



Research Compliance: Overview 

Overview of Research Compliance Areas:

- Biohazards → IBC
- Human Subjects → IRB
- Animals → IACUC/AACUC



Research Compliance: IBC/IRB/IACUC/AACUC

administrative services risk and compliance


Research Compliance: Biosafety 

Institutional Biosafety Committee
IBC




Research Compliance: IBC/IRB/IACUC/AACUC

administrative services risk and compliance

Research Compliance: Biosafety 


The Goal Of Biosafety ---- PROTECTION!

- Workers
- Lab support personnel
- Research materials
- Environment
- Family



Importance of Risk Assessment and Containment

Research Compliance: IBC/IRB/IACUC/AACUC

Research Compliance: Biosafety 

Definition of a biohazard:


A biohazardous agent is an infectious (pathogenic) substance produced from living organisms that has the potential for causing disease in other living organisms, including animals and plants

The Risks can be direct through infection or indirect through damage to the environment.

Biohazardous materials include:


- Organisms & viruses infectious to humans, animals or plants (bacteria, fungi, viruses, parasites, prions)
- Biologically active agents such as toxins
- Allergens or venoms
- Recombinant DNA

Research Compliance: IBC/IRB/IACUC/AACUC

Research Compliance: Biosafety 

Institutional Biosafety Committee (IBC)

- The IBC is a committee created under the NIH Guidelines to review all research involving Recombinant DNA and biohazard risks
- Required in order to comply with regulations and receive funding from the National Institute of Health (NIH); not just NIH funded projects
- TAMU IBC Contact:
 - Dr. Christine McFarland; BSO
979-845-6475
ctmcfarland@tamu.edu
 - ibc@tamu.edu



Research Compliance: IBC/IRB/IACUC/AACUC

Research Compliance: Biosafety



Who is required to submit an IBC application?

- All research at Texas A&M or a system component involving the following must be approved by the IBC **prior to initiation**:
 - Pathogens and potential pathogens of humans, animals, or plants
 - Materials potentially containing human pathogens (human blood, tissue, and cell lines; non-human primate blood, tissue, and cell lines)
 - Recombinant DNA (and RNA) including creating or use of transgenic plants and animals
 - Select agents and toxins including strains and amounts exempted from the select agent regulations
 - Any material requiring a Center for Disease Control (CDC) import license or a USDA permit

Research Compliance: IBC/IRB/IACUC/AACUC

Research Compliance: Biosafety



How to submit an IBC application?

- Electronic submission using IRIS
 - Integrated Research Information System
 - <https://imedris.tamu.edu>
 - Support Line: 979-845-4969
 - Same as SSO logon



- Email rcboutreach@tamu.edu to obtain access to IRIS
- PI is responsible for completing all parts of application and notifying IBC of any changes during the process
- Biosafety Officer (BSO) is assigned an application to review and will assign Associate Biosafety Officer to perform lab inspections
- Step by step instructions: <http://rcb.tamu.edu/iris/iris-submission-process>
- Additional Resources: <http://rcb.tamu.edu/biohazards/resources>

Research Compliance: IBC/IRB/IACUC/AACUC

Research Compliance: Biosafety



IBC Permits:

- If research involves rDNA and is subject to the NIH Guidelines, the application must be reviewed and voted on by the full board
- IBC chair may approve permits that are not subject to the NIH guidelines and do not require full review
- Permit approval is valid for 3 years with annual renewals
- Approval is agent and location specific
 - 1 IBC permit per PI
- Lab inspections are conducted annually
- The approval process generally takes 45-60 days to complete

Research Compliance: IBC/IRB/IACUC/AACUC

Research Compliance: Biosafety



IBC Permits MUST be amended when the following changes occur:

- New biological agents are added
- New personnel are added to a study (BL2 or higher)
- New laboratory locations are acquired or added
- New funding source is obtained

Research Compliance: IBC/IRB/IACUC/AACUC

Research Compliance: Biosafety



Biosafety Training:

- Enrollment in Biosafety Occupational Health Program (BOHP)
 - All personnel listed on an IBC permit at BL2 or BL3
 - <http://rcb.tamu.edu/bohp/forms/bohp-initial-questionnaire-v1-4-2012>
- NIH Guidelines Training:
 - Any PI conducting research involving rDNA
 - CITI Training Modules (Collaborative Institutional Trainign Initiative)
 - <http://rcb.tamu.edu/biohazards/training/nihttraining>
- In person classroom training for BL2 or BL3 labs
 - Blood Born Pathogens (BBP)
 - Biosafety Level 2 (BL2) Training
 - <http://rcb.tamu.edu/biohazards/training>

Research Compliance: IBC/IRB/IACUC/AACUC

Research Compliance: Human Subjects



Institutional Review Board
IRB



Research Compliance: IBC/IRB/IACUC/AACUC

Research Compliance: Human Subjects 

What is Human Subjects Research:

- **Definition of Research:**
 - A Systematic investigation, including research development, testing & evaluation, designed to develop or contribute to generalizable knowledge
 - What is the intent of your study?
- **Definition of Human Subject**
 - Living individual about whom an investigator conducting research obtains 1) data through intervention or interactions with the individual **OR** 2) identifiable private information
 - Is the identity of individual readily available?

Research Compliance: IBC/IRB/IACUC/AACUC


Research Compliance: Human Subjects 

Institutional Review Board (IRB)

- The IRB is a committee established to ensure that the rights and welfare of human subjects are protected
- Required in order to comply with regulations of the Department of Health and Human Services (DHHS) and to receive federal funding
- TAMU IRB Contact:
 - Dr. Cathy Higgins
979-458-4117
chiggins.tamu.edu
 - irb@tamu.edu



Research Compliance: IBC/IRB/IACUC/AACUC

Research Compliance: Human Subjects 

When is IRB Approval necessary?

- All Texas A&M AgriLife individuals, faculty, staff, or agents who are conducting research with human subjects must have review and approval by the TAMU IRB **prior to initiating** research
- Use of TAMU/AgriLife property or facilities for human subjects research
- Use of Texas A&M AgriLife's non-public information to identify or contact human subject research participants


Research Compliance: IBC/IRB/IACUC/AACUC

Research Compliance: Human Subjects 

How to submit an IRB application? 

- Electronic submission using iRIS
 - Integrated Research Information System
 - <https://imedris.tamu.edu>
 - Same as SSO logon
- Email rcb outreach@tamu.edu to obtain access to iRIS
- PI is responsible for completing all parts of application and notifying IBC of any changes during the process
- Assigned an IRB method and reviewed 1 of 3 methods
 - Exempt from certain regulations: **6 Exemption categories**
 - Expedited Review
 - Full Board Review

Research Compliance: IBC/IRB/IACUC/AACUC


Research Compliance: Human Subjects 

Regulatory Exemptions:

1. Research conducted in commonly accepted education settings involving normal educational practices
2. Research involving the use of surveys, interviews, or observation of public behaviors **unless** the identifying information is recorded **and** disclosure of the information would be damaging to the subject (Does NOT apply to children)
3. Research involving surveys, interviews, observation where subjects are elected or appointed public officials

NOTE: Exemption cannot be determined by PI, must still submit an application in iRIS and complete training

Research Compliance: IBC/IRB/IACUC/AACUC

Research Compliance: Human Subjects 

Regulatory Exemptions:

4. Research involving the collection or study of existing data documents, records, or specimen **if** the sources are publicly available **or** the information is recorded in a manner that the subjects cannot be identified
5. Research designed to study, evaluate or examine Public Benefit or Service Programs
6. Taste and food quality evaluation and consumption acceptance studies involving wholesome foods

NOTE: Exemption cannot be determined by PI, must still submit an application in iRIS and complete training

Research Compliance: IBC/IRB/IACUC/AACUC

Research Compliance: Human Subjects



IRB Protocols:

- Annual **continuing review** of protocols is required
- The approval process generally takes 30-45 days to complete regardless of type of review (exempt, expedited, full board)
- Once study is complete (no further data gathering/analysis), a **completion report** is required

Research Compliance: IBC/IRB/IACUC/AACUC

Research Compliance: Human Subjects



Human Subject Research Training:

- CITI Training
 - All PI, Co-PI, and study personnel associated with human subject research must complete
 - www.citiprogram.org
 - Course in the Protection of Human Subjects
 - "Social & Behavioral Research For Investigators and Key Study Personnel"
 - Must pass with a 90%
 - Completed once every 3 years



Research Compliance: IBC/IRB/IACUC/AACUC


Research Compliance: Animals



Institutional Animal Care & Use Committee
IACUC/AACUC



Research Compliance: IBC/IRB/IACUC/AACUC

Research Compliance: Animals 

When is IACUC/AACUC Approval necessary?

- All Texas A&M AgriLife individuals, faculty, staff, or agents who are conducting research, teaching or testing using animals must have review and approval by the TAMU IACUC or AACUC **prior to initiating** research

Research Compliance: IBC/IRB/IACUC/AACUC

Research Compliance: Animals 


Institutional Animal Care & Use Committee (IACUC)

- The TAMU IACUC is responsible for oversight, evaluation, and assurance of compliance for any **on campus** research, use, teaching and training and animals
- TAMU IACUC Contact:
 - Dr. Tennille Lamon
 - 979-458-4118
 - tennillek@tamu.edu

Agriculture Animal Care & Use Committee (AACUC)

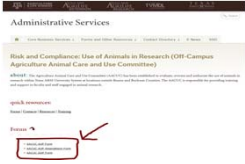
- The AACUC is responsible for oversight, evaluation, and assurance of compliance for any **off campus** research, use, teaching and training and animals at locations outside of Brazos & Burleson Counties
- AACUC Contact:
 - Dr. John Walker
 - 325-653-4576 x227
 - jwalker@ag.tamu.edu

Research Compliance: IBC/IRB/IACUC/AACUC


Research Compliance: Animals 

How to submit an application for an AUP:

- TAMU IACUC:
 - Electronic submission using iRIS
 - <https://imedris.tamu.edu>
- AACUC
 - Word form available on AgriLife Website: <http://agrilifeas.tamu.edu/risk-compliance/research-compliance/animals/aacuc/>
 - Follow directions on form and email completed AUP form to aganimal@ag.tamu.edu




Research Compliance: IBC/IRB/IACUC/AACUC

Research Compliance: Animals 

Animal Compliance Training:

- CITI Training
 - All PI, Co-PI, and study personnel associated with an AUP must complete
 - www.citiprogram.org
 - "Working with the IACUC Basic Course"
 - Must pass with a 80%
 - Completed once every 3 years
 - Email Alyce Ghedi for logon instructions
- Required to Self Enroll with Biosafety Occupational Health Program
 - May choose to opt out of services provided
- Semi-annual site inspections



Research Compliance: IBC/IRB/IACUC/AACUC

Research Compliance: iRIS Live Demo 

iRIS Demo



Research Compliance: IBC/IRB/IACUC/AACUC

Questions 

AgriLife Risk and Compliance
<http://agrilifeas.tamu.edu/risk-compliance>

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Research Compliance: IBC/IRB/IACUC/AACUC
