   4.6.6 Providing training services to researchers and IACUC members

5. Program Components

5.1 Protocol Review

All protocols submitted to the IACUC will be reviewed by the Vivarium Safety Officer during
the pre-review period prior to IACUC meetings. Each protocol will receive a preliminary hazard
risk identification and assessment with respect to the procedure(s) involved as well as the agents
used. Identification of a hazardous substance will rely on consultation of a number of sources
including technical websites maintained by federal agencies including CDC, NLM-Tox Net,
SDS data sheets, pubmed, and published standard operating procedures from reputable sources.
If further expertise is necessary, the relevant EH&S Officer, or Subject Matter Expert will be
solicited for technical assistance.

Once the risk identification and assessment is complete, the Vivarium Safety Officer will submit
all comments to be included in the IACUC/PI correspondence to the IACUC Administrator. In
addition, Vivarium Safety Officer will notify the Principal Investigator of the risks identified and
will arrange a safety considerations meeting if necessary. Notification will occur via telephone
and /or email.

If ULAR staff will not come into contact with the hazardous material or will not perform
operations involving any identified risks, the safety considerations meeting will not include the
campus Veterinarian or the ULAR staff.

5.2 Risk Assessment

The risk assessment performed by the Vivarium Safety Officer is a three-pronged approach
which includes evaluation of the agent, personnel (various predispositions), and the research
environment (whether it contains the adequate barriers and controls). With respect to the agent,
risk assessments will reflect the nature of the agent, the dose administered, as well as exposure
risks during procedures (e.g. preparation, administration). Risk assessment will also consider
susceptibilities specific to research personnel including pregnancy, immune compromise etc.
Finally, risk management will include the safety of the surrounding environment to protect
against injuries that may elevate the exposure risk.

5.3 Safety Consideration Meetings

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Upon completion of a hazard risk assessment, a safety considerations meeting will be initiated to meet the needs of effective hazard communication, and the development of standard operating procedures. Generally there are two levels of meetings. Full committee meetings are more inclusive, comprehensive and consolidated in that all stakeholders involved need to be present and actively discussing risk management as well as coordinating various responsibilities. Such meetings are reserved for rarely used agents or ones that pose a significant health hazard (e.g. HSV, Vaccinia). Exempt meetings, are intended for ubiquitous or mainstream agents that nevertheless present a significant safety hazard (e.g. anti-neoplastic drugs).

5.3.1 Joint Meetings

Joint meetings involve procedures and agents for which the risk management will involve coordination between vivarium and research staff. These typically involve less commonly used therapeutics, and toxins that require communication between both parties and agreements on special handling procedures. Such meetings begin with an assessment of the environment for appropriate engineering and administrative controls and PPE availability. If animal procedures are to be performed in the vivarium procedure rooms, an assessment for these facilities will be completed as well. Subsequently, there will be a session where the safety representative discusses the risks and effects and solicit input from stakeholders on safety management. The purpose of this meeting is to develop a SOP document that will be adopted by the laboratory for working safely with the agent. The developed SOP should be signed by all attendees and a copy kept in the lab safety binder for future reference.

5.3.2 Separate Meetings:
Separate meetings can be managed independently by vivarium and research staff without collaboration. The subject of these meetings will include widely used agents and procedures that have established risk management practices. However, the same activities will be conducted with respect to discussion of safety issues, environmental assessment, and culminate in the development of standard operating procedures that will be retained by the stakeholder for guidance and a signed copy by the Vivarium Safety Officer for records.

5.4. Standard Operating Procedures (SOP)

A standard operating procedures document will be developed by the Vivarium Safety Officer following the safety considerations meeting to maximize its relevance to the procedure and the conditions of the research environment. The SOP must be reviewed by faculty and other research personnel who will be performing the procedure. Prior to use, the SOP document must be signed by all those who are listed on the protocol performing the procedure. Principal Investigators will be responsible for the training of new staff to follow the SOP when performing the intended procedures.

Specific elements of the SOP include:
1. Specific exposure hazards and health hazards
2. Safety issues to consider
3. Agent preparation safety guidelines
4. Administration of agent to animals
5. Animal handling and animal waste pathways
6. Agent waste pathways
7. Emergency instructions in case of exposure/spill (various routes discussed)

5.5. Hazard Communication Animal Door Signs

Following a safety considerations meeting, hazard communication door signs will be generated to suit the hazard present in the room. Information on the door sign will include:
1. Nature of the hazardous agent (e.g. biological or chemical)
2. Specific agent name
3. Potential route of entry
3. Specific PPE required for room entry, animal handling and cage changing

Signage will also be present on cages containing exposed animals. These labels will be the standard ULAR hazard cage cards and will be placed standing behind the cage identification card. Information on these labels will include:

1. Nature of the hazardous agent (e.g. biological or chemical)
2. Specific agent name
3. Handling requirements (e.g. fume hood or biosafety cabinets)
4. PPE required handling the animals
5. Cage cleaning, and bedding disposal guidelines
6. Carcass disposal guidelines

Both door signs and cage labels should be placed whenever exposed animals are present in the animal holding room. Such signage will be removed when the exposed animals are no longer present in the facility. The PI will be responsible for putting posting the signage for both the door and the cages.

6. Training Requirements

Depending upon the nature of the research, research personnel are required to take certain training courses. The baseline requirement for all research personnel includes Hazardous Waste and Laboratory Safety Fundamentals training which requires renewal every three years. Personnel working with animals are required to take animal handling and vivarium training course with annual refresher courses through CITI. Research staff who work with risk level 2 agents and or human or non-human primate blood, or cell lines needs to complete the Blood-Borne Pathogens training course annually. Other trainings specific to research that maybe applicable include Viral Vector Training, Aerosol Transmissible Diseases (ATD), Radiation Safety, and Laser Safety.

7. Information and External References

7.1 Toxicology Data Network: http://toxnet.nlm.nih.gov
7.2 Centers for Disease Control and Prevention: www.cdc.gov
7.4 Association of Assessment and Accreditation of Laboratory Animal

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Care: http://www.aaalac.org
7.5 California Occupational Safety and Health Administration: http://www.cal-osha.org
7.6 National Library of Medicine: www.pubmed.com
7.7 UCI Training and Employee Development: www.uclc.uci.edu
7.8 ULAR vivarium Training: https://www.citiprogram.org

8. Appendices

A. Program Process
B. Compliance Process

Review IACUC protocols

Hazards identified

PI notified via IACUC pre-review comments
PI notified via email from Biosafety/Vivarium Specialist

Non-response reported to IACUC committee at meeting

Protocol is tabled administratively pending compliance
D. Hazardous Cage Cards