

Division of Research

Quarterly Research Administration Meeting



January 14, 2013

AGENDA



- **Welcome and Introductions**
- **Pre Award Update**
- **Post Award Update**
- **Budget & Cost Analysis Update**
- **Technology Update**

Division of Research
Vice President's Office Update

- **Welcoming Remarks**
- **Introduction of Division of Research Team**
- **Introduction of New Attendees**
- **Future Quarterly Research Administrators Meeting for 2013**
 - April 30, 2013
 - October 29, 2013
 - All meetings are from 10:00 am – 12:00 pm in the MARC Pavilion
- **Slides will be posted on the Division of Research website after meeting**

Division of Research

Pre Award Update

▪ **Pre-Award Personnel Update**

- Welcome to Veronica Delgado and Ka Ng
- Congratulations to Kristen Rivera promoted to Grants Specialist
- Congratulations to Courtney Casci promoted to Assistant Director

▪ **Revisions to the NSF PAPPG**

- FastLane has been modified to display three separate text boxes in which proposers must provide
 - an Overview
 - address the “Intellectual Merit’ and
 - “Broader Impacts” of the proposed activity.
- Proposals that do not separately address the overview and both merit review criteria in the one-page Project Summary will be returned without review.

Division of Research *Pre Award Update*

▪ **Revisions to the NSF PAPPG -- Continued**

- The Project Description must contain a separate section within the narrative, a discussion of the broader impacts
- Results from Prior NSF Support includes current funding.
- If there are no references cited, a statement to that effect should be included in this section of the proposal
- rename the “Publications” section to “Products”
 - products may include, but are not limited to, publications, data sets, software, patents, and copyrights.
- If no person months and no salary are being requested for senior personnel, they should be removed from Section A of the budget.
- Additional details at http://research.fiu.edu/announcements/documents/12262012_NSF_PAPPG_Revisions_Summary.pdf

Division of Research *Pre Award Update*

▪ **Changes to NSF Progress Report Submissions**

- The National Science Foundation (NSF) will be transferring all project reporting from FastLane to Research.gov on March 18th, 2013
- the NSF will be freezing all project reporting in Fastlane as of February 1st, 2013
- the overdue date for all project reports will be extended for reports to become overdue between January 31st, 2013 and April 30th, 2013
- After March 18th, 2013 PIs and Co-PIs will use the Project Reporting Dashboard in Research.gov to submit all
 - Final
 - Annual
 - Interim Project Reports
 - Project Outcomes Report.

▪ Additional details

<http://research.fiu.edu/announcements/documents/01072013-NSF-Fastlane.pdf>

Division of Research *Pre Award Update*

▪ **NIH Public Access Policy**

- NIH will delay processing of noncompeting continuation awards starting in Spring 2013 if the investigator(s)' publications arising from that award are not in compliance with the NIH public access policy.
- will be implemented as a part of the required use of the Research Performance Progress Report (RPPR)
- PIs will need to use their eRA Commons My Bibliography link to access My NCBI (National Center for Biotechnology Information) to report their publications.
- PIs who submit RPPRs with non-compliant publications will be sent an email by the NIH providing a two-week window for compliance.

▪ Additional details at

http://research.fiu.edu/announcements/documents/12212012_NIH-Public-Access-Policy.pdf

Division of Research *Pre Award Update*

▪ **NIH Application Submission Deadline**

- Effective immediately DOR will require that all NIH Grants.gov submissions be ready for submission to the sponsor no later than 24 hours before the sponsor's deadline.
- NIH applications must be error free in order to move forward for consideration.
- Submissions made after the deadline will overwrite the previous submission and are subject to the NIH late policy
- NIH 48 hour error correction window must be used prior to the sponsor's deadline

▪ **New Cost Share Form**

- To be used effective immediately

▪ **New Consultant Commitment Form**

- Will be required at proposal stage from all consultants
- Permits compliance with new FCOI regulations

Division of Research *Pre Award Update*

▪ **Computer and Electronic Devices Sponsored Projects**

- computers and electronic devices (mobile phones, tablets, printers) are generally used for many different activities (for example, instruction, research, community service, administration,)
- general guidance is that these devices do not meet the threshold requirements that permit the direct charging of their acquisition to a sponsored project.
- In certain specific and unique situations the purchase of computers and electronic devices can be an allowable direct charge to federally funded projects when the conduct of the research requires their exclusive use
- the computer must be used primarily (at least 95%) for the programmatic conduct of the sponsored project. If a computer is 100% funded from a Federal sponsor, the computer should not be used for non-programmatic purposes.

▪ **Computer and Electronic Devices Sponsored Projects – Cont.**

▪ Computer uses that are considered exceptional and a basis for specific and unique consideration of an exception include:

- 1. Controlling an instrument
- 2. Acquiring data from an instrument
- 3. Numerical calculations and simulations
- 4. Image and video analysis
- 5. Data analysis and manipulation
- 6. Data mining
- 7. Writing computer code for the sponsored project
- 8. Preparation of testing materials and recording of participant responses

Division of Research *Pre Award Update*

▪ **Computer and Electronic Devices Sponsored Projects – Cont.**

▪ Computer uses that are not considered exceptional and should not be purchased on sponsored projects include:

- 1. Preparing proposals
- 2. Preparing progress reports related to the research or sponsored project
- 3. Preparing publications related to the research or sponsored project
- 4. Preparing presentations related to the research or sponsored project
- 5. Accessing library resources (journals, books, etc)
- 6. Administrative activities including email, internet research, budgeting, procurement, human resource management, effort reporting
- 7. Making presentations at conferences

▪ Additional details at

<http://research.fiu.edu/announcements/documents/01102013-Computer-Purchase.pdf>

▪ **Introduction of Post Award Staff**

▪ **Budget Modification Request Form**

- Question #1 has been revised to include; “if salary of key personnel is being adjusted, explain the % of effort change by this action”
- Questions #4 & #5 had language changed to; “...transfers reducing F&A...” instead of “affecting F&A”

▪ **Smart Internal Billing**

- “Descr” field should detail expense otherwise an attachment should be provided
- This is necessary to document for invoicing, reporting & audit purposes

Division of Research *Post Award Update*

▪ **Employee Payroll Allocations**

- Important to keep up with allocations
 - Review when award is set up
 - New employees, or existing employees to update allocations when award begins
 - Review when award ends
 - Existing employees to adjust allocation or terminate employees when award ends

▪ **Costs at the end of an award**

- It's a red flag to auditors when large amounts of costs are incurred at the end of an award
- Costs should be necessary & items used during the award period
- 90 days prior to the end of an award, reminders are sent to the PI, & Project Managers

Division of Research

Budget & Cost Analysis Update

▪ **EFFORT REPORTING**

- Fall 2012 Pre-Review Kickoff 1/22/13 - 2/4/13
 - Use this time to check effort cards and resolve any issues before the time sensitive certification period.
 - Effort cards can be monitored year round, so effort cards can be reviewed and questions/issues addressed any time during the semester. You don't have to wait until the pre-review period.
- Fall 2012 Certification Period 2/5/13 - 3/6/13
- Effort Coordinators' assistance is crucial and in order to have 100% compliance must **"process"** effort cards once the faculty have certified their effort.
- Those areas not abiding by these deadlines are subject to have their college and/or PI F&A returns swept back permanently.

▪ **F&A RETURNS TO CENTERS & PIs**

- Jul - Dec 2012 F&A returns being calculated for centers & PIs and estimated to be returned during February 2013.
- Feedback on SharePoint link to access F&A return data
- VERY IMPORTANT – F&A return funds are to be used to reinvest and grow research. They can be used towards training and research related expenses only.

Division of Research

Budget & Cost Analysis Update

▪ **PAYROLL TRANSFERS**

- Feedback on what are the main reasons their areas process payroll transfers?
- Why aren't payroll allocations being maintained regularly?
- Payroll transfers received after 90 days that affect effort may be denied.
- Payroll Detail Report issues need to be communicated directly to Jackie Barba in HR

▪ **RECHARGE CENTERS**

- Inquiries for possible Recharge Centers should be directed to us in the Budget & Cost Analysis (BCA) office within the Division of Research (DoR)
- Central email is recharge@fiu.edu
- Website for more details on Recharge
<http://research.fiu.edu/facilities/recharge/documents/rechargeSOP.pdf>

▪ **COLLEGE RESEARCH EXPENSES**

- Colleges to continue to use the E&G IDs setup to track research related college funded expenses
- This data is critical to the annual NSF Report

Salary Actions for Grant Funded positions

- Any salary increases or decrease need to be review by Compensation Department
- DoR will approve for budget purposes.
- Change in allocations

- RACC Certificates

Division of Research Human Resources - DoR

FLORIDA INTERNATIONAL UNIVERSITY ADMINISTRATIVE/STAFF CHANGE IN STATUS FORM

1 EMPLOYEE INFORMATION - CURRENT

FIRST NAME:	LAST NAME:
EMPLOYEE ID:	PRIMARY DEPT./PROJ. ID:
POSITION #:	STANDARD HOURS:
ORG CODE:	EMPLOYEE CLASS:
JOB CODE/TITLE:	CURRENT SALARY: \$ -

2 CHANGE REQUEST

REQUESTED EFFECTIVE DATE:

CHANGE IN ORG. CODE CHANGE IN EMPLOYEE CLASS CHANGE IN ALLOCATION

ACTION/ONE-TIME AWARD:	ONE-TIME AWARD AMOUNT: \$ -
PRIMARY DEPT./PROJ. ID:	APPT. END DATE:
PROP. POSITION #:	PROP. STANDARD HOURS:
PROP. ORG. CODE:	PROP. EMPLOYEE CLASS:
PROP. JOB CODE/TITLE:	PROPOSED SALARY: \$ -
PROP. ADMIN. CODE/TITLE:	CHANGE AMOUNT/PERCENT: \$ - 0%
PROP. WORKING TITLE:	DIRECT REPORT TO VP?:
BUILDING CODE:	ROOM #:
REPORTS TO EMPL. ID:	POSITION #:

JUSTIFICATION

Required for all Actions/Allocations

3 ALLOCATION

REQUESTED EFFECTIVE DATE:

	DEPARTMENT/ PROJECT ID	START DATE	END DATE	%	ALLOCATED AMOUNT
1				100.00	\$0.00
2				0.00	\$0.00
3				0.00	\$0.00
4				0.00	\$0.00
5				0.00	\$0.00
6				0.00	\$0.00
				100.00	\$ -

Division of Research *Technology Update*

■ **FIU Research Website Changes**

- Consolidated two separate FIU Research related sites into one site at <http://research.fiu.edu>
- Reorganized and streamlined content
- Added new sections (e.g. Research Facilities)

The screenshot shows the FIU Research website homepage. At the top, there is a search bar and a navigation menu with links for FIU HOME, ABOUT US, ADMISSIONS, ACADEMICS, RESEARCH (highlighted), ATHLETICS, NEWS, and GIVING. The main content area features a large banner for the 'WOW - FIU unveils 12-fan Wall of Wind' with a photo of a man in a lab coat and a red text box. Below the banner is a sidebar with 'About FIU Research' and a list of links including Facts & Figures, Division of Research, Research Centers, Research Facilities, Colleges and Schools, Reports, and Research Foundation. The main content area is divided into three columns: 'SNAPSHOT' featuring a profile of Javier Francisco-Ortega, 'NEWS' with a list of recent articles, and 'EVENTS' with dates for Quarterly Administrators Meetings. At the bottom, there are sections for 'PUBLICATIONS', 'ANNOUNCEMENTS', and 'FUNDING'.

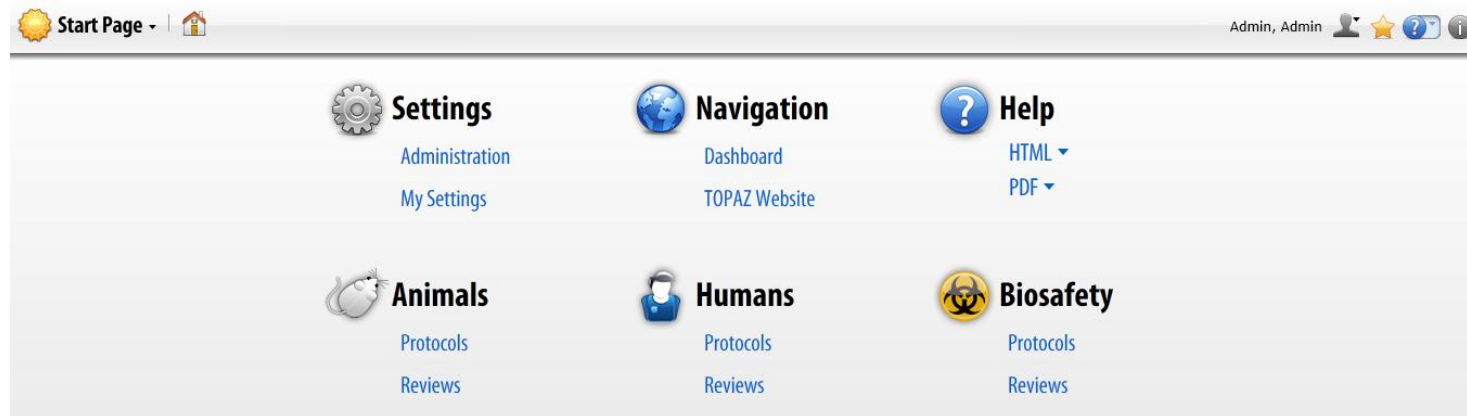
Division of Research *Technology Update - Topaz Implementation*

▪ **Topaz Implementation – Project Update**

- IBC go-live was June 2012.
- IACUC go-live was July 2012.
- IRB go-live was January 2, 2013.

▪ **TOPAZ Project Information page:**

- <http://research.fiu.edu/topaz>



▪ **ORI Update**

- IRB Principal Investigator Requirements
- IRB Online Training Requirements
- IRB Informed Consent Requirements

Division of Research



Office of Research Integrity Updates

Agenda

- IRB Human Research Updates
- Benefits & Key Features of TOPAZ
- Simple Five Step Submission
- Sources for Help
- Questions

IRB Updates

- **New IRB Principal Investigator Requirements (As of 01/02/13)**
 - Students are no longer be permitted to serve as Principal Investigators on IRB protocol submissions.
 - For all new IRB submissions and/or renewals, student researchers need to be listed as Co-Investigators or Key Personnel.
- **New IRB Online Training Requirements (As of 01/02/13)**
 - The IRB will only be accepting the CITI IRB Training Course, which is more thorough and comprehensive than the NIH PHRP IRB Training Course.
 - This new requirement applies to all new IRB submissions and to all IRB renewals.
 - More information on [IRB Training Requirements](#) web page.

IRB Updates

- **New IRB Informed Consent Requirements (As of 01/02/13)**
 - Researchers are now required to use the FIU Informed Consent Templates when developing their consent documents.
 - More information is available on the [Informed Consent Information](#) web page.
- **New Online IRB Protocol Submission System (As of 01/02/13)**
 - A new TOPAZ Electronic Protocol Application System has been deployed, which allows investigators to submit their protocols electronically online.
 - More information is available on the [IRB TOPAZ System](#) web page.

What is Topaz?



Provides online IACUC protocol submission and review management to help ensure FDA, USDA, OLAW and GLP Compliance



Provides online IRB protocol submission and review management to help ensure FDA and OHRP compliance.



Provides online IBC protocol submission and review management to help ensure NIH compliance.

What are the Benefits?

- Secure and easy to use web-based system.
- Eliminate the need for paper, Go Green!
- Efficient way to prepare and submit protocols.
- Streamlined review process.
- Electronic access to your protocols and approval letters.
- Backup of your protocols if your hard drive crashes.
- Check protocol status
- Run reports, exports, and more...

Key Features

- Pre-Submit
- Easy Copy Function
- Conditional Style Questions
- Filtering of Form Questions
- Rich Text Editing
- Amendments and Renewals pull up Protocol History
- Attach Files and Links to Protocols
- Compare Protocol Versions with Tracked Changes
- Electronic Signatures

Accessing TOPAZ

- Log into the system using your Panther ID and FIU MyAccounts password (LDAP)
- Topaz System Website: <https://topaz.fiu.edu/>
- Principal Investigators with active IRB, IBC and IACUC protocols should have access to login.
- If you are unable to login, visit the *Topaz System Access Request Form* – located on the Topaz Information web page:
<http://research.fiu.edu/topaz/>

Submitting a Protocol

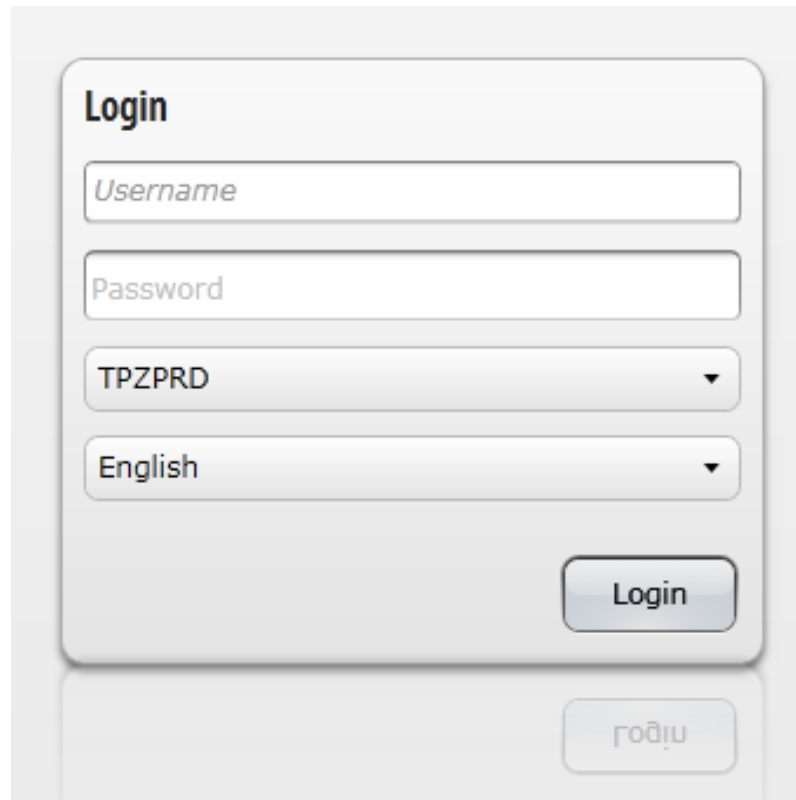
■ Simple Five Step Submission Process

1. Log into the TOPAZ System
2. Select “Protocols”
3. Select “Create Original Protocol”
4. Select the Appropriate Form
5. Complete the Form and Submit



Submitting a Protocol

Step 1: Log into the TOPAZ System



The image shows a login form for the TOPAZ System. The form is titled "Login" and contains the following fields and controls:

- A text input field labeled "Username".
- A text input field labeled "Password".
- A dropdown menu currently displaying "TPZPRD".
- A dropdown menu currently displaying "English".
- A "Login" button.

The form is set against a light gray background with rounded corners. Below the main form, a faint, semi-transparent version of the same form is visible, suggesting a scrollable interface.

Submitting a Protocol

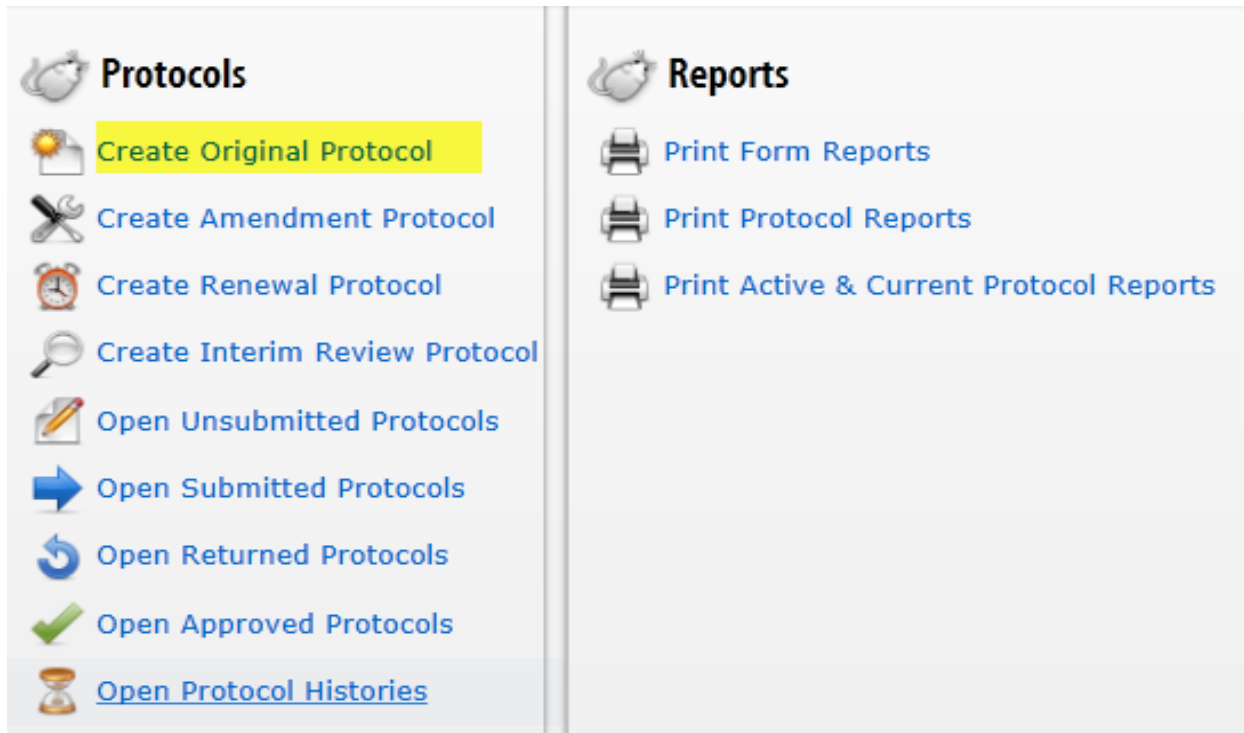
Step 2: Select “Protocols”

The screenshot shows a web application interface with a top navigation bar and a main content area. The top bar includes a "Start Page" dropdown, a home icon, and user information "Admin, Admin" with profile, star, question mark, and info icons. The main content area is divided into six sections:












- Settings** (gear icon): Administration, My Settings
- Navigation** (globe icon): Dashboard, TOPAZ Website
- Help** (question mark icon): HTML, PDF
- Animals** (mouse icon): **Protocols** (highlighted), Reviews
- Humans** (person icon): **Protocols** (highlighted), Reviews
- Biosafety** (biohazard icon): **Protocols** (highlighted), Reviews

Submitting a Protocol

Step 3: Select “Create Original Protocol”




The screenshot displays a web interface with two main sections: "Protocols" and "Reports".


- Protocols:**
 -  [Create Original Protocol](#) (highlighted in yellow)
 -  [Create Amendment Protocol](#)
 -  [Create Renewal Protocol](#)
 -  [Create Interim Review Protocol](#)
 -  [Open Unsubmitted Protocols](#)
 -  [Open Submitted Protocols](#)
 -  [Open Returned Protocols](#)
 -  [Open Approved Protocols](#)
 -  [Open Protocol Histories](#)
- Reports:**
 -  [Print Form Reports](#)
 -  [Print Protocol Reports](#)
 -  [Print Active & Current Protocol Reports](#)


Submitting a Protocol

Step 4: Select the Appropriate Form

Select Form |

 Filter

 Export Grid

 Reports

<input type="checkbox"/>	Name	Description
<input type="checkbox"/>	IACUC Approval Form	For Intial Research Review Submissions
<input type="checkbox"/>	IACUC Field Study Approval Form	For Initial Off-Site Field Research Submissions
<input type="checkbox"/>	IACUC Tissue Use/Transfer Form	For Studies Only Involving Animal Tissues

Page 1 of 1.
5 total record(s) found.

Submitting a Protocol

Step 5: Complete the Form and Submit

The screenshot shows a web-based form titled "IACUC Approval Form" with a version number of 1.2. The interface includes a navigation bar at the top with "Animal Protocols", "Main", "Protocol Forms", and "Protocols". A toolbar contains icons for "Create Original Protocol", "Save", "Copy", "Compare", "Presubmit", "Submit", "Signoff", and "Reports". On the left, an "Outline" panel lists seven sections: 1 ADMINISTRATIVE DATA, 2 PROJECT INFORMATION, 3 ANIMAL REQUIREMENTS, 4 RATIONALE FOR ANIMAL USE, 5 EXPERIMENTAL DESIGN & PROCEDURES, 6 AFFIRMATION OF COMPLIANCE, and 7 OFFICE USE ONLY. The main content area displays the "1 ADMINISTRATIVE DATA" section with the following fields:

- Reference Number:** This number is system generated. The input field contains "20044".
- Protocol Number:** This number will be assigned after the protocol has been processed. The input field is empty.
- Title:** Provide the Project Title. The input field is empty.
- Department:** Select your Department. A dropdown menu is present.

Sources for Help

- The following resources are available to assist investigators:
 - Detailed Topaz User Guides and Quick Reference Guides:
<http://research.fiu.edu/topaz/>
 - Email the FIU Topaz Help Desk at:
topaz-help@fiu.edu
 - Call (305) 348-2494.

- **OLAR Update**

- Laboratory Animal Research Historical Perspective

Laboratory Animal Research

A Historical Perspective



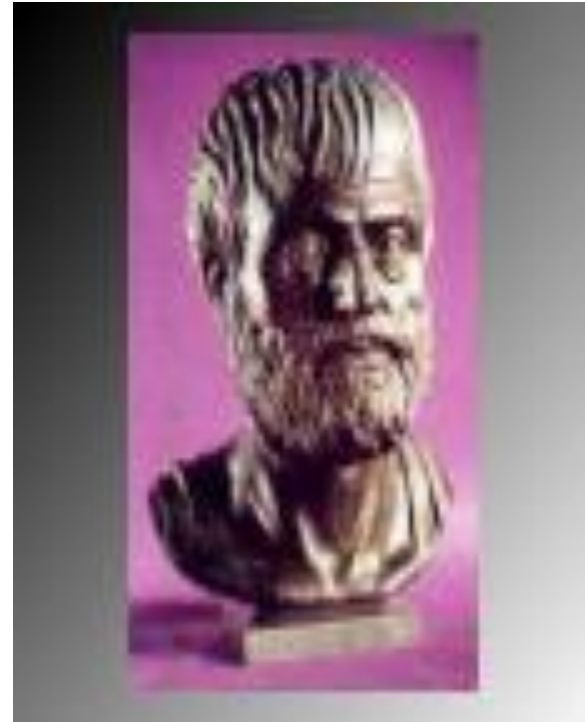
**Horatiu V. Vinerean DVM,
Diplomate, American College of
Laboratory Animal Medicine
Director, Laboratory Animal Research
Attending Veterinarian**

ORIGINS OF ANIMAL EXPERIMENTATION

- Animal experimentation and the experimental method have had almost a common evolution.
- Hippocrates symbolized the beginnings of rational, scientific medicine, a necessary prerequisite to the use of animals for experimental purposes.
- Plato, Socrates, Aristotle, and others began to think and reason in terms of a philosophy of science, and animal experimentation was a logical outgrowth of this thought.

ARISTOTLE (384-322 BC)

- Founder of biology
- First to make dissections that revealed internal differences of animals
- “We should venture on the study of every kind of animal without distaste; for each and all will reveal to us something natural and something beautiful.”



Laboratory Animal Research

A Historical Perspective

ERASISTRATUS (304-25 BC)



- Founder of physiology
- First to perform experiments on living animals
- Established in pigs that the trachea was an air tube and the lungs were pneumatic organs
- Utilized crude metabolic cages in a study of bird physiology

Laboratory Animal Research

A Historical Perspective

GALEN (AD 130-200)

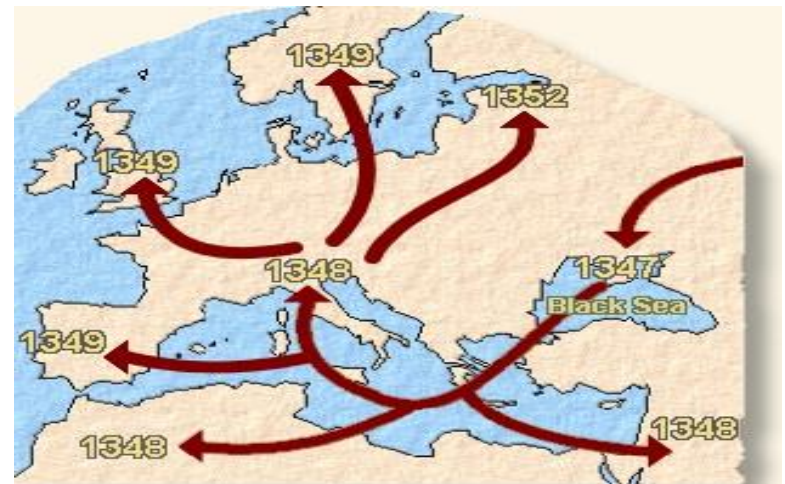
- Performed anatomical dissections of pigs, monkeys, sheep, oxen, lions, wolves, birds, at least one elephant, and many other species
- His favorite dissection subject was the Barbary ape (*Macaca sylvanus*)
- Many of his conclusions about human anatomy were based on this species



Laboratory Animal Research *A Historical Perspective*

BACKGROUND OF AGENTS USED AS POTENTIAL BIOWEAPONS

- 400 BC Scythian archers used arrows dipped in blood and manure or decomposing bodies
- 1346-1347 – Tartars catapulted bodies of bubonic plague victims over the walls of the city of Kaffa (Fedosia, Ukraine)
- 1495 – The Spanish infected French wine with blood from leprosy patients
- The mid 1600's Polish generals put saliva from rabid dogs into hollow spheres



The Plague's Progress

Laboratory Animal Research *A Historical Perspective*

ANDREAS VESALIUS (1514-1564)

- Considered the founder of modern anatomy
- Used dogs and pigs in public anatomical demonstrations
- Tested, among other things, the effects of tracheotomy and artificial respiration on the strength and character of the heart beat



Laboratory Animal Research

A Historical Perspective

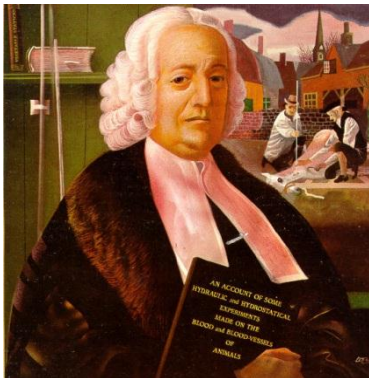


- Sir William Harvey (1578-1657)
 - published on the movement of the heart and blood in animals

- Jean-Baptiste Denys (1643-1704)
 - performed first blood transfusion

- Stephen Hales (1677-1761)
 - reported the first measurement of blood pressure

- François Magendie (1783-1855)
 - studied experimental physiology in animal models

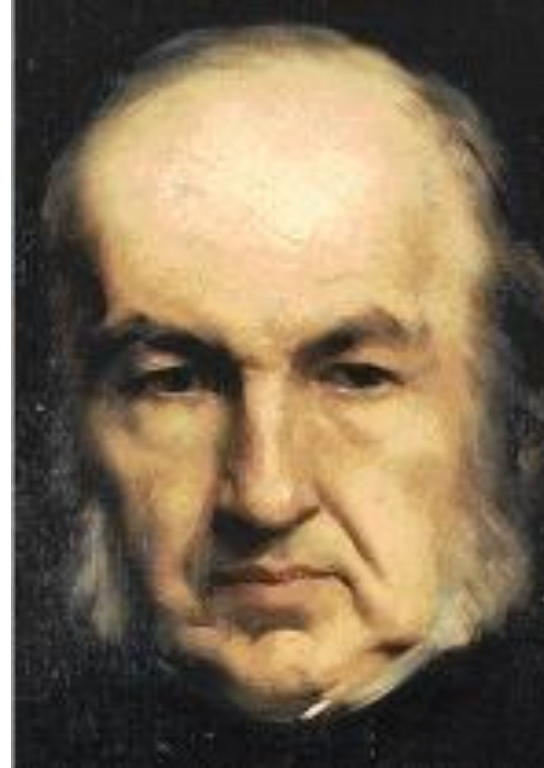


Laboratory Animal Research

A Historical Perspective

CLAUDE BERNARD (1813-1878)

- Referred to as the founder of experimental medicine
- Developed and described highly sophisticated methods of animal research.
- Instructional methods included live demonstrations



Laboratory Animal Research
A Historical Perspective

EARLY ANESTHESIA METHOD



Laboratory Animal Research *A Historical Perspective*

EDWARD JENNER (1749-1823)



- First physician to inoculate against disease
- Recognized that local milk maids who contracted Cow pox were protected from Small pox
- Jenner vaccinated (the word vaccine comes from the Latin word *vacca* meaning cow) a boy with serum collected from a cow pox lesion of a local milk maid
- Two months later he challenged the boy with small pox

LOUIS PASTEUR (1822-1895)

- Pasteur was a chemist (not a physician)
- He developed the process of pasteurization to prevent wine from souring, and then in milk to prevent it from spoiling
- His in-vivo work utilizing a disease of silk worms led him to discover the germ theory of disease that is perhaps the single most important medical discovery of all time
- Doctors of the time thought him a quack



Laboratory Animal Research

A Historical Perspective

LOUIS PASTEUR (1822-1895)



- Pasteur suffered a stroke, married, and soon after postulated the germ theory
- His wife, Marie Laurent, dedicated herself to managing all details of his life so that “he might retain the full freedom of his mind for his investigations”
- In turn, Louis Pasteur always found time each year for a vacation in the country with his wife. He put away his microscope and notebook. For two weeks he devoted himself completely to her happiness.”

Laboratory Animal Research
A Historical Perspective

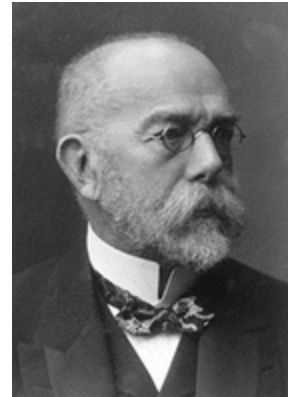
LOUIS PASTEUR (1822-1895)

- Upon a return from one such vacation Pasteur mistakenly inoculated a chicken with a bottle of old broth containing the infectious agent for chicken pox
- He had meant to use a fresh vial and expected the chicken to become sick and die. The chicken lived and proved protected against the disease
- In this way, as a direct result of his devotion to his wife, attenuated vaccines were discovered
- Combining this finding with his work on pasteurization, he created a heat attenuated anthrax vaccine
- In 1885, utilizing a rabbit model, he developed the first rabies vaccine

Laboratory Animal Research

A Historical Perspective

- Robert Koch (1843-1910)
 - Koch's postulates were developed using mice infected with anthrax
- John Call Dalton (1825-1889)
 - an American M.D. physiologist, studied under Claude Bernard
 - included live demonstrations in animals in his teaching at the College of Physicians and Surgeons in New York City



1. Newspaper reporter
2. John Call Dalton
3. William Williamson Wellington
4. Abel Lawrence Peirson
5. Charles Hosea Hildreth
6. William Thomas Green Morton
7. Jonathan Mason Warren
8. Gilbert Abbott
9. John Collins Warren
10. Eben H. Frost
11. Charles Frederick Heywood
12. Henry Jacob Bigelow
13. Augustus Addison Gould
14. Solomon Davis Townsend

BEGINNINGS OF VETERINARY MEDICINE EDUCATION

- École nationale vétérinaire d'Alfort – France (1765)
- Faculty of Veterinary Medicine – Bucharest, RO (1861)
- CVM – Guelph, Canada (1862)
- CVM – Iowa State University (1875)
- Cornell University was granting DVM degrees through their College of Agriculture (1879)

Laboratory Animal Research *A Historical Perspective*

- By the end of the nineteenth century, the number of animals used was small and no special attention was paid to their care, maintenance, and diseases. This is indicated by the absence of published information on this subject prior to 1900.
- From 1900 to 1920, no adequate facilities existed for the laboratory species in medical institutes...Epizootics were common, and experiments often were disrupted by the inability of investigators to obtain healthy animals and maintain them under uniform environmental conditions.

Laboratory Animal Research
A Historical Perspective

EARLY VETERINARIANS IN LABORATORY ANIMAL SCIENCE IN US

- D. E. Salmon (1850-1914)
- Simon Brimhall (1863-1941)
- Carl Schlotthauer (1893-1959)
- Karl Meyer (1884-1974)
- Charles Griffin (1889-1955)
- Nathan Brewer (1904-2009)



Laboratory Animal Research *A Historical Perspective*

- D. E. Salmon (1850-1914)
 - First D.V.M. in the U.S., Cornell University, 1879
 - The bacterial genus *Salmonella* is named for D.E. Salmon
- Simon Brimhall (1863-1941)
 - First veterinarian to fill a position in laboratory animal medicine at the Mayo Clinic
 - His position was the prototype for the present role of laboratory animal veterinarians

Laboratory Animal Research
A Historical Perspective

CARL SCHLOTTHAUER (1893-1959)

- First veterinarian to attain a full professorship for laboratory animal medicine-related academic activities
- He was active in community humane society activities
- Was a founding member of the Animal Care Panel (ACP), the precursor to the American Association of Laboratory Animal Science (AALAS)
- He was a charter Diplomate of the American College of Laboratory Animal Medicine (ACLAM)
- Dr. Schlotthauer was attached to the Veterinary Corps during the First World War

Laboratory Animal Research
A Historical Perspective

CHARLES GRIFFIN (1889-1955)

- Dr. Griffin pioneered the concept of the development of 'disease free' animal colonies
- His work with *Salmonella* transmission led feed manufacturers to improve the processing of laboratory animal diets
- In 1952 his paper on bacterial diseases in lab animals was the most thorough treatment to date

Laboratory Animal Research *A Historical Perspective*

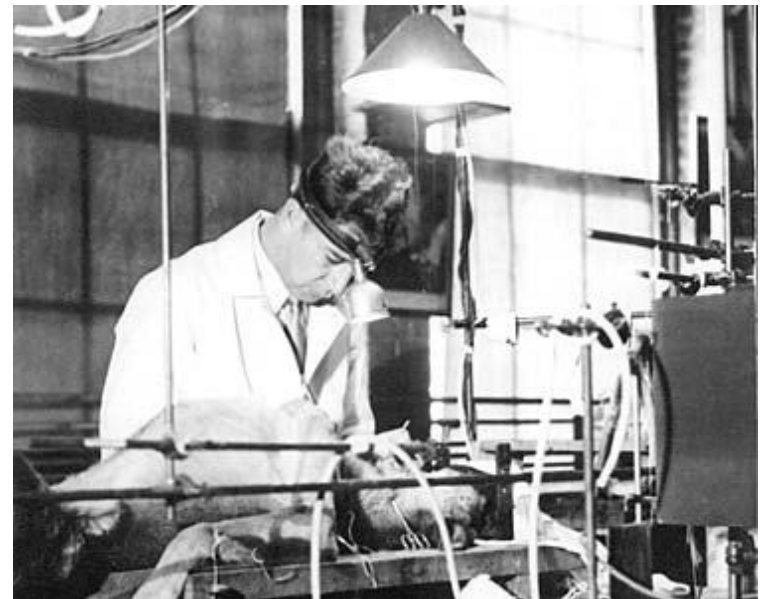
- During and immediately following World War II, a large number of pharmaceutical companies expanded their research and development programs.
- Veterinarians were employed to direct the enlarged animal facilities serving these programs.

Laboratory Animal Research

A Historical Perspective

NATHAN BREWER (1904-2009)

- In 1945, his position at the University of Chicago was created to increase the public confidence in the university's animal use at a time when Chicago was a hot bed for antivivisection activists.
- Many investigators at the university opposed the creation of the veterinarian position. They feared that a veterinarian would dictate the conditions of care and use of animals



THE ORGANIZATIONS OF LABORATORY ANIMAL SCIENCE

- National Association for Biomedical Research (NABR)
- The American Association for Laboratory Animal Sciences (AALAS)
- The Institute for Laboratory Animal Research (ILAR)
- American College of Laboratory Animal Medicine (ACLAM)
- Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International)

Laboratory Animal Research
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NATIONAL ASSOCIATION FOR BIOMEDICAL RESEARCH

- Created as The National Society for Medical Research in 1946 by the Association of American Medical Colleges to counter antivivisection activities and to promote public understanding of the needs and accomplishments of animal experimentation.
- NSMR developed educational material and provided legal council to scientists attacked by the Hearst newspapers.
- In the 1980's NSMR merged with the Association for Biomedical Research to become the National Association for Biomedical Research (NABR).



Laboratory Animal Research
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THE AMERICAN ASSOCIATION FOR LABORATORY ANIMAL SCIENCES

- Began in 1950 as the Animal Care Panel (ACP) and grew out of informal meetings begun in 1946 that Dr. Nathan Brewer organized in Chicago for local and visiting lab animal veterinarians,
- In May of 1950 five founding veterinarians sent out a letter to those interested in the care of lab animals proposing a national organization. The response was overwhelmingly positive
- The first meeting was held on November 28th, 1950. The name Animal Care Panel was chosen to indicate informality, and collegiality of all involved, but also “because at the time, federal grant funds could be used freely to pay for trips to committee and panel meetings, but only two trips a year were permitted to meetings of associations.”

Laboratory Animal Research *A Historical Perspective*

THE AMERICAN ASSOCIATION FOR LABORATORY ANIMAL SCIENCES - AALAS

- In the second meeting, committees were formed to draft “animals care standards” and “regulations for the care of the dog.”
- By the fourth meeting, “how to” papers were the minority and presentations of research reviews predominated
- Original research papers and commercial exhibits appeared in the sixth meeting in 1955
- The ACP developed the first “Guide for Laboratory Animal Facilities and Care” in 1963
- The ACP worked to enhance the stature and training of lab animal technicians.

Laboratory Animal Research

A Historical Perspective

THE INSTITUTE FOR LABORATORY ANIMAL RESEARCH

- In the early 1950's scientific standards for laboratory animal production, genetics, breeding, husbandry, and transportation did not exist.
- Education and training in lab animal medicine were in an undeveloped state.
- The National Research Council appointed the Animal Resource Committee in 1952 to address these issues.
- The committee recommended establishment of an Institute of Animal Resources (IAR).

Laboratory Animal Research
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THE INSTITUTE FOR LABORATORY ANIMAL RESEARCH

- IAR began full time operations in 1953 and was renamed the Institute of Laboratory Animal Resources (ILAR) in 1956, and again renamed the Institute for Laboratory Animal Research in the late 1990's.
- ILAR is the major standards-development organization within lab animal science.
- During the early years of ILAR and AALAS, they had common areas of overlap. In 1962 the executive committees of each organization agreed on a division of responsibility that solidified ILAR's role in standards development.
- They have subsequently published the Guide for the Care and Use of Laboratory Animals.
- In 1967 they developed the first guidelines for education and training in lab animal medicine.

Laboratory Animal Research
A Historical Perspective

AMERICAN COLLEGE OF LABORATORY ANIMAL MEDICINE

- On February 18, 1957, the College was chartered. It is a specialty board recognized by the American Veterinary Medical Association.
- The College has grown steadily and its active membership is now 1044 Diplomates, of which 870 are active Diplomates, 155 are retired Diplomates and 18 are honorary members.
- The basic policies and concepts of the College have not changed since its formation. The testing and certification of qualified veterinarians in this specialty continues to have the highest priority. Educational programs of the College also receive strong emphasis to appraise the membership and the scientific community of advances in laboratory animal medicine.

Laboratory Animal Research

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AAALAC INTERNATIONAL

- The Association for Assessment and Accreditation of Laboratory Animal Care International.
- 1957-1960 ACP formed committees to develop standards of care and an accreditation process.
- 1962- an NIH grant funded ACP to develop standards resulting in the 1963 publishing of *Guide for the Laboratory Animal Facilities and Care*- the precursor of today's Guide.
- Voluntary pilot site visits began in 1963.
- ACP incorporated the American Association for Accreditation of Laboratory Animal Care as a privately operated organization on April 14, 1965 with it's first meeting April 30th of the same year.
- 1983-1985- With changes in the Guide, AAALAC's accreditation purpose expands to include not just animal care and care facilities, but animal use as well.

Laboratory Animal Research

A Historical Perspective

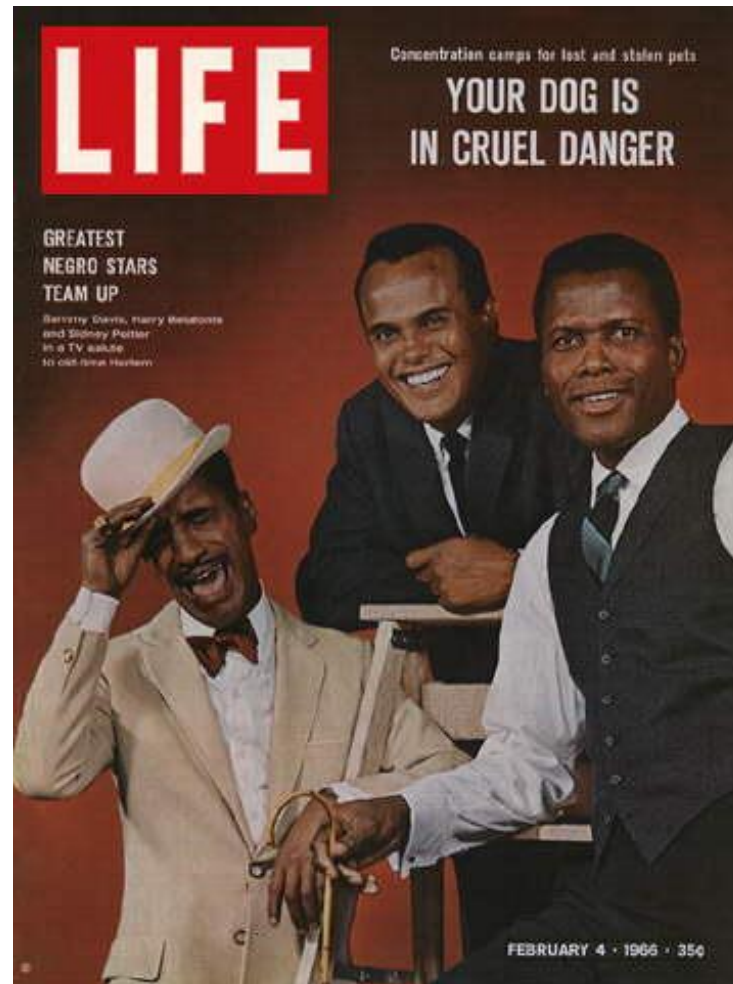
AAALAC INTERNATIONAL

- Over 870 organizations in 36 countries are currently accredited by AAALAC
- AAALAC International continues to use the Guide as its standard as it promotes the responsible treatment of animals in science through voluntary accreditation and assessment programs.
- AAALAC accreditation standards which are higher than PHS standards. AAALAC - a voluntary accrediting agency available to any institution that uses animals, seal of good housekeeping. Any institution can apply for accreditation, and if you get it, then you are abiding by practices well above the minimum standard of care.

ORIGINS OF LAWS, REGULATIONS, GUIDELINES

- Prior to 1966 no federal law existed in the United States specifically regulating acquisition or care of research animals.
- In the late 1950's and early 1960's, animal welfare organizations argued for legislation to curb alleged "pet stealing" and abuse of animal in laboratories. They used the media to effectively generate public interest in their causes.

Laboratory Animal Research *A Historical Perspective*



1966 LABORATORY ANIMAL WELFARE ACT

- In 1966, in response to public outcry, generated by two articles in the popular press, Congress passed the Laboratory Animal Welfare Act. The name of the Act has since been changed to the Animal Welfare Act
- Focus on preventing thefts of dogs and cats.
- Registering facilities with dogs and cats.
- Developed 8 areas of minimum standards
 - Housing -Shelter -Feeding -Separation of Species
 - Watering -Sanitation -Ventilation -Adequate Vet. Care

ANIMAL WELFARE ACT AMENDMENTS

- 1970
 - Report number of animals by pain category.
 - Require appropriate use of anesthetic.
 - Include all warm blooded animals except rats, mice and birds.
- 1985
 - Establishment of IACUC.
 - Assign responsibility to IO.
 - Review of protocols.
 - Semiannual program review & inspections.
 - Search for alternative to painful procedures.
 - Personnel qualifications.
 - Environmental enrichments to NHP's.
 - Exercise for dogs.

Laboratory Animal Research

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RATS/MICE EXCLUSION FROM AWA

- It's probably because 90%+ of the animals used in research are rats and mice and the USDA thought they wouldn't have enough manpower to enforce the law but could cut the workload a lot by eliminating rats, mice.
- Most of these animals are used for toxicology testing at universities where you have to abide by GLP, FDA regulations, etc.

REGULATORY COMPLIANCE ANIMAL WELFARE ACT REGULATIONS

- Licensing/Registration of research facilities
- Attending veterinarian and adequate veterinary care
- Identification of animals
- Stolen animals
- Records
- Holding periods
- Specifications for the humane handling, care, treatment and transportation of various animal species



THE GUIDE FOR THE CARE AND USE OF LABORATORY ANIMALS

- In 1963, NIH published the first edition of the “Guide for Laboratory Animal Facilities and Care,” as developed by the Standards Committee of the ACP
- Revised several times since 1963 by ILAR’s Committee on Revision of the Guide, it is now the Guide for the Care and Use of Laboratory Animals
- Since 1963, NIH and other granting agencies have required scientific institutions to provide assurance of compliance with the standards in the guide as a condition for receiving funds for research.
- The guide is used as the basis for accreditation by AAALAC

REGULATORY COMPLIANCE - THE GUIDE

- Institutional policies and responsibilities
- Monitoring the care and use of animals
- Veterinary medical care
- Personnel qualification and training
- Occupational health and safety
- Animal housing and environments
- Physical plant (construction, HVAC, etc.)

Laboratory Animal Research *A Historical Perspective*

REGULATORY COMPLIANCE

PUBLIC HEALTH SERVICE POLICY ON HUMANS CARE AND USE OF LABORATORY ANIMALS

- PHS Policy for short
 - Include animals for research, teaching, education, demonstration. Defines animals as any warm blooded vertebrates - no exclusions.
 - Based on the Guide

Policies: not laws. You need not comply unless you want the benefit. If you do not want federal funding, you do not have to comply.

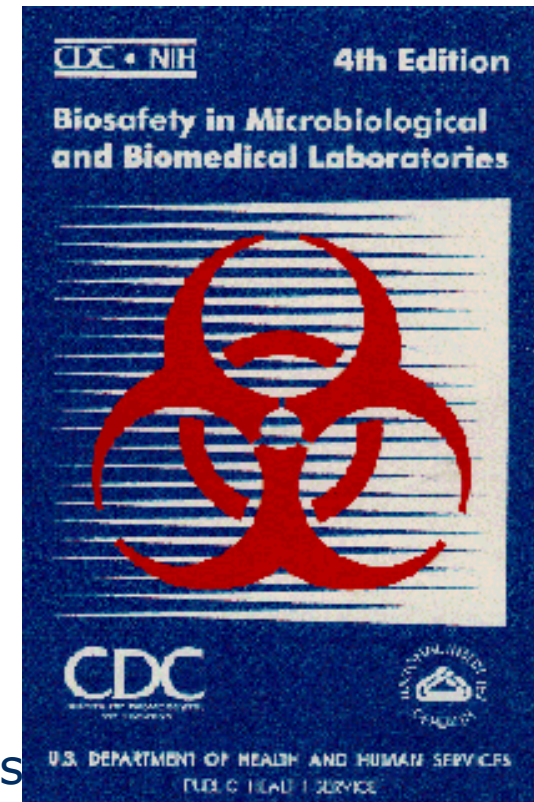


Public Health
Service Policy on
Humane Care and
Use of Laboratory
Animals

Laboratory Animal Research *A Historical Perspective*

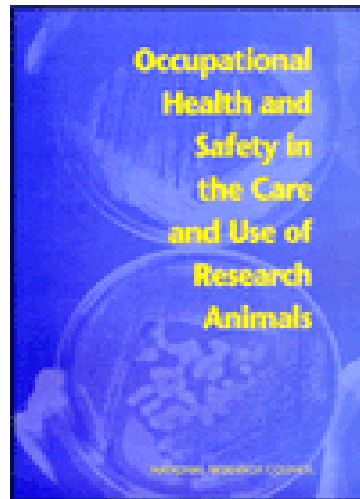
REGULATORY COMPLIANCE BIOSAFETY IN MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES

- BMBL for short
 - Principles of biosafety
 - Laboratory Biosafety Level criteria
 - Animal Biosafety level criteria
 - Risk Assessment
 - Recommended BSLs for infectious agents
 - Agent summaries
 - Immunoprophylaxis
 - Transportation and transfer of biological agents



Laboratory Animal Research *A Historical Perspective*


OCCUPATIONAL HEALTH AND SAFETY LABORATORY SAFETY



- Facility Standard Operating Procedures
- Good Laboratory Practices (GLP)
- Good Manufacturing Practices (GMP)
- OSHA principles/audits

CAUTION!
AUTHORIZED PERSONNEL ONLY

SUITE:
DIVISION:
BIOSAFETY LEVEL:
AGENT(S) USED:



ENTRY REQUIREMENTS: DEMONSTRATED IMMUNITY TO AGENTS LISTED ABOVE.
[] = Only required for personnel working directly with agent and selected at risk personnel

SUITE SUPERVISOR:

CONTACT	NAME	OFFICE	PHONE EXT.	HOME PHONE
FOR ENTRY OR ADVICE				
IN EMERGENCY				
IN EMERGENCY	Safety Office	RL-113	619-2934	CALL SECURITY AT 2267

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MANY MORE REGULATIONS



Getting Nauseous?

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MANY MORE REGULATIONS

- Guide for the Care & Use of Agricultural Animals
- Guide for the Care & Use of Mammals in Neuroscience and Behavioral Research
- Guidelines for Behavioral Research Using Animals (NIMH Report)
- Guidelines for Use of Fish in Research
- Guidelines of the American Society of Mammalogists for the Use of Wild Mammals in Research
- Guidelines to the Use of Wild Birds in Research (3rd Edition – 2010, The Ornithological Council)
- United States Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training

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MANY MORE REGULATIONS

- Use of Animals in Department of Defense Programs - Directive 3216.01 (2010)
- CITES (Convention on International Trade in Endangered Species of Wild Fauna and Flora)
- Lacey Act
- Endangered Species Act
- Marine Mammal Protection Act
- AVMA Guidelines on Euthanasia (2007)
- DEA Regulations
- FDA Regulation (21CFR)

Questions?