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Protocol for animal handling in pharmaceutical or medical fields

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Abstract

All persons working with experimental animals must receive training regarding procedures and equipment to ensure their safety and that of the animals. Training must occur prior to the handling of animals. The principal investigator/professor is responsible for ensuring that personnel working on the project are aware of any risks to health and safety and that proper precaution are in place to reduce or eliminate the risks. Many tasks in animal facilities require moderate to heavy physical labor, and performing these tasks may expose personnel to a variety of risks (e.g., moving heavy equipment (strains), slippery floors, electrical hazards when washing, noise). Each person must exercise due caution when performing such tasks. The flight zone is an animal's "personal space". The size of the flight zone varies with the tameness of the animal, and other animal-related factors. Completely tame animals have little or no flight zone and allow a person to touch them. An untamed animal, however, will begin to move away when the person enters the edge of the flight zone. Different species defend themselves in different ways. For example, a mouse, rat, hamster or dog may bite, a rabbit may struggle furiously and kick or sometimes bite to try and escape, a cat may scratch (with intent) or bite; a cow or horse may kick. The approach to restraining the animal, including any equipment used for restraint, is to prevent the animal from taking such action while ensuring it is safely and humanely restrained. Although the correct approach to handling and restraint can be understood from printed and audio-visual materials, practice is essential.

Keywords: Animals; Equipment; Clinical signs; Handling

1. Introduction

All persons working with experimental animals must receive training regarding procedures and equipment to ensure their safety and that of the animals. Training must occur prior to the handling of animals. The principal investigator/professor is responsible for ensuring that personnel working on the project are aware of any risks to health and safety and that proper precaution are in place to reduce or eliminate the risks. Policies and programs required under Federal/State Occupational Health and Safety laws and regulations are implemented by members of NJIT. Such programs must support a safe working environment in our animal facilities.[1]

2. Physical Hazards Associated With Experimental Animal Care and Uses

2.1. Avoiding Physical Injuries

Many tasks in animal facilities require moderate to heavy physical labor, and performing these tasks may expose personnel to a variety of risks (e.g., moving heavy equipment (strains), slippery floors, electrical hazards when washing, noise). Each person must exercise due caution when performing such tasks. Although an understanding of basic animal behavior in the human/experimental animal interaction can help to avoid injuries, it cannot replace the skills that are

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learned by working directly with the animals. Faculty and staff must have appropriate training in animal handling and related skills. For others, material presented in this manual can serve as a useful introduction to handling animals safely in an experimental animal facility.[2]

2.2. To work safely with an experimental animal a person should

- understand basic animal behavior during handling
- maintain appropriate vaccination status
- understand how to communicate with the animal
- use appropriate restraint techniques and equipment properly
- identify any animals that may be unpredictable
- wear appropriate protective clothing and equipment

2.3. Basic Animal Behavior Related to Handling and Manipulations

The flight zone is an animal's "personal space". The size of the flight zone varies with the tameness of the animal, and other animal-related factors. Completely tame animals have little or no flight zone and allow a person to touch them. An untamed animal, however, will begin to move away when the person enters the edge of the flight zone. When the person is outside the flight zone, an animal (or group of animals in a herd) will turn and face theperson while maintaining a safe distance.When animals are in small cages or pens, all human "intrusions" are inside the animal's flight zone. Therefore, it is very important to condition the animals to regular handling to reducethe apprehension and stress. When an animal is apprehensive (e.g., about being picked up), aggressive (e.g., about to attack), or defensive (e.g., protecting itself, or its young), its posture and other behavioral signs can give clues about its state and possible intentions. In many mammalian species the "warning" posture includes: a lowered head, ears down or back, and in smaller animals, the mouth open in a snarl.

2.4. Communicating With the Animal

Your voice, your touch, and your smell, are all important cues used by animals. To establish a two way familiarity before a project starts, the people who will be handling or restraining the animals should talk to, touch, and regularly handle each animal. The conditioning period after transport to the laboratory is an excellent time to begin (usually one or two weeks).Consistency in handling each animal is important. Most laboratory animals learn very quickly who their regular handlers or caretakers are, and accept the handling without undue stress.[3-4]

2.5. Using Appropriate Restraint Techniques

Different species defend themselves in different ways. For example, a mouse, rat, hamster or dog may bite, a rabbit may struggle furiously and kick or sometimes bite to try and escape, a cat may scratch (with intent) or bite; a cow or horse may kick. The approach to restraining the animal, including any equipment used for restraint, is to prevent the animal from taking such action while ensuring it is safely and humanely restrained. Although the correct approach to handling and restraint can be understood from printed and audio-visual materials, practice is essential. Appropriate handling and restraint methods have been developed for most laboratory animal species. Skills in the appropriate handling and restraint methods should be attained BEFORE the research project starts.[5]

2.6. Use of Restraint Equipment

For some procedures such as intravenous injection in a rabbit or blood sampling in a rat, restraint devices or equipment are useful to ensure that the procedure is done safely for both the animal and the person. Correct use of such restraint devices will help avoid unnecessary stress or injury to the animal during the procedure.Conditioning the animal to accept the restraint device is important to minimizing the risk of injury both to the animal and to the handler.[5]

2.7. Use of Chemical Restraint

The safe handling of some species either in the laboratory or in the field may require the use of "chemical" restraint. Chemical restraint is the use of sedatives or anesthetics to control an animal's activity and thereby allow certain procedures to be done with minimal stress to the animal. Some drugs are useful for chemically restraining animals in circumstances where physical restraint represents a serious risk of harm to the animal or the handler.

2.8. Wearing Appropriate Protective Clothing

Protective clothing appropriate for the procedures should be worn at all times; as per University requirements. – OSHA PPE standard (29CFR1910.132). The associated experiments and protocols may be reviewed by bio safety committee (using OSHA 1450 or similar form)

2.9. Identifying Problem Animals

Any animal known to be difficult to handle should be so identified to all who might be working with it (e.g., weekend staff, veterinarian, and new personnel).

3. Immunization of Staff

3.1. Tetanus Vaccination

To minimize the risks associated with any penetrating wounds such as animal bites or needle sticks, all persons working in laboratory animal facilities must maintain their tetanus vaccination status per NJIT biosafety policy and guidelines.

3.2. Other Vaccinations

Depending on the species handled (e.g., non-human primates), other immunizations may be recommended as part of a health and safety program by the NJIT Biosafety committee. All protocols should be sent to NJIT Biosafety committee for their approval. Appropriate records on the vaccination status of all employees should be maintained by the institution and their representatives.

3.3. Animal-Related Injuries, Management and Reporting

Any animal-related injury that may be serious should be handled by the usual emergency medical care system: apply the appropriate first aid. An accident report is to be complete. Any minor injuries or incidents (e.g., a laboratory mouse or rat bite) should be handled by the appropriate first aid, and an accident report filed. This procedure is required for documenting all injuries, including minor ones, in case complications develop later. Accident Report Forms can be obtained from the Department of Environmental Health and Safety or Human Resources.

3.4. Safe Waste Disposal Practices in Animal Facilities

Work in animal facilities commonly involves use of sharp instruments. All sharp items (e.g., needles, scalpels, capillary tubes, etc.) must be handled safely, and placed in designated sharps containers for disposal as per university policy. Needles should never be recapped and re-used. See University policies and procedures.

3.5. Animal Waste Disposal

All animals, animal wastes and related materials should be disposed of as per University policy for example, this might involve collection of all such materials for incineration or other safe disposal. Disposal of non-contaminated waste (dirty bedding, feed, etc.) is handled through regular waste disposal.

3.6. Biological Hazards of Working with Experimental Animals

3.6.1. Zoonoses

Definition

Zoonosis is a disease of animals that may under natural conditions be transmitted to humans. What this really means is a disease that it is communicable between animals and humans. The list of potential zoo noses related to working with animals in research, teaching or testing is quite long, and numerous books have been written on the subject. Risks are very low when dealing with the common small laboratory animal species. There are several reasons for this low risk: commercial suppliers of laboratory animals have done an excellent job of producing disease free animals; and institutions generally have developed good occupational health and safety programs that include active monitoring and care programs. The risk of exposure to zoonotic diseases is greater for those who work with experimental animals from random sources (including cats, dogs and most livestock), and for field researchers studying wild animals in their habitat. Working with non- human primates in the laboratory is a special case because of the many zoonotic concerns.

Routes of Exposure

Common routes of exposure to infectious organisms are:

- aerosol (inhaling the organisms)ingestion (swallowing the organisms)
- absorption through the skin, through mucus membranes or skin wounds injection (accidental, in research) Personal protective equipment appropriate to the route of exposure for a particular infectious organism, and appropriate practices, will minimize the risk of exposure.

3.6.2. Some Common Zoonoses

Rabies

Rabies can infect any mammal, including humans. Purpose-bred laboratory animals are not a likely source of rabies. However, wild animals, animals obtained from random sources, or livestock, may carry rabies. These concerns should be processed through NJIT Biosafety committee for appropriate approvals.

Organism name and synonym

Rabies - a rhabdovirus, Rabies, Hydrophobia.

Reservoir

Wild and domestic animals (e.g., dogs, cats, foxes, coyotes, skunks, raccoons) and bats Livestock and rodents may be secondary hosts if infected by abiting animal.

Mode of Transmission

Most commonly by a bite which introduces the virus from the saliva of a rabid animal. May be airborne in caves inhabited by infected bats.

Incubation Period

Usually a few weeks, but may be up to a year or longer. The virus propagates in nerves. Thus the site of the wound (distance from the brain), presence of nerves at the wound, etc., influence the incubation period

Clinical Disease

Once clinical signs appear, the clinical course is short - usually less than 10 days with death due to respiratory paralysis.

Signs include apprehension, behavioral changes, spasms of swallowing muscles, delirium, weakness progressing to paralysis.

Epidemiology

Worldwide distribution with some rabies free areas. All mammals susceptible. Communicability: Infected animals shed virus for a few days before clinical signs appear. From then until the death of the animal, it is infectious.

3.6.3. Diagnosis and Prevention

Pre-exposure immunization of all individuals at high risk (those who will handle animals, including laboratory workers, veterinarians and other animal handlers) should be used. The human diploid cell vaccine (HDCV) is currently used. Postexposure treatment includes immediate first aid by generously flushing the wound and washing with soap and/or antiseptics, and providing post- exposure treatments as directed by the physician (e.g. rabies immune globulin, and vaccination).[4]

3.6.4. Hantavirus Infection

Hantavirus is carried by rodents, especially deer mice. The virus is found in their urine and feces, but it does not make the animal sick. It is believed that humans can get sick with this virus if they come in contact with contaminated dust from mice nests or droppings.

Organism name and synonym

Hantavirus, an RNA virus in the Bunyavirus family.

Synonyms

Hantavirus, Hantavirus pulmonary syndrome (HPS), Sin Nombre Virus (SNV) in

North America.

Reservoir

Wild rodents such as Peromyscus (deer mouse) and Microtus species in the Americas. Mode of Transmission: Inhalation of the virus in the dust from areas where infected rodent excreta (urine and feces) are present is the most common route. Rodent bites may transmit the disease.

Incubation Period

Average two to four weeks but may be shorter or longer.

Clinical Disease

Hantavirus Pulmonary Syndrome (HPS) is characterized by a sudden onset fever, pain, vomiting, and onset of respiratory distress and prostration. Mortality rates are high despite symptomatic treatment.

Epidemiology

Occurs throughout much of North America including the western provinces.Communicability: Not thought to be communicable between persons.

Diagnosis and Prevention

Use of personal protective equipment to avoid inhaling the dustparticles with virus, and other direct contact in high risk areas should be used.Field biologists and persons working in previously "contaminated" buildings are at risk.

3.6.5. Exposure Control Plans

Any circumstances that present particular risks of zoonotic infections should be identified before the risks are encountered. This includes immune compromised states (e.g., HIV infection, antirejections drugs or steroids, pregnancy, etc.).Occupational Health and Safety regulations commonly define a requirement to develop a written "exposure control plan" for workers required to handle, use or produce an infectious material or organism or likely to be exposed. Responsibility for this rests with the employer. Such a written plan includes: identifying workers at risk, routes of infection, signs and symptoms of disease, vaccination, engineering controls, personal protective equipment, personnel training, safe work practices and procedures, dealing with accidents, and investigating accidents.[2]

3.6.6. Biohazards as Part of Research Programs

When experiments are planned that will involve bio-hazardous agents, both the University Environmental health and safety office, and the University Department - Laboratory Biosafety Guidelines must be consulted.

3.6.7. Chemicals and Animals

When a project uses chemicals or bio-hazardous agents that can affect humans, the animal care staff must be notified and the cages clearly marked with the starting date. A material safety data sheet (MSDS) must be easily available indicating the nature of the effects of the drug/chemical, the appropriate handling methods for cages, animals and waste products as well as emergency contact/treatment information.

3.6.8. Bio-safety Guidelines and Levels of Containment

The information provided in this section will give the reader a general understanding of the levels of biohazard control required to work with bio-hazardous agents safely in animal facilities. It is not intended to be definitive or complete. The attitudes and actions of those who work in the laboratory determine their own safety, and that of their colleagues and of the university community. Laboratory equipment and design can contribute to safety only if they are used

properly by people who are genuinely concerned and knowledgeable about safety issues. Biohazards are rated at four levels with a risk group associated with each level. Containment levels refer to the physical requirements and risk groups refer to the pathogenicity of the organisms. Biosafety Level 1 is required to manage the lowest risk and Bio-safety Level 4 is required to manage the highest risk to human or animal health.[7]

Bio-safety Level 1

Risk Group 1 infectious agents are biological agents that are unlikely to cause disease in healthy workers or animals (i.e., low individual and community risk).Facilities required to contain risk group 1 organisms include - Containment Level 1:No special facilities, equipment or procedures are required standard well-designed experimental animal and laboratory facilities and basic safe laboratory practices suffice hand-washing facilities must be provided disinfectants must be properly used

Bio-safety Level 2

Risk Group 2 infectious agents are pathogens that can cause human or animal disease but, under normal circumstances, are unlikely to be a serious hazard to laboratory workers, the community, livestock, or the environment (i.e., moderate individual risk, limited community risk). Laboratory exposures rarely cause infection leading to serious disease; effective treatment and preventive measures are available and the risk of spread is limited. Risk Group 2 infectious agents include, for example: E. coli; salmonella; some fungi like ringworm; California encephalitis viruses; human herpes simplex viruses; many influenza viruses; Transmissible Gastroenteritis of swine; Mouse Hepatitis Virus; and a few parasites.[3]

3.7. Facilities, equipment, and procedures required to contain risk group 2 organisms at Level 2

- laboratory separated from other activities
- biohazard sign
- room surfaces impervious and readily cleanable
- equipment should include an autoclave
- certified HEPA filtered class I or II biological safety cabinet for organism manipulations
- personal protective equipment to include laboratory coats worn only in the laboratory, gloves
- worn when handling infected animals
- all contaminated material to be properly decontaminated[1,9]

Bio-safety Level 3

Risk Group 3 infectious agents are pathogens that (1) usually cause serious human or animal disease, or (2) which can result in serious economic consequences, but do not ordinarily spread by casual contact from one individual to another (i.e., high individual risk, low community risk), or (3) that can be treated by anti-microbial or anti-parasitic agents. Risk Group 3 pathogens include bacteria such as anthrax, Q Fever, tuberculosis, and viruses such as hanta viruses, Human immunodeficiency viruses (HIV - all isolates), eastern and western equine encephalitis viruses.

3.7.1. Facilities, equipment and procedures required to contain risk group 3 organisms include

- specialized design and construction of laboratories, with controlled access double door entry and body shower
- all wall penetrations must be sealed
- ventilation system design must ensure that air pressure is negative to surrounding areas at all times, with no recirculation of air
- air exhausted through a dedicated exhaust or HEPA filtration system
- minimum furnishings are all to be readily cleanable and sterilizable(fumigation)
- laboratory windows are to be sealed and unbreakable and backup power available

3.7.2. Equipment must include

- an autoclave
- certified HEPA filtered class II biological safety cabinet for organism manipulations
- a dedicated hand washing sink with foot, knee or automatic controls, located near the exit

3.7.3. Personal protective equipment should include

solid front laboratory clothing worn only in the laboratoryhead covers and dedicated footwear, gloves worn when handling infected animals appropriate respiratory protection, depending on the infectious agents in use.

3.7.4. Exit procedures should include

- showers, depending on infectious agents used and manipulations involved• all animal wastes are to be disposed of as contaminated laboratory materials all activities involving infectious materials are to be conducted in biological safety cabinets or other appropriate combinations of personal protective and physical containment devices Laboratory staff must be fully trained in the handling of pathogenic and other hazardous material, in the use of safety equipment, disposal techniques, handling of contaminated waste, and emergency response. Standard Operating Procedures must be provided and posted within the laboratory outlining operational protocols, waste disposal, disinfection procedures and emergency response. The facility must have a medical surveillance program appropriate to the agents used, which includes serum storage for all personnel working in the containment laboratory and an accident reporting system.[10]

Bio-safety Level 4

Risk Group 4 infectious agents are pathogens that usually produce very serious human or animal disease, often untreatable, and may be readily transmitted from one individual to another or from animal to human or vice-versa directly or indirectly, or by casual contact (i.e., high individual risk, high community risk).Risk Group 4 infectious agents are all viruses, such as, Ebola viruses, Herpes B virus (Monkey virus), Foot and Mouth Disease. Containment Level 4 is the highest level of containment and represents an isolated unit that is completely self-contained to function independently. Facilities are highly specialized, secure with an air lock for entry and exit, Class III biological safety cabinets or positive pressure ventilated suits, and a separate ventilation system with full controls to contain contamination. Only fully trained and authorized personnel may enter the Level 4 containment laboratory. On exit from the area, personnel will shower and re-dress in street clothing. All manipulations with agents must be performed in Class III biological safety cabinets or in conjunction with one-piece, positive pressure-ventilated suits.[4]

3.7.5. Allergies to Laboratory Animals

Laboratory animal allergy (LAA) may be the most prevalent occupational hazard facing people working in experimental animal facilities. Surveys have revealed that up to 44% of people working with laboratory animals develop allergies to one or more species, and they usually become allergic within 3 years of first exposure. Almost all species of common laboratory animals can trigger an allergic reaction. All ergiesto the rat, rabbit, mouse, guinea pig, cat and dog are the most common. The animal allergens are mostly small molecular weight proteins such as albumen. These proteins occur in the serum and tissues, but also in the saliva, urine and skin dander. When animals groom themselves, the salivary proteins also end up on the skin, and on the dander particles that flake off and become aerosolized. Allergic reactions can be classified according to the site of the reaction: upper respiratory lower respiratory; skin; generalized; anaphylactic.

3.8. Risk Factors for Becoming Allergic to Laboratory Animals

The risk factors for becoming allergic to laboratory animal allergens (LAA) include atopy (an inherited, familial tendency to develop some form of allergy such as hay fever, asthma, and eczema), smoking, gender and intensity of exposure. There is a correlation between atopy and the potential for developing LAA, and a stronger positive correlation between atopy and development of lower respiratory symptoms (asthma).There is a strong correlation between the intensity of exposure to the allergen, and the severity of symptoms. However, any allergen exposure, even very low levels, will trigger symptoms in allergic individuals.

3.9. Factors Affecting Animal Allergen Levels in Laboratory Animal Rooms

Ventilation and Relative Humidity Directional room ventilation, negative flow laminar ventilated cage racks, or ventilated racks assist in reducing particles in room air. Low relative humidity results in higher dust and allergen levels. A relative humidity of 50-65% significantly reduces the quantity of allergen being aerosolized.[2]

3.9.1. Type of Bedding

Studies have shown that sawdust/wood chip bedding results in higher levels of aerosolized allergen in rodent rooms than corncob bedding. Use of processed paper products and absorbent pads result in lower levels of aerosolized allergens.

3.9.2. Cleaning and Sanitation Practices

A high level of cleanliness results in reduced levels of allergens circulating in laboratory animal rooms. There is a strong correlation between the intensity of exposure to the allergen, and the severity of symptoms. However, any allergen exposure, even very low levels, will trigger symptoms in allergic individuals.

3.9.3. Reducing Exposure to Allergens

There are several approaches to reducing exposure to laboratory animal allergens. Housing rodents in filtered cages and ventilated cage racks, use of ventilated waste dumping stations and laminar flow hoods for animal manipulations, will all help minimize exposure to laboratory animal allergens? Maintaining a high level of cleanliness, and using a bedding type that minimizes aerosol dust particles will also help minimize exposure to laboratory animal allergens. The appropriate use of personal protective equipment such as good quality particulate masks and gloves can significantly reduce exposure to animal allergens. Such equipment should be provided for all staff required to work in high exposure areas. As well, good personal hygiene (i.e., regular hand washing, showering, etc.) should be practiced.[5]

3.9.4. University Departmental Responsibilities

There are several departmental responsibilities to minimize the impact of laboratory animal allergies. These include education programs for staff, improved engineering standards for ventilation and relative humidity, and provision of appropriate personal protective gear. Education programs that cover topics such as symptoms, risks, defining risk zones and tasks, proper use of personal protective equipment, and health counseling for affected and at-risk staff, are very important.

3.9.5. Chemical Safety

Experimental animal facilities routinely contain various chemicals such as detergents, disinfectants, anesthetics, tissue preservatives (e.g., formalin). Most staff will be familiar with safe work practices for use of these chemicals. A laboratory animal facility should follow the OSHA Workplace Hazardous Materials Information System, which consists of labeling chemicals, maintaining safety data sheets (SDS) and employee education programs. [6-7]

3.10. Radiation Safety

NJIT will already have a program in place to ensure work with ionizing radiation, including isotopes injected into animals as part of their research use, is done safely. Training and licensing of users and facilities are mandated.[10]

4. Conclusion

These updated guidelines on the use of mammals, including wild species, emphasize that investigators are responsible for compliance with federal and state guidelines regulating care and use of animals in research, exhibition, and instruction. Investigators should work with IACUCs to develop research protocols that allow scientific research objectives to be completed successfully while complying with animal welfare regulations. A rational, well-justified protocol, written succinctly and completely, will facilitate a positive and productive dialog with the IACUC. The task of the IACUC is to provide assurance to federal regulatory agencies and the public that animal research is being accomplished in accordance with the regulations and intent of the AWA and to work with researchers and educators to develop appropriate protocols. IACUCs must be strong advocates for animal welfare and humane animal use in research and education, especially when investigators provide clear justification for animal use and expertise upon which the IACUC can rely. These interactions foster strong, positive, and professional relationships between the IACUC and the investigator.

Compliance with ethical standards

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Disclosure of conflict of interest

The author has no conflicts of interests to declare.

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