Safety Panel Discussion: OARS, DLAM & HRPP

June 12, 2023

Northeastern

Division of Laboratory Animal Medicine (DLAM) & Institutional Animal Care and Use Committee (IACUC)

Common Species Used at NU

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Animal Research Models:

- Cancer
- Drug Development
- Drug Delivery-(Nanoparticles)
- Behavior Studies-drugs, stress, etc.
- Imaging Studies
- Limb regeneration and healing

The Research Team

- The Principal Investigator (PI)- This person submits the research project/protocol to the IACUC and is responsible for their staff (Post-Doc, Grad Students, Under grads, and Staff)
- The Animal Care Staff: Animal technicians, managers, etc.
- Veterinary Staff: The Attending Veterinarian and veterinary technician

DLAM
(Division of Laboratory Animal Medicine)

- DLAM currently provides animal husbandry and care for approximately 3,000 laboratory animals annually including: mice, rats, hamsters, and rabbits..
  - Includes animal husbandry and veterinary care.
- Provides hands on training to research staff on the proper use of animals.
- Provides support to the research enterprise.

The IACUC

- The NU-IACUC oversees the humane and ethical care of laboratory animals, adequacy of animal facilities, animal health, and occupational and student health as related to animal diseases. The IACUC also oversees the use of live fish at the Marine Science Center in Nahant, MA as well as the use of all live aquatic species on the Boston Campus.
- The Committee reviews all proposed protocols and amendments and asks for revisions/clarifications from the investigator/instructor prior to giving full approval. The committee also reserves the right not to approve proposed protocols/amendments.

Composition of IACUC

- Northeastern has 9 voting members plus a few non-voting members.
- Composition is as follows:
  - NU Faculty, Staff, and Research Scientists
  - A Veterinarian
  - A Non-Scientist
  - A Non-Affiliated Member
- The committee has a Chair and a Vice-Chair
- The committee typically meets on a monthly basis.

The Animal Protocol and Animal Hazard Addendum:

- The PI must complete and submit an an animal care and use protocol and submit the form electronically (email) for review and approval by the IACUC.
- Pre-review option: For new PI's and researchers, we suggest that they have their new protocol pre-reviewed.
- Forms can be found at https://research.northeastern.edu/animalcare/
- Completed protocols are to be emailed to iacuc-office@northeastern.edu
- No work with animals may begin until the protocol is fully approved and all personnel working with animals have been properly trained.
- Once approved, to change any procedures in the protocol the PI must submit an amendment and have approved prior to initiation.

The Animal Hazardous Materials Addendum (AHA)

- The AHA must be submitted with any protocol or amendment that uses hazardous materials (Biological, chemical or radiation) with live animals.
- This document outlines the safety procedures that be followed while working with the animals and how the waste and cages will be handled after treatment of the animals.
- This document is shared with OARS, particularly the IBC for their support of the guidelines laid out in the AHA.

Submitting Protocol Approval Letter for a Federal Grant

- To request a congruency letter, the PI is to submit the following:
  - A completed Grant Protocol Congruency Form (on DLAM/IACUC Website)
  - The Animal Section of the grant

DLAM and IACUC Contacts:

- The DLAM/IACUC Administrative Office is located in 012 Mugar
- Sean Sullivan is the DLAM Director. He can be reached at either x3958, x3955, or s.sullivan@northeastern.edu
- Submissions to the IACUC Office should be sent to: iacuc-office@northeastern.edu
- The DLAM/IACUC Administrative Assistant is Erin Credle e.credle@northeastern.edu or x3958
- DLAM/IACUC web page(need to sign in with NU Credentials): https://research.northeastern.edu/animalcare/

Northeastern University
Academic and Research Safety

Research Safety

Environmental Health & Safety (EHS)

Office of Academic and Research Safety (OARS)

Environmental Compliance and Occupational Safety (ECOS)

Why we do what we do.

We understand the personal, political and reputational impacts

- Fatalities
- Injuries
- Careers/Reputations destroyed
- Liability

Ownership of Research Safety at NU

Colleges, Departments, PIs: EVERYONE

How EHS supports PIs and the Colleges to meet compliance, and go beyond.

- Consultation on risk assessments, hazard analysis.
- Oversight of laboratory risk management platform (BioRAFT/SciShield)
- Comprehensive, interactive training programs
- Laboratory safety programs, chemical hygiene guidance, audits, and much more
- Management of hazardous waste vendors
- Oversight of the Institutional Biosafety Committee, and reviews of all biological research protocols
- Management of the Radiation Safety Program

Global EHS Network

Education and Research Safety
Office of the Provost

Marne Smith

Jamie Tessler

PI Onboarding

PI and Lab Recognition/ small grant

Safety Leadership training

Northeastern University
Academic and Research Safety

Office of Academic and Research Safety (OARS)

BOSTON CAMPUS

Meet the OARS Team

Andrea Voehringer

Director

Christopher Bingel

Radiation Safety Officer

Whitney Hess

Assistant Director/Chemical Hygiene Officer

Lorena Altamirano

Biosafety Program Manager, Institutional Biosafety Officer

Peter Schneider

Senior Consultant

Peggy Jiacheng Lei

Learning Design and Systems Support Specialist

Meet the OARS Team

Alex Desimone

Biosafety Specialist II

Collin Burkhard

Laboratory Safety Specialist

May Hulsman

Administrative Assistant

Conor Donovan

Laboratory Safety Specialist

Tiffany Troxell

Administrative Specialist

Laboratory Safety

2022

3,300 Trained in Laboratory Safety

4,500 Researchers

18,000 Different Chemicals

65,000 Chemical Containers on Campus

7,600+ lbs. & 7,300+ gallons of Chemical Hazardous Waste Generated

Radiation Safety
2022

81 Lasers

Boston, Nahant, Burlington

84 Radiation Workers

531 Trained in Radiation

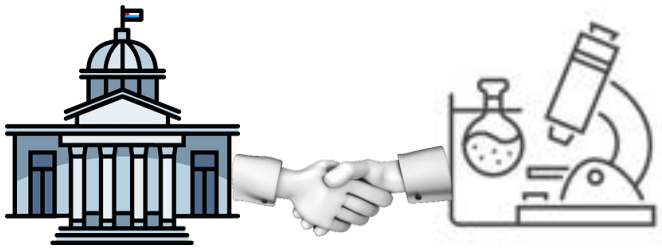
Includes x-ray and laser training

47.3 ft^3 of Radioactive Waste Disposed

Includes amount of waste stored

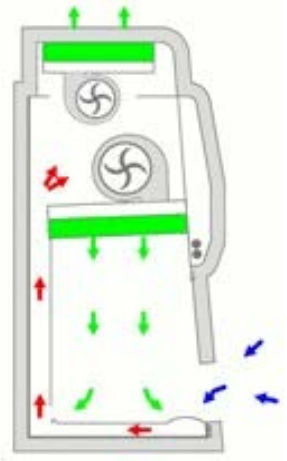
Biological Safety

2022



Work with 11 Government Agencies

137 Laboratories Supported

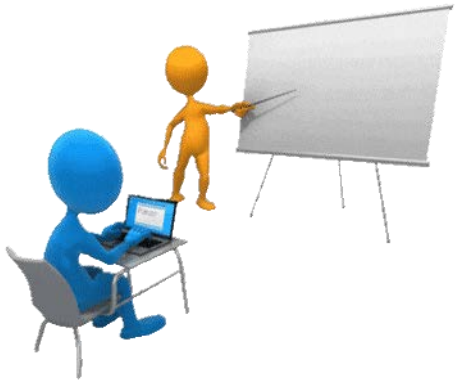


150 Biosafety Cabinets Certified

3,147 Trained in Biosafety

2,474 boxes (76,732 lbs.) of Biological Waste Collected

Learning Design & Training Management



31 Training Courses

Online and In-person

19,000+ Person/Course Interactions per year

Brand new website built

oars.northeastern.edu

Questions?

OARS (director Andrea Voehringer) for Boston.

Marne Smith and our office for Global.

Human Subject Research & NU's IRB Process

Roles & Responsibilities

Institutional Review Board

- Oversees all research that involves and meets the definition of human subjects
- Protect the rights and welfare of human subjects recruited to participate in research activities conducted by Northeastern University
- Responsible for approving and continuingly reviewing all human subject research
- Suspend or terminate research when risks to participants are elevated or in incidences of noncompliance

Human Research Protection Program

- Protect human subjects participating in research
- Promote and facilitate safe, ethical, and compliant human subject research
- Partner with investigators and the research community
- Serve as a conduit between the IRB/IRB members and the research team members
- Point of Contact for participants when questions and concerns arise
- Document management: Approved protocols and attachments; review determinations; correspondence with research team; meeting minutes

Does the activity meet the HHS definition of research?

Yes	No	
☐	☐	a) Is the activity a systematic investigation, including research development, testing, or evaluation?
☐	☐	b) Is the activity designed to develop or contribute to generalizable knowledge?

If YES to both questions, the activity meets the definition of research, please continue

Does the activity meet the HHS definition of human subject?

a) Are the data obtained about living individuals?

b) Are data collected through interaction or interventions with individuals?

c) Is identifiable individual private information being obtained (e.g., chart reviews, info. from data or tissue repositories)?

d) Are data or specimens received by the investigator with identifiable private information?

e) Are the data/specimens coded with a link back to the individual?

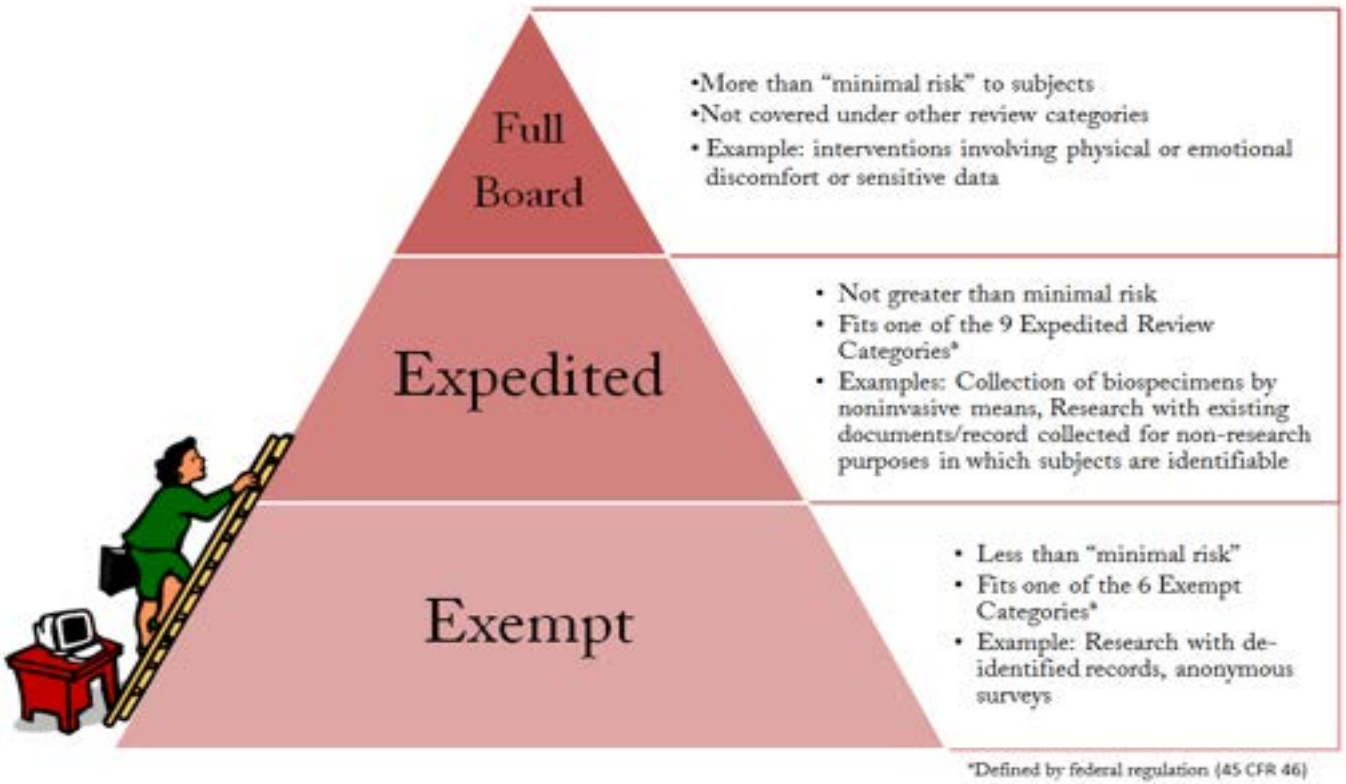
Belmont Report:
45 CFR, part 46

- 1974: Basic regulations established
- 1991: Adopted by 16 federal agencies
- 2018: Revised Common Rule

Applying the Belmont Code

Beneficence	Justice	Respect for Persons
- Obligation to do no harm - Obligation to do good - Evaluate the risk to benefit ratio	- Fairness in recruiting - Burden and benefits shared equally - Considerations to vulnerable populations	- Treat people as autonomous agents with freedom of choice - Protect those with diminished autonomy - Develop mechanisms to obtain informed consent - Respect privacy
✓ Criteria #1: risks to subjects are minimized ✓ Criteria #2Risks to subjects are reasonable in relation to benefits	Criteria #3: equitable selection of subjects	✓ Criteria #4: Informed consent will be sought from prospective subjects ✓ Criteria #5: Informed consent will be appropriately document ✓ Criteria #6: The research plan makes adequate provision for monitoring the data collected ✓ Criteria #7: Adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data

Levels of IRB Review



Investigator Responsibilities

The PI takes ultimate responsibility for the protection and rights and welfare of human subjects, the conduct of the study, and the ethical performance of the project

- Complies with all applicable federal, state, and local laws, policies of any funding agencies and cooperating institutions – including international agencies
- The correct information provided in the IRB application is complete and accurate
- The project will be performed by qualified personnel and completed for everyone engaged in the research
- No changes are implemented prior to IRB approval
- Annual review is sought and approved, when applicable
- Unanticipated incidents are promptly reported to the IRB

Collaborative Research Initiatives

Goal: Reduce the administrative burden with duplicative reviews and manage the complexity of multi-site research

1. Two paths:
(i) SMART IRB
(ii) Northeastern's Intake Reliance Form
2. Determine who should serve as the IRB of Record:
- Where are the majority of activities taking place?
- Do we have the expertise?
- What type of data will our researchers receive and in what form?
3. Authorization Agreement (IAA & IIA)

Note: Authorization agreements are only initiated for non-exempt studies

How we…Partner with our research community

Provide education and training	Assist in applying additional federal, state and university policies:	Develop resources
• New faculty member orientation • Graduate student seminars • Class specific presentations • Brown bags • Host webinars	• FDA, DoD, NIH • DCFS, Mass DOC, local schools • Mandated reporting • Research conducted in other jurisdictions	• Templates Consent forms, participant info • Checklists Research with children, international research, written consent • Guidance Determining HSR, conducting research with employees and students, compensating research participants, reliance agreements, research w/prisoners. Gender inclusivity

Submitting to the IRB & Helpful Tips

- Complete the protocol application form
- Provide all attachments: consent form and scripts, data collection instruments, & recruitment material
- Submit to IRBReview@northeastern.edu
- Reference the designated IRB # when corresponding with the IRB
- Allow for time for the office to process and review the submission
- Retain all study documents as detailed in the approved protocol

Resources

- **Northeastern University human research protection program**
- **CITI on-line training**
- **Office for HRP decision charts**
- **Other guidance from HHS/OHRP**

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