



Research Compliance and You

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What is Research Compliance?

- Professional and moral obligation to the protection of research subjects and to the safety of research personnel, students, and the public.
 - Strict adherence to all federal, state, and university requirements.
 - May include:
 - Licensing
 - Permitting
 - Committee or Board Approval
 - Scrutiny of Research Methods from Colleagues or Peers
 - Inspections and Audits

Primary Focus

- ❑ Human Subjects
- ❑ Animal Subjects
- ❑ Biohazards

Human Subjects

- ▶ Protection of human subjects is paramount!
 - ▶ Ethical use of humans as subjects of research
 - ▶ Institutional Review Board (IRB)
 - ▶ Review research protocols
 - ▶ Ethical research
 - ▶ Is the research necessary?
 - ▶ Is the benefit to society worth the risk to the subjects?
 - ▶ Informed consent
 - ▶ Voluntary participation
 - ▶ Subject selection

Common Rule Changes

- ▶ New requirements regarding informed consent process
- ▶ Allows the use of broad consent
- ▶ Established new exempt categories
- ▶ Created single IRB requirements
- ▶ Created limited review of certain exempt research
- ▶ Removed continuing review for certain research activities
- ▶ Clarified some concepts
- ▶ Removed the requirements to register the FWA for research not federally supported

Animal Subjects

- ▶ Like humans, we must protect animals in research!
 - ▶ Institutional Animal Care and Use Committee (IACUC)
 - ▶ Ethical research
 - ▶ Is the research necessary?
 - ▶ Is the species and number of animals acceptable?
 - ▶ Are the animal holding facilities acceptable?
 - ▶ Is pain and distress on the animals minimized?
 - ▶ How long are the animals subject to the treatment?
 - ▶ Emergency situations
 - ▶ Euthanasia

Biohazard Definition

- ▶ An agent of biological origin that has the capability to produce harmful effects on humans, animals, plants, or the environment; i.e. microorganisms, toxins and allergens derived from microorganisms, and allergens and toxins derived from plants or animals.

Biohazards

- ▶ We must protect researchers, students, and the public from biohazardous substances.
 - ▶ Institutional Biosafety Committee
 - ▶ Conduct a risk assessment for biosafety and biosecurity
 - ▶ Review the control and use of biohazards and their vectors.
 - ▶ Agent hazards (Select Agents)
 - ▶ Facility design
 - ▶ Primary and Secondary Barriers
 - ▶ Experimental design/Procedures
 - ▶ Training of staff
 - ▶ Hygiene

Other Items for Consideration

- ▶ Responsible Conduct of Research
- ▶ Fire and Life Safety
- ▶ Hazardous Materials
 - ▶ Shipping
 - ▶ Handling
 - ▶ Storage
 - ▶ Waste
- ▶ Export Controls
- ▶ Controlled Substances

AND YOU!

- ▶ We all have the responsibility to ensure research is conducted within the constraints of all applicable federal, state, and institutional laws, rules, regulations, policies, procedures and practices.
- ▶ It is the responsibility of each researcher to facilitate monitoring of research compliance, and when necessary, take active measures to ensure compliance obligations are met.