

C-3. SAFETY GUIDELINES - ANIMAL PATHOGENS

I. SCOPE

The Pathogen Registration and Animal Study Proposal programs are applicable to all Principal Investigators (PIs) who conduct animal research at the NCI-Frederick where animals may harbor known or potential human pathogens. It also applies to any off-site investigator who conducts animal research at the NCI-Frederick or utilizes technical animal support services provided by the NCI-Frederick.

II. PURPOSE

The IBC Pathogen Registration, IACUC Animal Study Proposal, and LASP Animal Health Monitoring Programs are intended to protect the health and safety of the NCI-Frederick employees, the public, the environment, and animal populations. The programs are designed to meet the requirements for the Institutional Biosafety Committee (IBC), the Institutional Animal Care and Use Committee (IACUC), the Guide for the Care and Use of Laboratory Animals, NIH Guidelines, Animal Welfare Assurance for the Office for Protection from Research Risks (OPRR) and accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALACI).

III. DEFINITIONS

Association for Assessment and Accreditation of Laboratory Animal Care International (AAALACI) - Is the organization that reviews the animal care and use program, inspects and accredits laboratory animal facilities for compliance with the humane and safe use of laboratory animals.

Institutional Animal Care and Use Committee (IACUC) - Is a committee established by the Public Health Service Policy (Public Law 99-158) and the Animal Welfare Regulations (Public Law 99-198). The IACUC reviews and approves all Animal Study Proposals and maintains relevant documentation.

Office for the Protection from Research Risks (OPRR) - Responsible for the implementation of the Public Health Service Policy. It is the office within NIH responsible for reviewing and issuing Animal Welfare Assurances for all research involving the use of animals.

Zoonotic Agents - Disease producing organisms transmissible from animals to man under natural conditions. Such a disease process is known as a zoonosis.

IV. **RESPONSIBILITIES**

A. NCI-Frederick Management

1. Responsible for ensuring that all animal research studies are conducted in compliance with the provisions of the NIH guidelines and with the approval of the IACUC and the IBC (as applicable).
2. Establish and implement policies and procedures for the safe conduct of animal studies and ensure compliance with the NIH guidelines and recommendations of the IBC and IACUC.
3. Ensure appropriate training regarding the safe use of laboratory animals to relevant staff including PIs, technicians, and animal care personnel regarding the safe use of laboratory animals.

B. Principal Investigator (PI)

1. Animal studies with known human pathogens (including zoonotic agents) must be presented by the investigator for conceptual approval to the Director, Laboratory Animal Sciences Program. If there is support and concurrence that the study can be conducted, formal approvals are required. The PI must submit a detailed; (1) Animal Study Proposal to the IACUC and; (2) a Pathogen Registration Form for approval by the IBC.
2. Detailed operational protocols for technical support, animal housing and human surveillance must be developed as a team with conjunction with relevant input from the animal facility manager, technical staff, the Environment, Health and Safety Program (EHS), Occupational Health Services (OHS), and the PI.

C. EHS

1. The Biological Safety Officer (BSO) will assist requestors (PI, animal facility manager, technical staff as appropriate, and OHS) on safety issues related to the use of zoonotic agents and animal pathogens. Assistance in completion of relevant IBC registration documents is provided upon request.

2. All Animal Study Proposals are reviewed and approved by the EHS. Animal studies involving known human pathogens require an NCI-Frederick IBC registration form and must be reviewed and approved by the IBC.
3. The Occupational Health Services will establish and maintain health surveillance programs for personnel actively engaged in animal studies, especially those that may involve occupational exposure to zoonotic agents.

D. Employee

1. Must follow relevant policies and procedures (i.e., SOPs) for the safe handling of animals with known or potential zoonotic agents.
2. Report to their supervisor and OHS any conditions of illness, immunosuppression, or chemotherapy.

V. **PROCEDURES**

A. Animal Studies Introducing Known Human Pathogens

1. All procedures are conducted at the appropriate Biosafety Level as determined by the professional judgement of the BSO using the most current version of NIH/Centers for Disease Control and Prevention (CDC) guidelines (Biosafety in Microbiological and Biomedical Laboratories) as minimal criteria.
2. The research and animal care personnel must utilize available engineering controls and must wear appropriate personal protective equipment, taking all precautions to avoid contact with potentially infected material.
3. Waste and used supplies from these animals must be bagged within the ventilated engineering control in which they are housed or manipulated and the outside of the bags disinfected with a 10% chlorine bleach solution prior to being autoclaved.
4. All individuals who may come into contact with infected animals or potentially infected waste must notify OHS and be enrolled in an appropriate surveillance program.

B. Naturally-Occurring Animal Pathogens Potentially Harmful to Humans (Zoonotic Agents)

A number of microbial agents naturally occurring in animals are known to infect humans. Infected animals may appear perfectly healthy; therefore, personnel should at all times follow the same Standard Precautions, including using personal protective equipment when handling animals or entering laboratory animal facilities.

1. Non-Human Primates

At present, no live non-human primates are housed at the NCI-Frederick, however off-site SAIC-Frederick employees provide caretaking and medical care to the non-human primate colony at NIH-Bethesda.

Individuals working with non-human primates or tissues, blood, etc. of non-human primates origin should be particularly cautious since biological similarities between these animals and humans make them a greater hazard. Risk of exposure can be reduced or eliminated by avoiding direct contact with the animal's waste, bodily secretions, tissues and blood. This can be accomplished by:

- a. Wearing the proper protective equipment.
- b. Using specialized housing such as negative pressure or isolation units.
- c. Ensuring that all of the protective shielding is in place and the unit is operating according to manufactures or EHS guidelines.
- d. Adherence to proper disinfection and sanitation procedures.
- e. Rapid notification to the supervisor/manager when there is an equipment failure.
- f. Injuries involving body fluids or contaminated sharps from non-human primates are potentially very hazardous and must be reported immediately to one's supervisor and OHS. Treatment of the injury begins at the worksite as outlined in the OHS Guidelines and the Animal Exposure Surveillance Program.

- g. The non-human primate care staff at NIH Bethesda have extensive protocols (in addition to the above) which must be followed.

2. Rodents

- a. Individuals who work with rodents and related species are also at a small risk of potential exposure to primary infectious agents.
- b. At NCI-Frederick, rodents and related species, while routinely monitored for zoonotic and other infectious agents, must be handled with the same respect and precautions as if known to be infected.
- c. The use of Standard Precautions and protective equipment can not be underestimated and should protect the individual from exposure if implemented and used correctly.

C. Opportunistic Pathogens

- 1. The rodent populations at NCI-Frederick may harbor a number of opportunistic pathogens which, under the right circumstances, may cause disease in humans.
- 2. Individuals who are immunosuppressed by illness, chemotherapeutic agents, or other medical drugs may have an increased level of risk.
- 3. Individuals who may be at risk should inform their supervisor and be immediately evaluated by OHS.

D. Xenobiotic Transplants

- 1. The deliberate introduction of human cells or tissues into immunodeficient rodents, a process called xenobiotic transplantation, can pose a zoonotic hazard to persons contacting these animals. The IACUC has adapted USPHS recommended guidelines for the prevention and control of infectious diseases associated with xenotransplantation of human cells/tissue into animals. These requirements include:

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- (i) Registration of the proposed work with BOTH the IACUC and the IBC.
- (ii) Screening of human cell lines for potential human pathogens.
- (iii) Use of engineering controls as appropriate to the pathogen risk.

VI. REFERENCES

Guide for the Care and Use of Laboratory Animals (Institute of Laboratory Animal Resources/National Research Council) Biosafety in Microbiological and Biomedical Laboratories, current version.