

**Report on Investigation of Allegations of Noncompliance with the
Public Health Service Policy on Humane Care and Use of Laboratory Animals
at the University of Texas Medical Branch**

Office of Laboratory Animal Welfare

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Preface

The Office of Laboratory Animal Welfare (OLAW) herein presents its evaluation, under provisions of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), of specific animal related activities conducted at the University of Texas Medical Branch (UTMB).

Based on the results of an audit conducted by the National Institute of Allergy and Infectious Diseases (NIAID), an internal investigation, and a targeted joint site visit by OLAW, NIAID, and the U.S. Department of Agriculture (USDA), OLAW determined that specific animal activities were not being conducted in accordance with the PHS Policy. Under the Health Research Extension Act of 1985, (Public Law 99-158), OLAW notified UTMB that the conditions of animal care, treatment, and use did not meet applicable guidelines and that the institution must take corrective actions. Subsequently UTMB took appropriate actions. Following review OLAW accepted UTMB's efforts and found the institution to be in full compliance with the PHS Policy.

OLAW forwarded this report to UTMB on 2/7/17 and requested the institution to identify any errors of fact. The 2/17/17 response indicated that in the discussion of Exhibit #22, the 11/23/15 OLAW letter, the text should have referenced "tail snipping" rather than "toe clipping." Also, UTMB suggested which information in the report should be redacted for privacy reasons. OLAW made the correction and informed UTMB that the responsibility for document redaction rested with the NIH Freedom of Information Act officials and that the suggestions would be forwarded to the appropriate personnel.

Report on Investigation of Allegations of Noncompliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals at the University of Texas Medical Branch

Background

This report is the result of an investigation of allegations of noncompliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) against the University of Texas Medical Branch (UTMB). A complaint was submitted to the Office of Laboratory Animal Welfare (OLAW) by the organization Stop Animal Exploitation Now (SAEN) on August 19, 2015 stating that, according to a site visit report prepared by the National Institute for Allergy and Infectious Diseases (NIAID), nonhuman primates infected with Marburg virus were not being euthanized at a humane endpoint but were allowed to die overnight. Furthermore, SAEN stated that a source connected to UTMB alleged that the site visit report had been withheld from the Attending Veterinarian (AV) and the Institutional Animal Care and Use Committee (IACUC) thus preventing them from performing an investigation. Also, SAEN alleged that the biocontainment veterinarian had not been informing the IACUC about primate deaths and the AV had recently been terminated. SAEN stated that the concerns violated UTMB's Animal Welfare Assurance (Assurance) and that following OLAW's investigation the Assurance should be revoked.

OLAW obtained a copy of the January 26-29, 2015 audit report which evaluated a NIAID study involving infectivity and lethality of Marburg virus in nonhuman primates following intramuscular challenge. The site visitors found that primates died during the night and that the number of animal observations did not increase although the clinical signs indicated a decline in health. The report indicated that in addition to the obvious serious animal welfare issues, crucial biomarker data were lost, impacting the study.

OLAW's authority is derived from the Health Research Extension Act (Public Law 99-158) which is implemented through the PHS Policy, applicable to PHS-conducted or supported research, research training, and biological testing activities involving live vertebrate animals. The Health Research Extension Act provides a reasonable opportunity for institutions to take corrective action when conditions of animal care, treatment or use do not meet applicable guidelines. Institutions that conduct PHS-supported research are required to have a current OLAW-approved Assurance. The Assurance is a document that verifies that PHS-supported research with live vertebrate animals is in accordance with the provisions of the PHS Policy. OLAW is authorized to restrict or withdraw approval of an institution's Assurance if that institution fails to correct identified deficiencies.

This Office evaluated the allegations, conducted a joint site visit involving OLAW, NIAID, and the U.S. Department of Agriculture (USDA), and presented a series of questions to UTMB for investigation by the Institutional Animal Care and Use Committee (IACUC).

OLAW Investigation:

On August 25, 2015 OLAW submitted a letter to the UTMB Institutional Official stating that according to the SAEN allegations:

- The NIAID audit contained information that constituted noncompliance with the PHS Policy in that nonhuman primates were not being euthanized upon reaching the established humane end point.
- The report was withheld from the Attending Veterinarian (AV) and the IACUC.
- The veterinarian in the biocontainment area was not informing the IACUC about primate deaths.
- The AV submitted a list of complaints for IACUC investigation and it is not clear an investigation occurred.

OLAW submitted the additional following questions:

- Has the IACUC addressed the complaints submitted by the AV?
- Were the established observation periods followed, including increased observations based on clinical signs: If not, how has this been corrected?
- Were the veterinarians promptly notified about clinical concerns such as depression, inappetance, or petechial rashes?
- Was the IACUC aware of the problems with inadequate animal observations?
- Is staff aware that animal concerns are to be reported promptly to the veterinary staff and is this being done?
- Are procedures in place to ensure that the biocontainment veterinarian is informed about environmental control problems in animal rooms such as high humidity?
- Why was OLAW not notified about the serious animal welfare issues identified by the NIAID site visitors?

In September, 2015 OLAW submitted a formal request for the NIAID report, UTMB response, and the NIAID review of the UTMB response. OLAW determined that a joint site visit with NIAID and USDA was necessary. The requested materials were provided and a joint site visit was planned.

On September 6, 2015 information was provided to OLAW by the former AV who expressed concerns about the primate studies.

On September 30, 2015 UTMB representatives met with NIAID to discuss the primate studies. A reverse site visit summary was produced.

On October 8, 2015 USDA staff produced a memo outlining an interview with a former UTMB veterinary staff member.

On October 27, 2015 OLAW sent a letter to UTMB indicating that a joint site visit would be conducted on November 17, 2015 with representatives from OLAW, USDA Animal and Plant Health Inspection Service (APHIS)/Animal Care, USDA APHIS Investigative and Enforcement Services, and NIAID. OLAW requested to meet with key personnel involved in the primate studies, to review records, and to see the facilities involved.

On October 29, 2015 UTMB provided a response to OLAW's August 25, 2015 initial inquiry as follows:

- The UTMB IACUC concluded that there was no noncompliance with the NIAID audit report but verified that eight primates on the study died overnight.
- The AV and IACUC were informed about the audit report.
- Mortality was expected in the study and the biocontainment veterinarian was required to notify the IACUC of adverse events.
- The former AV's complaints were reviewed by the IACUC and were not found to have a negative animal welfare outcome.
- The established animal observations were followed as outlined in the protocol.
- Four primates were euthanized upon reaching the humane endpoints. No other animals exhibited clinical signs that required notification of the veterinarian.
- The IACUC considered the animal observation schedules to be appropriate.
- An institutional policy was in place regarding prompt reporting of animal concerns and staff was trained on it.
- The biocontainment veterinarian was notified that humidity levels in the animals rooms were outside the normal range. Facility procedures were modified to provide documentation of future temperature/humidity deviations and the AV's actions.
- UTMB had not notified OLAW about the serious animal welfare issues identified by the NIAID site visitors because UTMB had not agreed with the assessment. The IACUC had re-evaluated the criteria on the Marburg study including observation frequency, items on the humane scoring sheets, euthanasia criteria, and assessment of pain and distress.

On November 3, 2015 OLAW conducted a search of all active NIH grants with an animal component made to UTMB and incorporated a copy of the results in the case file.

On November 4, 2015 OLAW responded to UTMB's October 29, 2015 letter and acknowledged the information provided but indicated that the Office was "extremely concerned with the functioning of the UTMB animal care and use program and with the ability of the IACUC to appropriately carry out its functions as outlined in the PHS Policy and described in the Assurance." The reasons for this concern were explained as follows:

- The NIAID site visit team was constituted by knowledgeable subject matter experts who voiced grave animal welfare concerns.
- A USDA interview with a former UTMB employee produced a statement that Biosafety Level 3 and 4 rooms housing species other than primates were not properly broken down and sanitized between studies; veterinary rounds in biocontainment were not done frequently enough to provide adequate animal care; there was insufficient communication between the AV and biocontainment veterinarian; the backup veterinarian was not notified when the AV was off site; and single housing of primates was not adequately justified.
- Testimony from the former AV indicated that the Marburg study was expected to have humane intervention and not progress to death as an endpoint, yet 75% of the primates were found dead. This outcome had not been reported to the AV and IACUC.
- The IACUC was unaware of the primate deaths until release of the audit report; remote monitoring of primates in the biocontainment suite was not routinely performed.

OLAW informed UTMB that under the provisions of the Health Research Extension Act of 1985, Public Law 99-158, that the institution was not meeting applicable guidelines outlined in the PHS Policy and commitments made in the Assurance and that UTMB must take corrective action. If corrections were not made, the Assurance would be withdrawn and PHS grants for animal activities would be withheld.

OLAW indicated that during the upcoming site visit and subsequent communications the following must be addressed:

- Development and adherence to humane endpoints
- Adjustment of frequency of animal observations in relation to clinical signs
- Prompt reporting of animal concerns
- Strong justification for single housing of primates
- Robust IACUC oversight of all containment activities
- Appropriate chain of command and oversight of projects conducted in containment
- Timely communication between clinical veterinarians and the AV

On November 10, 2015, OLAW sent a memo to UTMB requesting the following documents be made available for review by the site visitors:

- All relevant animal/clinical records for the primates on the Marburg study
- All IACUC records relevant to the study animals including protocols, minutes, concerns
- The most recent AAALAC site visit report
- The two most recent USDA inspection reports
- The two most recent semiannual program review and facility inspection reports
- Relevant biosafety SOPs, specifically addressing the BSL4 and after hour procedures
- Biosafety inspection records
- Any other documents relevant to the study animals and conduct of the study, including also Department of Defense studies of this type

On November 16, 2015 UTMB responded to OLAW's November 4, 2015 letter and stated that:

- A highly qualified AV with significant biocontainment experience was hired on September 1, 2015.
- Communication had been enhanced among the IACUC, IO, Animal Resources staff, AV, and biocontainment veterinarian. Nonhuman primate studies will be thoroughly reviewed to establish appropriate endpoint criteria. The policy for reporting adverse or unexpected outcomes had been revised. The IACUC will review USDA Category E studies more rigorously.
- In response to NIAID's audit and response, it was agreed that animal observations will be conducted more frequently and endpoint criteria will be carefully established.
- The IACUC had not approved the Marburg virus study to allow death as an endpoint and that the primates should have been euthanized prior to death. Animals nearing a critical stage in disease progression will be monitored more frequently. UTMB is committed to humane animal care and use.

- Rodent rooms used for ABSL-3 studies do not require complete decontamination between studies because the animals are in individually ventilated cages. Veterinary technicians are conducting daily documented rounds of all animal areas. There is daily conversation between the AV and biocontainment veterinarian. One of the justifications for single housing a primate is to prevent cross contamination by an infectious agent. The IACUC will thoroughly review requests for single housing primates.
- The adverse event reporting policy had been amended to improve reporting of unexpected mortality. The former AV had not raised concerns about the monkey deaths, monitoring frequency, or scoring criteria. The biocontainment veterinarian had failed to report the monkey deaths because he did not know this was a reportable event. The previous AV was terminated for documented performance concerns. UTMB has a non-retaliation policy and staff has been trained on it. The IO has no oversight responsibilities for the biocontainment laboratory.
- The camera system did not provide visualization of the primates on the Marburg study due to visual obstructions.

On November 17, 2015 a site visit was conducted by representatives from OLAW, USDA, and NIAID. The requested records were reviewed, key individuals were interviewed, and the BSL4 area was examined from the outside and via cameras.

Following the November 17, 2015 site visit and receipt of the November 16, 2015 UTMB letter, OLAW sent a letter on November 19, 2015 thanking the IO for arranging the visit, acknowledging the information provided, and asking the institution to address the following:

1) Veterinary access to animals in the BSL4 biocontainment area must be available at all times when necessary. Arrangements must be made to access animals in the BSL4 24 hours per day, seven days per week for emergency care as well as for research related purposes.

2) More veterinarians and veterinary technicians are to be "suit trained" to enter the BSL4 area.

3) Post-approval monitoring must be conducted in the BSL4.

4) Provide information on how the IACUC is refining humane endpoints and enhancing the details on the scoring sheets. Include information on the frequency of observations as it links to clinical signs of deteriorating health.

5) Provide information on enhanced training of staff that identify clinical signs in animals and conduct endpoint scoring to ensure minimal variability among observers.

6) Provide information on how documentation can be enhanced in the BSL4.

7) Provide an update on how animal records in the BSL4 can be enhanced.

8) Provide information on the establishment of SOPs and preplanned countermeasures for BSL4 accidental exposures to a variety of agents. Include information on health providers and treatment modalities.

9) Provide a copy of the revised policy for reporting adverse and unexpected events.

10) Explain how the loop will be closed regarding resolution of a complaint submitted to the hotline.

- 11) Ensure that Category E studies have extremely robust scientific justification for withholding analgesia. Ensure that palliative care must be given if consistent with the aims of the study.
- 12) Ensure that the IACUC attendance roster is in the minutes and that committee deliberations on protocol review are adequate and included.
- 13) Ensure that the protocol form elicits sufficient information from the Principal Investigator (PI) to allow the IACUC to appropriately evaluate the proposal.
- 14) Ensure that the IACUC solicits animal welfare clarification from the PI, not just scientific descriptions.
- 15) Provide a plan and schedule on how the IACUC will review previously approved studies to ensure that pain relief, scoring, and humane endpoints are addressed.
- 16) Encourage the attendance of PIs at IACUC meetings to present and discuss challenging studies such as Category E and BSL4 work.

On November 23, 2015 OLAW acknowledged another submission by SAEN regarding an alleged noncompliance involving tail snipping of mice at UTMB.

On December 18, 2015 UTMB provided the following response to OLAW's November 19, 2015 letter:

- 1) Appropriately trained research and Animal Resources Center staff now have access at all times to all animals in all areas of the BSL4 facility.
- 2) The new AV is undergoing training in order to access the BSL4 area. A senior clinical veterinarian is being recruited and will be trained for access to the BSL4 area. Additional husbandry and veterinary staff will be trained to work in the BSL4 area.
- 3) Three individuals are already trained to enter the BSL4 area and will conduct post-approval monitoring on behalf of the IACUC. This activity will also be used to review relevant policies with the investigators.
- 4) Investigators with Column E primate studies have met with the veterinary staff to refine endpoints, modify clinical scoring sheets, and add observation periods as necessary. Protocols are being amended to add more frequent animal observations based on clinical signs. Investigators must provide strong justification if allowing an animal to become moribund. Observation frequency will be increased for animals approaching their humane endpoints to ensure prompt euthanasia.
- 5) Both research and Animal Resource Center staff will receive training in the recognition of clinical signs, humane endpoints, and scoring to reduce variability among observers.
- 6) An individual trained in documentation will assist investigators with record keeping in the BSL4 area.
- 7) Use of an animal health form in the BSL4 area documents twice daily biscuit counts, general observations, appetite and clinical signs. The form was modified to allow time stamping of observations.
- 8) Standard operating procedures are in place addressing notification and response to a potential exposure in the BSL4 area. Staff in this area is trained on clinical signs of diseases under study and on biosafety measures. Infectious disease physicians are available at the nearby hospital. Steps are underway to preposition potential countermeasures for Ebola and other BSL4 agents.

- 9) The revised policy for reporting adverse and unexpected events was provided.
- 10) The institutional procedures for addressing animal welfare allegations have been modified to include communication to the complainant of the outcome of an investigation.
- 11) All Column E studies will require strong justification for withholding analgesia or non-medical palliative care.
- 12) Attendance rosters at IACUC meetings have now been included with the minutes. IACUC minutes will now include more detailed information on protocol deliberations.
- 13) The protocol form was revised and is being reviewed by the IACUC. The form will solicit additional detailed information on humane endpoints, clinical scoring, and use of analgesics.
- 14) The revised protocol form has incorporated many of the questions found in the OLAW sample form and will address animal welfare.
- 15) The IACUC is re-reviewing all previously approved Column E studies, based on risk, to evaluate pain relief, scoring, and humane endpoints.
- 16) The IACUC will now encourage investigators to attend meetings to present their work and to discuss challenges.

On December 22, 2015 OLAW accepted the corrective actions outlined in the November 19, 2015 UTMB letter and commended the institution on its prompt and thorough actions taken in response to OLAW's findings. A proposed enhanced reporting schedule was accepted to allow OLAW to monitor ongoing corrective actions. OLAW asked UTMB to address the allegation of noncompliance involving mice tail snipping which had been submitted by an anonymous whistleblower through SAEN.

On February 3, 2016 UTMB provided a response to the allegation involving mice and found it not to be true. It was determined that IACUC policy encourages local anesthesia for tail snipping of rodents 21 days of age or less but does not mandate its use. Animal technicians were found to have taken appropriate action by involving veterinary staff in response to noting the tail snipping.

On April 29, 2016 UTMB provided the following update on the corrective actions accomplished:

- 1) Veterinary access to animals in the BSL4 biocontainment area is available at all times for emergency care and research related purposes.
- 2) The AV has escort access into the BSL4. Two new senior clinical veterinarians have been hired and these individuals will also be trained for access to the BSL4 to carry out clinical responsibilities. Another veterinarian has also been hired. Three biohazard technicians and one biocontainment technologist are being recruited.
- 3) Protocols are now subject to post-approval monitoring in the BSL4 areas. Three senior staff from Environmental Health and Safety will now monitor approved protocol procedures and will use the visits to teach investigators about relevant animal care and use policies. Reports from the visits will be provided to the IACUC.
- 4) All Category E protocols are being re-evaluated for clinical scoring, euthanasia criteria, and enhanced scientific justification for withholding analgesics. The veterinarian worked with the investigators to refine endpoints, modify clinical scoring sheets, and add observation periods. Animals approaching a moribund state will be subject to increased observations and appropriate euthanasia.

- 5) Animal Resources Center (ARC) staff have received training on documentation. ARC staff will receive protocol specific training when involved in supporting the study. These pre-study meetings will be used to ensure minimal variability among staff in evaluation of clinical signs, scoring and humane endpoints.
- 6) Animal room/health status documentation is being revised to prevent inclusion of contradictory information regarding animal observations between medical and research records.
- 7) The ARC records in the BSL4 have been modified to include timestamp observations.
- 8) Efforts are underway to identify medical countermeasures for BSL4 agents and to preplace these to facilitate an immediate response to occupational exposures among biocontainment personnel. A Biocontainment Critical Care Unit is being established in the Emergency Department. Personnel now receive extensive biosafety training and qualified healthcare providers are available. Emergencies are handled the same whether after hours or on a weekend.
- 9) The policy for reporting adverse and unexpected events was revised.
- 10) Complainants reporting animal welfare concerns will be notified of the outcome. Staff was reminded to contact senior staff, the IACUC, or compliance hotline with concerns.
- 11) Strong scientific justification is now being required for withholding analgesics in Category E studies and palliative care will be considered.
- 12) The IACUC minutes now contain the attendance roster. IACUC minutes will now have substantial documentation of deliberations.
- 13) The protocol form has been revised and approved by the IACUC and solicits responses on humane endpoints, clinical scoring, and use of analgesics.
- 14) The revised protocol form differentiates scientific vs. humane endpoints and increases emphasis on clinical scoring for euthanasia purposes.
- 15) All previously approved Category E protocols will be re-reviewed. The high risk protocols are being reviewed first and at the time of this report the IACUC has re-reviewed or placed in the queue for approval 33% of the protocols.
- 16) Investigators are encouraged to attend IACUC meetings and present their work.

On May 4, 2016 OLAW concurred with the actions taken by the IACUC and institution to address the outstanding items requiring correction.

On July 27, 2016 UTMB provided the following update on the corrective actions accomplished:

- 1) The AV and a senior clinical veterinarian have been trained and may now enter the BSL4 area. A clinical veterinarian is being trained and an additional senior biocontainment veterinarian has been hired and has already undergone training which will allow access to BSL4 on 9/1/16. A Biocontainment Technologist and two Biocontainment Technicians have been hired and are being trained. A new Animal Technician will transition to a Biocontainment Technologist.
- 2) To enhance documentation in BSL4 there will be pre-study meetings to discuss clinical scoring, roles and responsibilities, and data collection. Training will be provided on documentation. Records will be reviewed by the Office of non-Clinical Regulated Studies and the IACUC.
- 3) The IACUC is continuing to review previously approved Category E studies to ensure that pain relief, scoring, and humane endpoints are addressed.

On July 29, 2016 OLAW accepted the corrective actions.

On January 6, 2017 UTMB confirmed that all Category E protocols had been amended, re-reviewed and approved, or closed at the request of the PI.

On February 7, 2017 OLAW accepted all of the corrective actions taken by UTMB and confirmed that the animal care and use program is now compliant with the provisions of the PHS Policy. The institution was informed that OLAW's investigation was closed and a draft copy of the case was summary was submitted for identification of any errors of fact.

Summary: In August 2015 OLAW received allegations concerning PHS-supported nonhuman primate studies on Marburg virus at UTMB. OLAW investigated and determined that the research was not being conducted in accordance with the IACUC-approved protocol and was not compliant with the PHS Policy on Humane Care and Use of Laboratory Animals. Specifically, the animals were not observed with increased frequency as the disease progressed. This resulted in monkeys dying instead of being euthanized at earlier IACUC-approved endpoints that would minimize pain and distress to the animals. Under the provisions of the Health Research Extension Act, OLAW informed the institution that it was not meeting the PHS Policy requirements and that certain corrective actions were necessary. If no actions were taken, OLAW would withdraw the institution's Assurance and that PHS funding for all animal activities would cease.

UTMB responded promptly and initiated numerous corrections throughout the animal care and use program. Corrections included 1) hiring a highly qualified AV with significant biocontainment experience, 2) enhancing communication among key animal use staff, 3) increasing animal observations especially as animals near a critical stage in disease progression, 4) ensuring prompt reporting of adverse or unexpected events, 5) establishing appropriate endpoint criteria, and 6) having the IACUC review USDA Category E studies more rigorously.

OLAW, USDA, and NIAID conducted a joint site visit to UTMB. Records were reviewed, institutional staff members were interviewed, and facilities were inspected. Following the visit, additional questions were presented to the institution. In response, UTMB made the following changes: 1) numerous individuals now have access to the BSL4 facility to provide monitoring and care, 2) investigators refined their Category E primate studies to address endpoints with strong justification for withholding analgesia, 3) animal health forms were revised, 4) the protocol form was revised to require detailed information on humane endpoints, clinical scoring, use of analgesics, and 5) the IACUC now oversees post-approval monitoring of protocols conducted in the BSL4 suite and has re-reviewed all Category E protocols.

OLAW assessed all of the actions that had been taken by UTMB and concurred that the institution was successful in correcting the original problems and in ensuring a compliant animal care and use program to prevent recurrence. Because UTMB was found compliant with the PHS Policy, the investigation was closed.

The University of Texas Medical Branch

Exhibits

- 1) 8/19/15 letter from SAEN alleging noncompliance with PHS Policy at UTMB
8/20/15 OLAW acknowledgement of receipt of allegations
- 2) 2/20/15 NIAID audit report of UTMB
- 3) 8/25/15 letter from OLAW to UTMB outlining the allegations of noncompliance
- 4) 8/25/15 notes from a conversation with the former UTMB Attending Veterinarian
- 5) 9/4/15 NIAID email memo stating that a formal request must be submitted for the audit report and response
- 6) 9/4/15 memo from OLAW to NIAID requesting a copy of the UTMB and NIAID responses to the audit
- 7) 9/8/15 memo from OLAW to NIAID Program Officer citing need for a site visit to UTMB;
OLAW response to NIAID regarding the request for the audit report
- 8) 3/13/15 UTMB response to NIAID audit
- 9) 4/30/15 NIAID response to UTMB response
- 10) 8/28/15 UTMB request for an extension to provide a response to the 8/25/15 letter, and
OLAW's reply
- 11) 9/6/15 letter to OLAW from former UTMB Attending Veterinarian
- 12) 9/30/15 UTMB reverse site visit summary with NIAID staff
- 13) 10/8/15 USDA memo regarding former UTMB employee review
- 14) 10/27/15 letter from OLAW to UTMB announcing the 11/17/15 site visit
- 15) 10/29/15 letter from UTMB responding to OLAW's 10/25/15 submission of allegations
- 16) 11/3/15 search of active UTMB grants
- 17) 11/4/15 letter from OLAW to UTMB responding to the 10/29/15 letter
- 18) 11/10/15 emails between OLAW and UTMB regarding the 11/17/15 site visit; See exhibit 20 for
site visit agenda

- 19) 11/16/15 letter from UTMB responding to 11/4/15 OLAW letter
- 20) 11/17/15 OLAW/USDA/NIAID site visit agenda; UTMB policies
- 21) 11/19/15 letter from OLAW to UTMB addressing findings of the site visit and acknowledging content of the 11/16/15 letter
- 22) 11/23/15 email from OLAW responding to SAEN's 11/21/15 email comments and submission of another allegation of noncompliance at UTMB involving mice
- 23) 12/18/15 letter from UTMB providing answers to OLAW's questions and outlining an enhanced reporting schedule
- 24) 12/22/15 letter from OLAW to UTMB accepting corrective actions
- 25) 2/3/16 letter from UTMB regarding noncompliance allegations involving mice
- 26) 2/3/16-3/28/16 emails between OLAW and NIAID regarding USDA actions and plans for a pilot study
- 27) 2/22/16 record of call from UTMB regarding personnel changes
- 28) 4/29/16 letter from UTMB to OLAW providing corrective actions for BSL4 and also addressing allegations regarding mice
- 29) 5/4/16 letter from OLAW to UTMB acknowledging corrective actions for BSL4 and also addressing the allegations regarding mice
- 30) 7/27/16 letter from UTMB providing an update on corrective actions
- 31) 7/29/16 letter from OLAW to UTMB accepting the corrective actions
- 32) 11/22/16 memo from NIAID providing a media report regarding a USDA fine for UTMB
- 33) 1/6/17 letter from UTMB providing information on the final corrective action
- 34) 2/7/17 final letter from OLAW to UTMB accepting the final corrective action, closing the investigation, and requesting a review for errors of fact
- 35) 2/17/17 letter from UTMB pointing out one error and suggesting redactions
- 36) 2/22/17 letter from OLAW thanking UTMB for reviewing the draft report