Regulatory Compliance at

Research Seminar Series
Grants Writing II
January 27, 2009
WHAT IS REGULATORY COMPLIANCE?

- Biosafety (IBC)
- Research with Human Subjects (IRB)
- Institutional Animal Care and Use (IACUC)
- Hazardous Waste Management
- Radiological Safety
- Safety Officer (effective Feb 1)
REGULATORY COMPLIANCE

• ...stands for nothing less than a constant striving for the highest ethical standards and a dedication to achieving recognition through integrity. By ensuring a comprehensive understanding of the regulatory environment, every researcher and member of a research team can contribute toward this objective.
SERVICES

- Training
- Facility Review
- Lab Certifications
- Calibrate Survey Meters
- Hazardous Waste Disposal
- Film Badges
- Committee Support
- Leak Tests
- Protocol Review
Office of Regulatory Compliance

Regulatory Compliance is an activity that involves every individual and unit associated with Mississippi State University. It relates directly to the caliber of research we conduct and our ability to share the knowledge and understanding contributed by our teachers and scholars. Regulatory compliance stands for nothing less than a constant striving for the highest ethical standards and a dedication to achieving recognition through integrity. By ensuring a comprehensive understanding of the regulatory environment, every researcher and member of a research team can contribute toward this objective.

Our Mission

- To assist MSU research community with adherence to federal and state regulations
- Provide guidance on regulatory issues
- Educate the research community on compliance requirements
- Promote ethical science
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<tr>
<th>Incident/Feedback form</th>
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<tr>
<td>Please use this form to report an incident or provide comments or feedback to the Office of Regulatory Compliance. No MSU employee, research participant or member of the public shall be discriminated against or be subject to reprisal for reporting violations of any regulations, policies, or standards. This incident/feedback form is completely anonymous, your IP address will not be recorded. The only way we will know your identity is if you choose to give us your information.</td>
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**Example**

**Address** - To: hazwaste-request@lists.msstate.edu
**Message** - subscribe
To unsubscribe from a list, send an e-mail to the list with unsubscribe in the message body.

**Example**

**Address** - To: hazwaste-request@lists.msstate.edu
**Message** - unsubscribe
You can also manage your subscriptions by visiting [http://www.msstate.edu/cgi-bin/majordomo](http://www.msstate.edu/cgi-bin/majordomo).
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BIOSAFETY

IBC: Institutional Biosafety Committee
BIOSAFETY

Discipline that addresses

(1) Safe handling &
(2) containment

2 things

Other hazardous biological material

and

Infectious microorganisms

Such as

Toxins, venom, prions, rDNA, raw sewage, animal waste, allergens, plants, transgenic animals, etc…
FOR EXAMPLE:

• Use of materials that require BSL-2/ABSL-2 facilities
• Research with ANY human specimen (blood, tissue, body fluid, cell culture, etc.)
• Use of rDNA technology
• Field work with transgenic or genetically modified organisms
REGULATORY REQUIREMENTS

• NIH Guidelines for Research Involving Recombinant DNA Molecules
  • Standards and procedures for rDNA research
  • Requires an Institutional Biosafety Committee (IBC)

• Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th Edition
  • DHHS recommendations for working with infectious agents at Biological Safety Levels 1 through 4

• Mississippi State Department of Health
  • “Adopted Standards for the Regulation of Medical Waste”

• OSHA Bloodborne Pathogens
  • Concept of universal precautions, etc.
PI RESPONSIBILITIES

• **Prior to initiating research:**
  • Consult Biosafety Officer
  • Perform risk assessment
  • Determine containment level (BSL-1, BSL-2, etc.)
  • Submit IBC application
  • Develop biosafety manual
    • SOP’s for hazardous procedures, equipment
  • Train lab personnel
  • If BSL-2, have BSO certify lab
  • Obtain necessary permits
PI RESPONSIBILITIES

• **During** the conduct of research:
  • Submit annual update form
  • Notify BSO/IBC of any significant changes or accidents
  • Annual BSL-2/ABSL-2 lab certification
  • Annual BBP training (if required)
  • Monitor compliance of personnel with SOP’s
  • Ensure compliance with all applicable regs and policies
HUMAN SUBJECTS RESEARCH

IRB: Institutional Review Board for the Protection of Human Subjects in Research
HUMAN RESEARCH PROTECTION PROGRAM

...protecting the rights, welfare, and well-being of the subjects

Significant events impacting regulations:

1946 Nuremberg Military Tribunal
1960’s Thalidomide Tragedy
1972 Tuskegee Syphilis Study Expose
APPLICABLE REGULATIONS

- U.S. Dept of Health and Human Services, Office for Human Research Protection (OHRP)
  - “Common rule”
    - www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm
  - Requires Federal Wide Assurance
- Food and Drug Administration (FDA)
  - regulates devices, drugs, biologics
- Family Educational Rights and Privacy Act of 1974 (FERPA)
- Health Insurance Portability and Accountability Act of 1996 (HIPAA)
WHAT REQUIRES IRB APPROVAL?


• **Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

  - AND -

• **Human subject** means a living individual about whom an investigator (whether professional or student) conducting research obtains:
  – (1) data through intervention or interaction with the individual, or
  – (2) identifiable private information.
PI RESPONSIBILITIES

• Prior to initiating research:
  – Attend IRB training
    • Monthly live training sessions during fall and spring semesters
    • Online training through CITI Program
    • Training must be renewed every three years
  – Submit IRB application
    • 118 designation
  – Obtain written IRB approval prior to beginning any aspects of the research involving subjects.
PI RESPONSIBILITIES

• **During** the conduct of research:
  – Respect the rights of human subjects
  – Adhere to the approved protocol
  – Submit modification request form
    • All changes must be approved by IRB *prior to* initiating any changes
  – Submit continuing review request form
    • As outlined in approval letter
  – Promptly report any adverse events or unanticipated problems
ANIMAL RESEARCH

IACUC: Institutional Animal Care and Use Committee
ANIMALS IN RESEARCH

“Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative.”

U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, IV
Regulations and Ethical Guidelines

Back to Regulations and Ethical Guidelines Menu

Directives for Human Experimentation

NUREMBERG CODE

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other means.

3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

4. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury may result. 

5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury may result.
ANIMAL CARE REGULATIONS

• USDA, Animal and Plant Health Inspection Service
  – Implements the Animal Welfare Act via the Animal Welfare Regulations

• DHHS, Office of Laboratory Animal Welfare
  – Implements the Policy on Humane Care and Use of Laboratory Animals
  – Requires an Animal Welfare Assurance

• AAALAC
  – Voluntary accreditation (CVM and A&S only)
PI RESPONSIBILITIES

• **Prior to initiating research:**
  – Pass the online animal user course
    • must be renewed every 4 years
  – Register with OHSP
    • update when changes occur
  – Submit IACUC application
    • after pre-review by IACUC member and consultation with LAV
  – Obtain written IACUC approval
  – Have facilities certified by IACUC
    • unless ag production study
PI RESPONSIBILITIES

• **During** the conduct of research:
  – Submit an annual update form
  – Submit amendment form if any changes occur
  – Monitor compliance of personnel with approved protocol
HAZARDOUS WASTE MANAGEMENT
HAZARDOUS WASTE

• Used material or unused surplus materials
  – Paint and related materials
  – Lab chemicals (alcohols, phenol, etc.)
  – Chemicals used in maintenance operations
  – Pesticides (2,4 D; pentachlorophenol; temik)
  – CRT monitors

• You become regulated when you use chemicals
  – No advanced permission required
REQUIREMENTS

• Proper disposal is mandated by Federal and State law
  – US Environmental Protection Agency (RCRA)
  – MS Dept of Environmental Quality
  – US Department of Transportation

• MSU Policy on Hazardous Waste generated at MSU – OP 79.1

• MSU fined $30,000 by MS DEQ in 2001 for waste related and environmental problems
PI RESPONSIBILITIES

• Waste must be properly managed at the point of generation
  – Annual training of waste generators
    • Off campus training sessions available
  – Proper labeling of containers
  – Proper container management
  – Timely disposal of materials

• Treatability studies must be coordinated through the Regulatory Compliance office

• Waste disposal costs are charged to the project or department
UNIVERSAL WASTE

• Batteries
  – NiCad
  – Lithium
  – Lead-Acid
• Light bulbs
  – Fluorescent

• Just because you toss it in the trash at home doesn’t mean it’s okay to do that on campus!
USED OIL

• Motor oil, hydraulic oil, cooking oil, etc.
  – Must be collected
  – Labeled properly
  – Disposed of properly

• Spilled oil waste must be promptly cleaned up and disposed of
RADIOLOGICAL SAFETY

Radiological, Chemical, and Laboratory Safety Committee
REQUIREMENTS

• Radioactive materials work is conducted under the requirements of the campus radioactive materials license
  – MS Dept of Health, Division of Radiological Health
• X-ray devices are operated in accordance with registration requirements
  – Issued to department and authorized user
• MSU Policy on Radiological, Chemical, and Laboratory Safety – OP 79.8
LICENSE

- MSU licensed for atomic numbers 1-98
  - Normal “life sciences” radioactive materials
  - Transuranics
  - Fissile materials in small quantities

- With proper campus approval, license permits radioactive work
  - on campus
  - at branch stations
  - in field studies on MSU property
PI RESPONSIBILITIES

• Complete an application
  – The PI is approved to use radioactive material
    • Students, technicians, etc. work under PI approval
  – Individual projects typically do not require approval

• PI, students, technicians must complete campus radioactive materials users training

• Budget for
  – Waste disposal charges
  – Personnel monitoring services (if required)
Other Safety

• Assistance can be provided for other safety issues such as
  – Air quality
  – Lab safety
  – Fire Code compliance
  – Assistance with DOT hazmat shipping
    • MSU Policy 79.09
Regulatory Compliance
Contact Information

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• Trina Smith, IACUC Administrator tsmith@research.msstate.edu, 325-0994
• Christine Williams, IRB Administrator cwilliams@research.msstate.edu, 325-5220
• Jonathan Miller, IRB Officer/Asst. Director, jmiller@research.msstate.edu, 325-2238

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