

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



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

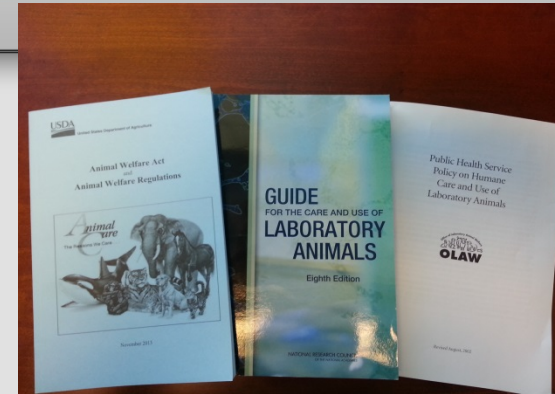


- Animal research is regulated by:
 - The Animal Welfare Act and the Animal Welfare Act Regulations
 - Public Health Service Policy on Humane Care and Use of Laboratory Animals (National Institutes of Health)
 - Health Research Extension Act of 1985
 - U.S. Government Principles for the Utilization and 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



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- TAMU
 - 15.99.07.M1 Use of Vertebrate 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.



- 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.

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.*

<u>Yes</u>	<u>No</u>		<u>If you checked yes at left:</u>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Human subjects, including survey data	Provide the IRB protocol #: _____
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Human tissue/cell lines	Provide the IRB protocol #: _____ and the IBC permit #: _____
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Protected health information (human subjects)	Provide the IRB protocol #: _____
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Vertebrate animals	Provide the IACUC protocol #: _____
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Animal tissues/cell lines	Provide the IACUC protocol #: _____
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Recombinant DNA/transgenic animals, plants	Provide the IBC permit #: _____
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Agents infectious to humans, animals or plants	Provide the IBC permit #: _____

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

Provide the IACUC protocol #: _____

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.*

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.*

Yes	No		If you checked yes at left:
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Human subjects, including survey data	Provide the IRB protocol #: _____
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Human tissue/cell lines	Provide the IRB protocol #: _____ and the IBC permit #: _____
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Protected health information (human subjects)	Provide the IRB protocol #: _____
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Vertebrate animals	Provide the IACUC protocol #: _____
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<input type="checkbox"/>	<input checked="" type="checkbox"/>	Recombinant DNA/transgenic animals, plants	Provide the IBC permit #: _____
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Agents infectious to humans, animals or plants	Provide the IBC permit #: _____

Avoid stumbling blocks

- Illegible forms/signatures

*Additional information can be obtained at <http://rcb.tamu.edu>
Office of Research Compliance and Biosafety, Division

Approval Recommended:

<i>A. C. ...</i>	Bio/Bio
**Chair	Dept.
<i>[Signature]</i>	Bio
Member	Dept.
<i>George D. ...</i>	Pro Bio
Name (Member)	Dept.
<i>[Signature]</i>	Bio/Bio
Name (Member)	Dept.

Approval Recommended:

<i>[Signature]</i>	Psyc
**Chair	Dept.
<i>[Signature]</i>	AYCIV
Member	Dept.
<i>[Signature]</i>	Psyc
Name (Member)	Dept.
<i>[Signature]</i>	Biol
Name (Member)	Dept.

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.



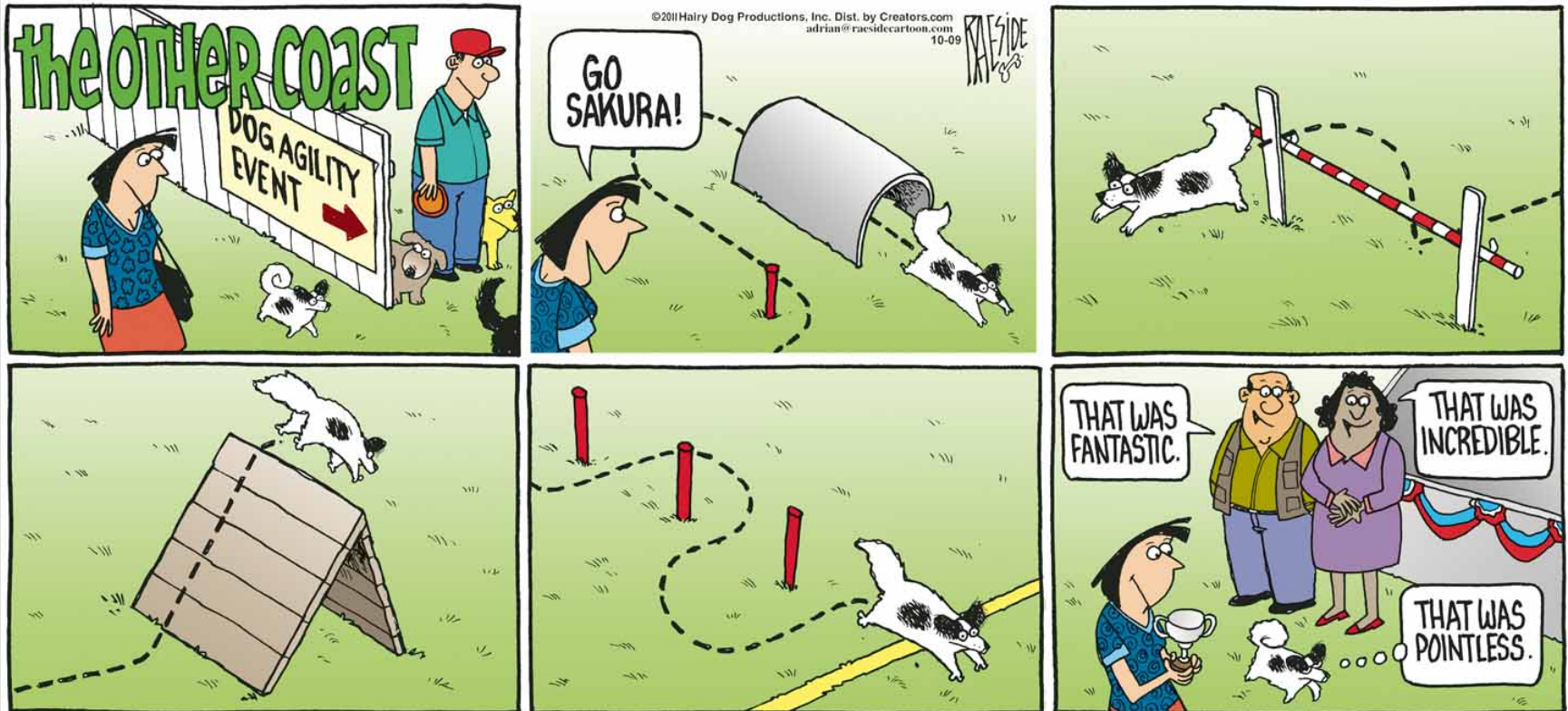
Avoid Stumbling Blocks: Ask for help!



- Animal Welfare Office (AWO)
 - 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!



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Office Contacts

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- Fax: 862-3176
- <http://rcb.tamu.edu>
- AWO Director: Dr. Tennille Lamon
- AWO Assistant Director: Mr. Ken Gillenwater
- Research Compliance Coordinators:
Dr. Gina Lungu, Ms. Lauren Douglas, Ms. Kim Green,
& Ms. Debbie Perry
- Post Approval Liaison: Dr. Melanie Landis



Questions?



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