Research Compliance Requirements

Office of Research Compliance, The Texas A&M University System
http://www.tamus.edu/research/research-compliance/
Principal Investigator Responsibility

It is the responsibility of Principal Investigators (or faculty advisors if research is conducted by students) 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 from one or more committees prior to initiation (or modification) of your research.
Humane Care and Use of Animals
All Research, Teaching and Testing 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, including activities that

- are conducted by System member personnel in the course of their employment by the System member, or
- use 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, including:

- Agriculture use
- Wildlife research
- Harvesting of animal carcasses or tissues specifically for research, teaching or testing.
Humane 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.
Humane 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.tamus.edu/research/research-compliance/animal-care-and-use/
Human Subjects Research
All Research Involving Human Subjects Must Have Approval Prior to Start of Work
Human Subjects Research

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
Human Subjects Research

*Research* means a **systematic investigation**, including research development, testing and evaluation, designed to develop or contribute to **generalizable knowledge** *(45 CFR 46.102).*
Human Subjects Research

**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.

*(45 CFR 46.102)*
Human Subjects Research

Examples of activities that *may* be human subject research:

- Surveys and Interviews
- Taking blood from living individuals for research
- The use of specimens or data from a repository or database
- Program evaluation, program assessment or demonstration project conducted for research
- Pilot studies, preliminary studies, or other preliminary research with human subjects
- Classroom research
- Observing or recording private behavior
- Obtaining private identifiable information that has been collected about or provided by individuals
If you are not clear what activities are, or are not, considered human subjects research, you should obtain guidance from your institution’s research compliance office.

http://www.tamus.edu/research/research-compliance/human-subjects/
Human Subjects Research

Review and Approval

The Institutional Review Board (IRB) reviews research involving human subjects and approves projects as appropriate.
Human Subjects Research

**Review and Approval**

Research with human subjects classified as “Exempt”—while exempt from federal regulations—must be reviewed and determined by the IRB to be exempt prior to start of work.
Human Subjects Research

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/research/research-compliance/human-subjects/
Use of Biohazards in Research, Teaching and Testing
All Research, Teaching and Testing Involving Biohazards Must Have Approval Prior to Start of Work
Use of Biohazards in Research

**Scope**

Any activity involving *biohazardous material* that:

- is conducted by System member personnel in the course of their employment by the System member or
- uses System member facilities or resources.
Biohazardous material is material containing or reasonably expected to contain:

- 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

**Biohazardous material** is material containing or reasonably expected to contain (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;
- Transgenic plants and animals or genetically modified organisms (GMOs) that lack federal approval for release.
Use of Biohazards in Research

Some examples of biohazardous materials:

- Human cancer cell lines
- Blood samples from students
- Samples from municipal waste treatment plant
- Transgenic corn not approved for release
- Transgenic fruit flies
- *E. coli* or other bacteria included in gene cloning kits
- Infectious agents isolated from plants or animals in nature.
Use of Biohazards in Research

Review and Approval

- The Institutional Biosafety Committee (IBC) reviews activities involving biohazards and approves projects as appropriate.

- Activities with biohazards classified as “Exempt” by the NIH, while exempt from federal regulations, must still be reviewed and approved at the System member level.
Use of Biohazards in Research

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.tamus.edu/research/research-compliance/biosafety/
Other Research Compliance Issues
Other Research Compliance Issue

Certain other activities may require non-committee review and approval prior to initiation (or modification) of your research.

- If your activities involve those shown in the next set of slides, contact your Research Compliance Office for specific requirements.
Export Controls

Examples
- International visitors / collaborations
- Shipment abroad
- International travel
- Release to a foreign national within the U.S. of controlled technology (i.e. deemed export)
Export Controls

Contact Information
A link to your institution’s export control program as well as additional information regarding export controls can be found at the link below:

http://www.tamus.edu/research/research-compliance/export-control/
Other Research Compliance Issues

Other Research Compliance areas include:

- Responsible Conduct of Research
- Financial Conflicts of Interest
- Use of Controlled Substances
- GXP:
  - Good Laboratory Practice (GLP)
  - Good Manufacturing Practice (GMP)
  - Good Clinical Practice (GCP)
The link below provides contact information for each System member’s research compliance program:

http://www.tamus.edu/research/research-compliance/research-compliance-officers/
Research Compliance Requirements
Self-Certification Acknowledgement

I hereby certify:

“I have reviewed the content of this training and agree to comply with the information contained in this course.”

__________________________  ______________________  ____________
Print Name  Signature  Date