

# 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:

- Information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- Uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

*(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



# Human Subjects Research

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 subjects in 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.



# Use of Biohazards in Research

***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 Issues

**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 links below:

Research Compliance

<http://www.tamus.edu/research/research-compliance/export-control/>

Research Security

<https://www.tamus.edu/research/research-security/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)





# Research Compliance Program

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