CPI Executive Committee Meeting
April 2, 2014, 11:30 a.m. – 1:15 p.m.
Donald L. Houston Building (West Campus) 200 Discovery Drive, Room 124

Expected attendees:

CPI Executive Committee attending (College/Unit):
- Niall Slowey, Chair (Geosciences)
- Mary Bryk, Vice Chair (COALS)
- Reza Langari, Past Chair (Engineering)
- Wolfgang Bangerth (Science)
- Mary Meagher (Liberal Arts)
- Lawrence Rauchwerger (Engineering)
- Eva Shipp (Rural Public Health)
- Lori Taylor (Bush School)
- Terry Thomas (Science)
- Victor Ugaz (Engineering)

Invited Guests attending (Unit):
- Brittany Bounds (Graduate Student Council)
- David Carlson (Texas A&M Health Science Center)
- Ralph Davila (Contract Administration)
- Costas Georghiades (Texas A&M Engineering Experiment Station)
- Glen Laine (Texas A&M University)
- Chris Lyons (Graduate Student Council)
- Craig Nessler (Texas A&M AgriLife Research)
- Katherine Rojo del Busto (Texas A&M University)
- J. Martin Scholtz (Texas A&M University)
April 2, 2014 Agenda
(11:30 – 1:15 p.m.)

CPI Executive Committee with guests (Moderated by Dr. Niall Slowey, CPI Chair)

(11:40 – 11:50) Discussion of DRAFT “Graduate and Professional Student Bill of Rights and Responsibilities” – Ms. Brittany Bounds, President, Graduate Student Council

(11:50 – 12:00) Updates on Research Compliance – Ms. Katherine Rojo del Busto, Associate Vice President for Research, Research Compliance Officer

(12:00 – 12:20) Research Compliance Committees – Dr. Glen A. Laine, Vice President for Research

(12:20 – 12:40) Follow up from EC meeting with Regents – Dr. Niall Slowey

(12:40 – 12:50) Update on deliverables from SSC/Compass contracts – Mr. Ralph Davila, Executive Director for Contract Administration, Texas A&M University

(12:50 – 1:00) Finalize April 9th meeting agenda – Dr. Niall Slowey
  - Findings from the 2013 Climate Survey and the ADVANCE Faculty Retention Studies – Dr. Lori Taylor
  - Update on SSC/Compass contracts – Mr. Ralph Davila

(1:00 – 1:15) Other business – Dr. Niall Slowey
  - Agenda items needed for April 16th CPI EC meeting with interim President and Provost
  - Other monthly meeting agenda items?

(1:15) Adjourn

Attachments

1) DRAFT: Graduate and Professional Student Bill of Rights and Responsibilities (provided at meeting)
2) Attachments: Draft of new System Regulation – Use of Biohazards in Research
3) Draft of new System Regulation – Use of Animals in Research
4) Scan of a PowerPoint presentation on research compliance training
5) EHS Procedures on Un-Manned Aerial Vehicles (UAVs, Drones)

The CPI is sponsored annually through funding from Texas A&M University Division of Research, Texas A&M Health Science Center, Texas A&M AgriLife Research, Texas A&M Engineering Experiment Station, and the Texas A&M Transportation Institute
Regulation # XX Use of Biohazards in Research

Approved XX XX, 20XX
Revised XX XX, 20XX
Next Scheduled Review: XX XX, 20XX

Regulation Statement

The Texas A&M University System is committed to protecting faculty, staff, students, visitors, the general public and the environment from the risk of potential exposure to biohazardous materials, and to ensuring that all activities involving biohazardous materials and the facilities used to conduct such work are in compliance with applicable federal and state laws, regulations and guidelines.

Reason for Regulation

This regulation provides guidance in complying with federal and state laws, regulations, and guidelines relating to research with biohazardous including, but not limited to infectious agents, biological toxins, select agents, recombinant and synthetic nucleic acid molecules and cells, organisms, and viruses containing such molecules.

Procedures and Responsibilities

1. BIOHAZARDOUS MATERIAL

1.1 Material containing or potentially containing:
   1.1.1 Biological agents (bacteria, rickettsia, fungi, viruses, protozoa, parasites and prions) that may cause disease in humans, animals, or plants;
   1.1.2 Recombinant or Synthetic Nucleic Acid Molecules as defined in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines);
   1.1.3 Human and non-human primate blood, tissue, cells and cell lines;
   1.1.4 Toxins of biological origin as defined in the Biosafety in Microbiological and Biomedical Laboratories (BMBL) document.

1.2 Recombinant and Synthetic Nucleic Acid Molecules - In the context of the NIH Guidelines, recombinant and synthetic nucleic acids are defined as:
1.2.1 Molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids;

1.2.2 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

1.2.3 Molecules that result from the replication of those described in (i) or (ii) above.

2. ADMINISTRATIVE REQUIREMENTS

2.1 Each member involved with research, teaching, or testing utilizing biohazardous material shall establish a rule for carrying out this regulation.

2.2 Procedures for use and storage of biohazardous material shall be consistent regardless of sources of funding.

2.3 The chief executive officer or designee of each member that conducts research with biohazards shall develop an Institutional Biological Safety Committee (IBC) or enter into a Memorandum of Understanding with another member with a registered IBC. Each IBC shall meet the requirements set out in the NIH Guidelines and register with the Office of Biotechnology Activities (OBA) of the National Institutes of Health (NIH), U.S. Department of Health and Human Services.

2.4 Each member that conducts research with biohazards shall develop written IBC procedures, including procedures relating to the review of biohazard protocols and reporting guidelines. Biohazard protocols shall be reviewed and approved in a manner consistent with the NIH Guidelines before the initiation of the research project.

3. GENERAL GUIDELINES

3.1 All faculty, staff and students must be aware of and are responsible for the safe and compliant use, storage, and disposal of biohazards used in research. Prior approval must be obtained for possession or use of biohazards.

3.2 Principal investigators (PIs) and department heads (or equivalent) are responsible for ensuring that all research involving biohazards (including protocols which may be exempt, as defined in the NIH Guidelines) is submitted to the member’s respective IBC for review and approval.

3.3 PIs shall submit continuing reviews to their respective IBCs, as directed by the IBC, but not less than annually.

3.4 Research involving biohazards must meet the criteria articulated in the most current versions of the following federal or state documents, requirements, and laws:
3.4.1 NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines);

3.4.2 The Public Health Service/Centers for Disease Control and Prevention/National Institutes of Health’s Biosafety in Microbiological and Biomedical Laboratories (BMBL);

3.4.3 Select Agents Regulations (42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121);

3.4.4 U.S. Department of Agriculture (USDA) regulations and permits as applicable;

3.4.5 Centers for Disease Control and Prevention’s (CDC) Etiologic Agent Import Permit Program (EAIPP) import permit requirements;

3.4.6 State of Texas Health and Safety Code Sections 81.301 – 81.306

Related Statutes, Policies or Requirements


Biosafety in Microbiological and Biomedical Laboratories (BMBL) http://www.cdc.gov/biosafety/publications/bmbl5/index.htm

System Regulation: 15.99.05 Research Compliance http://policies.tamus.edu/15-99-05.pdf

System Policy 24.01: Risk Management http://policies.tamus.edu/24-01.pdf

System Regulation 24.01.01: Supplemental Risk Management Standards http://policies.tamus.edu/24-01-01.pdf

Member Rule Requirements

A rule is required to supplement this regulation. See Section 2.1.
Contact Office

System Office of Research
(979) 458-6000
Regulation Statement

The Texas A&M University System is committed to the humane and ethical treatment of animals used in research, teaching and testing.

Reason for Regulation

This regulation provides guidance in complying with federal and state laws, regulations, and guidelines relating to the humane and ethical use of animals in research, teaching and testing.

Procedures and Responsibilities

1. ADMINISTRATIVE REQUIREMENTS

   1.1 Each member involved with the use of animals in research, teaching, or testing shall establish a rule for carrying out this regulation.

   1.2 All animals used in research, teaching, or testing regardless of the funding sources, shall be provided humane care and treatment.

   1.3 Each member must obtain USDA registration or license if required by the Animal Welfare Act.

   1.4 Each member must obtain a Public Health Service (PHS) Animal Welfare Assurance (Assurance) from the National Institutes of Health (NIH) Office of Laboratory Animal Welfare (OLAW) prior to performing any activity supported by PHS involving animals.

   1.5 The chief executive officer or designee of each member that conducts research with animals shall develop an Institutional Animal Use and Care Committee (IACUC) or enter into a Memorandum of Understanding with another member with an IACUC.

   1.6 The Guide for the Care and Use of Laboratory Animals must be followed when conducting research, teaching or testing activities involving non-agricultural animals.
1.7 The Guide for the Care and Use of Agricultural Animals in Research and Teaching must be followed when conducting research, teaching or testing activities involving food and fiber production in agricultural animals.

1.8 The use of vertebrate animals within each member, whether for research, teaching or testing purposes, shall be described in an Animal Use Protocol (AUP). The AUP is a form designed to capture relevant information regarding the appropriate use of the animals in research, teaching or testing activities.

1.9 For each project involving animals used in research, teaching, or testing, an AUP must be approved by the IACUC.

1.10 An approved and current AUP for all animal activities must be in place at all times animals are housed or used for research, testing or teaching.

1.11 All modifications to approved animal activities must be approved prior to initiation of the changes.

2. INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

2.1 The IACUC of institutions with an USDA registration shall be appointed, structured, and shall perform duties and functions as described in the Animal Welfare Act.

2.2 The IACUC of institutions with a PHA Assurance shall be appointed, structured, and shall perform duties and functions as described in the document "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."

2.3 The IACUC of institutions not required to obtain USDA registration and/or a PHS Assurance shall be appointed, structured, and shall perform duties and functions, with the exception of those activities involving reporting to the USDA, as described in the Animal Welfare Act.

3. USE OF ANIMALS IN AGRICULTURAL RESEARCH, TEACHING OR TESTING

3.1 Use of animals in agricultural research, teaching or testing is overseen by the IACUC. Agricultural research, teaching or testing is defined as research, teaching or testing activities involving horses, and other farm animals, not limited to livestock or poultry, used or intended for use as food or fiber, or used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber.

3.2 The Guide for the Care and Use of Agricultural Animals in Research and Teaching must be followed when conducting research, teaching or testing activities involving food and fiber production in agricultural animals.

3.3 When agricultural animals are involved in biomedical research, animal use and compliance must adhere to additional applicable federal guidelines.
4. ATTENDING VETERINARIAN

4.1 The Attending Veterinarian(s), or designee(s), shall provide guidance to the campus animal facility managers, animal users, and administrators on current standards for the care and use of animals in teaching, testing and research programs, and shall serve as the Attending Veterinarian of record under the Federal Animal Welfare Act.

4.2 The Attending Veterinarian(s) has direct or delegated authority for activities involving animals at the institution, serves as a voting member of the Institutional Animal Care and Use Committees (IACUC) and coordinates campus programs for provision of adequate husbandry and veterinary care of research, testing and teaching animals.

5. CARE AND USE OF NON-SYSTEM MEMBER OWNED ANIMALS

5.1 Non-System member owned vertebrate animals may not be used by a member’s faculty, students, or staff without prior approval of their IACUC. In addition to on-campus activity, this compliance requirement includes, but is not limited to, animal teaching, testing, and research conducted:
  5.1.1 In the field by faculty, students, or staff;
  5.1.2 By graduate students at other institutions as part of the completion of a degree;
  5.1.3 At another institution as part of a joint contract;
  5.1.4 Off-campus activities involving an undergraduate student as part of completion of a member’s undergraduate course;
  5.1.5 In the teaching of undergraduate and graduate courses;
  5.1.6 By graduate veterinarians for Continuing Education; and
  5.1.7 With client-owned animals participating in clinical research studies.

Related Statutes, Policies or Requirements (Required)


Public Health Service Policy on Humane Care and Use of Laboratory Animals (National Institutes of Health)

Health Research Extension Act of 1985

U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training

The Guide for the Care and Use of Laboratory Animals
Definitions (Optional)

**Animal**- Any live vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes.

**Animal Care and Use Program**- The activities conducted by and at an institution that have a direct impact on the well-being of animals, including animal and veterinary care, policies and procedures, personnel and program management and oversight, occupational health and safety, IACUC functions, and animal facility design and management.

**Animal Facility**- Any and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities, used for confinement, transport, maintenance, breeding, or experiments including surgical manipulation.


**Attending Veterinarian**- The veterinarian responsible for the health and well-being of all laboratory animals used at the institution.

**Institutional Official (IO)** - The individual who bears ultimate responsibility for the Animal Welfare Assurance Program and is responsible for resource planning and ensuring alignment of Program goals with the university’s mission.

**Institutional Animal Care and Use Committee (IACUC)**- An administrative body appointed by and reporting to the Vice President for Research in accordance with 9 CFR Chapter 1, Subchapter C, Part 2.31, P.L. 99-158, and the Health Research Extension Act of 1985. There may be more than one IACUC appointed by the Institutional Official.

**Public Health Service Policy**- Refers to Public Health Service Policy for the Humane Care and Use of Laboratory Animals (“PHS Policy”) which requires institutions to establish and maintain proper measures to ensure the appropriate care and use of all animals involved in research, research training, and biological testing activities conducted and supported by the Public Health Service.

**Use of animals**- Any activity involving vertebrate animals in which the natural life style or movements of the animals is perturbed. Use of animal carcasses, tissues and fluids obtained specifically for research, testing, or teaching purposes is also considered use of animals and is subject to review according to applicable regulations.
Member Rule Requirements

A rule is required to supplement this regulation. See Section 2.1.

Contact Office

System Office of Research
(979) 458-6000
Research Compliance Requirements

Principal Investigator Responsibility

It is the responsibility of the Principal Investigators (PIs) to carry out their research in compliance with all federal, state, and university requirements.

Committee Reviewed Research

Does your proposed research involve:
- Human Subjects?
- Animal Subjects?
- Biological Hazards?

If so, you will need approval prior to initiation of your research.
Humane Care and Use of Animals

All Research Involving Vertebrate Animals Must Have Approval Prior To Start Of Work

Humane Care and Use of Animals Scope:

- All research, teaching and testing utilizing living vertebrate animals requires review and approval prior to initiation. Includes activities that
  - is conducted by System member personnel in the course of their employment by the System member or
  - uses System member facilities or resources.
Humane Care and Use of Animals
Scope
- The use of animals is defined as any activity involving vertebrate animals in which the natural lifestyle or movements of the animals is materially altered
  - Includes agriculture use.
  - Includes wildlife research.

Human Care and Use of Animals
Review and Approval
- The Institutional Animal Care and Use Committee (IACUC) reviews animal use protocols and approves projects as appropriate.

Human Care and Use of Animals
Contact Information
- A link to your institution’s Animal Care and Use Program as well as additional information regarding the use of animals in research can be found at the link below:
  http://www.iamsu.edu/offices/researchcompliance/animal/
Human Subjects Research

All Research Involving Human Subjects Must Have Approval Prior To Start Of Work

Protection of Human Subjects Scope:

Any activity that involves research with human subjects that:

- is conducted by System member personnel in the course of their employment by the System member or
- uses System member facilities or resources.
Protection of Human Subjects
Scope – CFR 46.102 Definitions

**Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

---

**Human subject** means a living individual about whom an investigator (whether professional or student) conducting research obtains:

- Data through intervention or interaction with the individual, or

- Identifiable private information.

---

Protection of Human Subjects
Review and Approval

- The Institutional Review Board (IRB) reviews research involving human subjects and approves projects as appropriate.
- Research with human subjects classified as "Exempt", while exempt from federal regulations, must still be reviewed and approved at the System member level.
Protection of Human Subjects / IRB Contact Information

- A link to your institution's Human Subjects' Protection Program / IRB as well as additional information regarding the use of human subject research can be found at the link below:

  http://www.tamus.edu/offices/researchcompliance/human/
Use of Biohazards in Research

The Texas A&M University System is committed to protecting faculty, staff, students, visitors, the general public and the environment from the risk of potential exposure to biohazardous materials, and to ensuring that all activities involving biohazardous materials and the facilities used to conduct such work are in compliance with applicable federal and state laws, regulations and guidelines.

Use of Biohazards in Research
Scope

Any activity that involves biohazardous material.

- is conducted by System member personnel in the course of their employment by the System member or
- uses System member facilities or resources.

Use of Biohazards in Research
Definitions

Biohazardous material is material containing or potentially containing:

- Biological agents (bacteria, rickettsia, fungi, viruses, protozoa, parasites and prions) that may cause disease in humans, animals, or plants;

- Recombinant or Synthetic Nucleic Acid Molecules as defined in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines);
Use of Biohazards in Research
Definitions

**Biohazardous material** is material containing or potentially containing (cont):

- Human and non-human primate blood, tissue, cells and cell lines;
- Toxins of biological origin as defined in the Biosafety in Microbiological and Biomedical Laboratories (BMBL) document.

Use of Biohazards in Research
Definitions

**Biohazardous material** is material containing or potentially containing (cont):

- Transgenic plants and animals (Genetically Modified Organisms (GMOs))

Use of Biohazards in Research
Review and Approval

- The Institutional Biosafety Committee (IBC) reviews research involving biohazards and approves projects as appropriate.
- Research with biohazards classified as “Exempt” by the NIH, while exempt from federal regulations, must still be reviewed and approved at the System member level.
Research with Biohazards / IBC Contact Information

- A link to your institution's Biosafety Program / IBC as well as additional information regarding the use of biohazards in research can be found at the link below:

  http://www.tamu.edu/offices/researchcompliance/biosafety/

Other Research Compliance Issues

- Other Research compliance areas include:
  - Export Controls
  - Financial conflicts of interest
  - Use of controlled substances

Other Research Compliance Issues Contact Information

- The webpage at the link below provides contact information for each System member's research compliance program.

  http://www.tamu.edu/offices/researchcompliance/rcp/
EHS Procedures on Un-Manned Aerial Vehicles (UAVs, Drones)

Introduction

Un-manned Aerial Vehicles (UAVs) or Drones are a subject of Texas A&M research and testing programs, are often desired for use in special photography, and can serve a variety other possible functions. Operation of such UAVs outside of a controlled laboratory environment should normally be conducted in areas that are appropriate for such operations, e.g., low population density areas such as Riverside Campus runways. Safety and security considerations must be examined and risk mitigated in all such operations, regardless of location.

Safety and Security Considerations

1. Research, development or testing of UAVs or Drones - Experimental designs for UAVs or their control systems, testing of new or different payloads or onboard equipment, and similar research and development efforts should not be conducted overhead of persons or occupied building or vehicles.

2. UAV operations for the purpose of photography must be reviewed and approved by Marketing and Communications and the Audio Video Surveillance (AVST) Committee for the purpose of protection of privacy in images, protection of university marks and branding, and privacy and proprietary rights of images.

3. UAVs have altitude restrictions to ensure that risks of conflict with air traffic are minimized or eliminated. Coordination with Easterwood Airport, flight operations at Riverside Campus and/or the Easterwood Control Tower (FAA) are necessary.

Risk Assessment and Approvals

1. A safety plan should be completed for every UAV flight program that is to be conducted outside of the laboratory. Flight programs conducted under the auspices of the Engineering Program should submit a completed Project Safety Analysis (PSA) to the Engineering Safety Officer.

2. Completed PSAs or other safety plans for programs not under the Engineering Program (including commercial firms that wish to operate a UAV on or over TAMU property should be routed to the TAMU Environmental Health and Safety Department for review and approval. PSAs or safety plans should be submitted at least 30 days prior to proposed commencement of flight programs.

3. EHS reviews should include routing the PSA or other documentation to other appropriate entities on campus and in the community for review and comment.

4. Applicants for UAV operations must be notified in writing of approval or disapproval, reasons for disapproval, and any limitations on operations that are deemed advisable by EHS.