

Norrod, Candace

From: Thornton, Venita (NIH/OD) [E] <thorntov@od.nih.gov>
Sent: Monday, August 12, 2019 1:36 PM
To: Institutional Animal Care and Use Committee
Cc: Smith, Phil; OLAW Division of Assurances (NIH/OD)
Subject: RE: Amended OLAW Assurance for TTU (A3629-01)

Good Afternoon Karin –

I reviewed the documents submitted regarding the changes to the Occupational Health & Safety program at TTU (Assurance #A3629-01). The program changes noted do not require the submission of a revised Assurance document (with a new Signature & date by the IO). Also, OLAW will not retain the supplemental documents (i.e. forms) that were submitted. Please summarize these Program Changes in the next Annual Report to OLAW, and submit the information as an attachment to the Annual Report.

Also, please make sure to reflect these program changes in the IACUC meeting minutes, to be maintained in your institutional files.

If you have additional questions or you want to discuss further, please don't hesitate to contact me directly, or call the OLAW main office number.

Venita B. Thornton, DVM, MPH
CAPT - USPHS Commissioned Corps.
Senior Assurance Officer
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700-B Rockledge Drive
Suite 2500 / MSC 6910
Bethesda, Maryland 20892
Phone: 301.496.7163 (Main)
Phone: 301.451.4208 (Direct)
Fax: 301.480.3421
Email: thorntov@od.nih.gov

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From: Institutional Animal Care and Use Committee [mailto:iacuc@ttu.edu]
Sent: Friday, August 02, 2019 3:24 PM
To: Thornton, Venita (NIH/OD) [E] <thorntov@od.nih.gov>
Cc: Smith, Phil <Phil.Smith@ttu.edu>
Subject: Amended OLAW Assurance for TTU (A3629-01)

Hi Dr. Thornton,

As we discussed on June 21, 2019, attached are the revisions to the OLAW Assurance for Texas Tech University (A3629-01). We are requesting changes to our Occupational Health and Safety program. The changes were approved by the IACUC during the July 30, 2019 monthly meeting. I have also attached the revised and approved version of Policy 23, Pre-Exposure Vaccinations Policy and the TTU Animal Research Activity Release and Indemnity Agreement. Additional edits were also made in the document, which included adding information regarding our new facility, Experimental

Sciences Building II, and edits to the IACUC roster. All edits are shown as track changes. Please let me know if you need anything else in order to implement these requested changes.

Thank you,

Karin Fritz, M.S., CPIA

IACUC Coordinator/ACS Unit Manager

Experimental Sciences Building, Room 022A

Phone: (806) 834-6183 | Fax: (806) 742-4187

Box 43132 | Lubbock, TX 79409

www.depts.ttu.edu/iacuc/

karin.k.fritz@ttu.edu | iacuc@ttu.edu

Domestic Assurance Sample Document

The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals ([Policy](#)) requires that institutions have an OLAW-approved Animal Welfare Assurance before carrying out any activities involving live vertebrate animals. U.S. institutions receiving PHS funds through a grant or contract award are to use the Animal Welfare Assurance for Domestic Institutions (Domestic Assurance).

The Domestic Assurance should not be used by:

- Foreign Institutions
- Institutions that currently do not have their own animal care and use programs
- Institutions that are proposing animal activity to be conducted solely at a collaborating institution

If one of these bullets describes your institution or if you don't know whether your institution is required to submit an Assurance, contact us at olawdoa@mail.nih.gov for guidance.

How to use the sample document

We have provided this sample document to help you develop an acceptable Domestic Assurance. Specific instructions, information, and recommended references are provided in italicized text and should be deleted from the final document. Please strive for clear concise text. It will be easier for you to complete and for us to review the Assurance if you follow the format of this sample.

One or two page attachments can be used to provide the following:

- Organizational structure of the animal care and use program
- IACUC membership roster
- Facility and species inventory
- Most recent semiannual report of program and facilities. This is needed **only** for Category 2 programs, those not accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALAC).

All other program elements are to be described in the body of the Assurance. Do not send any other attachments. We do not accept additional documents, appendices, binders, or manuals.

Tip: If you are not familiar with the PHS Policy or are preparing an Assurance for the first time, we encourage you to visit the [PHS Policy Tutorial](#).

How to submit

Fax your completed Assurance to 301-915-9465 or e-mail to olawdoa@mail.nih.gov

Questions?

Contact the Division of Assurances by phone at 301-496-7163 or e-mail olawdoa@mail.nih.gov

Additional references

- Domestic Assurance webpage, <http://grants.nih.gov/grants/olaw/sampledoc/assur.htm>
- OLAW Online Seminar "Writing a Good Assurance," http://grants.nih.gov/grants/olaw/educational_resources/webinar_06092011.htm
- OLAW homepage, <http://grants.nih.gov/grants/olaw/olaw.htm>
- PHS Policy, <http://grants.nih.gov/grants/olaw/references/phspol.htm>

Animal Welfare Assurance for Domestic Institutions

I, Joseph Heppert, Ph.D, as named Institutional Official for animal care and use at Texas Tech University, provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy). This assurance applies to all animals used on PHS-funded studies at Texas Tech University.

I. Applicability of Assurance

This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS, PHHS and/or NSF (if applicable). This Assurance covers only those facilities and components listed below.

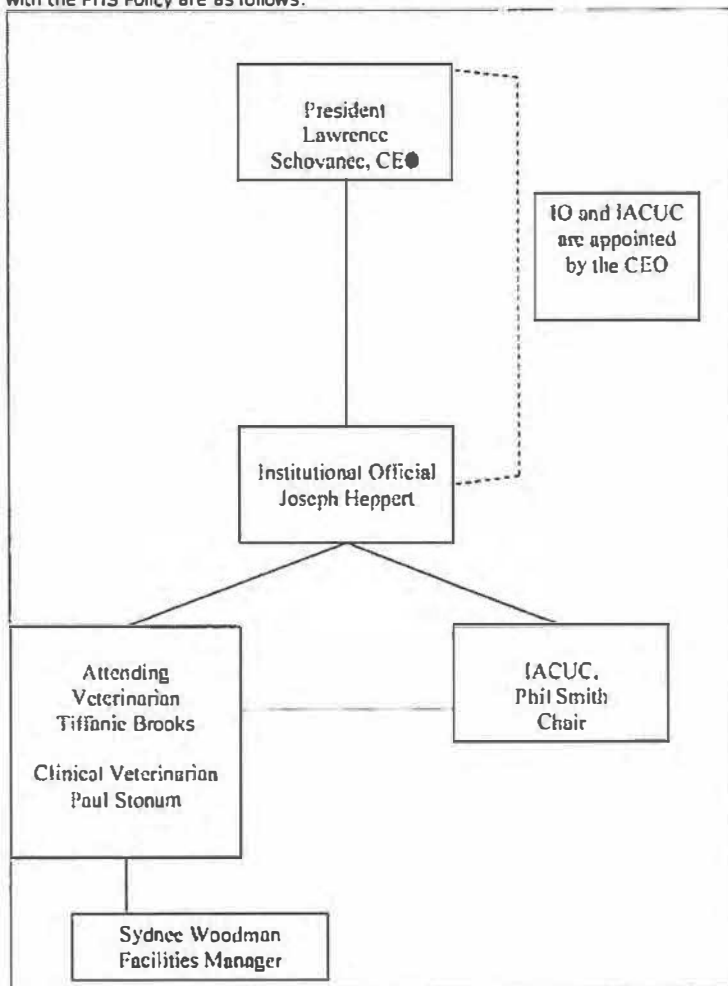
- A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name:
Texas Tech University; Departments of Biological Sciences, Chemical Engineering, Human Sciences, Animal and Food Sciences, Natural Resources Management, and the Institute of Environmental and Human Health.
- B. The following are other institution(s), or branches and components of another institution:

II. Institutional Commitment

- A. This Institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.
- B. This Institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."
- C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, and other applicable laws and regulations pertaining to animal care and use.
- D. This Institution has established and will maintain a program for activities involving animals according to the Guide for the Care and Use of Laboratory Animals (Guide).
- E. This Institution agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (subaward) or subcontract agreements have an Animal Welfare Assurance and that the activities have Institutional Animal Care and Use Committee (IACUC) approval.

III. Institutional Program for Animal Care and Use

A. The lines of authority and responsibility for administering the program and ensuring compliance with the PHS Policy are as follows:



B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:

1) Name: Tiffanie A. Brooks

Qualifications

• Degrees:

B.S. Animal Science Texas Tech University 1993
M.S. Animal Science Texas Tech University 1996

DVM Texas A&M University 2000

Diplomate of the American College of Laboratory Animal Medicine, 2013

- Training or experience in laboratory animal medicine or in the use of the species at the Institution:

~~Eighteen~~ Nineteen years' experience as a veterinarian (8 years in private practice, ~~10 years~~ in laboratory animal medicine and regulatory compliance). Successfully complete ACLAM board certification in the summer of 2013.

Authority: Dr. Brooks has direct authority given by the Institutional Official to implement all applicable provisions of the PHS Policy and the recommendations of the Guide. Dr. Brooks as the attending veterinarian has direct program authority and responsibility for animal activities at the institution. The Attending Veterinarian reports to and has direct and frequent communication with the Institutional Official. The Attending Veterinarian works with the Institutional Animal Care and Use Committee in implementing the PHS Policy and the recommendations in the Guide. Dr. Tiffanie Brooks has direct program authority and responsibility for the Institution's animal care and use program including access to all animals.

Time contributed to program: 100%, full-time employee

2) Name: Dr. Paul Stonum

Qualifications

- Degrees:

B.S. Animal Science Texas Tech University 1989

DVM 1994 University of Missouri

- Training or experience in laboratory animal medicine or in the use of the species at the Institution:

24 years' experience in dairy and mixed animal private practice

Responsibilities:

Provides clinical care for TTU research and teaching animals

Serves on the IACUC

Delegated program authority

Time contributed to program:

100%, full-time employee

- C. The IACUC at this Institution is properly appointed according to PHS Policy IV.A.3.a, and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The IACUC consists of at least 5 members, and its membership meets the composition requirements of PHS Policy IV.A.3.b. Attached is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations.

~~Notes: Sally Post does not have a scientific background. Sally previously oversaw the marketing and communications for the Office of Vice President for Research. Currently she is overseeing the marketing and communications for the museum at Texas Tech University. Sally is classified as a non-scientist on the IACUC roster.~~

D. The IACUC will:

- 1) Review at least once every 6 months the Institution's program for humane care and use of animals, using the Guide as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:
 - As an agent of the Institution, the Texas Tech University Animal Care and Use Committee shall review every six months (October and April) the institution's program for humane care and use of animals, using the Guide, 9 CFR, chapter I, subchapter A - Animal Welfare (Animal Welfare Act), the U. S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing Research and Training, Guide for the Care and Use of Laboratory Animals, Public Health Service Policy on Humane Care and Use of Laboratory Animals, and the Guide for the Care and Use of Agriculture Animals in Agriculture Research and Teaching as a basis for evaluation.

- The program review is completed at the scheduled April and October IACUC meetings immediately following the facilities inspections. The OLAW Sample Semiannual Program and Facility Review Checklist is used to evaluate the program.
 - All applicable items on the Program Review Checklist are evaluated by the IACUC as being acceptable, minor deficiency, or significant deficiency, and not applicable.
 - A reasonable and specific plan and schedule for correction of the deficiencies is stated.
 - The Program Review Report listing the deficiencies is signed by the IACUC and forwarded to the Institutional Official.
- 2) Inspect at least once every 6 months all of the Institution's animal facilities, including satellite facilities and animal surgical sites, using the Guide as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:
- As an agent of the Institution, the Texas Tech University Animal Care and Use Committee shall inspect every six months (October and April) all of the Institution's animal facilities that are being utilized (including satellite facilities) using the Guide, 9 CFR, chapter 1, subchapter A - Animal Welfare (Animal Welfare Act), the 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 Agriculture Animals in Agriculture Research and Teaching as a basis for evaluation is utilized as a supplemental resource.
 - The animal facilities inspections are conducted in April and October. The OLAW Sample Semiannual Program and Facility Review Checklist is used to evaluate the animal facilities. At a minimum two voting members attend each inspection.
 - All IACUC members are encouraged to participate in the inspection.
 - A minimum of three members of the Animal Care and Use Committee will be required to inspect and evaluate each animal facility.
 - All applicable items on the Facility Inspection Checklist are evaluated during the inspection as being acceptable; a minor deficiency or a significant deficiency.
 - A reasonable and specific plan and schedule for correction of the deficiencies is stated.
 - The animal facilities inspection report listing the deficiencies is reviewed and approved at the next scheduled IACUC meeting.
 - The animal facilities inspection report is signed by the IACUC and forwarded to the Institutional Official.
 - The Chair of the IACUC notifies the individual responsible for a facility regarding the findings of an inspection. If deficiencies are identified, the responsible individual must respond in writing within one week, two weeks, or 30 days to define action to be taken to correct deficiencies.
 - A timetable to initiate corrective action is included with the response.
 - Minor deficiencies are corrected within 30 days.
 - An understood target date for correction of significant deficiencies is 6 months from the date of citation or by the next IACUC facility inspection, whichever is sooner.
 - Significant deficiencies (defined as those that are or may be a threat to animal health or safety) require immediate corrective action.
 - After immediate action has been taken to correct any significant deficiencies, an administrative follow-up telephone call or e-mail is made within 30 days of the original inspection by a member of the IACUC that made the original inspection. Results of the follow-up are reported to the IACUC for consideration/discussion as an agenda item at the next full-committee meeting after follow-up contact.
 - Visual observations of corrective actions taken to correct significant deficiencies are confirmed at the next regularly scheduled facility inspection.
 - Inspections by the Animal Care and Use Committee will be performed more frequently if requested by the Attending Veterinarian.
- 3) Prepare reports of the IACUC evaluations according to PHS Policy IV.B.3. and submit the reports to the Institutional Official. The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows:
- After completion of the semiannual review of the animal programs and the inspections of the animal facilities (April and October), the IACUC Chair will prepare a report of the

Animal Care and Use Committee evaluations conducted as required by IV.B.3. of this Policy. The report is signed by a majority of the IACUC members.

- The report will contain a description of the nature and extent of the University's adherence to the Guide and this Policy and identify specifically any departures from the provisions of the Guide and this Policy, and will state the reasons for each departure. TTU currently has the following exceptions to the Guide, which each have been approved by the IACUC:
 - The following species are currently on protocols that have provided justification for the PI to individually house these animals: mice, swine, birds, dogs, cattle, sheep, rabbits, and ferrets.
 - There is a protocol involving mice that has an approved exception to the Guide in regards to room temperature and a separate one that involves food restriction.
 - One protocol has multiple exemptions including, cage change frequency, environmental enrichment, restricted food and water, and stress paradigm.
 - Feeding dogs food that is 6-8 months' post manufacture date.
 - ~~Feeding rodent diet 9 months post manufacture date.~~
 - Prolonged restraint and environmental stress measurement in mice.
- The report will include progress made since the last report with regard to programmatic issues or facilities.
- The report will include recommendations regarding any aspect of the institution's animal care and use program (e.g. facilities, personnel training, veterinary care, occupational health and safety).
- The report will distinguish significant deficiencies from minor deficiencies. If program or facility deficiencies are noted, the report must contain a reasonable and specific plan and schedule for correcting each deficiency.
- In the event there is a minority view, this too would be reported.
- The report (or a revision of the report) is signed by IACUC members to signify their endorsement of its content. The final report is then forwarded to the Institutional Official, Dr. Joseph Heppert.
- The report shall be maintained by the institution and shall be available to OLAW upon request.

4) Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:

Signage is posted at each animal facility, identifying procedures to report animal mistreatment or complaints without fear of reprisal. Complaints may be anonymous and a preliminary investigation will occur by the IACUC Chair and Attending Veterinarian. Preliminary investigations which reveal evidence of animal mistreatment trigger a formal investigation by a subcommittee of the IACUC appointed by the IACUC Chair in consultation with the Attending Veterinarian. Employees who make complaints about animal mistreatment may be entitled to certain protections under law and/or TTU policy (TTU OP 74.08). No employee, student, IACUC member or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting perceived noncompliance with any of the regulations or policies pertaining to animal care and treatment. Complaints may be made to the IACUC coordinators, Attending Veterinarian via a phone call or email or to any IACUC member. A subcommittee will prepare a report for the IACUC. The IACUC will immediately review the concern or complaint and will determine what action will be taken (majority quorum vote and minority opinions will be recorded). The Chair of the IACUC will immediately notify the individual(s) at whom the concern/complaint is directed, the relevant facility director, department head, dean, the Institutional Official, and the complainant. The IACUC will investigate the concern and communicate the findings to the reporting party and IO. The report includes findings and any corrective action. Animal welfare concerns or other non-compliance findings may need to be reported to governing bodies, such as OLAW, USDA or AAALAC.

5) Make written recommendations to the Institutional Official regarding any aspect of the Institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are as follows:

The Texas Tech University Animal Care and Use Committee will make recommendations to the Institutional Official in the semiannual report or at any other time as deemed appropriate regarding any aspect of the University's animal program, facilities, or personnel training.

- 6) Review and approve, require modifications (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals according to PHS Policy IV.C.1-3. The IACUC procedures for protocol review are as follows:

TIMING OF PROTOCOL REVIEW

Animal Use Forms (AUF) are received in the office of the IACUC Coordinators. All protocols/amendments must be submitted at least one week prior to an IACUC meeting to be reviewed and potentially approved at the upcoming meeting. If submitted less than one week prior to a regularly scheduled IACUC meeting protocols will not be reviewed until the next meeting.

DESIGNATED MEMBER REVIEW

Each IACUC member shall be provided with an electronic copy of proposed research, teaching, and demonstration projects and subsequent amendments to approved projects that involve the care and use of vertebrate animals. Any IACUC member may request full committee review (see section below) of any University-associated project or project amendment utilizing vertebrate animals. Each IACUC member shall have three working days from the time the electronic animal use protocol (AUP) or amendment is disseminated to the IACUC membership to ask questions, comment, or call for full committee review. Secondary DMRs and the appointed veterinarian will have four business days to respond with clarifications that the PI will need to address to the IACUC Coordinators. The secondary DMR and vet reviewer are not pre-reviews, they serve as DMRs along with the lead. The lead DMR will have one week to respond with clarifications, which includes reviewing all comments received thus far. The lead DMR, secondary DMR, and vet reviewer all receive the same documents simultaneously to review and they must all approve unanimously. If any member feels that any AUP or amendment should go before the full committee, then its review must be deferred to the next full IACUC meeting. Any member can make the decision to send the AUP or amendment to full-committee review at any time during the time period designated for providing this opportunity.

If no member calls for full committee review within three working days after dissemination of the electronic AUP or amendment, then the appropriately qualified IACUC members that are appointed by the IACUC Chair will serve as the designated reviewer(s). Reviewers are selected based on their area of expertise and department. A university veterinarian will review all AUPs and amendments. In the event more than one DMR is selected, the Chair will assign a lead DMR. No member may serve as a designated reviewer for any AUP or amendment in which the member has a conflicting interest (e.g., is personally involved in the project) except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum.

Once IACUC members have chosen designated member review (by virtue of not calling for full committee review), then the reviewer(s) assumes the responsibility for the full IACUC in granting approval, requiring modification, or sending the AUP or amendment for full review. However, at any point during the review process, any IACUC member (including DMR(s)) may request a full committee review of any AUP or amendment at which point the DMR process immediately ceases and the AUP or amendment is placed on the next full committee meeting agenda.

Designated reviewers will be chosen by the IACUC Chair from among all IACUC members, but consideration may be given to expertise and current workloads. Within one week of DMR assignment by the Chair and notification by the IACUC Coordinators, the designated reviewer(s) should request the IACUC Coordinators to seek clarification or pose questions

to the PI if need for such clarification exists. Once questions and/or revisions have been resolved to the satisfaction of the designated reviewer(s), and a total of at least three working days have passed since the IACUC received notice of the submitted protocol, and no member of the committee has requested full review, the designated reviewer may:

- 1) **approve;**
- 2) **require modifications** to secure approval (if additional, issues exist that require clarification); or,
- 3) **refer to full committee.**

In the event that the designated reviewer feels that approval should be withheld, the AUP or amendment will be reviewed by the full committee. Designated review may not result in withholding of approval. If an AUP or amendment is assigned more than one designated reviewer, the reviewers must be unanimous in any decision. It is not acceptable to proceed with only a majority vote. They must all review identical versions of the AUP or amendment and if modifications are requested by any one of the reviewers then the other reviewers must be aware of and agree to the modifications. If one or more of the DMRS disagrees, then the AUP or amendment must be referred to the full committee to review. The designated reviewer does not have the power to withhold approval, however, but must in such cases refer the AUP or amendment for full-committee review.

Under no circumstances will animal work be permitted to begin or resume until final written IACUC approval is granted.

FULL COMMITTEE REVIEW

Each IACUC member shall be provided with an electronic copy of proposed research, teaching, and demonstration projects and subsequent amendments to approved projects that involve the care and use of vertebrate animals. Any IACUC member may request full committee review of any University-associated project or project amendment utilizing vertebrate animals. Each IACUC member shall have three working days from the time the electronic animal use protocol (AUP) or amendment is disseminated to the IACUC membership to ask questions, comment, or call for full committee review. If any member feels that any AUP or amendment should go before the full committee, then its review must be deferred to the next full IACUC meeting. Any member can make the decision to send the AUP or amendment to full-committee review at any time during the time period designated for providing this opportunity.

If full committee review of an AUP or amendment is requested, approval of those research projects may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present. If full committee review is not requested by any IACUC member within three working days from the time the electronic AUP or amendment is disseminated to the IACUC membership, it may be reviewed via the designated review process.

No member may participate in the full committee IACUC review or approval of an AUP or amendment in which the member has a conflicting interest (e.g., is personally involved in the project) except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum. The IACUC Chair will assign a primary reviewer to present the AUP or amendment undergoing full committee review to the IACUC, or the members can discuss collectively with direction from the Chair. Primary reviewers are encouraged to take the initiative to contact the investigator prior to the meeting for clarifications, additional information, or in anticipation of questions the IACUC may raise.

There are three potential outcomes of full committee review of a protocol or amendment:

- 1) **Approval:** Requires an affirmative vote by a majority of the convened quorum present.
- 2) **Withhold Approval:** In the event that substantive questions prevent final approval or moving forward with the review process, the committee can wait

until the next meeting for revisions to be reviewed by the full committee. The committee members can also vote to withhold approval if they feel that the requirements of PHS Policy or other stipulations have not been satisfied.

Modifications Required (to secure approval): Diversion of a Pain Category "E" protocol into the DMR process requires a unanimous vote of the IACUC during a full committee meeting. A unanimous vote must be established in order for the AUP or amendment to go back to the DMR process. If a unanimous vote is not reached, then it will be reviewed at the next regularly scheduled meeting. IACUC members sign a document on a yearly basis indicating they agree that protocols considered for Full Committee Review may be sent through the Designated Member Review process upon a unanimous vote of committee members at an official IACUC meeting where quorum is obtained. Additionally, the document states they understand they can call any protocol for Full Review at any time. Committee members are given the opportunity to require that the requested modification(s) be brought before the next committee meeting. Through this process the PI is required to address clarifications that the IACUC outlines. The lead DMR will work directly with the PI to ensure clarifications are addressed. There is a SOP in place that outlines the DMR and FCR processes. During the initial IACUC member training, members are informed that they can, at any time request to see a revised protocol and they can also request FCR of any protocol/amendment. Under no circumstances will animal work be permitted to resume or begin until final written IACUC approval is granted.

Notification of Review Outcomes

The IACUC will notify PIs in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval. The IACUC procedures to notify PIs and the University of its decisions regarding protocol review are as follows:

- Upon completion of the review process, each PI receives a written notification of review decisions (approval, clarifications required, or table) and whether any special monitoring provisions will be required. Records of communication are maintained within the IACUC protocol files.
- Upon completion of the review process, a copy of the meeting minutes is provided to the IO. This informs the IO of all actions taken by the IACUC.

Review of Designated Reviews at Full Committee Meetings

At each regularly scheduled monthly IACUC meeting, members will be provided with a list of AUFs and amendments to previously approved protocols that have been processed via the designated review process since the previous IACUC meeting. Members can discuss any of these approvals as needed during the meeting. Full written descriptions of the AUFs and amendments will be made available to IACUC members upon request. During the IACUC meeting, the Chair will report DMR approvals of AUFs and amendments, as well as annual review and progress reports and protocol terminations received by the IACUC office since the last meeting.

The DMR process that has been implemented into our program was established in order to review AUPs and amendments as proficiently and timely as possible. Therefore, we do not have an expedited review process.

- 7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities according to PHS Policy IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:

Amendments to Approved Protocols

Principal Investigators (PIs) must inform the IACUC of any proposed significant changes to an approved protocol prior to the changes being implemented. The IACUC or a designated reviewer(s) must review and approve these changes as described in section III.D.6. Amendments must be submitted to the IACUC Coordinator on the Protocol Amendment Form.

Examples of significant changes include, but are not limited to:

- Increase or decrease in the number of animals, which includes more than a 10% increase from the original protocol approved number of animals
- addition of a new species
- new procedure or change/deletion in a procedure being used
- change in pain classification of the procedure
- major/critical change in post-procedural pain management
- change from terminal to survival surgery
- change in personnel conducting the procedures
- change of PI

If a proposed change to a protocol is minor, it may be handled administratively.

Examples of minor changes include, but are not limited to:

- addition or deletion of personnel
- change in title
- change in funding source
- change of location
- Increase or decrease in the number of animals, which includes less than a 10% increase from the original protocol approved number of animals

Amendments to USDA Pain Category "E" Approved Protocols

As described above, PIs must inform the IACUC of any proposed significant changes to an approved protocol prior to the changes being implemented. However, amendments to USDA Pain Category "E" protocols do not necessarily have to be brought before the full committee, and may be processed through the designated member review route as described in section III.D.6.

if:

- the requested change does not result in alterations to, or additional procedures that induce more than momentary pain or distress
- additional animals are requested, but no additional animals will be subjected to any procedures determined to cause more than momentary pain or distress
- the PI requests addition or modification of a procedure that does not induce more than momentary pain or distress

Determination of review route (full committee versus designated member review) will be determined by the IACUC Chairperson and/or Attending Veterinarian. This may be done in consultation with the PI or consultant having appropriate expertise.

- 8) Notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval according to PHS Policy IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:

- The Chair of the IACUC shall notify investigators in writing of its decision to approve, request modifications in (to secure approval), or withhold approval of those sections of the applications or proposals related to the care and use of animals. The IACUC Chair will also notify the IO and Office of Research Services of its ultimate decision to approve or withhold approval of those sections of the application or proposals related to the care and use of animals.
- If the IACUC withholds approval of an application or proposal, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
- The IACUC sends the IO minutes of meetings, which includes a list of protocol titles and actions. The IO may examine protocols and IACUC actions.

- 9) Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review at least once every 3 years according to PHS Policy IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows:

TTU Staff Involved in Post-Approval Monitoring

- 1) Post-Approval Monitor- Dr. Brittany Backus, PhD.

- 2) Attending Veterinarian- Dr. Tiffanie Brooks, DVM, DACIAM- conducts veterinary and facility rounds monthly
- 3) Clinical Veterinarian- Dr. Paul Stonum, DVM- conducts veterinary and facility rounds monthly; conducts farm and equestrian center rounds weekly
- 4) ACS Facilities Manager- Ms. Sydnee Woodman- conducts manager and facility rounds monthly

Purpose of Post-Approval Monitoring

The purpose of the post-approval monitoring position is to work with investigators in a supportive manner in order to assure that investigators are in compliance with Institutional Animal Care and Use Committee (IACUC) approved research protocols, and when applicable, grant funding agency requirements. This is a service-oriented position established to help investigators stay in compliance with approved protocols, guidelines, laws, and best practices. If animal use activities are determined to be non-compliant then the Post-Approval Monitor (PAM) will work in conjunction with the investigator to resolve the issue, and help the investigator get back in compliance quickly so that appropriate animal care is maintained and research is not compromised.

Post-approval monitoring of IACUC protocols is conducted to provide assurance to regulatory agencies, Texas Tech University, and the broader community, that animals are used in a humane manner that is consistent with IACUC approved protocols and all Federal and State Regulations.

Roles of the PAM:

- Correspond, document, maintain records, and consult with the IACUC such that the IACUC receives timely reports or updates on items of concern.
- Work in conjunction with investigators and research personnel to organize monitoring events to observe animal procedures and certify compliance with approved protocols.
- Work with, and in support of, investigators to assure research is conducted within the limits of approved protocols and in compliance with Federal Regulations.
- Assist investigators in understanding regulatory compliance and assure good science.

Required Protective Measures:

The PAM, as well as other visitors, shall wear the PPE prescribed for the specific activity/procedure of the laboratory.

Expectations:

1. Selection of Protocols for Review:
 - a. Active protocols involving the use of USDA Category C, D, or E will be selected for monitoring on a random basis or at the discretion of the IACUC and/or University Veterinarian.
 - b. Protocols involving less invasive procedures will be monitored at the discretion of the IACUC and/or veterinary personnel.
 - c. The PAM will schedule monitoring sessions with the Principal Investigator in advance.
2. Process of Monitoring:
 - a. The PAM shall use the "Post-Approval Monitoring Checklist" for the review which is made available to all PIs upon approval of an animal use protocol.
 - b. During each monitoring session, the PAM will compare procedures conducted in the laboratory with those listed in the approved protocol. Discrepancies between procedures performed in the lab and those listed in the protocol will be brought to the attention of the PI.
 - c. Animal misuse, mistreatment or neglect (welfare issues), and discrepancies which result in animal welfare concerns (deliberate animal misuse, mistreatment or neglect, or those that involve willful disregard for appropriate animal care) will be immediately reported to the IACUC and/or University Veterinarian. The IACUC staff, in conjunction with the University Veterinarian and IACUC Chair, will gather information to present to the IACUC for review and, if necessary, further investigation.
3. Process of Sharing Information Concerning the Review:

- a. The PAM shall discuss monitoring results with the PI and/or other research personnel before leaving the laboratory. If issues can be resolved during the monitoring session, the PAM will address them before leaving so that the investigator may remain in compliance. The PAM may make suggestions for improved procedural techniques and animal well-being. Issues that pose an immediate threat to animal welfare shall be referred to the IACUC and/or University Veterinarian.
 - b. The PAM shall send a written draft report of the monitoring results to the PI. Investigators will have an opportunity to respond within one week. The response and all correspondence thereafter will be filed with the report.
4. Follow-up Process:
- a. The PAM will follow up on any issues that require protocol modifications, orientation of new personnel, or training. The PAM will support the corrective action by providing required training and/or assistance with form preparation (amendment submission).
 - b. On occasion, additional monitoring sessions may be included as part of the follow-up to facilitate corrective actions.
5. Recordkeeping:
- a. A copy of the final compliance monitoring report shall be kept in the protocol file. Non-compliant information shall be entered into a Database for use as institutional trending or follow-up and determination of general training or informational needs.

Annual & Three Year Reviews

All approvals are for a period of 12 months. The IACUC shall conduct a continuing review, every 12 months, of applications and proposals that extend over a 1-year period. The Annual Review Form and Progress Report is used for this purpose. Individuals that have protocols that extend for over three years are required to complete a new Animal Use Form at three-year intervals.

- Yearly, at least two months before the anniversary month of the original approval of the protocol, the Principal investigator is prompted to submit an Annual Review Form and Progress Report for review and approval by FCR or DMR as described in section III.D.6.
 - Every third year, at least two months before the anniversary month of the original approval of the protocol, the Principal investigator is prompted to submit, in lieu of an Annual Review Form and Progress Report, a new Animal Use Form (which would be reviewed by the committee either FCR or DMR) for review and approval by the IACUC. The three year form request for PIs to report what has been accomplished and the number of animals used throughout the past three years, which is a complete de novo review as described in Part III.D.6. The procedures for review are the same as for the initial review.
 - Failure to submit an Annual Review Form and Progress Report or an Animal Use Form by the required deadline may result in closure of the protocol and its associated activities.
- 10) Be authorized to suspend an activity involving animals according to PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are as follows:
- The Texas Tech University IACUC is authorized to suspend an activity involving animals if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide, the institution's Assurance, or IV.C1.a.-g. of the PHS Policy.
 - The IACUC will suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC or through teleconference and with the suspension vote of a majority of the quorum present. Under exceptional circumstances when a teleconference is determined to be most appropriate, the following guidelines will be followed:
 - All members will be notified via Outlook Meeting Request.
 - All documentations pertaining to the meeting will be emailed to all members prior to the teleconference.
 - All members will be provided the documentation and have the technology capabilities to participate.
 - A quorum of voting members must be reached.
 - The teleconference allows all members to equally participate simultaneously.

- If a vote is called, each member will individually state if they approve, abstain, or not approve.
- If a member is not able to take part in the teleconference, they can still submit their comments to the IACUC Coordinator, IACUC Chair, or AV. Members not present on the teleconference cannot vote and do not count to meet quorum.
- The NIH Guide for Grants and Contracts NOT-OD-06-052 regarding approved methods of conducting IACUC business on a teleconference call will be followed.
- Written minutes of the meeting are maintained in the IACUC Office.
- A suspension will not occur before consultation with the responsible individual (that person in charge of the activity).
- Such consultation will allow the responsible individual to be informed of the cause for concern so that an opportunity is afforded to explain his/her side of the issue.
- If the IACUC suspends an activity involving animals, the IO, in consultation with the IACUC, shall review the reasons for the suspension, take appropriate corrective action, and report that action with a full explanation to OIAW, USDA, AAALAC International, and/or any other Federal agency funding this activity. The suspension could also be reported to funding agencies.

E. The risk-based occupational health and safety program for personnel working in laboratory animal facilities and personnel who have frequent contact with animals is as follows:

Hazard ID and Risk Assessment

- Risks associated with proposed animal use activities (including experimental hazards) are identified and mitigated during the protocol formulation and review process. The TTU Animal Use Form queries animal users for potential hazards including radiation, biological hazards (pathogens), toxic chemicals, and controlled substances. Once identified, animal users are directed to the appropriate safety committees for approval of proposed use of hazards and training. Animal Use Protocols will not be approved by the IACUC prior to approval from appropriate safety committees (e.g. IBC, IISC, RSC).
- For animal-specific hazards, risks are evaluated for individual users following guideline delineated in the TTU Animal User Risk Assessment. A previous iteration of the TTU animal user risk assessment document underwent major revisions by the IACUC OH&S subcommittee in 2012 in response to the new ILAR Guidelines. That document was further refined by a select group of Risk Assessment Reviewers including an Allergist, Wildlife Veterinarian, Laboratory Animal Veterinarian, Occupational Medicine Physician, and the Attending Veterinarian. Considerations included past, current, and future animal use activities at TTU. The risk assessment document was reviewed for completeness and revised according to reviewer recommendations. The most current revisions to the program occurred in September 2017 to reflect the implementation of the IACUC Policy 23: Pre-Exposure Vaccinations. These revisions implemented the requirement for pre-exposure rabies and tetanus vaccinations. The revised document is on file in the IACUC office. It has been implemented into web based program (Web-based Risk Assessment Program; WRAP) designed to evaluate risks to animal users on a yearly basis. The web link is: [2017-2018 Non-TTU November](#)
- The OH&S program will be reviewed and approved by the IACUC and evaluated every 6 months.
- Specific training and guidelines for prevention of common zoonoses pertaining to the animals involved in animal use activities are provided to the P.I. at the time of protocol, amendment and annual review approvals, during OH&S assessment, and posted on the IACUC web page.

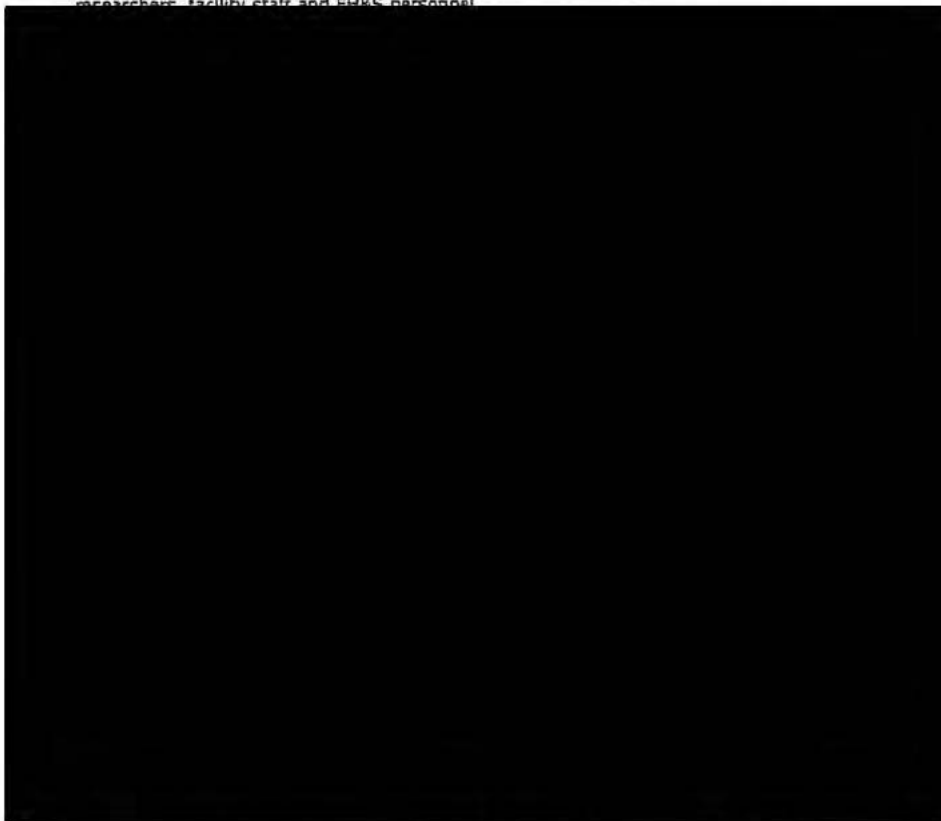
Reporting and Evaluating Exposure to Hazards, Injuries

Exposure to hazards and work related injuries are reported to the employee's supervisor and the individual is advised to seek medical attention. An incident report is submitted to the EH&S office within 24 hours and the risk management office is contacted after the exposure to evaluate workman's compensation. The incident is reviewed by EH&S and is followed-up with involved personnel to determine if changes to policies and SOPs are necessary to prevent additional exposures and/or injuries.

4/18/18

Facilities, Equipment and Monitoring

- The IACUC and Environmental Health and Safety provide oversight. Biohazards signs and required PPE are posted on room doors that contain hazardous agents. SOPs are reviewed by the various committees (i.e. IACUC, Institutional Biosafety Committee, Institutional Laboratory Safety Committee) or EH&S to ensure personnel are following proper handling techniques, using appropriate engineering controls and waste is. Chemical agents are stored in accordance to the segregation scheme outlined in the Texas Tech University Chemical Hygiene Plan (CHP) using flammable and corrosive cabinets, flammable refrigerators and other storage equipment as necessary. Biological agents are stored in accordance to the BMBL and CHP, with locations of usage and storage clearly labeled. Access to on-campus, biomedical animal facilities is limited to researchers, facility staff and EH&S personnel.



PPE

- New employees are required to read (and sign signature documentation forms associated with) protocols and SOPs and receive one-on-one training on proper use of PPE, safety practices and animal husbandry before working alone. The facility manager conducts scheduled rounds to inspect safety. PPE includes: changing into scrubs, using disposable gown, mask, shoe cover, head cover and gloves. Work surfaces are disinfected before, during and after procedures. Contaminated caging and waste is bagged and autoclaved.
- Personnel are trained in the proper operation and use of equipment and PPE. PPE is not worn outside of the animal facilities and street clothes are not worn inside animal

facilities. Swine center personnel are requested to shower out of the facility, and to show in if they have been in contact with swine within the past 72 hours. Hearing protection is provided and recommended when handling or working with swine.

- Much of the PPE that is used within the animal facilities is disposable. Lab coats, scrubs and coveralls are laundered onsite and not removed from the facility. Rubber boots are disinfected after each use. Biosafety cabinets and the waste dumping station are certified annually. Fire extinguishers, safety showers, eye-wash stations, and other safety equipment are inspected regularly by ACS and EH&S personnel.
- Environmental Health and Safety offers respirator fit testing and training for those individuals that require or choose to wear respiratory protective equipment. Facemasks are required to enter some animal rooms or offered to personnel who work in closed quarters with a high concentration of animals (e.g. poultry or swine). Personnel working at the feedmill have access to facemasks because of dust and feedstuff debris.

Personnel Training

- Principal Investigators must be a faculty member, have a Ph.D. or equivalent degree, and have experience conducting animal research. Investigators are trained in the requirements for the ethical and humane use of animals in research and are competent in handling and manipulating their research animals. All investigators, graduate students, IACUC members and technicians/staff that utilize live animals, regardless of prior experience, are required to complete and obtain a passing quiz score on the online Generic Training course (http://www.depts.ttu.edu/iacuc/training/Generic_Training/Online_Generic_Training/index.htm). This training presents the current laws, regulations, guidelines and policies concerning the use of live animals and occupational health and safety at Texas Tech University. The procedure for completing and submitting an Animal Use Protocol is also discussed. Individuals may also receive information regarding species-specific zoonotic exposure. They have the opportunity to discuss work related exposures, including allergens, with an occupational physician and receive prophylactic vaccines according to their potential risks. The OH&S Web-based Risk Assessment Program (WRAP) is designed to evaluate risks to animal users on a yearly basis. The web link is: [2017-2018 Non-TTU November](#). WRAP assesses each individual animal user's risk specific to proposed animal use activities. Additionally, WRAP provides animal users with species-specific zoonoses, allergies, and physical hazard information.
- Relatively few hazardous agents are used with animals at TTU. Animal use that involves a biohazard is reviewed and approved by the Institutional Biosafety Committee prior to the IACUC approval of the protocol. TTU EH&S provides laboratory safety training pertaining to chemical hazards. Animal users requiring use of radioactive materials must apply for, and receive a radioactive materials sublicense before purchasing. Will place orders for radioactive materials.
- Training of the research staff in the use of hazardous agents is the responsibility of the P.I. involved with that specific research.
- The Texas Hazard Communication Act requires a written Hazards Communication Policy. University OP 60.02 is the written policy.

Personal Hygiene

- Workers are informed of University operating policies for respiratory protection, protection from hazards and noise protection. (TTU OPs 60.05 and 60.09)
- Animal Care Services personnel are provided scrub suits, lab coats, and other appropriate PPE depending on animal room requirements (i.e. eye protection, booties, and gloves). Disposable PPE is disposed of outside of the animal room. Scrubs and lab coats are laundered on-site.
- Animal staff and students working at the Swine unit are provided complete on-site clothing (i.e. coveralls, rubber boots and hearing protection). They are also requested to shower out of the facilities. Toiletries are provided. Clothing is laundered on-site.
- Workers in field studies are provided protective clothing commensurate with the risks to which they are exposed.
- Hand sinks, showers and changing facilities are available to all employees.

- All visitors must wear boots and coveralls kept at the site and not wear street clothing; Showering in is required if the person has been around pigs or other at-risk species 72 hours before entering air spaces with pigs. Showering out is required at the Swine Center unless the visit is very brief (minutes; as in dropping off papers). (IACUC Policy 01)
- Eating, drinking and smoking are not permitted in animal rooms. Signage is posted at animal facilities.

Animal Experimentation Involving Hazards

Few hazardous agents are used, however, when a protocol is reviewed that may involve exposure to hazards, the following procedures are implemented:

- The Environmental Health and Safety office is notified of the proposed work. They will provide on-site oversight of the hazard exposure and require the IBC Protocol to be approved when BSL2 agents are used. Chemical and physical agents will be reviewed by Environmental Health and Safety and, if deemed particularly hazardous, the Institutional Laboratory Safety Committee to ensure proper SOPs and protocols are in place to minimize any risk posed to animals and researchers.
- The IACUC will not approve an animal use protocol before the Biosafety Committee and/or Institutional Laboratory Safety Committee has reviewed and approved the IBC Protocol and/or SOP, respectively.
- Personnel on protocols approved by the IBC committee are required to complete Laboratory Safety training, Biological Safety training and, if required, Bloodborne Pathogen training. The PI and laboratory staff are also required to receive specific training on the chemicals being used in the project. Depending on the agents the personnel will use, prophylaxes can be offered to help prevent disease in case of an exposure. If an exposure does occur, the supervisor is notified and appropriate actions are taken. EH&S is notified and protocols are reviewed to determine if changes need to be made to reduce the likelihood of future exposures.
- Both of the anesthesia machines are precision vaporizers and contain a soda lime and an activated charcoal canister for scavenging excess gas. If isoflurane is used in a closed container, it must be accomplished under a fume hood or biosafety cabinet. If isoflurane is used for field studies, it must be done in an open area to prevent excess gas accumulation and risk to personnel.
- Issues associated with exposure of personnel to hazardous materials are reviewed by appropriate safety committees (Institutional Biosafety Committee, Radiation Safety Committee, Institutional Laboratory Safety Committee), and each facility maintains its own specific Chemical Hygiene Plan. Therefore, potential exposures among personnel are evaluated prior to use of hazardous materials to minimize or eliminate potential risks. Further, animals are housed in individually ventilated cages. Cages are changed in a biosafety cabinet. Standard Operating Procedures are available to detail procedures for the decontamination of surfaces, rooms and equipment. All personnel are required to wear appropriate PPE.

Medical Evaluation and Preventative Medicine

IACUC

Occ-Med (provider)

IACUC Coordinator

Environmental Health and Safety (funding): ~~Individuals on their department are required to pay for half the cost of the pre-exposure rabies vaccination series.~~

- Our Occupational Health and Safety Program covers all individuals that work with animals. This includes faculty, staff, students, physical plant, and all other personnel that are listed on a protocol but are not affiliated with the university.
- ~~Hazard analysis and risk assessment of our animal use program aids in identification of individuals that would be categorized as high health risk. This includes individuals that are pregnant or plan to become pregnant within the next year, are immunocompromised, have moderate to severe allergies, and/or have moderate to severe asthma. Individuals working on PHS funded projects, including animal care staff, must complete a health history form which is then evaluated by Occ-Med, our Occupational Health provider. The physician will determine whether further evaluation is required based on the individual's risks. A form is then filled out by the physician and is returned to the IACUC coordinator. Environmental~~

Health and Safety, and the individual's supervisor. This ensures that animal users working on PHS funded projects complete the health history.

- All individuals must enroll in the Occupational Health and Safety program using the OH&S Web-based Risk Assessment Program (WRAP). It is designed to evaluate risks to animal users before initiation of animal use activities and again on a yearly basis. The web link for WRAP is: 2017-2018 Non-ITU November. WRAP assesses each individual animal user's risk specific to proposed animal use activities. Additionally, WRAP provides animal users with species-specific zoonoses, allergy, and physical hazard information.
 - All University animal users are afforded the opportunity to consult the occupational medicine service provider (Occ-Med). Individuals working on PHS funded projects, including animal care staff, must complete a health history form, which is then evaluated by Occ-Med, our Occupational Health provider. The physician will determine whether further evaluation is required based on the individual's risks. The physician returns a checklist form back to the IACUC coordinator ensuring that the health history was completed. The animal user is then cleared to work with animals.
 - Non-University personnel are provided their risk assessment and required to follow up with their institutional occupational health care services to determine their fitness to work. A signed release and indemnification form from the individual must be provided to the IACUC coordinator before animal work can proceed.
- Hazard analysis and risk assessment of our animal use program aids in identification of individuals that would be categorized as high health risk. This includes individuals that are pregnant or plan to become pregnant within the next year, are immunocompromised, have moderate to severe allergies, and/or have moderate to severe asthma. Individuals working on PHS funded projects, including animal care staff, must complete a health history form which is then evaluated by Occ-Med, our Occupational Health provider. The physician will determine whether further evaluation is required based on the individual's risks. A form is then filled out by the physician and is returned to the IACUC coordinator, Environmental Health and Safety, and the individual's supervisor. This ensures that animal users working on PHS funded projects complete the health history.
- We make available to all individuals-university personnel that work with animals a tetanus vaccination and pre-exposure prophylaxis. This includes all employees that work with animals. Animal users would also go to Occ-Med in the event they should need treatment for bites, scratches, illness or injury. WRAP also identifies individual animal users who, by reason of personal health status or heightened animal activity risk factors, are strongly encouraged to consult the occupational medicine service provider. Medical records of individuals (including evaluations, immunizations, etc.) who choose to consult with the occupational medicine provider are maintained by the occupational medicine provider. We do not require all personnel to receive an assessment from Occ-Med, but have this program in place for anyone that requests a qualified occupational health medical evaluation. However, we do require all PHS funded University users, including animal care staff, to complete a health history form to be evaluated by the Occupational Health provider. Occ-med and Environmental Health and Safety both maintain the records on individuals that utilize their healthcare team, and the services each person receives. Due to HIPAA laws, the IACUC office does not keep any record of medical evaluations for any individual.
- All animal handlers, which includes all employees who work with animals, are required to complete the open enrollment of WRAP, and re-enrollment is required annually. The WRAP identifies at-risk animal users (pregnant or plan to become pregnant within the next year; have an immunocompromised system; have moderate to severe allergies; have moderate to severe asthma) and provides species-specific precautions intended to prevent exposure to potentially hazardous agents, tissues, chemicals/toxins, or situations.
- All animal users are informed that in the event their health status changes, and especially if they transition into a high-risk category they should consult their respective occupational health program can utilize the Occ-Med program at any time they deemed necessary. Guidelines and zoonotic information are outlined for each species, along with appropriate PPE, importance of good personal hygiene, and other hazards that could be in their work environment. Facility personnel and PIs train personnel on PPE and equipment. University individuals-students and employees working on PHS funded projects, including animal care staff, must complete a health history form, which is then evaluated by Occ-Med, our

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Occupational Health provider. The physician will determine whether further evaluation is required based on the individual's risks. Personnel that are pregnant, have allergies or are immunocompromised will be evaluated and provided guidance to prevent further illness. The physician returns a checklist form back to the IACUC office, Environmental Health and Safety and the individual's supervisor ensuring that the health history was completed. The animal user is then cleared to work with animals.

- All individuals working with animals are required to receive a tetanus vaccination (that can be documented) every 10 years. (IACUC Policy 23)
 - Individuals working with animals that are high risk carriers of rabies and are not wearing appropriate PPE to mitigate their risk are required to receive the pre-exposure rabies vaccination series. Additionally, these individuals must have their titer checked every two years. (IACUC Policy 23)
 - Species-specific SOPs are available in the IACUC office to inform and protect animal users involved with these species.
- F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed there and the average daily inventory of animals, by species, in each facility is provided in the attached Facility and Species Inventory table.
- G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

Animal User Training

- All personnel involved with animal care and use at TTU must be trained in the requirements for the ethical and humane use of animals. Regardless of prior experience, all personnel involved in the TTU animal care and use program are required to complete the online Generic Training course. This course presents the current laws, regulations, guidelines and policies concerning the use of live animals and occupational health and safety at Texas Tech University. Individuals submit their certificate of completion of the course with a passing score to the IACUC office. An electronic training database has been developed and is maintained to keep training records of all animal users. Training records of all personnel listed on animal use protocols are checked against the database prior to protocol approval to ensure that listed animal users are properly trained. Additionally, PIs and all personnel listed on approved protocols are asked to read, acknowledge, understand, sign, and initial a signature documentation form that is included in each approved study notebook. Initials are checked against those conducting daily monitoring logs to ensure appropriate training.
- Species-specific training is provided by the Attending Veterinarian and/or Animal Care Staff when needed for specialized protocols. Specialized training is documented and records are maintained in the IACUC office. The Attending Veterinarian and Animal Care Staff are also frequently (at least monthly) and regularly involved in Post Approval Monitoring to ensure appropriate training among animal users.
- Personnel are trained in the requirements for the ethical and humane use of animals and to be competent in handling and manipulating animals. Regardless of prior experience, all personnel involved in the TTU animal care and use program are required to attend to complete the online Generic Training course. This course includes training on the following topics: animal care and use legislation, IACUC function, reporting concerns, occupational health and safety, ethics and concepts of animal use, the 3-R's, handling, aseptic technique, anesthesia/analgesia, and euthanasia. Principal Investigators must be a faculty member, have a Ph.D. or equivalent degree, and have experience conducting animal research. Based on research team expertise, species-specific training may be required and is offered through the Attending Veterinarian and/or Animal Care Services for research groups working with rodents or rabbits. For livestock species, students and staff are generally trained by highly experienced principal investigators or animal care staff members. A wildlife veterinarian is consulted on projects requiring specialized care for wildlife species.

IACUC training

- Each new animal worker/user must complete the online Generic Training course regarding animal care and use and occupational health and safety. New IACUC members are trained during a one-on-one session with the IACUC Chair. These training sessions are documented on a training

documentation form, which is kept on file in the IACUC office. IACUC members are encouraged to undergo additional training periodically. Members are sent to conferences such as IACUC 101 and SCAW. The AV and Clinical Veterinarian are required to receive 17 hours of continuing education credits annually to maintain their license. They regularly attend veterinary or laboratory animal medicine short courses or conferences. IACUC members have also participated in, and attended wildlife-specific training conferences, one of which was provided by SCAW.

- Each new IACUC member receives initial orientation and training directly from the IACUC Chair. At this orientation meeting they receive a 2-hour introduction to the Federal animal laws and policies, an overview of the TTU program and review processes, specific guidance about their role as an IACUC member, and their responsibilities in the review and designated review process. TTU pays particular attention to the following: 1) how the TTU form meets the requirements of the PHS and AWA; 2) requirements for the 200-word non-technical summary of the project; 3) what constitutes adequate rationale and justification for the proposed use and number of animals to be used; 4) how the required literature search should evidence the principles of the 3 R's; 5) the kinds of descriptions of all procedures and treatments applied to animals that we require for effective evaluation; 6) the USDA pain categories and TTU policy for full-committee review; 7) justifications required for conditionally or non-AVMA approved methods of euthanasia; and 8) humane endpoints and criteria for monitoring and intervention. Each new member is also provided with electronic copies of the ILAR Guide, USDA Animal Welfare Regulations & Policies, AVMA Guidelines for Euthanasia, the TTU IACUC Policies, AAALAC Information, PHS Policy, OLAW/ARENA IACUC Guidebook, current approved Animal Welfare Assurance, and numerous other animal care and use reference and training resources. All IACUC members are encouraged to attend IACUC 101 and SCAW and TTU subsidizes their travel. TTU usually sends 2-3 members per year. New IACUC members are allowed to learn by slowly integrating them into the process, letting them get several complex reviews completed before they are assigned to be Designated Reviewer. The Committee Chair, and any other IACUC member who chooses, regularly brings issues, example protocols, and cases from workshops and other sources to the monthly IACUC meetings to discuss specific problems and breaking issues in animal welfare.
- The Post Approval Monitor provides video and photos to IACUC members during the monthly meetings of recent PAMs, which serves as a training tool for IACUC members.
- Webinars through PRIM&R, NABR, and USDA are also offered periodically to IACUC members in a group setting.

IV. Institutional Program Evaluation and Accreditation

All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past 6 months and will be reevaluated by the IACUC at least once every 6 months according to PHS Policy IV.B.1.-2. Reports have been and will continue to be prepared according to PHS Policy IV.B.3. All IACUC semiannual reports will include a description of the nature and extent of this Institution's adherence to the PHS Policy and the Guide. Any departures from the Guide will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC's evaluations will be submitted to the Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

- (1) This Institution is Category 1 — accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request.

V. Recordkeeping Requirements

- A. This Institution will maintain for at least 3 years:
 1. A copy of this Assurance and any modifications made to it, as approved by the PHS
 2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations

3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was granted or withheld
 4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, Dr. Joseph Heppert.
 5. Records of accrediting body determinations
- B. This institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional 3 years after completion of the activity.
- C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

VI. Reporting Requirements

- A. The institutional reporting period is the calendar year (January 1 - December 31). The IACUC, through the Institutional Official, will submit an annual report to OLAW by January 31 of each year. The annual report will include:
1. Any change in the accreditation status of the institution (e.g., if the institution obtains accreditation by AAALAC or AAALAC accreditation is revoked)
 2. Any change in the description of the institution's program for animal care and use as described in this Assurance
 3. Any change in the IACUC membership
 4. Notification of the dates that the IACUC conducted its semiannual evaluations of the institution's program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official, Dr. Joseph Heppert
 5. Any minority views filed by members of the IACUC
- B. The IACUC, through the Institutional Official, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:
1. Any serious or continuing noncompliance with the PHS Policy
 2. Any serious deviations from the provisions of the *Guide*
 3. Any suspension of an activity by the IACUC
- C. Reports filed under VI.A. and VI.B. above should include any minority views filed by members of the IACUC.

VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official

Name: Joseph Heppert

Title: Institutional Official, Vice President for Research

Name of Institution: Texas Tech University

Address: (street, city, state, country, postal code)

Texas Tech University

Box 41075

Lubbock, TX 79409

Phone: 806-742-3904

Fax: 806-742-3788

E-mail: joseph.heppert@ttu.edu

Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure the humane care and use of animals as specified above.

Signature:



Date:

2 Aug 19

B. PHS Approving Official (to be completed by OLAW)

Name/Title:

Office of Laboratory Animal Welfare (OLAW)

National Institutes of Health

6705 Rockledge Drive

RKLL, Suite 360, MSC 7982

Bethesda, MD USA 20892-7982 (FedEx Zip Code 20817)

Phone: +1 (301) 496-7163

Fax: +1 (301) 451-5672

Signature:

Date:

Assurance Number:

Effective Date:

Expiration Date:

VIII. Membership of the IACUC

Date: November 27, 2017

Name of Institution: Texas Tech University

Assurance Number: A3629-01; AAALAC Accredited

IACUC Chairperson

Name*: Philip N. Smith

Title*: Associate Professor

Degree/Credentials*: Ph.D.

Address*: (street, city, state, zip code)

Texas Tech University

Department of Environmental Toxicology

Box 1163

Lubbock, TX

79409-1163

E-mail*: PHIL.SMITH@ttu.edu

Phone*: 806-834-6180

Fax*: 806-885-2132

IACUC Roster

Name of Member/ Code**	Degree/ Credentials	Position Title***	PIHS Policy Membership Requirements****
Tiffany Brooks	VM, MS, AAALAC	Attending Veterinarian	Veterinarian
Paul Stonum	VM	Clinical Veterinarian	Veterinarian
Sally Post	IA, MA	Ex-Officio Research and Academic Communications	NonScientist
Harvinder Gill	h.D.	Associate Professor	Scientist
Rob Lee	IS	Retired U.S. Wildlife and Fisheries	Nonaffiliated
Kerry Griffiths-Kyle	IS, Ph.D.	Associate Professor	Scientist
Vijay Hegde	IS, Ph.D.	Assistant Professor	Scientist
Erica Irilbeck	IS, Ed.D.	Assistant Professor	NonScientist
David Ray	IA, Ph.D.	Associate Professor	Scientist
Sydney Woodman	B.S., IATG	Facilities Manager Animal Care Services	Member
Ernest Smith	B.S., Ph.D.	Associate Professor	Scientist
Katharine	IA-Ph.D.	Associate Professor	Scientist
Richard Stevens	IS, Ph.D.	Associate Professor	Scientist
Lou Bensmore	IS, Ph.D.	Professor	Scientist
Jhones Sarturi	IS, Ph.D.	Assistant Professor	Scientist
Alexandra Protopopova	IS, Ph.D.	Associate Professor	Scientist
Rebecca Maloney	IS	Laboratory Safety	NonScientist

		Specialist	
Sean Childers	SA	Assistant Vice President for Operations	Nonscientist/Alternate
Arlene Garcia	MS, Ph.D.	Assistant Professor	Scientist/Alternate
Brad Goodwin	DVM, DACLAM	Retired Attending Veterinarian at University of Texas, Houston	Veterinarian/Alternate
Nathaniel Hall	Ph.D.	Assistant Professor	Scientist/Alternate
Manuel DeLeon	MS	Wildlife Biologist, Natural Resources Conservation Service	Nonaffiliated/Alternate
Matt Roe	MS	Assistant Vice President of EH&S	Nonscientist/Alternate
John Ross	Ph.D.	Assistant Professor of Environmental Toxicology	Nonaffiliated/Alternate

*This information is mandatory.

** Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this submission to OLAW. Sufficient information to determine that all appointees are appropriately qualified must be provided and the identity of each member must be readily ascertainable by the institution and available to authorized OLAW or other PHS representatives upon request.

*** List specific position titles for all members, including nonaffiliated (e.g., banker, teacher, volunteer fireman; not "community member" or "retired").

**** PHS Policy Membership Requirements:

Veterinarian	veterinarian with training or experience in laboratory animal science and medicine or in the use of the species at the institution, who has direct or delegated program authority and responsibility for activities involving animals at the institution.
Scientist	practicing scientist experienced in research involving animals.
Nonscientist	member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy).
Nonaffiliated	individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution. This member is expected to represent general community interests in the proper care and use of animals and should not be a laboratory animal user. A consulting veterinarian may not be considered nonaffiliated.

[Note: all members must be appointed by the CEO (or individual with specific written delegation to appoint members) and must be voting members. Non-voting members and alternate members must be so identified.]

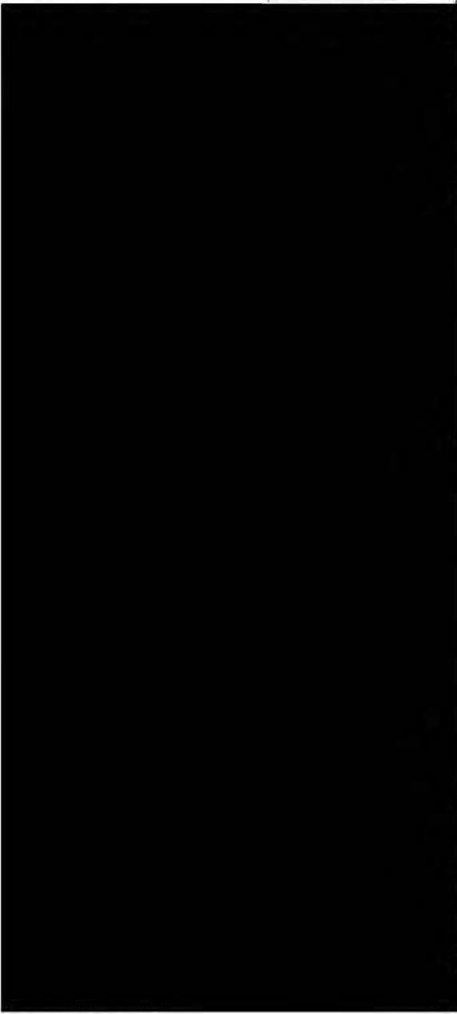
IX. Other Key Contacts (optional)

If there are other individuals within the institution who may be contacted regarding this Assurance, please provide information below.


Contact #1**Name:** Karin Fritz, MS, CPIA**Title:** IACUC Coordinator/Animal Care Services Unit Manager**Phone:** 806-834-6183**E-mail:** karin.k.fritz@ttu.edu

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4/8, 181

X. Facility and Species Inventory

Date: November 27, 2017			
Name of Institution: Texas Tech University			
Assurance Number: A3629-01; AAALAC Accredited			
Laboratory, Unit, or Building	Gross Square Feet (include service areas)	Species Housed (use common names, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog)	Approximate Average Daily Inventory
		Mice	862 (453 PHS)
		Mice, Ferrets, Rabbits	645 (159 PHS)
		Mice, Rats, Frogs, Fish, Reptiles	Reptiles = 26 Mice = 128 Rats = 85 Fish = 2,200 Frogs = 61
		Dogs, Pigs, Cats, Chickens	Dogs Pigs Cats 4-8 of each species, but not simultaneously Chickens = 24 Pigs = 625 Cattle = 150 Sheep = 130 Goats = 20 Horses = 3 Llama = 1 Dogs = 8 Cats = 10
		Pigs, Cattle, Sheep, Goats, Dogs, Llama, Cats	Horses = 39 Cattle = 99 Goats = 3 Cats = 4 Rodeo horses (non TTU) = 56 Boarder's horses (non TTU) = 77
		Horses, Cattle, Goats, Cats	Quail
		Quail	400
		Horse, Sheep, Goats, Cattle, Pigs	Horse = 1 Cattle = 5 Pigs = 5 Sheep = 5
		Fish	0
		Quail, Fish, Mice	Fish = 380 Quail = 114 Mice = 87

4/18/18

	Deer	45
	Frogs	0
	Rodents, Rabbits, Ferrets, Etc.	0

*Institutions may identify animal areas (buildings/rooms) by a number or symbol in this submission to OLAW. However, the name and location must be provided to OLAW upon request.

*Has PHS-funded projects

*May have PHS-funded projects in the future

Institutional Animal Care and Use Committee

From: Institutional Animal Care and Use Committee
Sent: Tuesday, January 22, 2019 3:01 PM
To: 'olawarp@mail.nih.gov'
Subject: Annual Report for Assurance #A3629-01
Attachments: TTU OLAW 2018 Annual Report.pdf

Hello,

Please find attached the Annual Report for Texas Tech University, assurance #A3629-01. Feel free to contact me if you have any questions.

Karin Fritz, M.S., CPIA

IACUC Coordinator/ACS Unit Manager

Experimental Sciences Building, Room 022A

Phone: (806) 834-6183 | Fax: (806) 742-4187

Box 43132 | Lubbock, TX 79409

www.depts.ttu.edu/iacuc/

karin.k.fritz@ttu.edu | iacuc@ttu.edu

Annual Report to OLAW

Institution: Texas Tech University

Assurance Number: A3629-01

Reporting Period: January 1, 2018 - December 31, 2018

This institution's Institutional Animal Care and Use Committee (IACUC), through the Institutional Official, provides this annual report to the Office of Laboratory Animal Welfare (OLAW).

I. Program Changes [Select A or B]

- ☒ A. There have been **no changes** in this institution's program for animal care and use as described in the Assurance. *[Skip to Item II.]*
- ☐ B. Change(s) in this institution's program for animal care and use as described in the Assurance have occurred during this reporting period. *(FAQ 6)*

Select all that apply:

- ☐ This institution's AAALAC accreditation status has changed *(PHS Policy IV.A.2.)*.
- ☐ AAALAC Accredited - Category 1
- ☐ Non-Accredited - Category 2
- ☐ This Institution's program for animal care and use has changed *(PHS Policy IV.A.1.a-i.)*.
[Attach a full description of the changes.]
- ☐ The individual designated by this institution as the Institutional Official has changed.
[Provide name, title(s), address, e-mail, phone, and fax numbers in Item V.]
- ☐ The membership of this institution's IACUC has changed. *[Provide current roster of members in Item VI.]*

II. Semiannual Evaluations

This IACUC has conducted semiannual evaluations of the institution's program and inspections of the institution's facilities (including satellite facilities) on the dates below. Reports of the evaluations and inspections have been submitted to the Institutional Official. The reports include any IACUC-approved departures from the *Guide* with a reason for each departure, any deficiencies (significant or minor) that were identified, and a plan and schedule for correction of each deficiency. *[Do not provide semiannual reports unless they include a minority view.]*

A. Program Evaluations

[Two dates (month/day/year) must be provided to satisfy the PHS Policy requirement that evaluations be done at 6 month intervals. If the IACUC conducted more than 2 evaluations of the program during the reporting period, please attach a list showing the dates.]

Date 1: April 25, 2018

Date 2: October 19, 2018

B. Facility Inspections

[Two dates (month/day/year) must be provided to satisfy the PHS Policy requirement that facility inspections be done at 6 month intervals. If the IACUC conducted more than 2 inspections of each site during the reporting period, please attach a list showing the dates.]


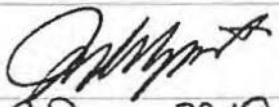
Date 1: April 24-25, 2018

Date 2: October 18-19, 2018

III. Minority Views [Select A or B]

- ☒ A. There were **no minority** views during this reporting cycle.
- ☐ B. Any minority views submitted by members of the IACUC regarding reports filed under PHS Policy IV.F. for this reporting cycle are attached.

IV. Signatures

IACUC Chairperson	Institutional Official
Name: Dr. Phil Smith	Name: Dr. Joseph Heppert
Signature: 	Signature: 
Date: 1/12/19	Date: 17 Jan 2019

V. Change in Institutional Official

Name: Joseph Heppert	
Title: Institutional Official, Vice President for Research	Degree/Credential: BS, Ph.D.
Name of Institution: Texas Tech University	
Address: [street, city, state, zip code] Box 42191 Lubbock, TX 79409	
E-mail: joseph.heppert@ttu.edu	
Phone: 806-834-6506	Fax: 806-742-4187
NOTE:	

VI. Change in IACUC Membership [Current roster]

Institution: Texas Tech University			
IACUC Contact Information			
Address: [street, city, state, zip code]			
Box 43132, Lubbock, TX 79409			
E-mail: iacuc@ttu.edu			
Phone: (806) 742-3853		Fax: (806) 742-4187	
IACUC Chairperson			
Name: Phil Smith			
Title: Associate Professor		Degree/Credentials: MS, Ph.D.	
PHS Policy Membership Requirements***:			
IACUC Roster [Provide below or attach]			
Name of Member/ Code*	Degree/ Credential	Position Title/ Occupational Background**	PHS Policy Membership Requirements***
Tiffanie Brooks	DVM, MS, DACLAM	Attending Veterinarian	Veterinarian
Harvinder Gill	MS, Ph.D.	Associate Professor	Scientist
Kerry Griffis-Kyle	MS, Ph.D.	Associate Professor	Scientist
Sydnee Woodman	BS, LATg	Facilities Manager	Member
Rob Lee	MS	Retired U.S. Wildlife and Fisheries	Community Member
Sean Childers	MS	Assistant Vice President for Operations	Nonscientist/Alternate
Sally Post	MA	Unit Manager, Museum	Nonscientist
David Ray	MAT, Ph.D.	Associate Professor	Scientist
Paul Stonum	DVM	Clinical Veterinarian	Veterinarian
Vijay Hegde	MS, Ph.D.	Assistant Professor	Scientist/Vice Chair
Bradford Goodwin	DVM, MS, DACLAM	Consulting Veterinarian	Veterinarian/Alternate
Erica Irlbeck	MS, Ph.D.	Associate Professor	Non-Scientist
Ernest Smith	BS, Ph.D.	Associate Professor	Scientist
Richard Stevens	MS, Ph.D.	Associate Professor	Scientist
Joe Neary	MA, Ph.D.	Assistant Professor	Scientist
Lou Densmore	MS, Ph.D.	Professor	Scientist
Jhones Sarturi	MS, Ph.D.	Assistant Professor	Scientist
Alexandra Protopopova	MS, Ph.D.	Assistant Professor	Scientist
Matt Roe	MS	Assistant Vice President of Research	Environmental Health & Safety/Alternate

		for Environmental Health & Safety	
Nathaniei Hall	MS, Ph.D.	Assistant Professor	Scientist/Alternate
Manuel DeLeon	MS	Wildlife Biologist, Natural Resources Conservation Service	Community Member/Alternate
Rebecca Maloney	MS	Laboratory Safety	Environmental Health & Safety
Arlene Garcia	MS, Ph.D.	Assistant Professor	Scientist/Alternate

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DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Division of Assurances
6700B Rockledge Drive
Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
Home Page: <https://olaw.nih.gov>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Division of Assurances
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163

January 23, 2019

Re: Assurance D16-00380 (A3629-01)
Report to OLAW for CY 2018

Joseph Heppert, Ph.D., BS
Vice President for Research
Texas Tech University
Box 42191
Lubbock, TX 79409

Dear Dr. Heppert,

This notice is to acknowledge that the Division of Assurances, Office of Laboratory Animal Welfare (OLAW) received and reviewed your institution's Annual Report that was submitted in accordance with Part IV.F. of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, revised 2015.

The Annual Report to OLAW is a key document in a continuing relationship with the PHS. It contains pertinent information regarding the policies and procedures in place to provide for the appropriate care and use of laboratory animals.

We look forward to receiving your next report for the period January 1, 2019 through December 31, 2019 within 30 days (January 31, 2020) of the end of the reporting period. Please include your Assurance number on your Annual Report and in all correspondence to OLAW.

Thank you for your attention to these matters.

Sincerely,

X

Program Assistant
Division of Assurances
Office of Laboratory Animal Welfare

cc:
IACUC Contact
IACUC Coordinator/ Animal Care Services Unit Manager