Office for Responsible Research

- Support for ISU’s four research compliance committees
- Support for investigators, instructors, grant coordinators, administrators
  - Guidance through the process
  - Find ways to conduct proposed research in compliance with the regulations
ISU Research Compliance Committees

- Institutional Review Board (IRB)
- Institutional Biosafety Committee (IBC)
- Radiation Safety Committee (RSC)
- Institutional Animal Care and Use Committee (IACUC)
Basic Compliance Steps

1. Committee approval
2. Approval of modifications or changes
3. Adverse events, spills, or accidents
4. Continuing review/post-approval monitoring
5. Study closure
Purpose:

- Support researchers in their obligations to ensure that the rights, well-being, and safety of human research participants are protected
- Ensure research is conducted in compliance with federal regulations

IRB is guided by federal regulations set forth by the Department of Health and Human Services and the Food and Drug Administration.

Note: Funding agencies may have additional requirements
IRB Approval is required for Research with Human Subjects

- **Research** = systematic investigation…designed to contribute to generalizable knowledge.

- **Human subject** = living individual about whom the researcher obtains…

  Data through **intervention or interaction** with the individual

  AND/OR

  **Private and identifiable information.**

- Decision trees on IRB website

- Online self-test in IRBManager
IRB Review Process basics

- Complete IRB application online in IRBManager
- IRB meets twice monthly on 1\textsuperscript{st} and 3\textsuperscript{rd} Tuesdays; submission deadline is two weeks prior
  - Most research does NOT require review by the convened IRB; no submission deadlines
- Budget 4-6 weeks for IRB review

Note: IRB approval must be obtained BEFORE any human subjects research activities begin
General Tips for IRB submissions

• Extra care in preparation will save you review time!

• Before submission, all personnel must:
  • Complete CITI human subjects protection training
  • Log into IRBManager using ISU credentials
  • Finalize design and logistics before submitting
  • Ensure application is complete and submit final versions of all requested study materials
  • For unusual situations, consult with IRB staff prior to submission
IBC = Institutional Biosafety Committee

Purpose: to review teaching and research projects to provide for the safe conduct of work involving hazardous biological materials

IBC is guided by federal regulations set forth by the National Institute of Health, Office of Science Policy, Office of Biotechnology Activities (OBA) – Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.
IBC approval is needed for:

- Use of recombinant or synthetic nucleic acid molecules, including transgenic animals or plants
- Use of human or animal pathogens
- Use of soil, seed, plants, plant pathogens, or other material received under a USDA APHIS compliance agreement or permit
- Use of biological toxins
IBC approval needed, cont.

- Administration of experimental biological products to animals
- Field releases of plant pests covered under a USDA APHIS Plant Protection and Quarantine (PPQ) permit
- Field releases of genetically modified organisms that are under a USDA APHIS PPQ or Biotechnology Regulatory Services (BRS) permit
IBC process basics

- Complete IBC protocol in *a-tune tick@lab* (a new electronic submission system)
  - The IBC meets once a month on the 2\textsuperscript{nd} Tuesday
  - Submission deadline is seven business days prior to meeting
- Subcommittees of the IBC meet on 1\textsuperscript{st} and 3\textsuperscript{rd} Tuesday for review of non-recombinant or synthetic acid research when enough protocols are submitted
- Plan for 4 weeks to receive IBC approval
General Tips for IBC submissions

• Be sure all questions on the form are completed

• Be sure to include the pertinent section of the NIH Guidelines that best describes the project (Section III - Experiments Covered by the NIH Guidelines)

• Do not use acronyms – full names are required on the IBC applications
General Tips for IBC submissions, cont.

- Include a clear experimental design description
- Include sufficient/complete information in the recombinant DNA section of the form
- Include sufficient information regarding decontamination and disposal methods
- Include sufficient procedures for laboratory safety and experimental procedures
- For projects that also involve animals, a corresponding IACUC application must be submitted
RSC = Radiation Safety Committee

Purpose: to ensure the safe use of radioactive materials and radiation-producing devices and ensure compliance with federal, state, and local regulations

RSC is guided by regulations set forth by the Iowa Administrative Code, ISU's Broad Scope Radioactive Materials License, and the Radiation Safety Manual.
RSC review process at ISU

- Projects that involve animal or human subjects also require IACUC or IRB approval
- Links to forms are found on ORR website
- Submit completed form to the Radiation Safety Officer
- The RSC meets once a semester; protocol review occurs as needed
IACUC = Institutional Animal Care and Use Committee

Purpose: to ensure that the humane care and use of animals in research and teaching and to ensure compliance with guidelines and regulations

IACUC is guided by federal regulations set forth by the United States Department of Agriculture and the Public Health Service – Office for Laboratory Animal Welfare.
IACUC approval is needed for:

Any activities that involve the use of live vertebrate animals in research, testing, or teaching.

Examples:

- research, including field studies and clinical trials
- use of blood donor animals
- breeding colonies
- scheduled courses
- continuing education offerings
One year later, time to submit an annual review!

The cycle of an IACUC Protocol

IACUC Administrator

Vet and member eReview

OR

IACUC Full Committee

DMR

Approved for 1 year

Administrative DMR Committee

Amendments? Submit a Modification application
General Tips for IACUC submissions

- Make sure all questions on the application are complete.
- Double check the animal numbers! Animal numbers need to match across several places in the protocol.
- Provide appropriate justification for animal numbers.
- Include information on the category D or E, including why alternatives are not appropriate for the study.
- Adequately explain the treatment groups.
- Include the criteria for early removal from the study.
- For projects that also involve pathogens, biohazards, etc., a corresponding IBC application must be submitted.
Remember…

• **Wait** until you have committee approval to begin
• Individuals listed on protocols must **complete** training
• You must strictly **adhere** to the approved protocol
• **Seek prior approval** for modifications
• **Report** adverse events/unanticipated problems
• **Report** protocol deviations
• Many protocols require **continuing review**
• Project **closure**
Electronic Protocol Submission

- IACUC and IBC – *a-tune tick@lab system*
- IRB – *IRBManager*
- Both use ISU netID/password to sign in, allow online access to protocols, handle routing online; etc.
  - IACUC and IBC – must request access for first-time use
  - IRB – log in to IRBManager one time to establish as a contact
- IRB – complete or renew human subjects training using the CITI modules
- Training sessions available – check ORR website
IRB – Federal Regulation Changes

- Effective January 21, 2019
  - Some expansion of exemptions
  - New clinical trial requirements
  - New informed consent requirements – strong focus on presentation and organization of consent information
  - Eliminating annual continuing review for some research
- sIRB – effective January 20, 2020
IRB – Training Series

- IRB 101 – Navigating the IRB Submission Process
- IRB Basics Series
  - Does This Project Need IRB Oversight?
  - Protecting Human Subjects
  - The Informed Consent Process
- Each offered once per per semester
- [https://www.compliance.iastate.edu/committees/irb/irb-process-training](https://www.compliance.iastate.edu/committees/irb/irb-process-training)
Contact Information

Office for Responsible Research

- IRB (Human Subjects) – irb@iastate.edu
- IACUC (Animal Subjects) – iacuc@iastate.edu
- IBC (Biohazards) – bphc@iastate.edu
- RSC (Radiation) – Scott Wendt khequ@iastate.edu

Website:  www.compliance.iastate.edu