

IBC Approval at TAMU Biosafety Program

**Council of PIs Meeting
April 13, 2016**

Presented by

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Director, Biosafety, BSO, RO

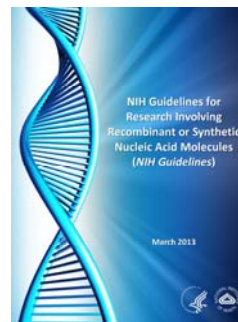


Why is IBC approval necessary?

NIH Guidelines for Research Involving Recombinant or Synthetic DNA Molecules (NIH Guidelines)

- http://osp.od.nih.gov/sites/default/files/NIH_Guidelines_0.pdf

1. ***Establish and implement policies for the safe conduct of recombinant research that ensure compliance with the NIH Guidelines;***
2. ***Establish an IBC to:***
 - *review the recombinant work*
 - *set appropriate containment to protect personnel and the environment*
3. ***Ensure appropriate training for the IBC members, PIs and laboratory staff related to lab safety and implementation of the NIH Guidelines; and***
4. ***Report any significant problems, violations of the NIH Guidelines or any significant research related accidents or illnesses to NIH/OBA.***



Compliance with the NIH Guidelines is a condition of funding.



Why is IBC approval necessary?

System Regulation 15.99.06 (<http://policies.tamus.edu/15-99-06.pdf>)

Requires system members involved with research, teaching or testing activities utilizing biohazards to:

1. **Establish a rule to carry out the system regulation and procedures for the use and storage of biohazards;**
2. **Establish an IBC (or use another system member's registered IBC);**
3. **Ensure that each IBC meets the requirements set forth in the NIH Guidelines and registers with the Office of Biotechnology Activities (OBA) of the NIH; and**
4. **Ensure that the IBC reviews and approves the activities with biohazards before initiation.**



Why is IBC approval necessary?

UNIVERSITY RULE 15.99.06.M1: Use of Biohazards, Biological Toxins and Recombinant DNA

– <http://rules-saps.tamu.edu>

1. **Describes the TAMU review and approval process for activities with biohazards;**
2. **Describes the roles and responsibilities of the PI, the BSO, the IBC, the RO and the IO.**
3. **Requires that all research, teaching and testing activities, including non-recombinant and exempt activities with biohazards, be reviewed and approved by the IBC, prior to initiation.**
4. **Recently revised to include institutional responsibilities for oversight and reporting of research described as DURC.**



UNIVERSITY RULE 15.99.06.M1 *Use of Biohazards, Biological Toxins and Recombinant DNA*

This rule applies:

- to all University employees, students and visitors who utilize rDNA and/or biohazardous agents or materials in the context of their research, teaching and/or testing activities.



- to these activities when they occur in University facilities, or other locations if the projects are funded or sponsored by the University, and/or if University faculty, staff or students are participating in activities utilizing biohazardous materials or rDNA.



UNIVERSITY RULE 15.99.06.M1 *Use of Biohazards, Biological Toxins and Recombinant DNA*

These requirements are also applicable to all activities involving the use of biohazards and/or recombinant DNA for which the University is responsible, regardless of source of funding or whether the activity is funded.



Materials which require TAMU Institutional Biosafety Committee (IBC) approval

- *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 IBC approval is required prior to initiation of work.



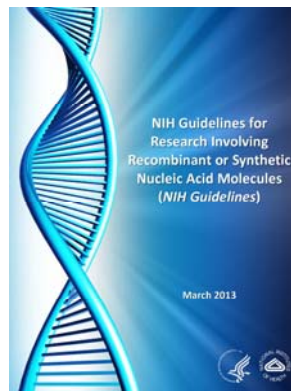
NIH Guidelines – Requirements for Institutional Biosafety Committees (IBC)

The *NIH Guidelines* require:

- IBCs to have no fewer than 5 members
 - ❖ Plant, plant pathogen, plant containment specialist
 - ❖ Animal containment specialist
 - ❖ At least 2, local, unaffiliated community members
 - ❖ BSO

IBC Meetings are open to the public

- Meeting minutes made available to the public, upon request

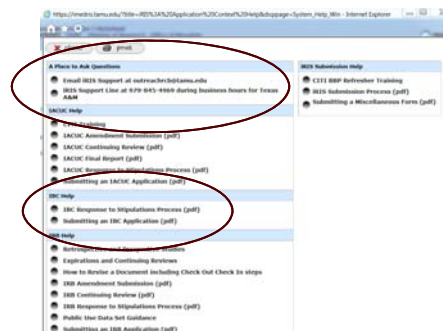


TAMU Institutional Biosafety Committee (IBC)

- Appointed by the Vice President for Research
- 11 members:
 - Chair: Dr. Carlos Gonzales
 - Vice Chair: Dr. Paul de Figueiredo
 - 5 faculty, 1 technical research staff, 2 community representatives, attending veterinarian, and 2 health and safety professionals
 - Six alternate members
 - Unaffiliated members – outside Brazos county
- Meets 4th Wednesday of each month
 - ❖ Meetings are open to the public



How do PIs obtain IBC approval at TAMU?



The first step - submit an application using the on-line submission software iRIS.

- Resources: instructional pdfs, sample application
- Revised initial application
- Identify a study contact



TAMU IBC approval process – Biosafety review



Administrative review is performed by the IBC coordinators:

Jeffrey Lane

Debbie Perry

Application information includes:

- *Lay and technical descriptions;*
- *List of biohazardous agents in use;*
- *A description of the recombinant activities;*
- *Location(s) of work; and*
- *Decontamination/Waste disposal methods.*



TAMU IBC approval process – Biosafety review



Scientific pre-review:

Ruchira Mitra, PhD

Jessica Bourquin, PhD

Susan Gater, MS

- *Grants, publications, AUPs, IRBs, etc.*
- *Assess the risks/recommend risk mitigations*
- *Schedule & conduct lab site visit*
- *Assign the submission to a meeting agenda, as appropriate*
 - *8 calendar days*



TAMU IBC approval process – full committee review



- Not all submissions require full committee review;
- ABSOs present the review;
 - Describe all activities with biohazards, recombinant activities, any biosafety concerns and how mitigated, etc.
- PIs are invited to attend;
- *IBC reviews submission and takes action:*
 - *Approve, or approve pending minor modifications*
 - *Table*
 - *Not approve*



IBC Training Requirements

University Rule & NIH Guidelines – must be completed by all PIs.
(annually → once and done)

For work with human pathogens: PIs and all personnel must complete:

- *Biosafety training – provided by the Biosafety Program*
 - BSL-2 training (annually → 5 years)
 - BSL-2 Initial (classroom); refresher (on-line)
 - BSL-3 training/annually
 - BSL-3 Initial and refresher (classroom)
- *Annual BBP Training – provided by the Biosafety Program*
 - BBP Initial (classroom); refresher (on-line)
- *Annual questionnaire for participation in the Biosafety Occupational Health Program*
- *Lab/agent specific training – provided by the PI*



Recommended, not mandatory:

- *BSC training – online/once*



IBC approval process – Communicate the outcome



IBC approval letters:

- are agent, location and biosafety level specific;
- List the section of the NIH Guidelines;
- list training requirements; and
- document any special provisos or conditions stipulated by the committee for the conduct of the research.



TAMU IBC permits



Valid for three years

Annual renewals and annual laboratory inspections are required.

- Total of 1585 labs visited in 2015
 - BSL-1(634); BSL-2 (702); BSL-3 (11); ABSL-1(100); ABSL-2 (115); ABSL-3 (4); BSL-1P (18); and ACL-1 (1)



IBC permits must be amended if adding new:

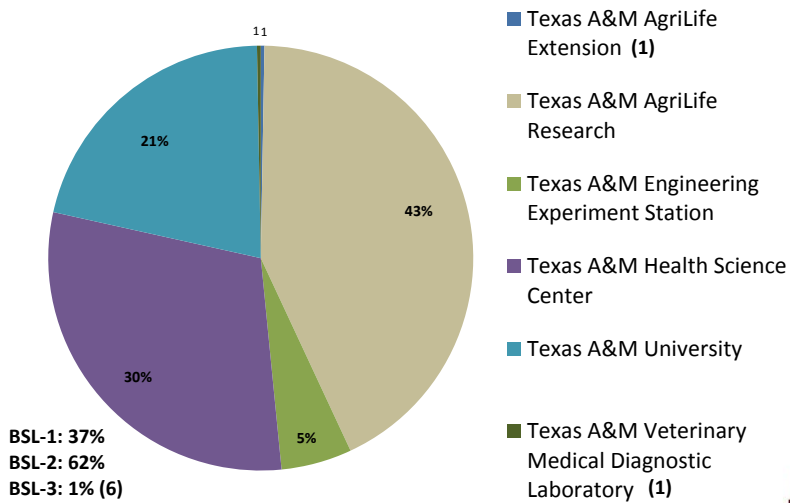
- agents,
- locations,
- recombinant work, or
- personnel (BSL-2 or higher)



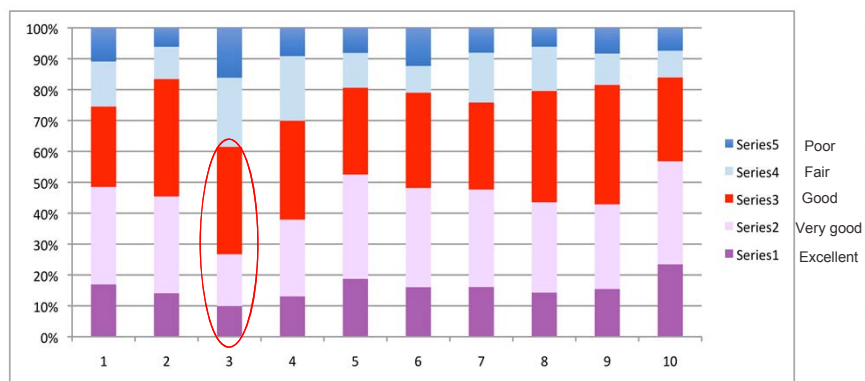
*Update permit at the same time



Biosafety/IBC Active Permits by Institution FY15



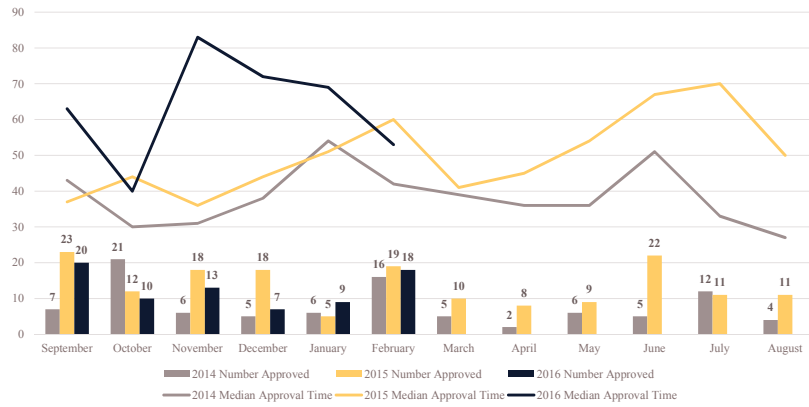
Institutional Biosafety Ratings



- | | | |
|-----------------------------------|----------------------------|--------------------------------|
| 1 – Knowledge of officers | 5 – Customer service | 9 – Inspection process |
| 2 – Time interaction w/staff | 6 – Staff knowledge | 10 – Prof'l handling incidents |
| 3 – Turnaround (1 st) | 7 – Turnaround (protocols) | |
| 4 – Turnaround (amendments) | 8 – Clarity of revisions | |



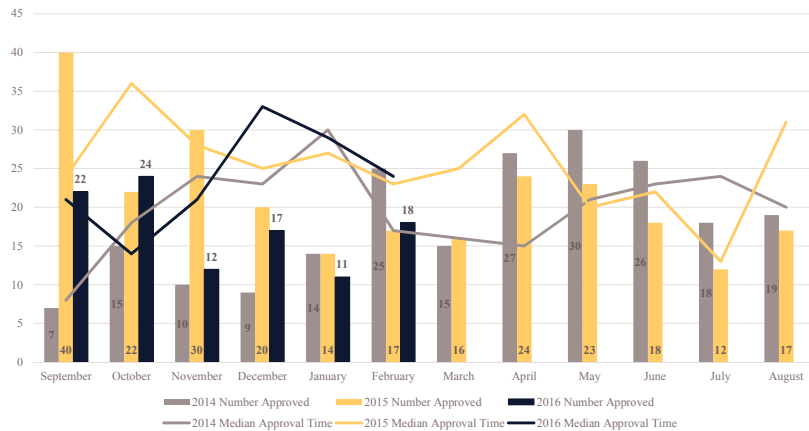
TAMU IBC
Comparison of FY 2014, FY 2015, and FY2016 (first half)
New applications/3YR renewals



	FY 2014	FY 2015	FY 2016 (6 months)
Total approved new applications	95	166	77
Overall median approval time in calendar days	37	47	58
Average approval time in calendar days	50	62	66



TAMU IBC
Comparison of FY 2014, FY 2015, and FY 2016 (first half)
Amendments



	FY 2014	FY 2015	FY 2016 (6 months)
Total approved amendments	215	253	104
Overall median approval time in calendar days	20	25	22
Average approval time in calendar days	27	32	30



Accomplishments

- DSAT registration renewed and extended for the maximum period of 3 years;
- Revised and streamlined the IBC application and annual renewal forms;
- Simplified IBC training requirements by reducing frequency of refresher trainings;
- Developed and implemented on-line biosafety occupational health enrollment management tool;
- In cooperation with Texas A&M AgriLife Research, implemented certification process for transgenic field studies, conducted under USDA/APHIS regulatory oversight, making an IBC permit no longer necessary;



Accomplishments

- Updated the biohazards rule to include provisions addressing oversight, review and approval of DURC;
- Developed and implemented new internal procedures to administer the review and approval of DURC;
- Identified and trained 6 new alternate and 18 new unaffiliated community members; 7 new IBCs have been registered with NIH/OBA.



Challenges

- Biosafety program responsibilities extend to campuses located in Amarillo, Corpus Christi, Dallas, Galveston, Houston, Kingsville, Lubbock, McAllen, Sonora, Stephenville, Temple, Uvalde, Weslaco, and Vernon.
- Local expansion of biosafety responsibilities: OTSC, BRF.

Moving Forward

- Continue to review processes and procedures for opportunities to enhance efficiencies and effectiveness and ease administrative burdens on researchers
 - ❖ Coordination with AWO, HSPP, and SRS



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: Christine T. McFarland, PhD**
- ❖ **Associate Biosafety Officers: Ruchira Mitra, PhD, Jessica Bourquin, PhD, and Susan Gater, MS**
- ❖ **IBC Coordinators: Debbie Perry and Jeffrey Lane**
- ❖ **Occupational Health: Sherri Evans and Lauren Horton**
- ❖ **Select Agent Program: Ndingsa Fomukong, PhD, Frank Cox, Wendy Wright and Jessica Cobos**

