TEXAS CHRISTIAN UNIVERSITY

A3542-01

Animal Welfare Assurance for Domestic Institutions

I, Bonnie E. Melhart, as named Institutional Official for animal care and use at Texas Christian University, provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

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. This Assurance covers only those facilities and components listed below.

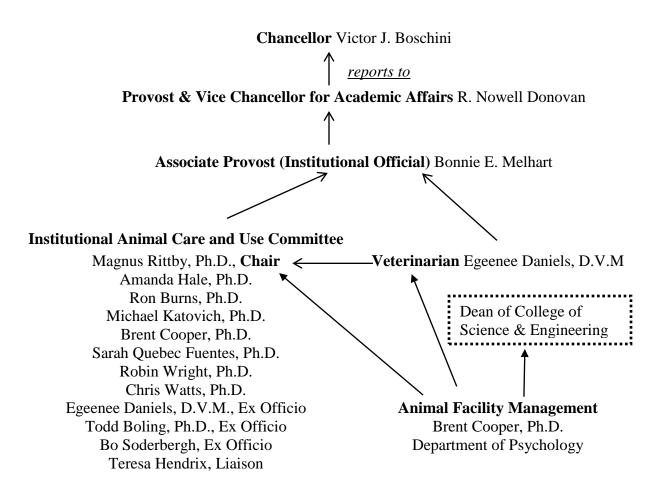
- A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name: Texas Christian University, 2800 South University Drive, Fort Worth, Texas
- B. The following are other institution(s), or branches and components of another institution: All components of TCU are physically located on the University's campus in Fort Worth, Texas, 76129. There are no off-campus satellite facilities and/or other covered components.

II. Institutional Commitment

- A. This Institution will comply with all applicable provisions of the <u>Animal Welfare Act</u> and other Federal statutes and regulations relating to animals.
- B. This Institution is guided by the "<u>U.S. Government Principles for the Utilization and Care of</u> <u>Vertebrate Animals Used in Testing, Research, and Training</u>."
- 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 (sub-award) 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: Egeenee Q. Daniels, D.V.M.
 - Qualifications
 - Degrees:
 - B.S. Agricultural Engineering and Agronomy, Southern University, 1980 B.S. Animal Science/Pre-Veterinary Medicine, Southern University, 1981 D.V.M. Louisiana State University School of Veterinary Medicine, 1986.
 - Training or experience in laboratory animal medicine or in the use of the species at the institution:

Postdoctoral studies in Laboratory Animal Medicine and epidemiology Currently Director of Laboratory Animal Medicine at University of North Texas Health Science Center, Fort Worth

Authority: Dr. Daniels has direct program authority and responsibility for the Institution's animal care and use program including access to all animals.

Time contributed to program:

Dr. Daniels devotes approximately five percent of his time (approximately 8-10 hours/month) to the TCU effort. 100% of the hours for the TCU effort are devoted to animal care and use.

Trained and certified laboratory animal technicians are available to assure adequate care of research animals.

 Though we have not needed backup services, Dr. Egeenee has arranged for backup veterinarian services for TCU in case he is unavailable --Name: Dr. Rhonda W. Daniels, D.V.M.

Qualifications:

- Degrees: She received the Doctor of Veterinary Medicine degree from Louisiana State University School of Veterinary Medicine in 1990.
- Training and/or experience in laboratory animal medicine: She has 25 years of experience with animal care in private practice. She has more than 14 years of experience assisting with lab animals in the practice of Dr. Egeenee Daniels, DVM.
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Authority: Dr. Rhonda W. Daniels, D.V.M. has the same program authority and responsibility as Dr. Egeenee Daniels, when acting in his stead.

Time Contributed to Program: We have not had to call on Dr. Rhonda W. Daniels to date. Her contributions would be no more than Dr. Egeenee Daniels, if needed.

- 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 in Part VIII is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles and specialties, and institutional affiliations.
- 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:

The TCU IACUC meets a minimum of three (3) times per year to evaluate the institution's policies regarding humane use and care of animals. We utilize a semiannual program and facility review and checklist developed at the University of North Texas Health Science Center (UNTHSC). The checklist is included as Attachment 2 of this document, pages 21-24.

At the semi-annual review and facility inspection the members of the IACUC are each given a printout of the compressed version of the Semiannual Review and Inspection Checklist (enclosed) associated with the *Guide for the Care and Use of Laboratory Animals: Eighth Edition.* The IACUC chair meanwhile refers to the full checklist document (enclosed) and leads the committee in a review and discussion of the areas under review, highlighting changes and issue that may have occurred/arisen since the last review. The IACUC has access to both documents above on the IACUC Sharepoint site.

Specifically the review addresses the <u>Occupation Health and Safety</u> by reviewing the training and information opportunities offered to all those who access facilities with animals. These includes information, training, oversight of health issues as well as chemical safety. The committee is asked to verify that appropriate safety measures and information are present in the vivarium during the subsequent facility inspection. Any health/safety concerns that has come to the IACUC's attention are reviewed followed by discussion of possible need for action.

The training for <u>veterinary care</u> is reviewed following the checklist with the IACUC veterinarian representative providing feedback/information to the IACUC regarding his observations/concerns with the facility/animals/procedures etc.

The status of the institution's status with respect <u>to assurance document</u>, USDA inspections are reviewed. The related documents are available to the IACUC on the IACUC Sharepoint site.

The <u>Guide</u> is available to all IACUC members on the IACUC Sharepoint site.

The <u>training program</u> is addressed in the discussions of health, safety, and veterinary care addressed above.

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:

The entire IACUC meets three times per year to inspect all animal facilities. All members are invited to participate; there are at least two voting IACUC members present at all inspections. We conduct a walk-through inspection of all facilities noting minor and major deficiencies using the standardized form. These inspections are typically made in conjunction with the semiannual program reviews.

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:

The TCU IACUC prepares all necessary reports and submits them to the Associate Provost for Research, with signatures of a majority of the IACUC membership. Any identified program and /or facilities issues are listed and corrective actions are proposed. The IACUC Chair follows up with the Associate Provost for Research, Veterinarian, and Animal Facilities Management to ensure issues are resolved quickly and appropriately.

Any deficiencies the IACUC identifies are reported to the Associate Provost for Research. The IACUC determines and issues a deadline for correction to the parties involved (generally protocol PIs). The PI, Animal Care Manager, and/or program dean must submit a plan to correct the deficiency that enables correction by the given deadline. The responsible party may request a reasonable deadline change within 10 days of the deficiency report if they have just cause. Deficiency findings are monitored periodically, at least as part of the review during regular IACUC meetings.

The TCU IACUC adheres completely to the *Guide for the Care and Use of Laboratory Animals.* The IACUC has not approved departures from the PHS Policy or from the Guide. If this were called for in the future, the IACUC will report all such approvals to the Institutional Official as soon as they occur and include in the semiannual report. Departures will have limited approval time, and will be reviewed by IACUC and the Institutional Official periodically (at least semiannually) for the duration of the approved departure.

For IACUC semiannual reports, if minority views exist they are included within the regular report.

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

All individuals who work with animals are informed in an annual meeting, generally held at the beginning of Fall Semester, that they should report any and all concerns regarding animal care and use to the Chair of the TCU IACUC who then investigates as appropriate to the concerns. The investigation is discussed with the entire IACUC membership and a plan of action is developed on a case-by-case basis. Anonymity of the individual expressing concerns is maintained at all times, and the only individual who knows who brought the concern is the IACUC Chair. If major issues are determined to exist by the IACUC, a report is forwarded to the Associate Provost for Research. In all dealings and investigations we follow the University Policy on Ethical Conduct in Research, which has as one of its tenets "that the privacy of an Accuser who reports apparent unethical conduct in good faith shall be protected to the maximum extent that is consistent with the fair treatment of the Accused. Retaliation against the Accuser shall be prohibited and will subject a person who retaliates to disciplinary proceedings by TCU."

This information and ways to report are included on the TCU IACUC website <u>http://www.research.tcu.edu/default.asp?id=page&pid=sp208&parent=188</u> It is also part of our in-person training for new faculty.

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:

Issues are discussed during meetings of the IACUC. Any and all recommendations and/or concerns regarding animal care and use are forwarded in writing to the Associate Provost for Research.

6) Review and approve, require modifications in (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: Individuals can download forms for new animal protocol proposal, amendment and annual review from the IACUC website (within the TCU Research website), located at www.research.tcu.edu.

The review and approval process is initiated by the PI sending a hard copy of the protocol, amendment, or annual review document to the veterinarian on the IACUC for preliminary veterinary approval. The PI also emails an electronic copy of the document to the IACUC chair. The veterinarian and the IACUC chair consult to determine if there is a requirement for modification prior to distribution of the document to the IACUC and if the document should be handled by FCR or by DMR (see below). If modifications are deemed necessary by the veterinarian or IACUC chair at this stage, the PI is contacted and an updated document is requested.

After the document receives veterinary preliminary approval, the chair of the IACUC electronically distributes the protocol to the full IACUC designating that the document is either subject to FCR or is suggested to be handled by DMR. The full IACUC needs to be in approval in order to proceed with DMR, or the document automatically moves to FCR.

a) Protocol Review and Approval

a.1) Full Committee Review

The committee meets to review documents using the FCR process as needed, typically in February, May, August, and November. All documents designated for FCR are discussed by the committee and for complex/contentious protocols the principal investigator is invited to respond to questions. At the convened meeting, with quorum met, the Committee votes for *approval*, *withholding of approval*, or for a *requirement for modifications* of each document.

- **Approval.** When protocols are approved after FCR, the investigator is notified by email, and the protocol may begin. Scanned copies of approved and signed documents are sent to the PI and animal caretaker and are also posted on the IACUC SharePoint site. Approved protocols are re-evaluated once a year if they continue beyond the initial one-year approval period.
- Requirement for Modifications. If modifications are requested the IACUC can vote to have the document returned to be approved by a DMR or that it be

returned to the IACUC for FCR after having been updated by the PI. If all members of the IACUC are present at the meeting, the committee may vote to require modifications to secure approval and have the revised research protocol reviewed and approved by designated member review, or returned for FCR at a convened meeting. If all members of the IACUC are not present at a meeting, the committee may use DMR subsequent to FCR, because All IACUC members have agreed in advance in writing that the quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.

When using DMR, the approval date is the date that the designated member(s) approve the study. Animal work conducted before this date must be reported to OLAW as a serious noncompliance with the PHS Policy. If the IACUC uses DMR, the IACUC Chairperson appoints one or more appropriately qualified IACUC members to serve as the designated reviewer(s).

The Chair informs the principal investigator of the committee's decision by email along with comments regarding improvements/corrections necessary for approval via either FCR or DMR. Any minority concerns are discussed with the investigator who may or may not incorporate those concerns into the protocol.

- Withholding of Approval. In the case of no approval by the IACUC, the PI is informed by the IACUC chair that approval of the submitted protocol is withheld. Reasons for withholding approval are shared with the PI, however, the actual committee members' votes are not shared. The reasons usually refer to relevant sections of *The Guide* in order that investigators are reminded to consult this reference when preparing protocols. The PI has an opportunity to address the concerns/ questions by the IACUC, either in person (i.e. at an IACUC meeting) or in writing.

a.2) Designated Member Review

A document may be considered in the DMR process in lieu of FCR as a result of the preliminary review by the IACUC chair and the veterinarian. In every case all IACUC members are given access to the document(s) in question and provided the opportunity to request that this review be handled via FCR or to approve that this be handled via DMR. The IACUC needs to be unanimous in order to proceed with DMR.

The IACUC Chairperson may appoint one or more appropriately qualified IACUC members to serve as the designated reviewer(s). Designated review may result in one of the following outcomes:

- Approval. When protocols are approved after DMR, the investigator is notified by email, and the protocol may begin. Scanned copies of approved and signed documents are sent to the PI and animal caretaker and are also posted on the IACUC SharePoint site. Approved protocols are re-evaluated once a year if they continue beyond the initial one-year approval period.
- Requirement for Modifications. If modifications are requested the designated reviewer can recommend to have the document returned to be approved by a DMR or that it be returned to the IACUC for FCR after having been updated by the PI. The Chair informs the principal investigator of the reviewer's decision by email along with comments regarding improvements/corrections necessary for approval via either FCR or DMR.
- Referral to the Full Committee. In the case where the designated reviewer cannot approve or potentially approve with required modifications, the reviewer sends the protocol back to the chair indicating that Full Committee Review is needed. Designated review may not result in withholding of approval.

If a protocol is assigned to more than one designated reviewer, the reviewers must be unanimous in any decision. They must all review identical versions of the protocol and if modifications are requested by any one of the reviewers then the other reviewers must be aware of and agree to the modifications. TCU does not commonly use more than one reviewer, however.

Projects that are ongoing will be evaluated once a year. Any significant departures from the approved protocol will be noted and the principal investigator will be advised. Compliance with the approved protocol will be enforced. Procedures not discussed in the original proposal must be approved by the IACUC (i.e. a new proposal or addendum to an existing proposal) or the experiments will be temporarily suspended and the protocol will be discussed for suspension at a called IACUC meeting.

IACUC addresses conflict of interest (undue influence) in several ways. The IACUC membership always include persons from outside TCU (non-affiliated, non-scientists). There are always faculty members from at least three departments. The Chair of the IACUC is faculty from a non-animal-researching discipline (Physics and Astronomy) who is an administrator at the college level. All of these membership requirements help avoid undue influence by any particular program or investigator. Researching members of the Committee are recused from discussion as a committee member or voting on their own protocol proposals. The researching member may stay for the discussion to answer questions, as any other researcher might. The chair of IACUC ensures that a quorum will be available before scheduling a meeting. In the case of a recused member for their authored protocol, the chair ensures that a quorum will be present with this member recused when planning the meeting schedule.

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:

Any researcher wishing to make significant changes to an approved protocol must ubmit an amendment form. The changes must receive veterinary approval, and then the amendment is reviewed by the IACUC membership using the procedure described previously (see section 6 of this part).

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:

All concerned investigators and personnel receive an email of the disposition. The investigator is provided in writing the reasons for any withheld approval. All relevant personnel related to animal care and use also receive a hard copy.

If protocol approval is withheld, the investigator may resubmit the protocol with revisions. If the investigator resubmits without the revisions requested by the IACUC, the submission may include written justification for the lack of revisions. Investigators may also attend the discussion part of the IACUC meeting when the revised protocol is being reviewed. However, they will be asked to leave the meeting before a vote is taken.

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: Once per year the TCU IACUC meets to discuss changes that might need to be made in accordance with PHS Policy.

a) What are the annual review procedures used for protocols that involve USDA-covered species? Do the annual review & approval procedures utilize FCR or DMR?

Though TCU does not currently permit protocols that use non-excluded animals, all protocols are reviewed to the same standards required for these, as described above. For annual review, each investigator completes the Annual Protocol Review Form and submits it electronically within thirty days of the first and second anniversaries of the initial IACUC approval. Annual review for continuing protocols usually utilizes DMR, but may utilize FCR if needed.

- b) How does the IACU conduct continuing review of ongoing activities & previously approved animal activities? Are FCR and/or DMR procedures followed as stated in III.D6?
 DMR procedures are as stated in III.D.6. The DMR is typically the IACUC veterinarian who conducts regular reviews of ongoing activities. Any unapproved activity or activity deviating from approved protocols are reported to the IACUC chair.
- c) Is the three year review a complete review of all continuing activities, completed by either FCR or DMR procedures (as in III.D.6). Clarify this.
 If the research or teaching activity is to continue beyond the three-year approved period, the investigator must complete a new application and the review is complete (de novo), utilizing either the FCR or the DMR procedures are as stated in III.D.6.
- 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:

TCU's IACUC tracks all minor and major deficiencies and violations of established rules and procedures for each laboratory. Following each inspection the head of each laboratory is informed of any problems that were noted that require correction but that do not require suspension. A plan of action to correct these problems is developed. A complete report is sent to the Associate Provost for Research who is also the Institutional Official. The investigator then corrects the problem within a reasonable (and agreed upon with IACUC Chair and Associate Provost) timeframe.

Problems may also be brought to the IACUC by a complaint (anonymous or otherwise), identification by the Animal Maintenance routine activities, observation by the Veterinarian, or by periodic inspections by the IACUC. As for deficiency, serious problems are given a deadline for correction.

In cases of significant non-compliance or repeated violations of IACUC rules, the IACUC reviews the matter at a convened quorum meeting. After discussion and by majority vote, the IACUC may vote to recommend appropriate sanctions to the Associate Provost for Research and may vote to suspend the active protocol. The Associate Provost, in consultation with IACUC, reviews the reasons for all actions, including suspension. Imposed appropriate sanctions are not limited to those recommended by the IACUC, and range from letters of warning to suspension of all animal use by the investigators involved. Protocol suspension, repeat training, and periodic supervision reports are typical sanctions imposed. The researcher is informed in writing of the issues, investigation steps followed, the sanctions imposed by IACUC and the Associate Provost, required remedies (if any), and deadlines for actions. The PI, Animal Care Manager, Dean, or other appropriate responsible party must submit a plan to correct the issue and/or request a reasonable deadline change within 10 days of receipt of the deficiency report. The investigator may request IACUC reinstate a protocol once an accepted plan has been implemented.

A full report of all these suspension activities and violations is reported to OLAW by the Associate Provost.

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: Graduate students and other personnel working daily in close contact with the animals are required to receive immunization against tetanus (at the University Health Center). There is no work currently being done at TCU that involves primates or infectious diseases such as rabies or hepatitis B. If these areas become relevant, the necessary precautions will be taken.

Students and other personnel are required to have all rodent bites examined by a physician at the Health Center on the TCU campus. Moreover, there is any indication of allergic reactions to the animals, the student or caretaker will be asked to see the campus Health Center physician to determine the nature of the reaction.

A one-day educational seminar is given at the beginning of each Fall semester to inform new scientists/students about zoonosis, personal hygiene, and the handling of hazardous materials. The Manager of the Animal Facilities leads this seminar together with the IACUC Chair. The annual seminar includes precautions for pregnancy, illness, and decreased immunocompetence.

Each person that handles animals or works in the animal facilities is required to fill out an animal handler's questionnaire to assess any possible vivarium allergy issues.

a) Is an Occupational Health Professional involved in planning and monitoring the program?

Yes, the IACUC works with the TCU Risk Management Office to develop strategies for minimizing occupational health hazards in the community. Through our Occupational Health Insurance policy, TCU Risk Management has contacts with occupational health professionals who advise the IACUC and vivarium personnel on appropriate protective equipment and medical precautions. These medical professionals, through our insurance arrangement, monitor incidents and make recommendations for changes to training and protocols as needed.

Additionally the Hazardous Materials Safety Coordinator provides compulsory training in general (including chemical) safety and the safety of handling biological materials.

b) What entity is responsible for monitoring the occupational health program? A medical evaluation or collection of a health history that meets federal, state and local HIPAA regulations as part of the risk assessment process is a required component of the occupational health and safety program. Please describe how this is accomplished by your institution. For guidance on the components of an occupational health and safety program please refer to the Guide, 8th edition, pages 17-23. Please clarify your response.

The IACUC oversees the program, in consultation with Risk Management and occupational health consultants. The IACUC has developed an allergy risk assessment document that collects medical history from personnel accessing the vivarium. When/if health concerns are identified this triggers a response through Risk Management.

The current assessment instrument is included as attachment 3, pages 25-35. Assessments are reviewed by medically trained health professionals affiliated with the University through our Occupational Health Insurance policy, and sensitive assessment survey materials are kept locked in the Risk Management physical location.

c) Is the program based on Risk Assessment and Hazard Identification?Yes, as described above, risks to individuals are assessed annually and our HazardousMaterials Safety Coordinator is routinely involved in assessing hazards in animal spaces.

d) Who and how are employees enrolled in the program?

Students and other personnel working with animals are automatically included in the program. At the annual vivarium training the general principles of safety, health hazards, etc. are discussed with all vivarium related personnel. Following this meeting each individual PI follows a training protocol to discuss in detail general and specific hazards associated with the work in their respective laboratories. Verification of personnel having had the training is kept in the animal caretaker's office in the vivarium in order to verify each person's eligibility to work in the lab.

e) Is training provided in the area of allergies, and hazards? Yes, this is part of the annual training program.

f) How are employees trained on precautions to be taken during personnel pregnancy, illness, or decreased immunocompetence?

The training includes precautions and directions for how to notify IACUC and health professionals for these conditions. The training presentation is available on the IACUC website for review by employees and students.

http://www.research.tcu.edu/default.asp?id=page&pid=sp208&parent=188

g) How and where is treatment provided in the event of bites, scratches, illness or injury? Is there a program for reporting injuries?

Animal care workers and investigators are directed to the TCU Health facilities in immediate cases. Directions for reporting and immediate actions to take are posted in the facility. This information is included in the annual vivarium and individual PI training described above. Long term treatment is determined by the medically trained occupational health professionals arranged by TCU Risk Management.

New questions for November 13 revision:

a) Is an Occupational Health Professional involved in planning and monitoring the program? What entity is responsible for monitoring the occupational health program?

Yes, occupational health professionals are part of the team available to us through our insurance policy, handled by TCU Risk Management. They provide planning and monitoring direction each year with review of training materials and with medical professional review of assessment data. They provide additional monitoring with each adverse medical incident.

Monitoring is an effort with several levels. The Facilities Manager, Animal Technician, and the protocol PIs are responsible for day-to-day monitoring of procedures and incidents. The IACUC is responsible for concerns or problems beyond the authority of the Manager and PIs or not attended to appropriately. TCU's Hazardous Materials Safety Coordinator is consulted frequently in case concerns relate to materials under his purview. TCU Risk Management is responsible for monitoring of incidents that may need to be reported and investigated further. Partnering with Risk Management are medically trained health professionals who monitor overall procedures with respect to any incidents and may advise corrections to standard protocol or processes if incidents warrant such changes or further investigation.

b) Are the staff at the TCU Risk Management Office medically trained health professionals?

No, TCU Risk Management Office staff are not medically trained health professionals. They rely on experts in occupational medicine, arranged through our insurance carrier, to advise and protect those working on TCU's campus.

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.

Provided in the attached Part X, page 15.

G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

A seminar on issues pertaining to animal maintenance and experimentation is given at the beginning of each Fall semester. The following topics are covered in the seminar: Animal Husbandry

Including animal housing and space recommendations Environmental parameters

Temperature Humidity Ventilation Illumination Noise

Food Water Bedding Sanitation and waste disposal Record keeping Emergency care and procedures Experimentation Handling Administration of drugs Behavioral testing Surgical procedures for rodents Euthanasia Proposal/Protocol Writing Alternative methods to animal experimentation Specific techniques and procedures appropriate to their specific laboratory assignment

In addition, students and graduate students are trained in specific techniques and procedures by the head of each appropriate laboratory. All training is documented by the procedures training form that all students must compete. The form is maintained with the IACUC for documentation.

a) Does the training program for scientists, animal technicians, and other personnel address methods that minimize animal pain and distress?

Training for IACUC members and animal researchers is presented at the beginning of each fall semester. Training includes the humane care and use of animals, determining the number of animals needed, and pain and distress minimization. Biennial training updates are required and may be satisfied with these options: Completion of the IACUC modules within the CITI training, conference/workshop attendance at an appropriate meeting that has been approved by the IACUC Chair, or repeat attendance at the annual training session.

- b) Does the training program address methods that minimize animal numbers used? See a) above.
- c) Describe in more detail how the IACUC members are provided orientation, background materials, resources, and /or training and continuing education. Are IACUC members provided copies of the PHS Policy, the OLAW/ARENA IACUC Guidebook and a copy of the approved Animal Welfare Assurance? Members serving for the first time are provided links to the PHS Policy and the Guide. Hard copies of the Guidebook and the approved Animal Welfare Assurance are provided.

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.

This Institution is Category 2 — not accredited by the <u>Association for Assessment and</u> <u>Accreditation of Laboratory Animal Care International (AAALAC)</u> As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request. The reports of the most recent evaluations (program review and facility inspection) – with signatures- are in attachment 1.

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, Bonnie E. Melhart, Associate Provost for Research.
 - 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, Bonnie E. Melhart, Associate Provost of Research. Semi-Annual reports were conducted on these dates in 2015: January 26 and June 25.
 - 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 Bonnie E. Melhart Name: Associate Provost for Research and Dean of Graduate Studies & University Programs Title: Name of Institution: Texas Christian University Address: (street, city, state, country, postal code) 2800 South University Drive Suite 3101, Sadler Hall TCU Bo 297024 Fort Worth, Texas 76129 Fax: 817.257.7484 Phone: 817.257.7104 B.Melhart@TCU.edu E-mail: 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. Bourie E. Melhart 11/20/2015 Date: Signature: B. PHS Approving Official (to be completed by OLAW) Venita B. Thornton, D.V.M., M.P.H. Senior Assurance Officer, Division of Assurances Office of Laboratory Animal Welfare (OLAW) NIH/OD/OER 6705 Rockledge Drive RKL 1, Suite 360-MSC 7982 Bethesda, Maryland 20892-7982 thorntov@od.nih.gov 123/15-n.t. 31, 2019 Date: Signature: Assurance Number: A3542-01 Expiration Date: Effective Date:

VIII. Membership of the IACUC

Date: October 28, 2015				
Name of Institution:	Texas Christia	n University		
Assurance Number: A	A3542-01			
IACUC Chairperson				
Name*: C. Magnus Rittb	у			
Title [*] : Professor of Physics and Associate Dean Science & Engineering			Degree/Credentials*: PhD, Physics	
Address [*] : Suite 102, Tucke TCU Box 298840 Texas Christian U Fort Worth, Texa	Jniversity	Center		
E-mail*: m.rittby@tcu.ee	du			
Phone*: 817.257.6377 Fax*: 817.257.7742				
IACUC Roster		· · · ·		
Name of Member/ Code ^{**}	Degree/ Credentials	Position Title***		PHS Policy Membership Requirements****
Ron Burns	Ph.D.	Professor, Criminal Justice		Nonscientist
Brenton Cooper	Ph.D.	Associate Professor, Psychology		Scientist
Sarah Quebec Fuentes	Ph.D.	Assistant Professor, Education		Nonscientist
Amanda Hale	Ph.D.	Associate Professor, Biology		Scientist
Michael Katovich	Ph.D.	Professor, Sociology		Nonscientist
Chris Watts	Ph.D.	Professor, Communication Sciences & Disorders		Scientist
Robin Wright	M.A.	Instructor, Modern Languages		Nonscientist
Egeenee Daniels	D.V.M.	Veterinarian		Veterinarian
Todd Boling	M.Div.	Associate Chaplain		Nonscientist
Bo Soderbergh	B.S.	Exec. Director Tarrant Area Food Bank		Nonaffiliated
Teresa Hendrix	M.P.A.	Assist. Director TCU Sponsored Programs		Liaison member
Bonnie Melhart	Ph.D.	Associate Provost		Administrative oversight

* 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: Dr. Tim Barth	: Dr. Tim Barth				
Title: Associate Dean for Research and Graduate Studies					
Phone: 817-257-7104	E-mail: t.barth@tcu.edu				
Contact #2					
Name: Lorrie Branson, J.D.					
Title: Director of Research Compliance Support and Training					
Phone: 817-257-7104	E-mail: I.branson@tcu.edu				