



Occupational Health Program for Laboratory and Animal Research

Responsible University Official: Associate Vice President, Research Integrity and Compliance/Lee Seabrooke

Policy Owner: Occupational Health Program Manager/Steven Cummings, MD

Policy Contact: Occupational Health Program Manager/Steven Cummings, MD

1.0 Reason for Policy

Saint Louis University is committed to maintaining a safe and healthy research environment where exposure to biological, chemical, and physical health hazards is kept to minimum levels.

The purpose of this policy is to ensure that all persons at the University who are at some level of risk because of their work in or near a research laboratory and/or an animal facility have access to the Occupational Health Program for Laboratory and Animal Research (OHP). The principal objective of the OHP is to prevent occupational injury and illness.

2.0 Policy Statement

Research at Saint Louis University must be conducted in full compliance with applicable local, state, and federal regulations as well as University policies/procedures. The Associate Vice President for Research Integrity and Compliance has established the OHP to assure compliance with these regulations and to promote a safe, healthy research environment.

3.0 Scope

This policy applies to all persons working at the University including staff, faculty, students, independent contractors, collaborators, and other non-University personnel who work in or near a research laboratory and/or an animal facility.

3.1 Authorized Personnel

All authorized personnel working in or having access to University animal research facilities must participate in the OHP. Participation in the OHP is also required under the Select Agent Rule (42 CFR 73) and under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

The level of participation of personnel in the OHP is based on a risk assessment of the hazards posed by their assigned duties and the research setting. Considerations include: animals used, hazardous materials used, exposure intensity, exposure duration, exposure frequency, personnel susceptibility, and history of occupational illness/injury in the workplace.

3.2 Non-University Research Personnel and Independent Contractors

Non-University Research Personnel and Independent Contractors working in or having access to University animal research facilities are required to participate in an occupational health program through their employer that is comparable to the University OHP.

Non-University employers must submit descriptions of their occupational health program to the University OHP office for review.

3.3 Exclusions

Individuals who need access to University animal research facilities for a brief time (e.g., inspectors, visitors, prospective students) are not required to enroll in the OHP if they will not be handling animals, biological materials, chemical materials, radioactive materials, or other hazardous materials. These individuals will be accompanied by and always follow the directions of Authorized Personnel while in University animal research facilities. It is the responsibility of the Authorized Personnel accompanying such individuals to inform them of appropriate occupational health and safety risks and to ensure that they abide by all University animal research facility policies and procedures. This includes verifying that individuals planning to enter University research animal facilities have read and signed the required Visitor Assumption of Risk and Release Agreement (see University Policy AC-006).

4.0 Procedures

4.1 Medical Evaluation

Research personnel listed on IACUC protocols and certain IBC protocols must be medically evaluated by OHP staff for work in the area(s) of research as outlined in the protocol. This may require additional medical services, i.e., immunizations, testing, and/or personal protective equipment (PPE).

OHP medical histories are evaluated primarily through review. Medical assessments are based on risk information available to the medical provider at the time of evaluation.

Concentra Occupational Health is the authorized primary medical provider for University work related injuries/illness.

4.2 Vaccinations

If potential for exposure exists, all personnel must be vaccinated prior to participating in research activities with biological agents for which a safe and effective CDC recommended vaccine is available. The IBC determines if protocol specific vaccines are required or recommended.

Routine immunizations are arranged through OHP staff.

Protocol specific immunizations are arranged through OHP staff when needed.

4.3 Respirator Protection

Research personnel listed on IACUC protocols and IBC protocols may be required to be medically cleared to participate in the Respirator Protection Program. Respirator medical clearance is provided through OHP staff.

The wearing of face sealing respirators such as N-95 respirators, half-face cartridge respirators, or full-face cartridge respirators requires fit-testing before use and annually thereafter. Fit testing is provided by OHP staff.

4.4 Medical Services Declination

Declination of medical services offered or required under the OHP may preclude an individual from some positions, projects, and/or research activities that have requirements for medical evaluations and preventative medical care.

Required enrollment/participation in the OHP may not be declined regardless of any medical service declination.

4.5 Training

Training is essential for adequate preparation to work safely in research laboratories and animal research facilities. The training and orientation of persons working in University animal research facilities will include an overview of the OHP and information regarding enrollment in the OHP. Mandatory Laboratory Safety and Compliance Training is provided by EHS and includes OHP awareness and enrollment instructions.

Personnel are required to complete all mandatory training.

Completion of OHP related training will be documented in accordance with applicable regulations.

5.0 Sanctions

Individuals who fail to comply with this policy and associated procedures will be denied access to all University animal research facilities. Disciplinary actions for non-compliance can result in suspension or termination of research by the IACUC or the IBC. A report of suspected misconduct or a report to government funding/regulatory agencies may be required. Disciplinary action will be guided by the University Faculty Manual, Staff Handbook, or student guidelines as applicable.

6.0 Responsibilities

The implementation of the OHP requires a collaborative effort in both laboratory and administrative offices.

The OHP is administered by the Associate Vice President for Research Integrity and Compliance supervising the OHP manager.

OHP collaborators include: Office of Research Integrity and Compliance (ORIC), Environmental Health and Safety (EHS), Department of Comparative Medicine (CM), the Institutional Animal Care and Use Committee (IACUC), and the Institutional Biosafety Committee (IBC).

OHP collaborators meet as necessary to discuss, review, and advise on health/safety issues regarding University research activities and related facilities.

Other University offices or departments may be consulted as needed: Human Resources (HR), Risk Management, Office of General Counsel.

Primary collaborator responsibilities are outlined below.

Authorized Personnel: Individuals must be authorized by the University to be allowed access to University animal research facilities and/or to use/handle animals. Authorized Personnel must –

1. Be enrolled in the OHP consistent with the enrollment requirements contained in this policy and associated procedures
2. Comply with all applicable laws, regulations, and University policies/procedures regarding specific hazards to which they may be exposed during performance of research activities
3. Complete required training and continuing education
4. As applicable, be listed as a study associate on an approved IACUC protocol and/or IBC protocol

Comparative Medicine (CM): This department will –

1. Assist in establishing and maintaining the OHP for faculty, staff, and students who work with or have substantial contact with laboratory animals
2. Monitor standards of hygiene among individuals involved with animal care/use
3. Proctor an animal use orientation course as well as provide targeted training for safe use of animals in research
4. Provide personal protective equipment (PPE) to all personnel who have contact with animals or hazardous materials within University animal research facilities
5. Advise on and monitor biohazard control policies/procedures as these apply to research animal care/use in collaboration with the IBC and/or EHS
6. Monitor laboratory animals for zoonotic diseases

Environmental Health and Safety (EHS): This office will –

1. Assist in establishing and maintaining the OHP for faculty, staff, students, and visiting scientists who work with Select Agents, Risk Group 3 recombinant or synthetic nucleic acid molecules, all other Risk Group 3 biological agents, and any Risk Group 2 biological agents warranting OHP participation

2. Monitor compliance with training requirements designed to mitigate risk to various exposures including biological, chemical, and radiation
3. Collaborate with Comparative Medicine, OHP staff, and other University departments/offices in assuring Principal Investigator and Authorized Personnel are compliant with the OHP

Institutional Animal Care and Use Committee (IACUC): This committee will --

1. Monitor IACUC animal use protocols to ensure that all faculty, staff, and students listed have completed required training
2. Evaluate the effectiveness of the OHP during each semiannual program review

Institutional Biosafety Committee (IBC): This committee will --

1. Monitor IBC protocols to ensure that all faculty, staff, students, and visiting scientists who work with Select Agents, Risk Group 3 recombinant or synthetic nucleic acid molecules, all other Risk Group 3 biological agents, and any Risk Group 2 biological agents warranting OHP participation have completed required training
2. Ensure that these individuals are active in required OHP medical surveillance through follow-up during IBC protocol approval and review processes

Occupational Health Program (OHP): This office will -

1. Provide medical assessments based on risk assessments available at the time
2. Arrange for routine immunizations for OHP participants, and arrange for protocol specific immunizations as recommended or required
3. Provide respirator fit testing and associated respirator medical evaluation in compliance with OSHA regulations governing the Respirator Protection Program
4. Maintain a confidential medical record on each OHP participant
5. Provide OHP training in conjunction with Comparative Medicine

Office of Research Integrity and Compliance (ORIC): This office will --

1. Establish and administer the OHP for those working in or having access to animal research facilities
2. Revise and update the OHP as necessary in consultation with the IACUC, IBC, EHS, and OHP manager
3. Ensure that training is provided for University faculty, staff, and students regarding safety in the care and use of laboratory animals

Principal Investigators (PI): Individuals approved to be Principal Investigators will --

1. Provide a safe environment for research personnel (including faculty, staff, students, and visiting scientists) working under their supervision
2. Provide personal protective equipment (PPE) to all personnel to ensure adequate protection for their assigned research activities
3. Make sure that all personnel receive training regarding risks associated with their assigned research duties and the safe conduct of those research duties

7.0 References

National Research Council. 1997. *Occupational Health and Safety in the Care and Use of Research Animals*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/4988>

National Research Council. 2011. *Guide for the Care and Use of Laboratory Animals: Eighth Edition*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/12910>

PHS Policy on Humane Care and Use of Laboratory Animals. 2015 <https://olaw.nih.gov/policies-laws/phs-policy.htm>

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. April 2019. https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm

CDC Select Agent Regulations: 42 CFR Part 73. [CFR-2022-title42-vol1-part73.pdf \(govinfo.gov\)](https://www.govinfo.gov/FR-2022-title42-vol1-part73.pdf)

APHIS Select Agent Regulations: 9 CFR Part 121. [eCFR :: 9 CFR Part 121 -- Possession, Use, and Transfer of Select Agents and Toxins](https://www.ecfr.gov/current/title-9/chapter-I/subchapter-A/part-121)

Biosafety in Microbiological and Biomedical Laboratories (BMBL), 6th Edition, U.S. Department of Health and Human Services, 2020. [Biosafety in Microbiological and Biomedical Laboratories—6th Edition \(cdc.gov\)](https://www.cdc.gov/biosafety/publications/bmbl6/)

Occupational Safety & Health Administration (OSHA) – Respiratory Protection, 29 CFR 1910.134, <https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134>

8.0 Definitions

Animal Facilities include all areas at the University where animals are housed and where animal research is conducted.

Authorized Personnel means, for the purposes of this policy, any person who has received the appropriate training/clearance to access/work in University animal research facilities. This includes, but is not limited to faculty, students, staff, and volunteers. This term does not refer to visitors, observers, and independent contractors.

Comparative Medicine (CM) is the department within Saint Louis University where laboratory research animals are housed. CM provides professional veterinary and technical support services to investigators using animals in IACUC approved experimental procedures.

Environmental Health and Safety (EHS) provides environmental health and safety leadership, expertise, guidance, and service in support of the University's teaching, research, and clinical mission. These efforts include basic fire/life safety, general workplace safety, biological safety, chemical safety, radiation safety, hazardous materials removal/disposal, and related safety/compliance training.

Institutional Animal Care and Use Committee (IACUC) is the committee appointed by the President of the University to review and approve protocols for the care/use of laboratory animals in research. The IACUC oversees the University animal care/use program and animal facilities. Research involving any live vertebrate animal requires the submission of an Animal Use Protocol (AUP) and approval by the IACUC.

Institutional Biosafety Committee (IBC) is the committee responsible for the safe conduct of biological research at the institution. Research involving any human, plant, or animal pathogen requires the submission of an IBC application and approval by the IBC.

Office of Research Integrity and Compliance (ORIC) is housed organizationally within the Division of Research Administration. ORIC is comprised of the Conflict of Interest Committee, Institutional Animal Care and Use Committee, Institutional Review Board, OHP, and the Office of Responsible Conduct of Research. ORIC is charged with ensuring compliance with government and institutional regulations regarding the conduct of research at the University.

9.0 History

Policy Number: RC006

Version number: 2

Effective Date: 01MAR2024

Replaces: Version number 1 dated 05DEC2011

Policies Rescinded: Occupational Health Program for Persons at Risk Relative to Exposure to Laboratory Animals dated 01OCT2004