Office for Responsible Research: An Introduction

Kerry Agnitsch
Assistant Director

November 2017
Office for Responsible Research

- Provide support for the four research compliance committees

- Provide support for investigators, instructors, grant coordinators, administrators
  - Help through the process
  - Find ways to conduct proposed research in compliance with the regulations
  - Answer questions
Compliance committees at ISU

- 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
IRB = Institutional Review Board

Purpose:

• Support researchers in their obligations to ensure that the rights and safety of human participants in research 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
Disclaimer

- Reviewing new regulations
- Update information accordingly
- New regulations effective January 2018 (maybe…currently under additional federal review)
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…

1) data through intervention or interaction with the individual,

   AND/OR

2) private and identifiable information.

“Self-test” to help you decide on IRB website (http://www.compliance.iastate.edu/irb/forms/docs/rih-self-test.docx)
Levels of IRB Review

Exempt –

A special category of IRB review for certain types of research

Expedited or Full-Committee –

All regulatory requirements apply; difference being who completes the review (IRB Chair vs. convened IRB)

Note: IRB approval must be obtained BEFORE any human subjects research activities begin
Exempt Review

- Federal regulatory requirements do not apply
  - Less information is needed for review
  - Quicker review process (budget 2-3 weeks)
- No continuing review required

Researchers still have ethical obligations, such as voluntary consent, confidentiality protections, etc.!
Non-Exempt
(a.k.a. Expedited or Full Committee Review)

- Federal regulatory requirements apply
- Submission of complete and final study materials (i.e. recruitment materials, consent document(s), surveys, etc.) is needed
- Budget 4-6 weeks for the review process
- Expedited research – no submission deadlines; applications reviewed in order received
- Full-committee review – IRB meets on 1\textsuperscript{st} and 3\textsuperscript{rd} Tuesday each month; submission deadline two weeks prior
General Tips for IRB submissions

Taking extra care in preparation will save you review time!

- Finalize design and logistics *before* submitting

- Do not copy/paste or use an old/borrowed form – you will miss something!

- Ensure application is complete and submit final versions of all requested study materials

- For unusual situations, consult with IRB staff prior to submission
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 of synthetic nucleic acid molecules
• 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 toxin
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, found on ORR website
- Submit completed forms by noon the first Tuesday of the month for review at that month’s meeting
  - The IBC meets once a month
- 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
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 also involve the use of 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
The cycle of an IACUC Protocol

Office of the Vice President for Research
General Tips for IACUC submissions

- Make sure all questions on the form are complete
- Double check the animal numbers! Animal numbers need to match across several places in the protocol
- Provide appropriate justification as to why certain animal numbers are needed
- 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
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
- Protocols require **continuing review**
- Project **closure**
Coming Soon…

- Electronic protocol submission!
- IACUC and IBC – *a-tune tick@lab system*
  - Early 2018
- IRB – *IRBManager*
  - January 2018 (we hope)
- Both use ISU netID/password to sign in; allow easy access online to all protocols; online routing; etc.
- Check committee websites for more information about training sessions
- Please close studies that are no longer active
- IRB – renew human subjects training using the CITI modules
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