Research Compliance-
Stumbling Block or Stepping Stone
on the Path to Graduation
Navigating Animal Compliance

- Understand the rules
- Follow the map
- Avoid the stumbling blocks
- Cross the finish line
Understanding the Rules:
Regulations that govern animal research

- Animal research is a privilege afforded to us through public trust

- Animal research is regulated by:
  - The Animal Welfare Act and the Animal Welfare Act Regulations
  - 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
  - Guide for the Care and Use of Agricultural Animals in Research and Teaching
  - United States Department of Agricultural Animal Care Policies
Understanding the Rules:
Regulations that govern animal research

• USDA
  – AWA, AWAR, Animal Care Policies
  – Most warm-blooded animals
    • except rats, mice, birds and agricultural production animals

• PHS
  – The Guide, PHS Policy, ILAR Guidebook
  – All vertebrates

• Ag Guide – farm animals for food or fiber studies

• AAALAC
  – Voluntary accreditation – “gold standard”
  – Requires USDA and PHS standards
Understanding the Rules: Regulations that govern animal research

• TAMU
  – 15.03.99.M0.01 Use of Animals in Research, Teaching, and Testing

• System
  – 15.99.07 Use of Vertebrate Animals
Understanding the rules

• Animal activities are any activity involving vertebrate animals in which the natural life style or movements of the animals is perturbed. This includes using tissues and fluids of vertebrate animals.

• “Use of Animals” may include:
  - Collecting fin snips
  - Obtaining fecal samples
  - Antibody production
  - Observation studies
  - Using animal cell lines
  - Blood and tissue samples for machine calibration
Understanding the rules

• All animal activities that involve the use of vertebrates in research, testing, or teaching must be approved by the Institutional Animal Care and Use Committee (IACUC) prior to initiation.

• Animal activities require an Animal Use Protocol (AUP) to be submitted through iRIS for review by the IACUC.
Understanding the rules

• IACUC
  • Review all animal activities that involve vertebrates used in research, testing, or teaching activities that occur on Texas A&M University campus within Brazos and Burleson counties, at the branch campus in Galveston, and all off-campus studies (including field studies) conducted by TAMU faculty and students.
  • Investigate all animal welfare concerns and incidents of noncompliance.
  • Inspect animal housing and procedure locations.
Understanding the rules

• Principal investigators must be faculty members and cannot be students.
  – Graduate students are listed as participants.

• **All participants** on an AUP are required to read and understand the procedures and protocols.
Understanding the rules

• All AUP participants must take the CITI training “Working with the IACUC, Basic Course”.

• All participants must be enrolled in the Occupational Health Program.
Follow the map:
Graduate Proposal Review Process

• All graduate proposals are reviewed by the three compliance offices to ensure congruency with applicable laws and regulations.
Follow the map: Graduate Proposal Review Process

• For proposals that have animal activities listed, the Animal Welfare Office will review for congruency with the listed AUP.
  – The activities outlined in the proposal must be congruent with the activities in the AUP.
  – The student must be an approved participant on the AUP if they participated in the activities.

☐ ☑ Vertebrate animals
☑ ☐ Animal tissues/cell lines

Provide the IACUC protocol #: 2013-0042/0043
Avoid stumbling blocks

• If the proposal and the AUP are not congruent, the student and their committee chair are notified and asked to clarify the incongruence.
  – May result in the proposal being returned for corrections which will delay the approval process.
Avoid stumbling blocks

• Fill out the information correctly

Tentative Title: Diving behavior, foraging ecology and habitat associations of female leatherback sea turtles (Dermochelys coriacea) from St. Croix, U.S. Virgin Islands

Verification of research regulatory compliance: Check each category below if included in any research to be reported in the final document and provide the requested protocol or permit numbers, if relevant. The student’s name must be included on any required IRB or IACUC protocols and/or the IBC permit. This is not an all-inclusive list of all possible required compliance approvals, so check the website* below for full information.

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Human subjects, including survey data</th>
<th>If you checked yes at left: Provide the IRB protocol #:__________</th>
</tr>
</thead>
<tbody>
<tr>
<td>☑️</td>
<td>☐</td>
<td>Human tissue/cell lines</td>
<td>Provide the IRB protocol #:__________ and the IBC permit #:__________</td>
</tr>
<tr>
<td>☑️</td>
<td>☐</td>
<td>Protected health information (human subjects)</td>
<td>Provide the IRB protocol #:__________</td>
</tr>
<tr>
<td>☑️</td>
<td>☐</td>
<td>Vertebrate animals</td>
<td>Provide the IACUC protocol #:__________</td>
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<tr>
<td>☑️</td>
<td>☐</td>
<td>Animal tissue/cell lines</td>
<td>Provide the IACUC protocol #:__________</td>
</tr>
<tr>
<td>☑️</td>
<td>☐</td>
<td>Recombinant DNA/transgenic animals/plants</td>
<td>Provide the IBC permit #:__________</td>
</tr>
<tr>
<td>☑️</td>
<td>☐</td>
<td>Agents infectious to humans, animals or plants</td>
<td>Provide the IBC permit #:__________</td>
</tr>
</tbody>
</table>
Avoid stumbling blocks

• Illegible forms/signatures
Avoid stumbling blocks

- Incidents of noncompliance are referred to the IACUC for investigation and potential corrective actions.
  - This will significantly delay the approval process.
  - May result in the student losing valuable time and research data.
  - May result in delayed graduation.
Avoid Stumbling Blocks: Ask for help!

• Animal Welfare Office
  – Liaison between the research community and the IACUC.
  – Protect the University and the researchers by assuring compliance to the laws and regulations.
Cross the Finish Line!
Cross the Finish Line!
Office Contacts

• Email: animalcompliance@tamu.edu
• Phone: 845-1828
• Fax: 862-3176
• http://rcb.tamu.edu

• AWAP Manager: Dr. Tennille Lamon
• Research Compliance Coordinators: Ken Gillenwater, Lauren Douglas, & Dr. Gina Lungu
• Post Approval Liaison: Dr. Melanie Landis
Questions?