



Animals in Research

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Why are animals used in research?

- Similar to humans in anatomy, physiology, and/or genetics
- Susceptible to many of the same diseases and conditions
- Biological similarity = effective models to study health, disease, prevention
- Results contribute to health improvements and quality of life for humans <u>and</u> animals



Animal Welfare

- Animal research is a privilege
- Animal care and good science go hand in hand
- Must adhere to "The 3Rs"
 - Refinement
 - Reduction
 - Replacement





Oversight of Animal Research

U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, 1985

- Applicable to all gov't agencies that conduct or sponsor animal research
- Transportation and care in accordance with the AWA
- Relevant to health and science
- Appropriate species and numbers
- Avoidance or minimization of discomfort, distress, & pain
- Appropriate sedation, analgesia, or anesthesia
- Humane euthanization
- Appropriate living conditions
- Appropriate qualifications and experience

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Oversight of Animal Research

Public Health Service Policy on Humane Care and Use of Laboratory Animals

- Applies to PHS-supported activities* involving animals in research, research training, and biological testing, including field research
- Covers all live, vertebrate animals
- Administered / enforced by OLAW
- Animal Welfare Assurance to comply
- Institutions must comply with the *Guide for the Care and Use of Laboratory Animals:* Eighth Edition (the *Guide*)



Oversight of Animal Research

Guide for the Care and Use of Laboratory Animals (the *Guide*)

- Considered primary reference on animal care and use
- Conduct of animal experiments "in accord with highest scientific, humane, and ethical principles"



 Addresses the 3Rs, roles and responsibilities, program requirements, physical plant/facilities, housing, diet, surgery, environment, veterinary care, occupational health and safety, etc.



Oversight of Animal Research

Animal Welfare Act and Regulations, 1966

- Applies to animals exhibited to the public, bred for commercial sale, used in medical research, or transported commercially
- Covers certain species: hamster, guinea pig, rabbit, cat, dog, nonhuman primate (not rats, mice, birds, fish, reptiles)
- Administered / enforced by the USDA



- Registration, routine unannounced site inspections
- Annual reporting of animal use, additional inventory and surgical recordkeeping



Oversight of Animal Research

Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC)

- Voluntary accreditation and assessment
- Standards above PHS Policy and the Guide
- On site review of facilities and program
- Exhibits excellence in animal care





Animal Care Program VIPs

- Institutional Official (IO)
- Attending Veterinarian
- IACUC / Compliance Staff
- Animal Care Staff / Lab Animal Technicians
- Investigators
- IACUC Members





Institutional Animal Care & Use Committee (IACUC)

- 5 members including veterinarian, animal research scientist, non-scientist, unaffiliated/community member
- Review and approve animal research
- Regular inspection of animal areas
- Regular review of animal care program
- Review of animal welfare concerns
- Suspension/termination of animal research

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Institutional Animal Care & Use Committee (IACUC)

- Considerations during protocol review:
 - Rationale and purpose
 - Clear description of procedures (3Rs)
 - Justification of species and number of animals
 - Appropriate sedation, analgesia, euthanasia
 - Health and safety of personnel
 - Training and experience
 - Humane endpoints
 - Surgery





Recognizing Animal Use in Grant Applications

- Live vertebrate animals, field research with interaction, educational use
- Does not include: dead animals (unless USDA), tissues/cells derived from animals, observation of animals, insects, crustaceans, eggs prior to hatching
- Key words to look for: rats, mice, rabbits, guinea pigs, dogs, cats, birds, fish, turtles, lizards, snakes, horses, specimen collection, transgenic animals
- No "exempt" designation for animal research



Grant Considerations

- IACUC approval prior to award
- Grant congruency
 Change of Scope



 Requires good coordination between Sponsored Projects/Grants Office & Compliance Office



Collaborations / Multi-Site

- Additional considerations:
 - Who owns the animals?
 - IACUC approval?
 - Responsibility for care and oversight of animals?
 - Will animals be transferred?
 - MOU for addressing these questions

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Institutional Considerations

- Costs of compliance and facilities
- Costs of non-compliance
 - Loss of funding, fines, negative publicity, loss of trust
- Public scrutiny, FOIA
- Animal rights organizations



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Questions?



Research and Biological Safety



Objectives

Understand the drivers for changing the safety culture in academic laboratories to provide broader safety support.

- Laboratory accidents
 - Fatalities in academic laboratories at Yale and UCLA
 - Explosions in laboratories at Texas Tech and the University of Missouri
- Hazardous Material Security





Federal Mandates vs Creating a Culture

- Mandates are top down driven and supported by institutional infrastructure
- Culture is what each of us does because it is the right thing to do – even when no one is watching



Regulatory Oversight Alphabet Soup

What does all the regulatory oversight mean?



Federal Mandates vs Creating a Culture

- HHS- OBA Biosafety/Biosecurity guided by the BMBL and NIH Guidelines
- CDC and DOJ– Select Agent Oversight
- EPA
- USDA Permitting
- NRCOSHA
- NRC Nuclear Regulatory Commission

Institutional Framework

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IBC - Institutional Oversight and Administrative
Support
EH&S - Support and Oversight
Health Services – Occupational Health
CDC – APHIS – FBI Divisions for Select Agents



Institutional Responsibilities

Oversee and Support Regulated Activities

- Setting the tone for a safe working environment
- Facility Maintenance
- Occupational Health and Safety
- Fire and Safety Training



Institutional Responsibilities

Oversee and Support Regulated Activities

- Occupational Health
- Recombinant and Synthetic DNA
- Chemicals of Concern
- Bloodborne Pathogens
- Radiation and Laser



Investigator Responsibilities

Each investigator and unit holds primary responsibility for maintaining a safety culture

- Setting the tone for safety in the lab
- Training staff and students on safety requirements specific to the work performed
- Don't allow working alone in the labe with special or high hazard materials

•Ensuring compliance with institutional training requirements



What is a student's responsibility?

- Complete assigned training
- Demonstrate proficiency in assignments
- Comply with PPE and safety requirements

"Remember, they are cooks and not chefs"



Demonstrating a Safety Conscious Culture

- Safety is everyone's responsibility
- Institution should commit to a campus environment that ensures the health and safety of their entire community (faculty, students, staff, and visitors)



Demonstrating a Safety Conscious Culture

- Good science is safe science
- Scholarly excellence and responsible conduct of research includes safety as a critical component
- Safety training and education are vital components of research and education



Demonstrating a Safety Conscious Culture

- An improved safety culture is necessary to implement true risk assessments and to reduce risk
- Diversity and flexibility of approaches and methods will be used by each institution to develop a strong safety culture unique to their local climate

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Look Inwardly at Current Practices

- We must continue improve training for working with hazardous substances
- Reinforce practices of working only with a buddy when working in a hazardous environment



Security

- Biological Materials
 - Select Agents
 - Dual Use Research
- Chemicals
 - Chemical Facility Anti-Terrorism (Total Bldg. Quantities)
 - Chemical Precursors
 - Controlled Substances
- Radioactive Materials



Important Concepts to Reinforce in the Lab

- Don't let students work alone on high hazard processes
- Provide Lab Coats and PPE to staff
 <u>Enforce the use of lab coats</u>
- Ensure lab staff is trained
 - Conduct / document the annual refresher training
- Correct all inspection findings in a timely manner
 Conduct your own audits and meetings
- Maintain your Chemical Inventory



Strategic Values for Implimenting Academic Safety Culture

Institution-wide Dynamics and Resources

- President/Chancellor renews commitment to increasing safety awareness
- Campus lead and leadership team
- Institutional Risk Assessment Process
- Institution Implements a process to report incidents and near misses
- Continuous improvement



Conclusions and Questions

Review of Objectives Questions



Acknowledgments

William Petuskey, AVP, KED ASU, Demonstrating a Shared Commitment to Safety, PPT 4-2016 Deona Willes, Running a Research Laboratory – Lab Safety, 10-2015 University of Southern California APLU Task Force, Guide to Implementing a Safety Culture, 4-2016 David Gillum, Rob Ott and Leon Igras, ASU EH&S



Conflict of Interest

Policies and Procedures for Financial Conflict of Interest Individual Conflict of Interest



Defining and Identifying

• Financial Conflict of Interest

- Significant financial interest (\$ threshold)
- PHS (among others) funding requirement

Individual Conflict of Interest

- Supervision of students
- Selection of award recipients
- Knowledge provides competitive edge (example: on detail to agency that is releasing a Broad Agency Announcement)
- Can involve ownership in a company
 - For example, cannot be owner/consultant of company receiving funds and PI.
- Effort is a separate, but related issue



Conflict of Interest

- May arise when an employee is in a position to gain financial advantage or personal benefit from his/her position, either through:
 - Outside professional activities (consulting/ownership) OR
 - Actions or decisions at institution (PI/Supervision of students/etc)
- COI may also arise in context of State Ethics Law
 - Restricts the relationships (employment, consulting and other) and financial interests that employees may have with outsiders:
 - Under institutional authority or
 - Those that do or seek to do business with Institution or the State
- Prohibits other things like:
 - Using prestige of office or confidential information for private gain
 - Asking for or accepting certain gifts
 - Representing parties in State matters for contingent compensation

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General Policy Overview

- Faculty/students/staff have an obligation to **report** *actual* or *potential* ethical, legal, financial, or other conflicts of interest and commitment
- Working with supervisors/department chairs/deans, faculty/students/staff must either find means to resolve or to manage any conflicts, or they must not participate in the activities that give rise to them



Disclosure

- Disclosure is *always* good
 - Allow the COI Committee to make the final determination
 - Significant professional activities outside the institution or the unit
 - "significant" to be determined by Unit Head, in consultation with unit faculty and approval by Dean or other appropriate administrator
- Other situations where a conflict or perception of conflict may occur



Key Items: Full and Prompt Disclosure

• When to Disclose:

- As situations arise, inform Unit Head (defined as the chair or director in an academic department, or a similar official in a non-academic unit, unless a different individual is designated by proper authority)
- Complete COI Disclosure Form and obtain signatures of Unit Head and Dean
- Submit to COI Disclosure Form to ORA or Research Compliance Office



Form and Procedures

COI Form

When to file:

- Initial Disclosure
- Annual Confirmation
- Change in circumstances
- When relationship ends

• FCOI Submission

When to file:

- Must be submitted prior to proposal for PHS funded research
- All "Key Personnel:" Anyone responsible for the design, conduct or reporting of the research.

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- Determined by the PI
- Annual Confirmation
- Change in circumstances



Form and Procedures (cont.)

<u>COI Form</u>

- Full Description
- Supporting Documentation (proposal)
- Ownership Information (* if applicable)
- Additional Information as Requested
- <u>Submit</u>
 - To Unit Head
 - Include proposed management plan to reduce or eliminate real or potential COI
 - Unit Head may help develop a management plan with the discloser
 - <u>To Dean, then to COI Administrator</u>

FCOI Form

- Disclosure only needs to be submitted at the time of proposal submission.
- Must be reviewed and acknowledged/approved prior to/at time of award



Requirements for Approval

• **Relationship may not**:

- Give improper advantage
- Lead to misuse of students or employees
- Interfere with employees' responsibilities
- Constitute a harmful interest (an interest found to impair impartiality in the conduct of research, the interpretation of results and/or the determination of research, professional or employment priorities)
- Otherwise violate policies, procedures or best interest of institution



Review and Approval

- COI Committee reviews and makes recommendation to President
- Restrictions may be imposed to manage, reduce, or eliminate, any actual, or potential COI
 - May include modifications to investigator's proposed management plan
- President's decision is final
- Approval may be withdrawn
 - Misrepresentation
 - Change in circumstances
- Management Plan Approval is filed with Chancellor and State Ethics Commission



Examples

- PI & Co-I Married
 - In same department, report to the same Chair
 - Management Plan
 - Recuse themselves from discussions related to each others' performance reviews
 - Inform those working on the grant of the potential COI in writing and have them sign indicating their acknowledgement
 - Any concerns or issues of grant employees will be referred to Department Chair or Director of Graduate Studies

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Examples (cont.)

• Hiring of a Consultant

- Dr. Jones Consulting w/ Acme, Inc.
- Acme, Inc. awarded MIPS grant
 - Part of work to be conducted at institution, with Dr. Smith (Faculty) as PI on Joint Project
 - Dr. Smith wants to hire Dr. Jones as a institutional postdoc on Acme, Inc. grant.
- Management Plan: Dr. Jones can be institutional post-doc or Acme, Inc. consultant, but not both.



Examples (cont.)

• Company Ownership

- Oversight Officials
 - Management Plan: Oversight Official is identified by the Pl. The Oversight Official must be at the same position as the Pl or above. The OO must also have appropriate expertise to monitor the work being conducted. The Oversight Official will provide oversight of COI concerns by conducting annual Reviews of project data and financial data.
 - Oversight Official Memo is signed by the PI and OO and added to the COI file
 - Oversight Committee: Small group composed of individuals best suited to oversee the COI concerns. Used in the event the PI cannot be removed from either side of the funded project.







Nurturing a Culture of Compliance

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Tips and Conclusions



Compliance = Cooperation

- Between sponsor and grantee
- Among investigators and administrators
- Among multiple campus oversight offices

Compliance helps protect the institution and its investigators



Common Contributors to Compliance Concerns

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- Inadequate resources
- Inadequate training
- Outdated/non-existent policies and/or procedures
- Lack of clear roles and responsibilities



Compliance Oversight

- GOAL: Identify and mitigate potential issues without compromising the conduct of research
- Engage top-down support as well as faculty and staff input in developing policies and procedures



Policies and Procedures

- Policy = applicability, requirements to comply;
 Procedure = how to comply
- Set clear roles and responsibilities
- Set consistent standards
- Communicate consequences
 - How is compliance with the policy enforced?
 - Consider carrots and sticks e.g., rewards for high compliance rates and penalties for non-compliance



Awareness and Training

A policy is worthless if no one knows about it.

- Promote awareness: emails, website, meetings, highprofile messages (e.g., Provost, Campus News)
- Easily accessible
- Offer training:
 - Mandatory or voluntary
 - New employees and continuing education
 - Policy/concept (Why)
 - Procedures for compliance (How)



Reporting abuses and illegal activities

- Make it easy to report concerns
 - Clear point of contact (one overall and/or one for each compliance area)
 - Confidentiality
 - Anonymity, hypothetical situations
 - Hotline
 - Take all concerns and findings seriously
- Act quickly to mitigate and to determine if (and when) external reporting is required
 - Communication plan; stakeholders/decision makers



Proactive compliance monitoring

- Internal reviews and assessments
 - Use internal audit findings as training case studies
 - Use internal risk assessments to focus compliance resources
 - Use institutional Internal Audit where possible for independent evaluation
- Create and share helpful metrics
- Communicate policy updates



The Benefits of an Effective Program

- A proactive approach to creating a compliance program will allow an institution to manage its compliance risk without imposing unnecessary constraints on the institution's operations
- Strong compliance programs benefit research institutions by <u>reducing</u>
 <u>the risk</u> of significant non-compliance
- Compliance programs reduce the <u>negative impact of having non-</u> <u>compliance discovered</u> by regulators or funding agencies
- The <u>accountability, clarity, and information</u> requirements of a strong compliance program are often beneficial in terms of institutional management



Conclusions and Questions



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