

Animal Welfare Office

Animal Compliance and Institutional Animal Care and Use Committee

Presented by
Tennille Lamon, DVM, MS, CPIA
AWO Director



Regulations For Animal Research

- Animal research is a privilege afforded to us through public trust
- Animal research is Federally 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
- Institutional Policies
 - TAMU
 - 15.99.07.M1 Use of Animals in Research, Teaching, and Testing
 - System
 - 15.99.07 Use of Vertebrate Animals



Animal Welfare Office (AWO)

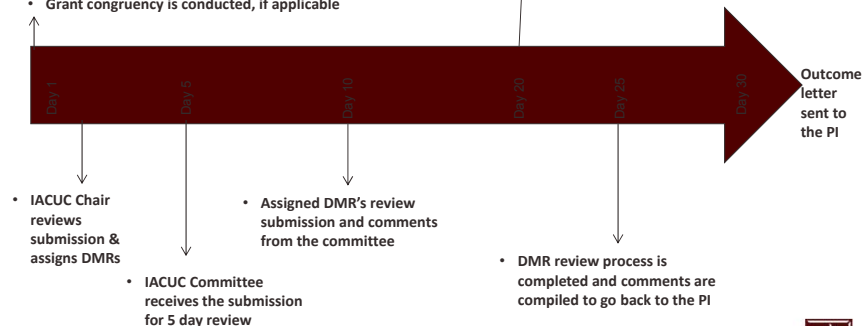
- Liaison between the research community and the IACUC
- Protect TAMU and researchers by assuring compliance with the laws and regulations
- Investigate/follow up on reports of animal welfare concerns
 - 11 anonymous concerns reported to the AWO office in 2016
 - 10 IACUC subcommittee meetings in 2016
 - 28 Adverse events reported to the IACUC in 2016
- Coordinate IACUC inspections of all areas where animals are housed or used and follow up on all inspection deficiencies
- Review all graduate student proposals for congruency with compliance regulations
- Provide compliance interface with other offices (SRS; OGAPS; MTA; EHS; HRPP; OHP; Biosafety)
- Coordinate responses to Freedom of Information Act (FOIA)/Public Information requests



Submission Process

Animal Welfare Office

- Pre-Review by the IACUC Office for completion
- BOHP & EHS assigned to review
- Attending Veterinarian assigned if Category D or E
- Biosafety assigned to review, if applicable
- CRRC assigned to review, if applicable
- Grant congruency is conducted, if applicable
- CITI Training of AUP participants is verified
- Coordinate with other committees/units to verify issues are resolved or need to be addressed in AUP



IACUC Committee



Institutional Animal Care and Use Committees

- Required by Federal Law- Animal Welfare Act & Public Health Service/OLAW
- Composition mandated by law & institutional policy
- Appointed by & report to Institutional Official (IO)
 - Currently have 23 members
 - Composed of:
 - 14 faculty members representing most colleges in which animal research is conducted
 - 2 facility managers
 - 6 staff members (EHS, Biosafety, CMP, AWO)
 - 1 community member



AUP Review Process

- Two review processes:
 - Designated member reviewer (DMR)
 - Two committee members are named DMR for each protocol
 - All committee members can review and comment on the protocol
 - The DMRs are responsible for approving the protocol or requesting modifications to gain approval
 - Full Committee Review (FCR)
 - Deadline for submission is one week prior to the meeting
 - The committee discusses the protocol at a convened meeting
 - The committee votes to approve, request modifications to gain approval, table, or withhold approval



AUP Review Process as Relates to External Funding

- **Externally funded protocols require a grant/scope of work congruency check prior to approval**

- PHS Policy IV.D.1,2. Applications or proposal...covered by this Policy...shall include verification of approval ...by the IACUC of those components related to the care and use of animals. [Protocols must match grant proposal].



- **Investigators are required to provide a copy of the grant or proposal at the time of AUP submission**
- **Any discrepancies between the grant and AUP must be reconciled prior to approval**



Challenges

- Expansion of Compliance Footprint
 - 3 IACUCs (College of Dentistry, IBT/Kingsville, TAMU)
 - More locations and facilities at TAMU
 - Increased activity:

	FY 2014 (amendments and initials)	FY 2016 (amendments and initials)	Percent Difference
IACUC	590	840	+42%
IBC	310	368	+18%
IRB	1370	1701	+24%

- Increasing compliance requirements for DOD funded projects



Programmatic Changes

- **Streamlining the AUP to better reflect information required in protocol and eliminate redundancy. Anticipated launch in Summer 2017.**
 - New form will include templates for common procedures
- **Changed the personnel addition process**
- **Increased the size of the IACUC to decrease the protocol review times**
- **VVC = Veterinary Verification and Consultation**
 - AV can approve certain changes in drugs, anesthesia and euthanasia w/o amendment



Veterinary Verification and Consultation (VVC)

- Specific changes to an AUP may be administratively verified through consultation with a Comparative Medicine Program (CMP) Veterinarian
- Changes allowed by the VVC are:
 - Changes to the dose, route, concentration, volume, and/or duration of an approved anesthetic, analgesic, or sedative
 - Changes to the dose, route, concentration, volume, and/or duration of an approved experimental substance as long as the change does not result in a change in study objectives or greater pain, distress, or degree of invasiveness.
 - Change in euthanasia to any method approved in the current AVMA Guidelines for the Euthanasia of Animals
- The Significant Changes described above may only be administratively verified according to IACUC-reviewed and –approved policies in consultation with an approved Veterinarian.



VVC Process

- CMP Veterinarians may be contacted via phone or email to request the change
- If the CMP Veterinarian verifies that the change is appropriate and acceptable for VVC, then they will email the AWO with the change.
 - Only the CMP Veterinarian may verify the requested change.
- The AWO will process the change, attach it to the appropriate AUP, and send an outcome letter to all AUP participants.

	AUP - Veterinary Verification and Consultation		
	AUP - Veterinary Verification and Consultation	 TAMU IACUC	Process Administratively



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Moving Forward

- **Ensure that TAMU continues to maintain a high quality program incorporating AAALAC best practices**
 - Next AAALAC site visit- Summer 2018
- **Updating IACUC Guidance Documents on the RCB Website**
- **Continue to evaluate IACUC composition, structure, and expertise**
- **Continue to review processes and procedures for opportunities to enhance efficiencies and effectiveness and ease administrative burdens on researchers**



AWO Contacts

- Email: animalcompliance@tamu.edu
- Phone: 845-1828
- 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?



Biosafety and the IBC

Council of Pls Meeting April 12, 2017

Christine T. McFarland, Ph.D.
Director, Biosafety, BSO, RO



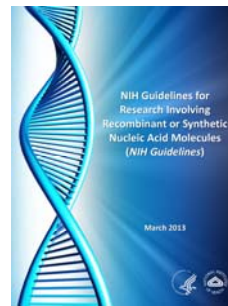
Office of Biosafety

- Biosafety Program
- Select Agent Program
- Biosafety Occupational Health Program



Why is IBC approval necessary?

- **NIH OBA: NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules**
- **System Regulation 15.99.06: Use of Biohazards in Research, Teaching and Testing.**
- **University Rule 15.99.06.M1: Use of Biohazards, Biological Toxins and Recombinant DNA and Dual Use Research of Concern.**



Materials which require TAMU Institutional Biosafety Committee (IBC) approval:

Biohazardous material is defined as -

- *Biological agents (bacteria, fungi, viruses, protozoa, parasites, and prions) that may cause disease in humans, animals or plants;*
- *Recombinant DNA, RNA, or synthetic nucleic acid molecules (as defined in the NIH Guidelines);*
- *Human (and non-human primate) blood, tissues, cells, and cell lines; and*
- *Toxins of biological origin, as defined in the BMBL document.*

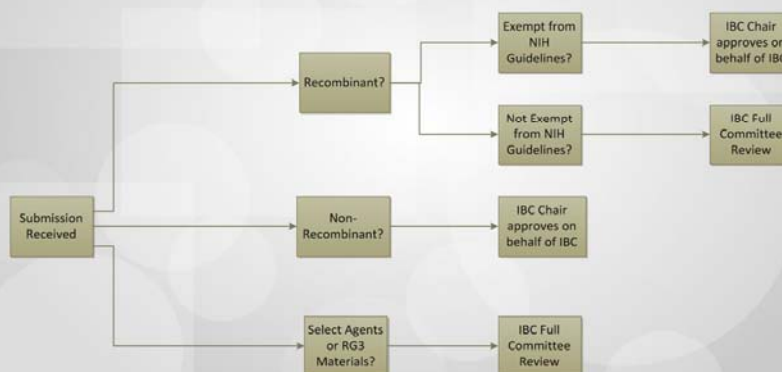


TAMU Institutional Biosafety Committee (IBC)

- Appointed by the Vice President for Research
- 9 IBCs; CS, Amarillo, Lubbock, Dallas, Temple, Houston, Kingsville/Corpus Christi, Uvalde, & Weslaco
- 12 members:
 - Chair: Dr. Carlos Gonzalez
 - Vice Chair: Dr. Paul de Figueiredo
 - 7 faculty, 1 technical research staff, 2 community representatives, and 2 health and safety professionals
 - 10 alternate members
- Meets 4th Wednesday of each month
 - ❖ Meetings are open to the public



Process for IBC Review and Approval



TAMU IBC permits

Valid for three years;

Annual renewals and laboratory inspections are required;

IBC permits must be amended if adding new:

- agents,
- locations,
- recombinant work, or
- personnel (BSL-2 or BSL-3)



Challenges

- Expansion of Compliance Footprint

- 9 IBCs, including TAMU IBC
- More locations and facilities:

Biosafety program responsibilities extend to AgriLife, TVMDL, and TAMHSC facilities located in Amarillo, Center, Corpus Christi, Dallas, Galveston, Gonzales, Houston, Kingsville, Lubbock, McAllen, Sonora, Stephenville, Temple, Uvalde, Weslaco, and Vernon.

Local expansion of biosafety responsibilities: Global Health Research Complex, MREB II

- Increased submission activity:

	FY 2014 (amendments and initials)	FY 2016 (amendments and initials)	Percent Difference
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View Ahead

- Continue transition to multi-IBC model
- Complete integration of HSC's Biosafety Occupational Health Program with TAMU's
- Continue responding to a rapidly growing research/biosafety enterprise resulting from construction of new facilities and expansion of existing facilities
 - Obtain federal approval for new and renovated facilities which will be working with select agents and toxins
- Continue reviewing processes and procedures for opportunities to enhance efficiencies and effectiveness and ease administrative burdens on researchers.



Office of Biosafety Contact Information

- ❖ Email: biosafety@tamu.edu or IBC@tamu.edu
- ❖ Phone: (979)-862-4549 (Biosafety)
(979)-862-4688 (IBC)
- ❖ Fax: (979)-862-3176
- ❖ URL: <http://rcb.tamu.edu/biohazards>

- ❖ **Director, BSO/RO: Dr. Christine McFarland**
- ❖ **Associate Biosafety Officers: Dr. Ruchira Mitra, Dr. Jessica Bourquin, and Ms. Susan Gater**
- ❖ **IBC Coordinator: Mr. Jeffrey Lane**
- ❖ **Biosafety Occupational Health: Ms. Sherri Evans and Ms. Lauren Horton**



Human Research Protection Program Update

Council of Principal Investigators April 12, 2017

Aliese Seawright, MS, CIP
Human Research Protection Program Director

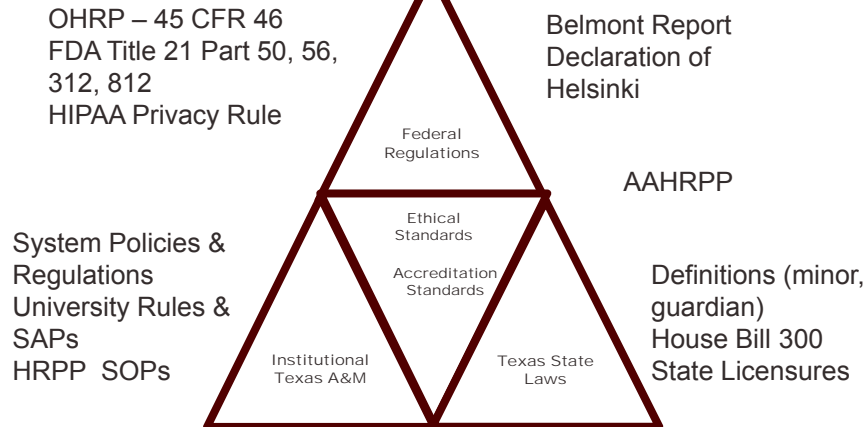


Working Together to Protect Humans in Research

- The Human Research Protection Program (HRPP) provides oversight for all human subjects research at Texas A&M University.
- The HRPP is not just an office but a system that works together to utilize the collective effort of all who share the responsibility to protect humans in research.
- The primary components of the HRPP:
 - **Institutional Official** – Vice President for Research
 - **Institutional Review Boards** – TAMU & College of Dentistry
 - **HRPP / IRB Administrative Office** – Post Approval Monitoring, Education and Outreach, Support for IRBs and Investigators
 - **Investigators** – Interaction and intervention with humans or their identifiable data in a manner that promotes respect for persons, beneficence and justice.



What Rules do we have to follow?



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Status of Changes to the Federal Common Rule

- The Dept. of Health and Human Services (HHS) along with 15 other federal agencies issued a final rule to update the Common Rule (45 CFR 46) in January, 2017.
- The intent of the new rule is to strengthen protections for people that volunteer for research without inappropriate administrative burdens, particularly in low risk research, and to allow more flexibility where appropriate to meet the ever changing dynamics of research.
- However, the new rule was subject to the Congressional Review Act for a period of 60 legislative workdays after it was issued. The 60 days are now up, but there has been no news.
- Conversations with OHRP indicate that guidance will be developed to help institutions with implementation. (Do institutions have to adopt the revised rule; what rules will currently approved research follow; will implementation dates change?)



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What changes can we make, now?

Q: What can we do now to implement flexibility where permissible?

A: Uncheck the box on the Federal Wide Assurance (FWA)

Q: What is the FWA?

A: It is a written agreement with the HHS Office for Human Protections (OHRP) that requires us to follow certain rules anytime we conduct research involving humans that is conducted or funded by a federal agency. (NIH, NSF, DOT, DOJ, etc.)

Q: How does this affect research that is not federally conducted or supported?

A: Institutions may voluntarily extend their FWA to cover all human subjects research regardless of the source of funding or no funding at all. Texas A&M University has extended their FWA to cover ALL research. This is called 'Checking the Box' on part 4(b) of the FWA.

Q: What can we do differently if we uncheck the box on the FWA?

A: Certain flexibilities may be introduced to research that is not federally funded or federally regulated and no more than minimal risk. (Different reporting requirements, additional categories of review, etc.)



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Equivalent Protections

- Understand that all research will remain subject to Texas A&M University's ethical standards. This is a requirement of the FWA regardless of whether or not the box is checked.
- Accreditation standards require Texas A&M University to have equivalent protections in place for all research regardless of funding.
- This means that all research involving humans at Texas A&M University is subject to the policies of the TAMU HRPP.
- Approximately 69% of AAHRPP accredited organizations do not check the box on their FWA because accredited organizations are more equipped to provide equivalent protections.



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Other Changes in the Works

- New work-flows are being implement in iRIS in an effort to improve consistency and generate reliable records without unnecessarily increasing the burden to investigators.
- The following three areas will have a truncated application that requires a reduced amount of input compared to the standard iRIS application for human subjects research.

Human Subject's Determination:

i Does my project involve human subjects research?

R **Delayed Onset Determination** (45 cfr 46.118) Request for delayed onset of human subjects research in funded studies, only.

S **External IRB Review:** Deferral to an external IRB that is not part of TAMU. (Limited circumstances)



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What else are we working on?

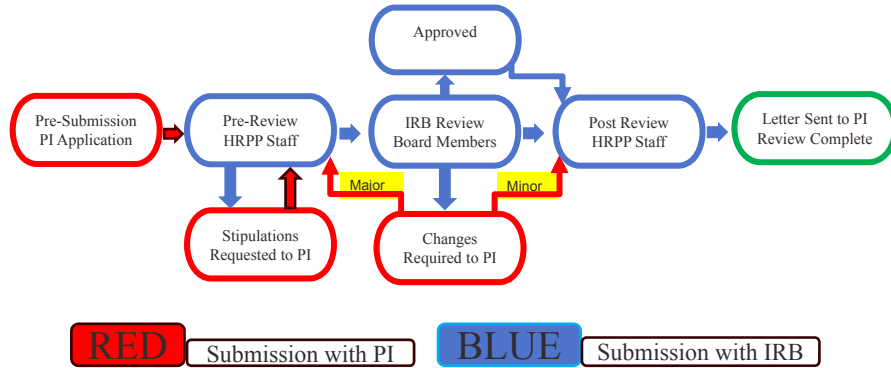
- AAHRPP reaccreditation application is due in 2 months;
 - Program evaluations
 - IRB evaluations
 - SOP updates
 - Ongoing training & education
 - Updates to website and outreach materials
- The total number of submissions for all categories of IRB review during the first quarter of 2017 was about 22% higher than the first quarter of 2016:

1st quarter 2016	1st quarter 2017
824	1009



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IRB Review Process – Workflow



Contact the HRPP Liaison Assigned to your Area for Help

Assigned Area	HRPP Liaison	Email	Phone
Bush School Of Government and Public Service	Jennifer Rau-Hug	jenniferhug@tamu.edu	979.845.7037
College of Agriculture and Life Sciences	Amy Donnellan	adonnellan@tamu.edu	979.862.3653
College of Architecture	Graeme Wright	graemewright@tamu.edu	979.862.4681
College of Dentistry	Graeme Wright	graemewright@tamu.edu	979.862.4681
College of Education & Human Development - HLKN	Denise Puga	denisepuga@tamu.edu	979.458.5590
College of Education & Human Development - EAHR	Jennifer Rau-Hug	jenniferhug@tamu.edu	979.845.7037
College of Education & Human Development - EPSY	Jennifer Rau-Hug	jenniferhug@tamu.edu	979.845.7037
College of Education & Human Development - TLAC	Graeme Wright	graemewright@tamu.edu	979.862.4681
College of Engineering (except Biomedical and Computer Science & Engineering)	Graeme Wright	graemewright@tamu.edu	979.862.4681
College of Engineering - Biomedical	Denise Puga	denisepuga@tamu.edu	979.458.5590
College of Engineering - Computer Science and Engineering	Jennifer Rau-Hug	jenniferhug@tamu.edu	979.845.7037
College of Geosciences	Amy Donnellan	adonnellan@tamu.edu	979.862.3653
College of Liberal Arts - (except Psychology)	Graeme Wright	graemewright@tamu.edu	979.862.4681
College of Liberal Arts - Psychology	Denise Puga	denisepuga@tamu.edu	979.458.5590
College of Science	Amy Donnellan	adonnellan@tamu.edu	979.862.3653



Contact the HRPP Liaison Assigned to your Area for Help

Assigned Area	HRPP Liaison	Email	Phone
Libraries	Denise Puga	denisepuga@tamu.edu	979.458.5590
Mays Business School	Jennifer Rau-Hug	jenniferhug@tamu.edu	979.845.7037
School of Law	Graeme Wright	graemewright@tamu.edu	979.862.4681
Texas A&M - Galveston	Amy Donnellan	adonnellan@tamu.edu	979.862.3653
Texas A&M Health Science Center	Jennifer Rau-Hug	jenniferhug@tamu.edu	979.845.7037
Texas A&M AgriLife Extension Service	Amy Donnellan	adonnellan@tamu.edu	979.862.3653
Texas A&M AgriLife Research	Amy Donnellan	adonnellan@tamu.edu	979.862.3653
Texas A&M Engineering Experiment Station	Graeme Wright	graemewright@tamu.edu	979.862.4681
Texas A&M Engineering Extension Service	Graeme Wright	graemewright@tamu.edu	979.862.4681
Texas A&M Transportation Institute	Amy Donnellan	adonnellan@tamu.edu	979.862.3653
Texas A&M - Qatar	Graeme Wright	graemewright@tamu.edu	979.862.4681
Other Units	Denise Puga	denisepuga@tamu.edu	979.458.5590



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Human Research Protection Program General Contact Information

- Phone: (979) 458-4067
- Fax: (979) 862-3167
- Email: irb@tamu.edu
- Location: General Services Complex,
Suite 2701



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**Questions will be taken at the end
of all compliance presentations.**

Thank you!

