Research Compliance
What is Research Compliance?

- Conformance with Federal, State, and Local Regulations and University Policies
  - Protection of human subjects
  - Welfare of laboratory animals
  - Safe use of radioactive material and radiation-producing machines
  - Safe conduct of recombinant DNA research and work with biological agents
  - Export Controls; Conflict of Interest
  - Attention to safety and integrity issues
ODU Protocol Review
Committees

IRB
Institutional Review Board
IACUC
Institutional Animal Care & Use Committee
IBC
Institutional Biosafety Committee
RSC
Radiation Safety Committee

Submissions through IRBNet starting Fall, 2014
• IRB, IACUC, IBC
Institutional Review Board (IRB)

Committee responsible for review of human subjects research
- ALL Federally-supported research and non-exempt research
- Meets monthly

Exempt research (no Federal support) can be reviewed by Human Subjects Review Committees housed within each college

When needed, determinations of need for human subjects approval are made in the Office of Research
Collaborative Work

- All federally-funded and non-exempt human subjects research MUST be reviewed by the ODU IRB
- Expedited reviews can take place if another institution’s IRB has conducted an initial review
Human Subjects Training

• All investigators must document on-line training within the past 12 months from:
  • http://www.citiprogram.org
  • A copy of the certificate must accompany proposal applications to the IRB (and NIH)
• Responsible Conduct of Research Training is also required on certain NSF and NIH projects
• RPIs must ensure training of all personnel
Institutional Animal Care and Use Committee (IACUC)

Committee responsible for review of research and teaching protocols involving live, vertebrate animals

- Meets monthly
- Some protocols also require review by IBC, RSC, and/or Environmental Health & Safety

Animal Welfare Act and PHS Policy guide program

AAALAC (Association for the Assessment & Accreditation of Laboratory Animal Care International) accreditation
Review Process

• There are 9 voting members on the IACUC including the Attending Veterinarian, an ODU EHS staff member, ODU research faculty, Director of Research Compliance and a community member

• Pre-review conducted by subcommittee before review by full board
IACUC Review & Training

- Protocol submission dates on ODU website http://www.odu.edu/research/compliance/animals
- Training requirements (CITI, Occupational Health, etc.)
Institutional Biosafety Committee (IBC)

Committee responsible for review of research and teaching protocols involving:

- recombinant DNA (rDNA) that are considered non-exempt under the NIH “Guidelines for Research Involving Recombinant DNA Molecules.”
- BSL 1 & 2 biological agents (no BSL 3 & 4 at ODU)
- Select agents & toxins

Protocols involving exempt rDNA requires IBC registration at ODU
Institutional Biosafety Committee (IBC)

- 9 member committee; meets as needed
- Every application undergoes full board review
- Similar training requirements (i.e. CITI, Occupational Health)
Radiation Safety Committee (RSC)

Committee responsible for the review of applications for the possession and use of sources of ionizing radiation

- Radioactive materials
- Radiation producing machines
- Establishes the policies and procedures for conduct of the Radiation Protection Program
- Meets quarterly
Radiation Safety Training

- Required for faculty or students who have little or no experience with radioactive materials
- Radiation Safety Officer (RSO) teaches a 6-hour course
- Users are required to pass test
- There is a shorter course for those using radiation producing machines
ODU Research Conflict of Interest Policy

- Provides clarity in definitions for COI issues
- Policy applies to “employees, students, volunteers, employees of affiliated organizations, and visitors to the institution”
- Places enforcement of the policy within the academic unit where the research is conducted
- Establishes *de minimis* threshold of $5000 for disclosure in accordance with Federal regulations
Disclosure

- Key to all parts of this policy
- Disclosure statements are sent to an individual’s department chair, division head, or dean
- Reviewed for existing or potential COIs
  - Additional information may be requested to determine if an impermissible COI exists
- Supervisors shall meet with employees to develop a COI management plan
Export Controls

- Certain equipment and information may be restricted to foreign nationals due to economic or security concerns
- Two sets of regulations that may impact research
  - Export Administration Regulations (EAR)
  - International Traffic in Arms Regulations (ITAR)
- Regulations do not restrict access to US Citizens or Legal Permanent Residents (unless specifically stated by Federal agency)
How do we handle export controls?

- Determination of “fundamental research” applicability
- Determination of applicability of regulations to the research team
- Creation of a Technology Control Plan
Other Compliance Issues

- Controlled Substances
- Bloodborne Pathogens
- Laser Safety
- Hazardous Materials
- Electrical Safety

There are forms online and training is available for each of these topics
Resources

- Office of Research – Research Compliance
  - http://www.odu.edu/researchoffice
- Collaborative Institutional Training Initiative (CITI)
  - http://www.citiprogram.org/

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