OFFICE OF RESEARCH COMPLIANCE
AGENDA

1. Office of Research Compliance
2. Areas of Responsibility
3. Institutional Animal Care and Use Committee (IACUC)
4. Institutional Biosafety Committee (IBC)
5. Institutional Review Board (IRB)
6. Research Misconduct
7. Financial Conflicts of Interest in Research
8. Animal Use Protocol
9. Institutional Review Board Application
10. Institutional Biosafety Permit Application
AREAS OF RESPONSIBILITY

- Animal Care and Use
- Biosafety
- Human Subjects Research
- Research Misconduct
- Sona Research Participant Enrollment System
- Financial Conflicts of Interest in Research
- Animal facilities inspection
- Lab certification
- Noncompliance Investigations
- Program review
- Standard Operating Procedures in Research
- iRIS (coming soon)
IACUC

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE
IACUC

The IACUC is responsible for oversight of the animal care and use program and its components as described in the USDA Animal Welfare Act (AWA) and Regulations, the Public Health Service (PHS) Policy on Humane Care, the Ag Use Guide, and the Use of Laboratory Animals (Policy) and the Guide for the Care and Use of Laboratory Animals (Guide). Its oversight functions include an ongoing assessment of animal care and use.

An IACUC is comprised of at least 5 members containing: 1 veterinarian, 1 animal scientist, 1 non-scientist, 1 local unaffiliated person.
IACUC FUNCTIONS

- Review, at least once every six months, Tarleton’s program for humane care and use of animals.

- Inspect all of the animal facilities, including animal study areas/satellite facilities.

- Prepare reports of IACUC evaluations and submit the reports to the Institutional Official (TSU’s VP-RIED).

- Review and investigate legitimate concerns involving the care and use of animals.

- Make recommendations to the Institutional Official regarding any aspect of the research facility’s animal program, facilities, or personnel training.

- Review animal use protocols (AUP) and Standard Operating Procedures (SOP) involving the care and use of animals for research, teaching, or coaching.

- Suspend an activity involving animals when necessary; take corrective action and report to the funding agency.
IBC

INSTITUTIONAL BIOSAFETY COMMITTEE
The IBC is federally mandated in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Modules. The IBC reviews research involving biohazards and inspects/certifies labs using the CDC Biosafety in Microbiological and Biomedical Labs (BMBL). The IBC’s main goal is the protection of public health, environmental protection, and preventing economic harm from biological agents.

An IBC is comprised of at least 5 members containing: 1 animal expert, 1 plant expert, 1 non-scientist, 2 local unaffiliated persons.
WHAT MAY FALL UNDER THE IBC?

- Recombinant DNA
- Synthetic Nucleic Acid Modules
- Human pathogens
- Animal pathogens
- Viral agents
- Vectors
- Human biological material
- Bacteria
- Plant pathogens
- Inoculants
- Fungi
- Toxins
IBC FUNCTIONS

• Review permits and SOPs for research and teaching activities involving biological agents.

• Inspect and certify labs where biological agents are used.

• Review and investigate legitimate concerns in research projects involving biohazards and biological agents.

• Make recommendations to the Institutional Official regarding any aspect of the research facility’s biosafety program, facilities, or personnel training.

• Suspend an activity involving biological agents when necessary; take corrective action and report to the funding agency.
IRB

INSTITUTIONAL REVIEW BOARD
The IRB is responsible for the review and monitoring of human subjects research and investigating legitimate concerns in human subjects research.

An IRB is comprised of at least 5 members with varying backgrounds with at least 1 scientist and 1 non scientist.
WHAT IS HUMAN SUBJECTS RESEARCH?

• Research involving:
  • Live subjects
  • Identifiable data
  • Private information
  • Bodily materials
WHY IS THE IRB SO IMPORTANT?

THE STANFORD PRISON EXPERIMENT

TUSKEGEE SYPHILIS EXPERIMENT
RESEARCH MISCONDUCT

HANDLING RESEARCH MISCONDUCT
RESEARCH MISCONDUCT

Research misconduct falls under 3 categories:

• **Plagiarism**: appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

• **Falsification**: manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

• **Fabrication**: making up data or results and recording or reporting them.
RESEARCH MISCONDUCT

Common research issues that are NOT research misconduct that will be forwarded to the appropriate office:

• Personnel conflicts
• Misuse of funds
• Breach of contract
• Authorship Disputes
FCOI
FINANCIAL CONFLICTS OF INTEREST IN RESEARCH
A Significant Financial Interest (SFI) is a financial interest consisting of one or more of the following interest of the Investigator and their spouse or children that reasonable appears to be related to the Investigators institutional responsibilities:

- Stocks, bonds, ownership interests exceeding $5,000 when aggregated
- Intellectual property rights and interests

Does NOT include:

- Monies paid to the investigator by the institution
- Income from consulting or guest lecturing
SUBMISSION PROCESS

IACUC (AUP), IBC (PROTOCOL), IRB (APPLICATION)
IACUC ANIMAL USE PROTOCOL (AUP)

- The use of animals in research is a continual process.
- Animal use and methods must be evaluated and justified on a risk vs. reward basis.
- Animal use has many documentation requirements
  - Outside/Cooperating facilities
  - Memorandums of understanding
  - Permits
  - Boarding agreements
- Expires every 3 years
## COMMON AUP MISTAKES / HOLD-UPS

<table>
<thead>
<tr>
<th>Mistake</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inconsistent numbers</td>
<td>Missing or inconsistent training for numbers</td>
</tr>
<tr>
<td>Expired / Missing training</td>
<td>Training has expired or is missing</td>
</tr>
<tr>
<td>Missing signatures</td>
<td>Signatures required for approval but missing</td>
</tr>
<tr>
<td>Missing MOU</td>
<td>Memorandum of Understanding missing</td>
</tr>
<tr>
<td>Missing alternatives &amp; research</td>
<td>Alternatives or research documentation missing</td>
</tr>
<tr>
<td>Weak justification</td>
<td>Justification for research weak or insufficient</td>
</tr>
<tr>
<td>Missing permit</td>
<td>Permit required for research but missing</td>
</tr>
<tr>
<td>Incomplete / Missing rosters</td>
<td>Rosters required for research but incomplete</td>
</tr>
</tbody>
</table>
IBC PROTOCOL

• The use of biological agents falls under a continuing review.

• Technical descriptions should be thorough and easy to understand to a non-scientist.

• Agents and strains should be spelled correctly and consistent.

• Risk assessments should include information of risks to health, environment, and economic damage and exposure control should be described.

• Expires every 3 years

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**Trainings**

<table>
<thead>
<tr>
<th>CITI</th>
<th>TrainTraq</th>
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<tbody>
<tr>
<td>Responsible Conduct of Research</td>
<td>Bloodborne Pathogens for Research Personnel</td>
</tr>
<tr>
<td>Introduction to Biosafety</td>
<td>Lab Safety</td>
</tr>
<tr>
<td>Project-specific trainings</td>
<td>Biosafety Level 1 or 2</td>
</tr>
</tbody>
</table>
COMMON IBC PROTOCOL MISTAKES / HOLD-UPS

- Expired / Missing training
- Missing signatures
- Poor technical descriptions
- Misspelled agents
- Incomplete training signature page
- Incomplete / Missing rosters
- Incomplete sections
- Missing agents from tables
IRB APPLICATION

- Informed consent is a process, not just a form
- All efforts must be made to protect subject information
- Consent vs. assent
  - Consent: Able to make the informed decision to participate
  - Assent: Guardian must consent on behalf of subject
- Selection criteria and study population must be justified when using specific groups
- Expires annually unless continuing review is requested
# TYPES OF IRB REVIEW

<table>
<thead>
<tr>
<th>Not Human Subject Research</th>
<th>Exempt</th>
<th>Expedited</th>
<th>Ceded</th>
<th>FCR</th>
</tr>
</thead>
<tbody>
<tr>
<td>No interaction or intervention with living individuals</td>
<td>Minimal Risk</td>
<td>Minimal Risk</td>
<td>Partnered Project</td>
<td>More than minimal risk</td>
</tr>
<tr>
<td>Neither provider or recipient of the specimens or data can be linked to an identifiable individual</td>
<td>Educational Evaluations</td>
<td>Does not meet an exemption category</td>
<td>Relies on other institution</td>
<td>Minors</td>
</tr>
<tr>
<td></td>
<td>Educational tests</td>
<td></td>
<td>Requires IAA</td>
<td>Special population</td>
</tr>
<tr>
<td></td>
<td>De-identified data</td>
<td></td>
<td>Requires partner institution determination</td>
<td>Use of video</td>
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<td></td>
<td>Publicly available information</td>
<td></td>
<td></td>
<td>Compromising interviews</td>
</tr>
<tr>
<td></td>
<td>Taste &amp; food quality evaluation</td>
<td></td>
<td></td>
<td>Biomedical</td>
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<tr>
<td></td>
<td>Consumer acceptance studies</td>
<td></td>
<td></td>
<td>Benefits to some but not all subjects</td>
</tr>
</tbody>
</table>
COMMON IRB APPLICATION MISTAKES / HOLD-UPS

- Poor background and justification
- Missing data management
- Not describing the informed consent process
- Not describing selection criteria or study population
- Not using IRB application
- Missing trainings
- Missing signatures