FIU | Research & Economic Development

Research Compliance: IRB, IACUC, and IBC

Monthly Research Administration Meeting
September 2022

What Do We Do?

The FIU Office of Research Integrity (ORI) – provides assistance in several areas of research compliance:

- Human Subject Protection (IRB)
- Animal Welfare (IACUC)
- Biosafety (IBC)
- Dual Use Research of Concern (IRE)
- Conflicts of Interest in Research (COI-RC)
- Foreign Influence
- Lab Safety Committee (LSC)
- Boating and Diving Safety
- Responsible Conduct of Research (RCR)
- Research Misconduct

Human Subject Research (IRB)

Institutional Review Board (IRB) - committee established to protect rights and welfare of human research subjects.

- Federally mandated for all institutions conducting research with human subjects.
- IRB approval required regardless of whether the study is funded or not.
- Regulated by the Office of Human Research Protection (OHRP).

How Many IRBs Does FIU Use?

IRB #1: FIU Social and Behavioral IRB (SB-IRB)

- Reviews non-medical research protocols

IRB #2: FIU Health Sciences IRB (HS-IRB)

- Reviews medical and health research protocols (except those that meet the WCG IRB review criteria)

IRB #3: WCG IRB (Formerly WIRB)

- Commercial IRB (Central IRB)
- Reviews studies w/ FDA drugs, devices, and biologics

What is an FWA?

Institutions that receive federal funds for research involving human subjects are required to have a Federalwide Assurance (FWA) number.

- FIU's FWA number is 00000060

Each FIU IRB has a registration number:

- HS-IRB: IRB00008168
- SB-IRB: IRB00008169

Steps for Obtaining IRB Approval

- Step 1: Determine if You Need IRB Review
- Step 2: Complete the CITI Online IRB Training Course
- Step 3: Determine the Review Type
- Step 4: Prepare an Informed Consent Document
  - https://research.fiu.edu/irb/informed-consent-information/
- Step 5: Review the Guidelines and Policies
  - https://research.fiu.edu/irb/policies-procedures/
- Step 6: Submit an Application
  - https://topaz.fiu.edu
- Step 7: Application Review Process

What is a Human Subject?

- IRB Approval is required when conducting “research” with “human subjects (regardless of funding).

- A “human subject” is defined as a living individual about whom an investigator (whether professional or student) conducting research:
  - Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
  - Obtains, uses, studies, analyzes, or generates, identifiable private information or identifiable biospecimens

What is a Research?

- Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Complete CITI Online IACUC Training

- All individuals that will be engaged in conducting research with human subjects need to complete the CITI Program online training:
  - "Biomedical Human Research Investigators Course" or
  - "Social & Behavioral Human Research Investigators Course"

What are the Different Types of IRB Review?

- **Exempt Review**
  - Minimal risk research
  - Must fall under a specific exemption number
  - Review process averages 2 weeks
- **Expedited Review**
  - Minimal risk research.
  - Must fall under a specific expedited number
  - Review process averages 3 weeks
- **Full-Board Review**
  - More than minimal risk
  - Not eligible under an Exempt or Expedited category of review
  - Review process takes at least 4 weeks

Application Review Process

- **Pre-Review:** Submission is first pre-evaluated by the IRB Coordinator for completeness. This pre-review will normally take at least 5 business days, but could be longer depending on different factors.
- **IRB Member Review:** After the Pre-Review (and all revisions have been addressed), the protocol will be assigned to a reviewer. This review will normally take at least 5 business days, but could be longer depending on different factors.
- **Full Board Review:** If it is determined that Full Board Review is necessary, the protocol will be placed on a meeting agenda.
- **Final Approval:** Researchers need to wait until they receive an email containing the final approval letter and the stamped consent form(s) before the research can begin.

What if Another Institution will Conduct All of the Research with Human Subjects?

- If the grant proposal involves research with human subjects, then the prime awardee is always considered as “engaged” (regardless if ALL of the research activities with human subjects will be subcontracted to another institution).
- When an institution is “engaged”, then the institution needs to have an FWA and needs to be covered under an IRB approval.
- More information on “engagement” can be found here:
  - https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html

When is an IRB Reliance Required?

- NIH Single IRB (sIRB) Requirements
  - More than one domestic site conducting the same human subject research protocol
  - NIH requires for a sIRB plan to be included in the grant application along with letters of support from participating sites.

- DHHS Single IRB Requirements
  - More than one domestic site conducting human subject research (each site can be doing different activities)

IRB Buzzwords

- Audio Recordings
- Biobank
- Biological Sampling
- Biological Specimens
- Blood Drawing
- Clinical Trial
- Consenting
- Data Analysis
- Data Collection
- Data Repositories
- Drug
- Focus Group
- Human Subjects
- Human Tissues
- Imaging
- Intervention

IRB Buzzwords

- Interview
- Medical Device
- Medical Records
- MRI
- Observations
- Participants
- Placebo
- Radiation
- Randomization
- Recruitment
- Survey
- Video Recordings

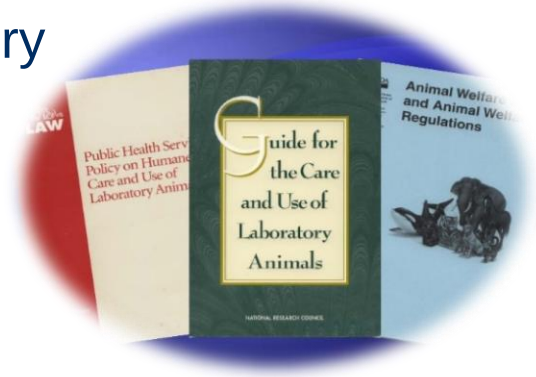
Helpful IRB Links

- Obtaining IRB Approval:
  - https://research.fiu.edu/irb/obtaining-approval/
- IRB Reliance Requirements:
  - http://research.fiu.edu/irb/irb-reliance-requirements
- Single IRB Mandate:
  - http://research.fiu.edu/irb/single-irb

Animal Welfare Protection (IACUC)

Institutional Animal Care and Use Committee (IACUC) is required by Federal law to oversee the humane care and treatment of animals.

- Animal Welfare Act (AWA)
- Office of Laboratory Animal Welfare (OLAW)
- The Guide for the Care and Use of Laboratory Animals, 8th Edition
- AVMA Guidelines
- USDA - Regulated Species
- AAALAC Accreditation * *Not a Regulation* *



Why Have an IACUC?

- Voice for the animals, they cannot consent
- Ensures all animal research, teaching and training is done ethically and humanely
  - Funded/Unfunded
- Enforce the 3 R's:
  - Refine,
  - Reduce, and
  - Replace

IACUC Approval Types

- IACUC Lab: Work conducted in a Lab or Facility.
- IACUC Field: Work conducted out on the Field in the Animals natural habitat.
- IACUC Exemption:
  - Observation in the wild
  - Use of Invertebrates
  - Carcass/Biospecimen (animal is not euthanized for our purpose)

Steps for Obtaining IACUC Approval

- Step 1: Determine if You Need IACUC Review
- Step 2: Complete the CITI Online Training/EHS Risk Assessment
- Step 3: Review the Guidelines and Policies
  - https://research.fiu.edu/iacuc/policies-procedures/
- Step 4: Submit an Application
  - https://topaz.fiu.edu/
- Step 5: Application Review Process

Determine if You Need IACUC Approval

- The FIU IACUC program encompasses all animal use by the University.

- FIU IACUC approval is required for all research, teaching and training that involve animals or animal tissues/carcass.

Complete CITI Online IACUC Training

- All individuals that will be engaged in conducting animal activities need to complete the CITI Program online training:
  - Working with the IACUC – Lab Course; or
  - Working with the IACUC – Field Course

IACUC Application Review Process

- **Admin Review:** Submission is first looked over by the IACUC Coordinator for completeness.
- **Pre-Review:** The IACUC reviews the application and they are given the opportunity to call for a Full Board Review. *(Timeframe: 5 days)*
- **Designated Review:** The protocol will be assigned to a reviewer for their review and approval. *(Timeframe: 5 days)*
- **Full Board Review:** The protocol will be placed on a meeting agenda.
- **Final Approval:** Once you have received an email with your approval memorandum, the activities can begin.

IACUC Buzzwords

- Analgesia
- Anesthesia
- Animal
- Biological Specimens
- Carcass
- Euthanasia
- In Vivo
- Invertebrates
- Manipulation
- Observations
- Sedation
- Surgery
- Vertebrates
- Veterinarian

Biosafety Protection and Research with rDNA/sNA (IBC)

- The Institutional Biosafety Committee (IBC):
  - Oversees research that involves recombinant and/or synthetic nucleic acid molecules to protect the safety of personnel, community and environment
- FIU uses 2 IBCs:
  - Internal (FIU IBC)
  - External (Advarra – Gene Therapy)
- Required Regardless if Exempt from the NIH Guidelines
- Funded/Unfunded

What is Recombinant and Synthetic Nucleic Acid Molecules?

- (i) molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids;
- (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or
- (iii) molecules that result from the replication of those described in (i) or (ii) above

Why Have an IBC?

Why Have an IBC?

- Oversee the production, process and disposal of potentially hazardous materials in conjunction with EH&S

- Enforce Safety Practices
  - Personal Protective Equipment (PPE)
  - Environmental Controls
  - Biosafety Levels (1 – 4)

Laws and Regulations

- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
- Office of Science and Policy (OSP)
- American Biological Safety Association (ABSA)
- Centers for Disease Control and Prevention (CDC) Biosafety Website

IBC Approval Types

- IBC Approval Form: Requires Full Board Review.

- IBC Exemption: IBC Chair Review and if applicable EH&S.

Steps for Obtaining IBC Approval

- Step 1: Determine if You Need IBC Review
- Step 2: Complete the CITI Online IBC Training Course
- Step 3: Review the Guidelines and Policies
  - https://research.fiu.edu/ibc/policies-procedures/
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Do You Need IBC Approval?

- Are you creating any synthetic (>100 bp) or recombinant nucleotides or ligating DNA from two (2) different sources or re-ligating DNA from the same source?
- Are you acquiring genetically modified organisms, transgenic organisms and/or rodents, or plasmids?
- Are you working with synthetic RNA (>100 bp)?
- Are you working with CRISPR technology?

Complete CITI Online IBC Training

- All research personnel that will be engaged in conducting recombinant or synthetic nucleic acid activities need to complete the CITI Program online training:
  - Biosafety & Biosecurity Course

IBC Application Review Process

- **Admin Review:** Application is looked over by IBC Coordinator for completeness.
- **Pre-Review:** The IBC will review and provide comments on the application prior to the Full Board Meeting in order to get clarification and ensure a timely review process. *(Timeframe: 5 days)*
- **Designated Review:** This method is used for exempt protocol applications, renewals and amendments (that do not increase the biosafety level). This review method will take at least 5 business days, unless the protocol requires several revisions, as well as, the current workload of submissions.

IBC Buzzwords

- AAV
- Clone/Cloning
- Competent Cells
- Cosmid
- CRISPR/Cas9
- Drug Resistance Trait
- Electroporation
- Express/Expression
- Foreign Gene
- Fosmid
- Fusion Protein
- Gene Ablation
- Gene Gun
- Genetically Engineered/Modified
- Genome Altered
- Helper Virus
- Knock-out
- Lentivirus

IBC Buzzwords

- Ligation
- Ligase
- miRNA
- Mutagenesis
- Oncogene
- Plasmid
- Promoter
- Protein Expressed
- Reagents
- Recombinant (rDNA)
- Restricted Agents
- Somatic Cells
- Synthetic Nucleic Acid (SNA)
- Targeted Mutant
- Transfect or Transfection
- Transformation
- Transgenic
- Vector

Do Not Hesitate…

- To Ask Questions
- To Raise Concerns
- To Provide Feedback