

A Biosafety Officer's Responsibilities with Respect to Research Animals

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Some of the Species

- Small
 - Mice
 - Rats
 - Hamsters
 - Guinea Pig
- Medium
 - Cats
 - Rabbits
 - Dogs
 - NHP
- Large
 - NHP
 - Horses
 - Cattle
 - Pig



Topics to Cover - 1

- Regulations
- IACUC
- Animal Contact Program (ACP)
- Emergency Response Plan (ERP)
- Facilities
 - Design/Renovation input
 - Periodic Inspections

Topics to Cover - 2

- Program
 - Risk Assessment
 - Establish PPE
 - Training to SOPs
 - Medical Surveillance
 - Incident Response & Management
 - Waste Management
 - Security



Why BSO Involvement?

- Overlap between the IBC, IACUC & ACP
- Early knowledge of proposed protocols
- Opportunity to Register all
 - ABSL-2 & higher agents
 - Toxins
 - Construction of Knockout & Transgenic Animals
 - Any work using recombinant DNA in animals
- University/Company wide Animal Contact Program (ACP) – Medical surveillance

Role - Animal Research

- Review all training & security measures
 - Better view of emergency response needs
- Review design criteria for new construction
 - Input to ABSL level animal/agent dependent
- Review plans for all proposed renovation & new construction
 - Input to ABSL level of containment needed
- Assign projects to the appropriate Biosafety level following Risk Assessment

Role - Animal Research

- Conduct risk assessment
 - Per animal species
 - Per protocol agents & hazards
- Conduct inspections
 - Periodic opportunity to evaluate
- Ensure regulatory compliance
- Review & set PPE requirements
- Help maintain AAALAC Accreditation

Types of Hazards

- Chemical/Radiation – Use & Storage
 - Cleaning agents/disinfectants
 - Anesthetics
 - Drugs (therapeutic & investigational)
 - Maintenance – paints, lubricants
 - Fire – flammable liquids
 - Compressed gases – oxygen, air
 - Radioactive isotopes & X-Rays
- Involve other EH&S as needed

Types of Hazards

- Biological
 - Allergens
 - Zoonotic infections (animal diseases transmissible to humans)
 - Experimental agents (e.g. viral vectors)
 - Any recombinant organisms
 - Infectious organisms
 - Regulated select agents

Why BSO Involvement in the Animal Contact Program?

- Better able to respond to accidents & incidents
- Support to Animal Care Services management & workers



Animal Contact Program

- Key Items
 - Pre-employment physical
 - Full questionnaire to determine sensitivities, allergies, existing skin issues & screen for potential behavioral issues (fears, myths)
 - Required vaccinations
 - Required follow-up



Animal Contact Program

- Program completion is required prior to work with or around animals
- Consists of a Health Statement, Health Questionnaire & Risk Assessment
- Occupational Medicine reviews the forms & will follow up as needed
- BSO should be fully screened to enter all animal areas & have full ACP clearance

Animal Contact Program

- Immunizations & Blood Drawn
 - Tetanus shot required (others as needed)
 - Rabies shots for hands on work with unvaccinated carnivores
 - Q-fever titers as needed for sheep and goats
 - Toxoplasma titer (females working with cats)
 - Blood banking as required
 - TB testing for all primate workers

Biological Hazards - Allergens

- Animal-related allergy - important health hazards for animal workers
- Health surveys of persons working with lab animals show up to 56% are affected by animal-related allergies
- Allergens found in:
 - urine of rats & mice
 - urine, saliva, & pelts of guinea pigs
 - rabbit pelts
 - cat saliva & dander, dog dander
 - horse serum



Allergen Control Recommendations

- Increase ventilation rate & humidity, animal housing
- Ventilate animal-housing/handling areas separately
- Ventilated racks or filter-top animal cages
- Decrease animal density (# animals/room)
- Keep cages & animal areas clean
- Use absorbent pads or corncob bedding vs. sawdust
- Provide appropriate PPE to animal handlers (gloves, lab coats, particulate respirators, face shields)

Risk Assessment for Animal Handlers/Workers

- Immunization /Screening History
 - What immunization have they had
 - Proof if possible
 - Serum banking
 - Where & why
 - Screening
 - Respiratory
 - TB

Risk Assessment

- Environmental Allergies/Asthma/Skin Problems
 - Past exposure to animals
 - Known allergies, asthma issues, or skin issues
 - Chronic medical conditions
 - Immune system status & issues
 - Medications

Medical Assessments

- Review of risk assessment
- Targeted physical examination if necessary
- Fitness for Duty Assessment
- Baseline serum collection & storage
- Immunizations
- Titers when indicated
- Other lab work when indicated

Medical Assessments

- Respirator clearance & spirometry
- Respiratory fit testing & training programs
- Interventions to protect research animals
 - TB screening
- Repeat all interventions at appropriate intervals



Periodic Review

- When needed:
 - Baseline & when leaving or termination
 - At least annually
 - Review of risk assessment, changes if necessary or signatures
 - Duty change
 - New risk assessment form
 - Health status change
 - New risk assessment form
 - Annual questionnaire

Emergency Response

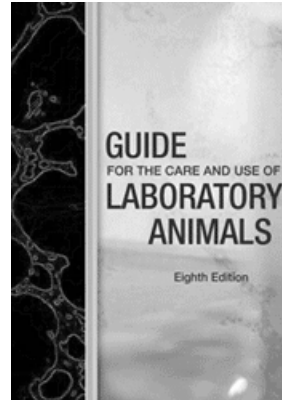
- Special attention to the animal models, workers & facilities
 - Mother nature
 - Near-by fires
 - Animal activists
 - Security
 - First aid
 - Bite Kits for Primates
- Full risk assessment & Threat analysis
 - Potential hazards
 - Probability & Consequence
 - Think outside the box

BSO Should Know Regulations

- Regulations covering the care & use of Laboratory Animals play a significant role in all aspects of animal containment from the design of the facilities to the ethical treatment of various species
- Failure to follow the regulations can result in facility closure & significant fines

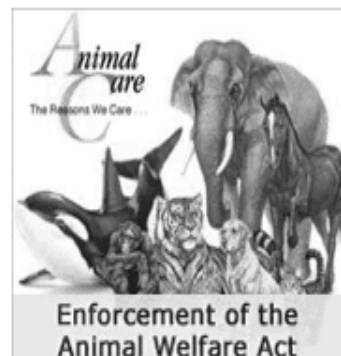
Regulatory Agencies

- USDA (APHIS) for the Animal Welfare Act
- NIH (OLAW) for PHS – the Public Health Services Policy
- AAALAC - Accreditation



Additional Guidelines, Regulations & Policies

- CDC's BMBL Guideline
- CDC Select Agents Laws
- FDA Good Manufacturing & Laboratory Practices Regulations
- Entities own Standard Operating Procedures
- State & Local Regulations that may apply



Regulatory Overview

The use of laboratory animal subjects is based on the following regulations:

- The Laboratory Animal Welfare Act of August 24, 1966 (Public Law 89-544)
- The Food Security Act of 1985, Subtitle F, Animal Welfare
- The Food, Agriculture, Conservation, & Trade Act of 1990, Public Law 101-624

Regulations to Know

In addition, the following are used:

- US Government Principles for the Utilization & Care of Vertebrate Animals Used in Testing, Research & Training
- Guide for the Care & Use of Laboratory Animals
- The Public Health Service (PHS) Policy on Humane Care & Use of Laboratory Animals
- Endangered Species Act of 1973 (Public Law 93-205; 87 Statute 884)

Role Played by IACUC

The Institutional Animal Care & Use Committee (IACUC) must evaluate research experiments with regard to the welfare of the animal subject & the potential for pain & suffering of the subject



Why Should the BSO Serve on the Institutional IACUC?

- Reviewing all animal protocols always gives BSO advance hazard notice:
 - New animal models
 - Biological agent registration
 - New rDNA/Chemicals/other hazards
 - New workers for ACP
 - New information - Emergency Response Plan
 - New training needs

Animal Care Waste Materials

- Non-infectious animal waste & bedding can go directly to general trash in most states
- Potentially infectious animal waste & bedding must go directly to a permitted incinerator or be autoclaved or otherwise inactivated prior to final disposition
- All known Infectious animal waste & bedding **MUST** first be autoclaved or otherwise inactivated
- Carcass disposal, infectious or not?

Primates – Special Hazards

- Handling Protocols
- PPE
- Cage Location
- Cage Design
- Hazard Zone
- Monkey B Virus
- Bite Kits



Monkey B Virus

- Viral Shedding is Intermittent & can Occur in the Absence of Visible Lesions
- Negative Today does not mean Negative Tomorrow
- Know the Early Signs of B Virus Infection
- Immediately Report any Injury
- Report any Symptoms of Monkey B Virus

Primate Handling

- Plan Ahead
- Use Chutes & Tunnels to Separate Primates
- Use Squeeze Back Cages to Restrain
- Avoid Primate Fluids & Secretions
- Use Task Appropriate PPE
 - Arm length reinforced leather gloves
 - Long sleeve garments
 - Face shield or mask with goggles

Conclusions - 1

- A BSO active in the IACUC & periodic inspections of animal areas is in the loop on who could be working directly with the animals activating the animal contact program & training



Conclusions - 2

- A BSO involved directly with Animal Services personnel will be more in tune to the emergency needs of both the workers & the animals



Conclusions - 3

- A BSO who maintains contact & participation with the IBC, IACUC & ACP will have a more complete program & have the knowledge & opportunity to evaluate & register hazards early

