Sponsored Research Compliance Regulations and Requirements

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Learning Objectives

- Before You Begin
- At the point of proposal
- Compliance Committees
- At the point of award

Institutional Biosafety Committee (IBC)

Responsible for the safe use of:

- Recombinant or Synthetic nucleic acids
- Human or NHP blood, cells, tissues, fluids, secretions
- Biological toxins
- Bacteria, virus, fungi, yeast, parasites and prions

In accordance with

& Federal Select Agent Program

All covered materials must be listed on approved lab IBC Registration prior to use

IBC Areas of Concern

Protecting study participants, research staff, community, and environment

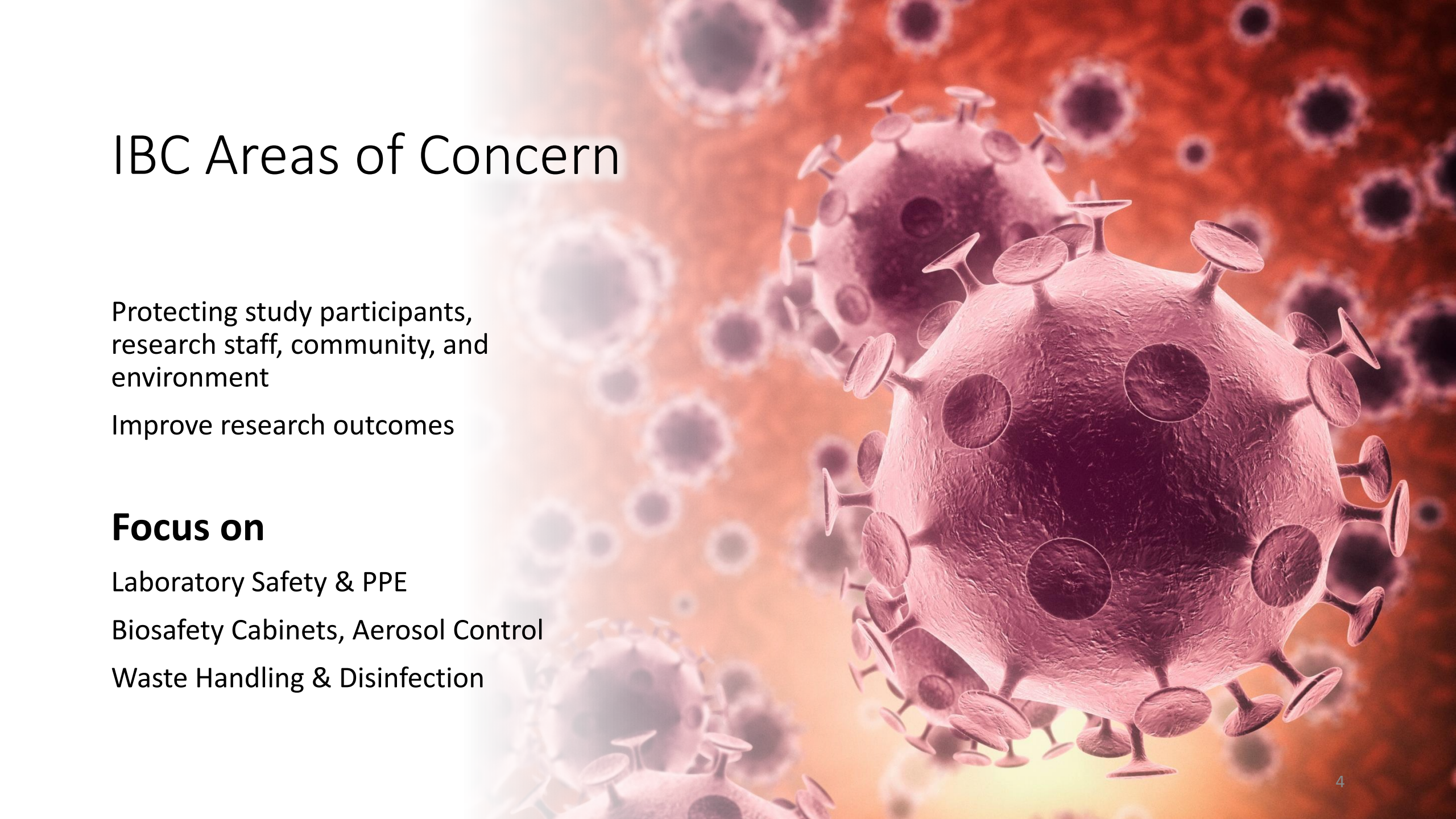
Improve research outcomes

Focus on

Laboratory Safety & PPE

Biosafety Cabinets, Aerosol Control

Waste Handling & Disinfection



Unmanned Aircraft System (UAS) Review Board

Responsible for:

- To review, approve and monitor the use or proposed use of UAS's, also known as unmanned aerial vehicles and drones
- Adhere to university Policy on Use of Drones
- Further information on federal regulations governing use of drones may be found at the FAA's website

IRB: Is it Human Subjects Research?

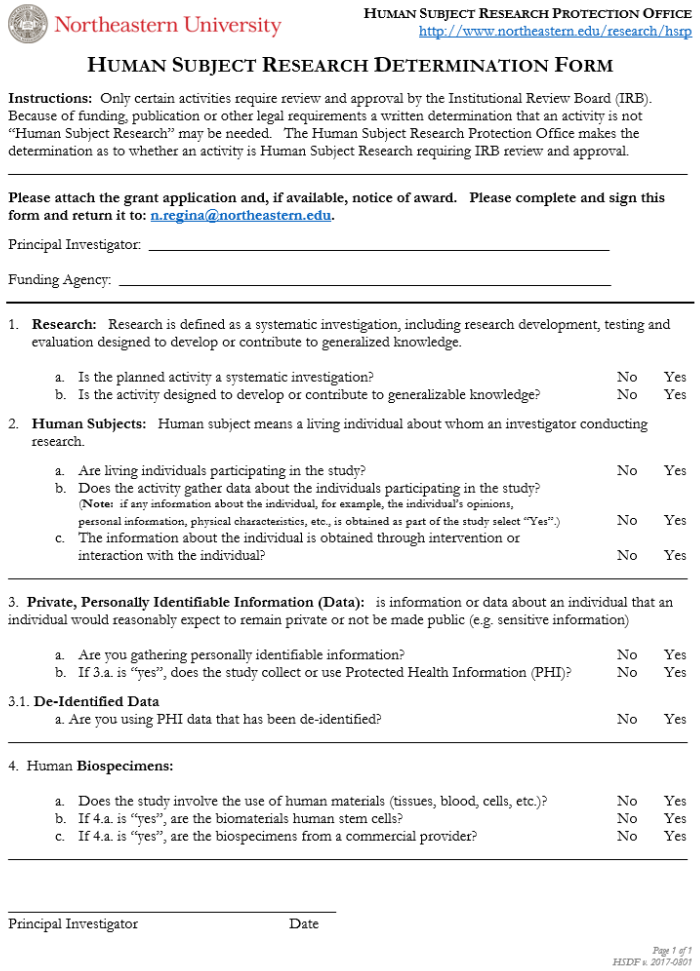
Is it ***Research***?

- Systematic investigation
- Develop or contribute to generalizable knowledge

Does it involve ***Human Subjects***?

- Gather data about living individual participants
- Via intervention or interaction with the individual

Not sure? Use the HSR Determination Form



Northeastern University

HUMAN SUBJECT RESEARCH PROTECTION OFFICE
http://www.northeastern.edu/research/hsrp

HUMAN SUBJECT RESEARCH DETERMINATION FORM

Instructions: Only certain activities require review and approval by the Institutional Review Board (IRB). Because of funding, publication or other legal requirements a written determination that an activity is not "Human Subject Research" may be needed. The Human Subject Research Protection Office makes the determination as to whether an activity is Human Subject Research requiring IRB review and approval.

Please attach the grant application and, if available, notice of award. Please complete and sign this form and return it to: n.regina@northeastern.edu.

Principal Investigator: _____

Funding Agency: _____

1. **Research:** Research is defined as a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalized knowledge.

   a. Is the planned activity a systematic investigation? No Yes
   b. Is the activity designed to develop or contribute to generalizable knowledge? No Yes

2. **Human Subjects:** Human subject means a living individual about whom an investigator conducting research.

   a. Are living individuals participating in the study? No Yes
   b. Does the activity gather data about the individuals participating in the study? (**Note:** if any information about the individual, for example, the individual's opinions, personal information, physical characteristics, etc., is obtained as part of the study select "Yes".) No Yes
   c. The information about the individual is obtained through intervention or interaction with the individual? No Yes

3. **Private, Personally Identifiable Information (Data):** is information or data about an individual that an individual would reasonably expect to remain private or not be made public (e.g. sensitive information)

   a. Are you gathering personally identifiable information? No Yes
   b. If 3.a. is "yes", does the study collect or use Protected Health Information (PHI)? No Yes

3.1. **De-Identified Data**

   a. Are you using PHI data that has been de-identified? No Yes

4. Human **Biospecimens:**

   a. Does the study involve the use of human materials (tissues, blood, cells, etc.)? No Yes
   b. If 4.a. is "yes", are the biomaterials human stem cells? No Yes
   c. If 4.a. is "yes", are the biospecimens from a commercial provider? No Yes

_____
Principal Investigator Date

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IRB Regulations

- 45 CFR 46: Protection of Human Subjects
- Department of Health & Human Services
- Common Rule

Focus On:

- Safety
- Consent
- Privacy

IRB Areas of Concern

Special Participants (Children, People who are pregnant, incarcerated, or cognitively impaired)

Alterations to Consent (Waiver of Consent, Deception, Documentation of Consent)

Drug or Medical Device Studies

Collaborations or Multi-Site Studies

IRB Timeline

At Proposal

- Determine whether IRB approval is needed
- Complete required CITI training
- Begin developing & submitting IRB protocol

At Award

- IRB Approval should be in place
- Continuing review period indicated on Approval Letter
- For multi-year awards, IRB approval of scope may be acceptable

Follow Up with IRB/NU-RES when Human Subjects Research begins

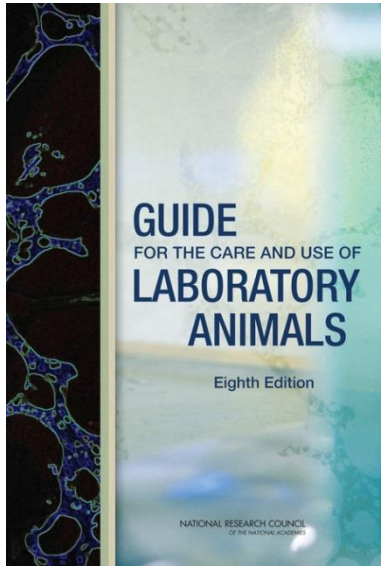
IACUC Regulations

IACUC reviews the use of **live, vertebrate animals** in Testing, Research, and Training.

PHS/OLAW

Regulated by PHS Policy and The Guide

Covers all live, vertebrate animals

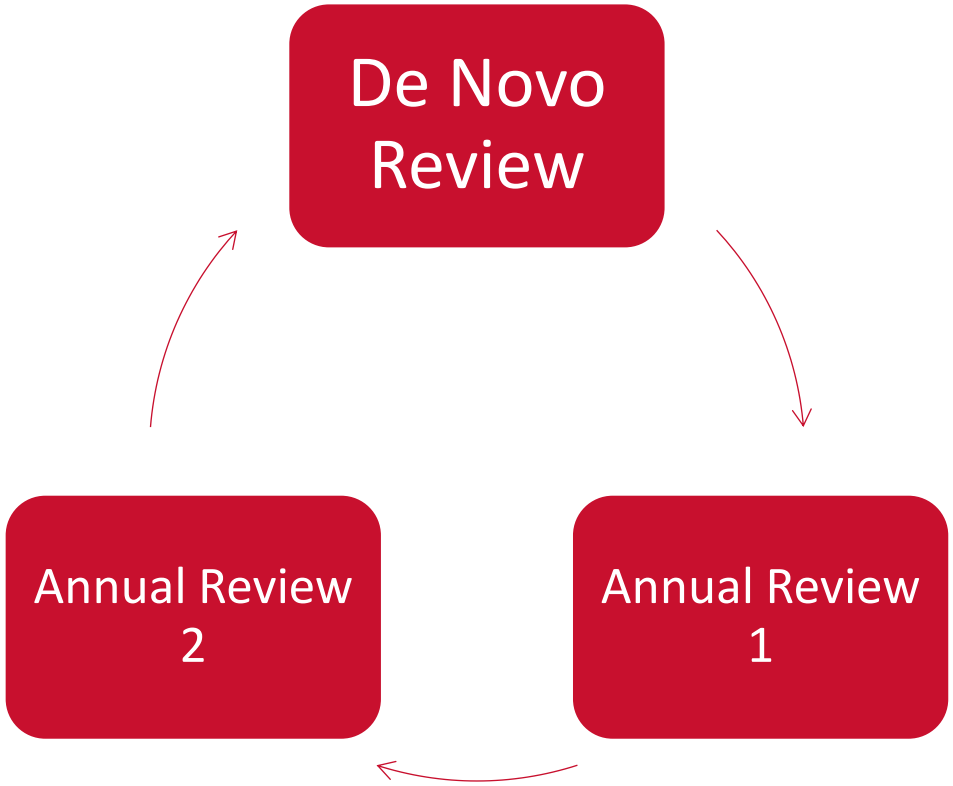


USDA/APHIS

Regulated by the Animal Welfare Act

Covers all warm-blooded animals except for mice, rats, and birds bred for research

IACUC Review Cycle



Submit amendments off-cycle as needed

IACUC Areas of Concern

Use of Modern, Humane Techniques

Justification for animal use procedures & numbers

Management of pain & distress

Use of biohazards, transgenics, and recombinant DNA (in partnership with IBC)

IACUC approval must **always** be secured before work with animals begins.

IACUC Timeline

At Proposal

- Complete required training
- Consult with lab animal vet on procedures and pain/distress management
- Begin developing & submitting IACUC protocol

At Award

- IACUC Congruency Check
- Submit amendment if necessary

IACUC approval must **always** be secured before work with animals begins.

Tips from the RRC

Start early and plan ahead!

If you’re unsure about anything, contact Research Compliance

Keep projects and protocols organized

Contact Information

	How to Submit	Who to Contact
IBC	BioRAFT	biosafety@northeastern.edu
IRB	E-Mail Forms on Website	Nan Regina – n.regina@northeastern.edu Kate Skophammer (CPS) – k.Skophammer@northeastern.edu
IACUC	E-Mail Forms on Website	iacuc-office@northeastern.edu
UAS/Drones	E-mail Forms on Website	UAS Review Board at UASRB@northeastern.edu
Research Compliance		researchcompliance@northeastern.edu

Questions?

Thank You!

LVX
VERITAS
VIRTVS