



# SAINT LOUIS UNIVERSITY

## Occupational Health Program for Laboratory and Animal Research

**Policy Number:** RC-006

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**Classification:** Research Compliance

**Effective Date:** 05DEC2011

**Responsible University Official:** Vice President for Research

### 1.0 INTRODUCTION

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. In an effort to mitigate risk and ensure compliance with applicable local, state, and federal regulations, the University has established the Occupational Health Program for Laboratory and Animal Research.

### 2.0 PURPOSE

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

### 3.0 PERSONNEL AFFECTED

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 animal facility. All individuals working in or having access to Saint Louis University research laboratories or 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 Recombinant DNA by individuals working with Risk Group 3 recombinant materials.

### 4.0 DEFINITIONS

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

**Authorized Personnel** means, for the purposes of this policy, any person who has received the appropriate clearance and training to work in or have access to research laboratories and/or animal facilities at the University. 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 in which laboratory research animals are housed. CM provides professional veterinary and technical support services to investigators using animals in IACUC approved experimental procedures.

**Employee Health (EH)** provides work related healthcare services for employees of Saint Louis University.

**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 and use of laboratory animals in research. The IACUC oversees the Institution's animal care and use program and 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.

**Institutional Official (IO)** is the appointed individual at the University legally authorized to certify on behalf of the research facility that the animal care and use program meets all requirements of federal, state, local, and institutional requirements are met.

**Office of Environmental Health and Safety (OEHS)** 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 and life safety, general workplace safety, biological, chemical and radiation safety; hazardous materials removal and disposal, and related safety and compliance training.

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

**Radiation Safety Committee (RSC)** is the committee responsible for oversight of the safe use of radioactive materials in research and clinical use at Saint Louis University and Saint Louis University Hospital.

## **5.0 POLICY**

### **5.1 Regulatory Compliance**

Research at Saint Louis University must be conducted in full compliance with all applicable local, state, and federal health and safety regulations, as well as University policies and procedures. The Vice President for Research, as the Institutional Official (IO), has established the Occupational Health Program (OHP) for Laboratory and Animal Research as well as administrative policies and procedures to assure compliance with these regulations to promote a safe, healthy research environment.

### **5.2 OHP Program Administration**

The University's OHP for Laboratory and Animal Research is administered by the Associate Vice President for Research in collaboration with the Office of Environmental Health and Safety (OEHS), Employee Health (EH), Department of Comparative Medicine (CM), the Institutional Animal Care and Use Committee (IACUC), the Institutional Biosafety Committee (IBC), the Office of Research Integrity (ORI), and Human Resources (HR).

#### **5.2.1 OHP Advisory Committee**

The implementation of the OHP program requires a collaborative effort in both laboratory and administrative offices. To facilitate this effort the IO has established the OHP Advisory Committee for Laboratory and Animal Research. This committee meets quarterly and as necessary to discuss, review, and advise on health and safety issues regarding University research activities and related facilities. The committee is chaired by the Associate Vice President for Research and includes members from CM, EH, HR, IACUC, ITS, and OEHS. The Vice President for Research is an ad hoc member. Staff support is provided by the Office of Research Integrity.

### **5.3 OHP Program Participation and Applicability**

All individuals working in or having access to Saint Louis University research laboratories or animal research facilities must participate in the Occupational Health Program for Laboratory and Animal Research as delineated in this section unless specifically exempted.

### 5.3.1 Authorized Personnel

All authorized personnel working in or having access to Saint Louis University research laboratories or animal research facilities must participate in the Occupational Health Program for Laboratory and Animal Research. The extent and level of participation of such personnel in the OHP is based on a risk assessment of the hazards posed by their assigned duties and the applicable setting including: animals and hazardous materials used; exposure intensity, duration, and frequency; susceptibility of personnel; and history of occupational illness and injury in the workplace.

### 5.3.2 Non-University Research Personnel and Independent Contractors

Non-University Research Personnel and Independent Contractors working in or having access to Saint Louis University research laboratories or animal facilities are required to:

1. Participate in an occupational health program through their employer that is comparable to the University's OHP;
2. Sign a verification of participation in a comparable occupational health program, cosigned by the manager of that OHP, and
3. Submit the necessary records to EH for review.

Non-University Research Personnel and Independent Contractors working in or having access to Saint Louis University research laboratories or animal facilities are required to participate in the Saint Louis University OHP to the extent that their employer provided OHP is lacking critical elements of the Saint Louis University OHP specific to their work at Saint Louis University. This may include, but is not limited to: required training, medical evaluation, required vaccinations, respiratory protection program, and other elements of the SLU OHP. The cost, if any, for compliance (e.g., vaccinations, medical evaluation, etc.) will be the responsibility of the Non-University Personnel and Independent Contractors.

### 5.3.3 Visitors

Visitors are exempt from participation in the University's OHP (see Section 8.0 of this policy). Visitors to animal facilities and laboratories are subject to University Policy AC-006, which stipulates they are required to sign the Visitor Assumption of Risk and Release Agreement.

## **5.4 Medical Evaluation and Preventive Medicine**

The medical provider for the OHP is the Office of Employee Health (EH). EH provides pre-placement medical evaluations. OHP medical histories are evaluated primarily through review. Medical assessments are based on risk information available to the medical provider at the time. Routine immunizations are provided and protocol specific immunizations are provided when needed. EH is the authorized primary medical provider for work related injuries/illness.

#### 5.4.1 Medical Evaluation

Research personnel listed on all IACUC and some IBC protocols, or subsequently added to such protocols, must be medically evaluated by Employee Health 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).

#### 5.4.2 Vaccination Requirements

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

#### 5.4.3 Respiratory Protection Program and Personal Protective Equipment (PPE)

Research personnel listed on certain IACUC and IBC protocols, or subsequently added to such protocols, may be required to be medically cleared to participate in the Respiratory Protection Program, including the wearing of respirators such as N-95 masks, half-face cartridge respirators, and/or full-face cartridge respirators, and associated fit-testing.

#### 5.4.4 Medical Services Declination

Declination of medical services offered or required under the OHP may preclude an individual from some positions and/or projects that have requirements for medical evaluations and preventative medical care. Required participation in the OHP, regardless of any medical service declination, may not be declined.

### **5.5 Training**

Training is essential for adequate preparation to work safely in laboratories and animal facilities. The training and orientation of persons working in the laboratory and research facilities shall include an overview of the OHP and information regarding enrollment in the medical evaluation and preventive medicine program components.

#### 5.5.1 Mandatory Training

Personnel are required to attend all mandatory training as outlined in the OHP guide and their reporting unit's guidelines.

#### 5.5.2 Documentation

Completion of OHP related training must be documented in accordance with the applicable regulations and as outlined in the University OHP guide.

## 6.0 RESPONSIBILITIES

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

1. Be enrolled in the University's OHP for Laboratory and Animal Research, consistent with the enrollment requirements contained in this policy and related procedures;
2. Comply with all applicable laws, regulations; SLU policies and procedures regarding specific hazards to which they may be exposed during their employment;
3. Complete required training and continuing education; and
4. As applicable, be listed as a study associate on an approved IACUC and/or IBC protocol.

**Comparative Medicine** shall:

1. Assist in establishing and maintaining an 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 and 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 animal facilities;
5. Advise on and monitor biohazard control policies and procedures as they apply to research animal care and use in collaboration with OEHS; and
6. Monitor laboratory animals for zoonotic diseases.

**Employee Health** shall:

1. Provide pre-placement medical evaluations for personnel participating in the OHP.
2. Provide medical assessments based on identified risks available at the time of the medical assessments.
3. Provide routine immunizations to OHP participants, and provide protocol specific immunizations as recommended or required.
4. Provide respirator fit testing and associated medical evaluation in compliance with OSHA regulations governing the Respiratory Protection Program.
5. Maintain a confidential medical file on each OHP participant.
6. Evaluate and treat work related injuries and illnesses.
7. Provide OHP training in conjunction with CM and OEHS.

**Institutional Animal Care and Use Committee (IACUC) shall:**

1. Monitor IACUC protocols to ensure that all faculty, staff, and students listed to be exposed to animals in research have attended required training; and
2. Evaluate the implementation of the OHP during the semiannual review of the SLU Animal Care and Use Program.

**Institutional Biosafety Committee (IBC) shall:**

1. Monitor IBC protocols to ensure that all faculty, staff, students, and visiting scientists exposed to any Select Agents, Risk Group 3 recombinant DNA molecules, (as well as any other Risk Group 3 biological agents; and any Risk Group 2 biological agents warranting OHP participation) have attended required training; and
2. Ensure through follow-up that these individuals, as required, are enrolled in the medical surveillance program during the IBC protocol review and approval process.

**Office of Environmental Health and Safety shall:**

1. Assist in establishing and maintaining an OHP for faculty, staff, students, and visiting scientists who work with Select Agents, Risk Group 3 recombinant DNA molecules, as well as any 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, ionizing and non-ionizing radiation; and
3. Collaborate with Comparative Medicine, Employee Health, Human Resources, and other University departments in assuring Principal Investigator and Authorized User compliance with OHP – Laboratory and Animal Research requirements.

**Office of Research Integrity shall:**

1. Establish and maintain OHP for Laboratory and Animal Research for those working in or having access to research laboratories or working with animals in research or having access to animal facilities;
2. Implement this policy and develop and update forms as necessary in consultation with the IACUC, IBC, OEHS, HR, and EH;
3. Ensure that training is provided for University faculty, staff, and students regarding safety in the care and use of laboratory animals;
4. Administer the OHP in cooperation with IACUC, IBC, OEHS, HR, and EH.

**Principal Investigators:** Individuals approved by SLU to be Principal Investigators are required to:

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 that will ensure adequate protection for their assigned activities; and
3. Make sure that all personnel receive training regarding risks associated with their assigned duties and the safe conduct of those duties.

## 7.0 NON-COMPLIANCE

Individuals who fail to comply with this policy and procedures associated with it, including participation in the OHP, will be denied access to all University research laboratories and animal facilities. Disciplinary actions for non-compliance can result in suspension or termination of research by the University's Institutional Animal Care and Use Committee (IACUC), the Institutional Biosafety Committee (IBC), and/or a report of suspected misconduct, and/or reporting to government regulatory agencies. Disciplinary action will be guided by the University's Faculty Manual, Staff Handbook, or student guidelines.

## 8.0 EXCLUSIONS

Individuals who need access to research laboratories or animal facilities for a brief time (e.g., inspectors, visitors; prospective students) are not required to enroll in the OHP program if they will not be handling animals, biological, chemical, radioactive materials, or other hazardous materials. These individuals will be accompanied by and follow the directions of Authorized Personnel at all times while in SLU research laboratories or animal 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 SLU research laboratory and animal facility policies and procedures. This includes verifying that individuals planning to enter animal facilities and/or labs have read and signed the required Visitor Assumption of Risk and Release Agreement (see University Policy AC-006).

## 9.0 REFERENCES

*Occupational Health and Safety in the Care and Use of Research Animals*, National Academy Press.

*Guide for the Care and Use of Laboratory Animals*, 8<sup>th</sup> edition. Institute of Laboratory Animal Resources, National Research Council, 2011.

PHS Policy on Humane Care and Use of Laboratory Animals, 2002.

Saint Louis University [A3225-01] Animal Welfare Assurance In Accordance with the PHS Policy for Human Care and Use of Laboratory Animals. Section E.

Saint Louis University Policy AC-006: Visitors to Animal Facilities and Labs

NIH Guidelines for Research Involving Recombinant DNA Molecules, May 2011.

CDC Select Agent Regulations: 42 CFR Part 73, October 16, 2008.

APHIS Select Agent Regulations: 9 CFR Part 121, October 16, 2008.

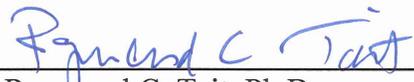
Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5<sup>th</sup> Edition, U.S. Department of Health and Human Services, 2009.

## **POLICIES RESCINDED**

Occupational Health Program for Persons at Risk Relative to Exposure to Laboratory Animals, October 2004.

## **APPROVAL SIGNATURES**

**This policy was approved by:**



Raymond C. Tait, Ph.D.  
Vice President for Research  
Saint Louis University

Date: 12/4/2011

## **VERSION HISTORY**

<b>EFFECTIVE DATE</b>	<b>VERSION NUMBER</b>	<b>MODIFICATION</b>
05DEC2011	1.0	New Document