RESEARCH INTEGRITY

THE ABCs OF IACUC, IBC, IRB, AND MTAs AT UNF

Dawn P. O’Connor
Assistant Director for Research Integrity
RESEARCH INTEGRITY (RI) - ACTIVE ADHERENCE TO ETHICAL PRINCIPLES AND PROFESSIONAL STANDARDS ESSENTIAL FOR THE RESPONSIBLE PRACTICE OF RESEARCH.

ACTIVE ADHERENCE - ADOPTION OF THE PRINCIPLES AND PRACTICES AS A PERSONAL CREDO, NOT SIMPLY ACCEPTING THEM AS IMPOSITIONS BY RULE MAKERS.

ETHICAL PRINCIPLES - HONESTY, THE GOLDEN RULE, TRUSTWORTHINESS, AND HIGH REGARD FOR THE SCIENTIFIC RECORD.

HTTP://ORI.HHS.GOV

THE RI OFFICES ARE LOCATED WITHIN THE OFFICE OF RESEARCH AND SPONSORED PROGRAMS (ORSP)
RI COMMITTEES AND ACTIVITY

IACUC – Institutional Animal Use and Care Committee

IBC - Institutional BioSafety Committee

IRB - Institutional Review Board

MTAs - Material Transfer Agreements
IACUC, WHAT IS IT?

Institutional Animal Care and Use Committee

According to Federal Mandate...

Institutions that use live vertebrate animals in research, teaching, research training, and/or biological testing must establish an Institutional Animal Care and Use Committee (IACUC) to oversee and evaluate all aspects of the institution's animal care and use program.

The IACUC is a self-regulating entity with authority derived from two sources: (1) the Animal Welfare Act (AWA), and (2) the Health Research Extension Act (Public Health Service Act) which is administered through NIH’s Office of Laboratory Animal Welfare (OLAW).
OLAW ASSURANCE FOR IACUC

Office of Lab Animal Welfare, for the protection of animal subjects – via a legally binding assurance, UNF assures we will comply with Federal Regulations because we obtain federal funding.

Assurance A4572-01
Expires: 12/31/2016

Anonymously report possible problems with animal welfare related to teaching and research at UNF via this link: http://www.unf.edu/research/IACUC.aspx
IACUC, WHO IS IT?

Minimum of 5 members
• a veterinarian
• a practicing scientist experienced in animal research
• a person whose primary concerns are in a nonscientific area, and
• one person who is unaffiliated with the institution except as a member of the IACUC (aka a nonaffiliated member)
IACUC MEMBERSHIP 2013-14

• Chairperson, Scientific Member, Biology
• Vice Chairperson, Scientific Member, Biology
• Scientific Member, Biology
• Nonscientist, UNF’s EH&S
• Veterinarian
• Veterinarian
• Veterinarian
• Nonscientist Member
• Nonaffiliated Member (Community Member)
• Ms. Dawn P. O’Connor, Ex Officio
WHAT IS REQUIRED FOR IACUC REVIEW?

Currently, faculty are principal investigators (PIs) on IACUC protocols.

Students work as research assistants (RAs).

Protocol documents for completion can be found on UNF’s IACUC webpage:

http://www.unf.edu/research/IACUC.aspx

Permits may be required; when true, they must be submitted with protocol.

Required training for PIs and RAs via the Collaborative Institutional Training Initiative (CITI) www.citiprogram.org

RAs must be named and training documents included in IACUC protocol paperwork.
IBC, WHAT IS IT?

Institutional Biosafety Committee

This committee is the body of institutional oversight of recombinant DNA (rDNA) research and teaching

"As a condition for NIH funding....institutions shall ensure that research conducted at or sponsored by the institution, irrespective of the source of funding, shall comply with the NIH Guidelines." (Section 1-D)

"The institution must establish and implement policies that provide for the safe conduct of research and ensure compliance with the NIH Guidelines." (Section IV-B-1-a)
ASSURANCE FOR IBC

NIH assurance, when required
  Not applicable to UNF at this time
IBC, WHO IS IT?

• Minimum of 5 members
• Collective experience and expertise in recombinant DNA technology and capability to assess the safety of recombinant DNA research and to identify any potential risk to public health or the environment.
• At least two members shall not be affiliated with the institution - apart from their membership on the Institutional Biosafety Committee - and who represent the interest of the surrounding community with respect to health and protection of the environment (e.g., officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns in the community).
IBC, MEMBERSHIP 2013-14

- Dr. Michael Lentz, Chairperson, Biology
- Mr. Brandon Smith, Vice Chairperson and Biosafety Officer, UNF’s EH&S
- Dr. David Beall, Community Member, FSCJ
- Ms. Jamie Moon, Member, Biology
- Dr. Matthew Myntti, Community Member
- Dr. Jody Nicholson, Member, Psychology
- Dr. Judith Ochrieter, Member, Biology
- Dawn P. O’Connor, Ex Officio
WHAT IS REQUIRED FOR IBC REVIEW?

Currently, faculty are principal investigators (PIs) on IBC protocols

Students work as research assistants

Protocol documents for completion can be found on UNF’s IBC webpage

Internal training mechanism required for all persons working with rDNA (faculty and students) and available through Brandon Smith, IBC Vice Chairperson and UNF’s Biosafety Officer, via this link:

http://www.unf.edu/committee/biosafety/Training_Registration.aspx

IBC application, and forms based on type of biohazardous material to be utilized
BIOSAFETY LEVELS

BSL 1 - Biosafety level one, the lowest level, applies to work with agents that usually pose a minimal potential threat to laboratory workers and the environment and do not consistently cause disease in healthy adults.

BSL 2 - Biosafety level two would cover work with agents associated with human disease, in other words, pathogenic or infectious organisms posing a moderate hazard. Examples are the equine encephalitis viruses and HIV when performing routine diagnostic procedures or work with clinical specimens.

BSL 3 - Work with these agents is strictly controlled and must be registered with all appropriate government agencies. Examples are Yellow fever, St. Louis encephalitis, and West Nile.

BSL 4 - Extremely dangerous and pose a high risk of life-threatening disease. Examples are the Ebola virus, the Lassa virus, and any agent with unknown risks of pathogenicity and transmission.

UNF is equipped for and approved at Biosafety Level (BS) Level 2

- No anthrax teaching or research at UNF, that requires BSL3
IRB, WHAT IS IT?

Institutional Review Board

Is charged with protecting the rights and welfare of people participating in research.

The IRB reviews plans for research involving human subjects.

Institutions that accept research funding from the federal government must have an IRB to review all research involving human subjects (even if a given research project does not involve federal funds).

The Food and Drug Administration and the Office of Protection from Research Risks (part of the National Institutes of Health) set the guidelines and regulations governing human subjects research and IRBs.
FEDERALWIDE ASSURANCE (FWA)

Via our Federalwide Assurance for the Protection of Human Subjects UNF assures we will comply with Federal Regulations related to all human subject research because we obtain federal funding for some research and sponsored programs.

FWA #: FWA00000737
Institution: University of North Florida
Expires: 07/18/2016
IRB, WHO IS IT?

The IRB must have at least 5 diverse members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.

- one member whose primary concerns are in scientific areas, and
- at least one member whose primary concerns are non-scientific
- include a person knowledgeable in institutional commitments and regulations, applicable law, and standards of professional conduct and practice
- include a least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution
- the IRB shall consider the type of community from which the institution will draw its research subjects. A representative from that type of community, including minorities shall be considered in the IRB membership
IRB MEMBERSHIP 2014-15

- Dr. Jennifer Wesely, Chairperson
  - Criminology and Criminal Justice
- Dr. Stephen Ames, Community Member
  - Mayo Clinic
- Dr. Kathaleen Bloom, Member
  - Nursing
- Mr. Rick Buck, Esq., Non-Scientific Member
  - General Counsel’s Office
- Dr. Brian Fisak, Member
  - Psychology
- Dr. Catherine Hough, Member
  - Nursing
- Dr. Krista Paulsen,
  - Sociology & Anthropology
- Dr. Susan Perez, Vice Chairperson
  - Psychology
- Dr. Janice Seabrooks – Blackmore, Member
  - Exceptional and Deaf Education
- Dr. Brenda Vose, Prisoner Rep.
  - Criminology and Criminal Justice
- Mr. Ray Wikstrom, Member, Non-Scientific Member
  - Military Veterans Resource Center
- Ms. Dawn P. O’Connor, Ex officio
Faculty, staff, doctoral and master’s thesis students can be principal investigators (PIs) on IRB protocols

Students working on doctoral or master’s projects can be CO-Is

Undergrads can be research assistants (RAs)

Required training via Collaborative Institutional Training Initiative (CITI)

www.citiprogram.org (Group 1 Biomedical Research Investigators and Key Personnel or Group 2 Social Behavioral Researcher Investigators and Key Personnel)

CITI is required for anyone intervening or interacting with participants (including electronic surveying) or who have access to identifiable information
MTA, WHAT IS IT?

Materials Transfer Agreement is an agreement between provider institution and receiving institution.

Via an MTA institutions outline what material will be shipped, to and from whom, and also what is allowable with the outcomes (e.g., whether results can be used in publications). Thus, an MTA is the mechanism used to protect institutions’ and researchers’ rights.

MTA are usually generated by the provider institution

UNF subscribes to PHS/CDC UBMTA

(Uniform Biological Materials Transfer Agreement)
MTA, WHAT IS REQUIRED?

UBMTA implementing letter, or
UNF’s MTA agreement

These documents can be requested by calling ORPS 620.2455

*Some material must be approved and/or monitored by UNF’s Environmental Health and Safety (EH&S) Office
Q & A

Ask me about:

- Information I presented
- Other research-related questions, specifically compliance
- Concerns or myths I can dispel
REFERENCES

http://iacuc.ou.edu/whatisiacuc.asp
http://www.autm.net/AM/Template.cfm?Section=Technology_Transfer_Resources&Template=/CM/ContentDisplay.cfm&ContentID=2810
http://www.nhhn.org/body.cfm?id=2774
http://www.unmc.edu/ibc/index.cfm?CONREF=3
YOUR RESEARCH INTEGRITY ADMIN TEAM

The Office of Research and Sponsored Programs
http://www.unf.edu/research/ committee title
IACUC, IBC, or IRB

email: IACUC@unf.edu
IBC@unf.edu
IRB@unf.edu

Kayla Champaigne
Coordinator for Research Integrity
Building 3, Suite 2511
904.620.2312
K.Champaigne@unf.edu

Kayla is UNF’s content expert for IRBNet

Dawn P. O’Connor
Assistant Director for Research Integrity
Building 3, Suite 2512
904.620.2316
Dawn.OConnor@unf.edu

Ms. Eva Espique-Bueno
Research Integrity Assistant