

Office of Research Services
Animal Care and Use Committee
Minutes of April 21, 2020

Members Present: Mr. Scott Green, [Redacted by agreement] Dr. Jill Ascher, [Redacted by agreement]
[Redacted by agreement]

Members Absent:

ACUC Coordinator:

Visitors: [Redacted by agreement]

The meeting was called to order at 1:03pm. The meeting was held via videoconference due to concerns about COVID19 and the requirement to maintain "social distancing."

- **Review Minutes from the March 17, 2020 Meeting**

The March 17, 2020 minutes were reviewed. A motion was made by [Redacted by agreement] and seconded by [Redacted by agreement] to approve the minutes as written. The motion passed unanimously.

- **Review Responses to ORS ACUC Spring Findings**

The responses to the spring findings for the semi-annual review were reviewed. Areas under the deficiencies tab that still say pending were identified as either need to be changed to completed, if they have been completed, or the date needs to be updated. Dr. [Redacted by agreement] raised the question on whether it should be suggested to the facilities that staff should receive training on checking expired items. This is something that has occurred in the past. Also, any training that is completed should be documented for verification. Ms. [Redacted by agreement] will take care of the uncertified equipment in [Redacted by agreement] raised a question about the items for discussion, but per Mr. Green, these are just suggestions.

- **Semiannual Program Review and Facility Inspection Checklist**

Upon reviewing the OLAW checklist, under the IACUC section, Ms. [Redacted by agreement] asked that the training program be focused on, as far as IACUC evaluating effectiveness of the training program; would like to have some way of being confident that we are evaluating our training program for the benefit of both IACUC and the contract staff. [Redacted by agreement] had contracts provide sample training records for use during semi-annual review. Mr. Green brought up the idea of asking contract staff to come to an ACUC meeting and give a brief overview of staff training program; in terms of gov't staff the contractors probably document completed training better than the gov't.

Under the IACUC Membership and Functions, [Redacted by agreement] mentioned the inclusion of new members.

Under IACUC Training, Mr. Green asked [Redacted by agreement] if the previously scheduled workshop would be rescheduled and it appears it will be, but the exact date is unknown. Dr. Ascher

asked if OLAW site visitors had any questions or suggestions about the training program and Mr. Green mentioned that [Redacted by agreement] had some questions about training but didn't look at specific documentation.

Under Veterinary Care: #4. Dr. Ascher asked if we have own formulary and [Redacted by agreement] responded yes for several species, but not all in one place on V drive or SharePoint. Under Veterinary Care #5. [Redacted by agreement] mentioned that changes were made to the AVMA euthanasia guidelines.

Under Cagewash, [Redacted by agreement] asked if we still have temperature problems in cagewash. Mr. Green replied that it's addressed when it comes up, but is an ongoing concern. Ms. [Redacted by agreement] mentioned that in [Redacted by agreement] it's ongoing but not currently an issue; during summer months, humidity will become an issue occasionally. Dr. Ascher asked if we have someone that inspects safety concerns/hazards for employees and how do we make sure this is being done consistently. Mr. Green mentioned [Redacted by agreement] usually has DOHS come out and evaluate the environment for safety.

- **Semiannual Program Review Report**

Under Section A, #3, [Redacted by agreement] asked if we should add DVR SOPs and Dr. Ascher responded with "yes." Under Section A, #4 the question was raised if an "X" should go under second line; [Redacted by agreement] thinks it should be under the third line; concluded that since this is talking about the report as a whole, not solely inspections, it should be kept where it is (first line).

Under Section C, #2, Dr. Ascher asked if Facility Managers should be added. Mr. Green replied, we don't have anyone new. [Redacted by agreement] asked if import officers should be included; [Redacted by agreement] mentioned that she was replaced; but Dr. Ascher does not think it needs to be put into the report; this was agreed upon.

Under Section D, #1 (Departures from the Guide), [Redacted by agreement] asked if increased time between sanitation procedures is a deviation. (b)(6); [Redacted by agreement] mentioned that it does not need to be included in the report, just in the performance standard section.

Mr. Green asked if everyone is good and Dr. Ascher seconded that report looks good. Mr. Green asked that everyone send [Redacted by agreement] an email once they have signed the report signature page and send it on to the next person so that she can keep track of the progress.

- **Ongoing Deficiency List**

Dr. Ascher asked if we want to add that due to COVID19, some completion dates (April, May, June) might not be met. Conclusion: facility management can put that in the comment section if they feel there will be a delay.

- **OLAW safety review request of [Redacted by agreement] rodent changing procedures**

Dr. Ascher mentioned that we should have gotten an answer back from safety by now about PPE and precautions for the [Redacted by agreement] rodent cage changing concern, but would like [Redacted by agreement] to send a follow-up email [Redacted by agreement] about safety concerns.

- **Review ORS ACUC ASP Submission and Review Guidelines**

Mr. Green reviewed the ORS policy of DMR. No further discussion of the topic pursued.

- **Follow-up with Co-Housing Rodents Policy and discussion with Vets**

Due to current focus on the COVID 19 pandemic, vets did not get to discuss this at their monthly meeting. It will be added to the May meeting agenda for discussion.

- **NHP incident:** [Redacted by agreement]

Dr. Ascher gave a recap of the health issues with the primate: over the weekend the veterinarian on call called the lab responsible for the animal, which said the animal could be euthanized if the vet felt it was necessary; veterinarian decided euthanasia was not necessary, but the animal died over the weekend. Dr. Ascher followed up with the veterinarian involved and [Redacted by agreement], and Dr. [Redacted by agreement] will make sure to review any issues with weekend-vets who are not familiar with her [Redacted by agreement] area. Going forward, any questions should be emailed to the lab responsible, followed by a call to the Facility Veterinarian. This incident was followed-up with by the DVR vets well and will be used as a training experience to prevent this from occurring again. The veterinarian involved will touch base with [Redacted by agreement] and [Redacted by agreement] before covering that facility in the future. Mr. Green asked if anyone thinks this should be an OSHA reportable, and no one thought it was necessary.

- [Redacted] **ACUC Case Report**

[Redacted by agreement] gave a recap of incident. Dr. Ascher mentioned there was some confusion between DVR and NIAID about who should be responsible for the clinical care of this animal. [Redacted by agreement] mentioned whenever the animal was reported to DVR tech staff, NIAID staff would say that DVR shouldn't worry about it because NIAID veterinarians are taking care of the case. This left the DVR veterinarians out of the loop. Dr. Ascher mentioned concerns about the lack of collaboration and confusion with contract staff about the need to still report cases to the DVR veterinarians. [Redacted by agreement] mentioned that weekly tech meetings will be started between the DVR and NIAID staff and moving forward formal case transfers will be completed so that both institute veterinarians are aware and informed. Dr. [Redacted by agreement] believes that NIAID was giving a drug and there was an adverse reaction, but they didn't want to address the injection site reaction due to desire to continue the compound drug; possibility that NIAID was trying to avoid having to cease use of the drug. Dr. Ascher thinks this should be shared for NIAID to report this incident to their IACUC. Mr. Green brought up the idea that the vet techs should update the veterinarians about what was discussed during their weekly meetings and Dr. Ascher agreed. Mr. Green would like the committee to be updated on whether weekly meetings are successful and helpful in facilitating communication between both DVR and NIAID veterinarians and vet techs. Dr. [Redacted] mentioned that staff should not be taking directive from another institute's veterinarian without consulting with their own veterinarian first. Dr. Ascher asked if committee should provide this review to the APD and IACUC chair of NIAID. A vote was conducted: is it a reportable for DVR? Consensus is "No"; is it something that we need to bring to attention of NIAID ACUC chair and NIAID APD for their consideration? Consensus is "Yes."

- **DMR approvals: ORS-06, ORS-19, and NCATS amendment (2020-12)**

Mr. Green mentioned that the revisions requested at the March meeting were made and approved by DMR and the most recent NCATS amendments regarding COVID19 research were also approved by DMR.

- **NINR protocol Initial Submission (PI=** Redacted by agreement **)**

Mr. Green mentioned that Dr. Ascher is working with NINR staff to address the issues on their ASP. Dr. Ascher mentioned that she already got an answer and sent it to Redacted by agreement and will see what additional help is needed; the ASP appears to be in good shape. Mr. Green mentioned that we may get the protocol submission next month to review; might start project in August due to current COVID situation.

- **AAALAC delayed**

Mr. Green mentioned that AAALAC has been delayed until the upcoming Fall. Redacted by agreement
Redacted confirms it will possibly occur in October.

A motion to adjourn was made by Dr. Ascher and seconded by Redacted by agreement The motion passed unanimously. The meeting was adjourned at 2:48pm.

ORS ACUC Meeting Minutes

Members Present:

Mr. Scott Green

Redacted by agreement

Dr. Jill Ascher

Redacted by agreement

Redacted by agreement

Members Absent:

Redacted by agreement

ACUC Coordinator:

Visitors:

Redacted by agreement

The meeting was called to order at 1:04 pm. The meeting was held via videoconference due to concerns about COVID19 and the requirement to maintain "social distancing."

Items to be Discussed

- **Review Minutes from April 21, 2020 Meeting**

The April 21, 2020 minutes were reviewed. A motion was made to approve by Mr. Green and the motion passed unanimously.

- **Follow-up on retraining on checking for expired items**

Dr. Ascher asked if Redacted by agreement can report back to committee at next month's meeting about if this is working or not. Redacted by agreement said SOP states expired items should be checked every two weeks. Dr. Ascher stated that it was concerning that more expired items were found six months after the last inspection, where a lot of expired items were already found. Dr. Ascher asked if the SOP states that a facility vet should check for expired items. Redacted by agreement mentioned that the facility vet should make sure SOPs are being followed. Mr. Green mentioned that facility staff/management should be walking through their areas prior to ACUC inspections to address these issues, since it is announced when an ACUC inspection is scheduled. Redacted by agreement mentioned that there is now a monthly vet rounds form where each vet should do a walk through; this is something vets are doing to contribute; this month is the first month, so next month he will be able to gauge if things are getting better.

- **Review OLAW observer notes**

Mr. Green talked about the letter received from OLAW about their findings and areas where they want a response. Responses should be given by the end of July. Positive things mentioned: centrally available pharmacy, automated euthanasia system (Euthanex), continuity of operations plans and asked to use that in an upcoming webinar, SX equipment, enrichment program (rabbit pair housing), and activity play cages. Areas where they would like to see improvement: way pups are counted is inconsistent between institutes, level of detail for ACUC minutes (Mr. Green doesn't think that applies to us), encourage nonaffiliated members to participate in semi-annual inspections (our members seem well invested), concerns about caging for large male

pigtails (doesn't seem appropriate for size of animals), use of portable chillers in rooms to address heating issues (can impact number of air changes), and humidity concerns (potential to lead to dermatitis). Mr. Green asked Dr. Ascher "do you want to add anything?" Dr. Ascher didn't have anything to add but mentioned that if anyone wants to discuss it further, she is glad to do so. [Redacted] and [Redacted] with [Redacted] will be able to give an update. Mr. Green asked if anyone had any questions about items in report. Dr. Ascher mentioned she was really pleased with their findings and favorable view of DVR.

- **Follow-up with reporting primate incident to the APD and ACUC chair of NIAID**

Mr. Green mentioned that during the last committee meeting we discussed some of the concerns about communication between DVR vets and NIAID vets. We sent a letter to the NIAID ACUC chair and APD but haven't received any feedback. Dr. Ascher has been in communication with the APD, but also has not received any feedback. Mr. Green gave some suggestions for improvement in the letter as well. This subject will be followed-up on during next ACUC meeting.

- **Discuss NHPs at [Redacted] on long term holding, not on active studies**

Dr. Ascher mentioned Mr. Green started looking into this. Dr. Ascher asked [Redacted] and [Redacted] to make a list of all animals that are single housed and asked for a listing of animals that are not on study. There are about ten that aren't on study (on holding protocol); some are SIB animals. The question that should be asked is what's the cost of housing these animals, since money generally gets people's attention. Mr. Green mentioned that some of these animals might be some of the animals identified by OLAW as not being in the right sized caging. Mr. Green said this topic should be kept on the agenda for next month and hope they get back to us. Dr. Ascher agreed and said if they don't get back to us, then maybe we should take more proactive steps.

- **Guinea Pig incident**

[Redacted] gave an overview of the guinea pig incident and the circumstances around it. A baby guinea pig managed to slip out the lixit hole at the back of the cage and fell into the gravity flow water drip collection container and drowned. Caretakers checking behind the guinea pig cages started when a previous guinea pig got its head caught. To prevent another accidental escape and drowning, a wire bar lid was added on top of bin where water collects so that animals won't land in the pooled water if another escapes; adjusted caps around lixit so that the hole is no longer available for babies to access and potentially escape. The opening/space at the back of the cage by the lixit was previously discussed when breeding started, but no one thought it would be an issue, per Dr. [Redacted]. The purchasing of new guinea pig caging has been in the works. Mr. Green mentioned that the procurement is moving forward and asked how they are adhering the water bottle lid to lixit. [Redacted] replies it fits on the lixit, as shown in the picture shared with the committee. Mr. Green asked if it was just one pup and [Redacted] replied yes, just one, no others escaped. Mr. Green felt a follow up investigation would probably not reveal more information, after discussing the matter [Redacted] Mr. Green asked the committee if anyone else felt like we should further investigate. Dr.

Ascher mentioned that [Redacted by] and others have done a good job. Mr. Green asked, "does anyone feel this is a reportable incident?" Dr. Ascher replied that it should be considered since it is the second incident involving the accidental death of a guinea pig. [Redacted by] mentions that the other death was an adult guinea pig. Dr. Ascher thinks it is an OLAW reportable incident. [Redacted by] mentions it's standard guinea pig caging, so it's similar to an accident when a mouse cage floods. Dr. Ascher asked "breeding is a new thing for us, correct?" [Redacted by] replied "correct." Mr. Green is hesitant to call it reportable for a one-time incident. The rest of the committee states their votes: Dr. [Redacted by] voted no; [Redacted by] votes no; [Redacted by] votes no; [Redacted by] votes no; Dr. [Redacted by] votes no; [Redacted by] votes no; [Redacted by] votes no, it was an accident; Mr. [Redacted by] votes no. [Redacted by] asked if the caging will be changed. Mr. Green replies that we're in the process of ordering new caging. [Redacted by] asked if this event prompted the purchasing of new cages. Mr. Green replies that there were previous discussions about it, but this incident probably fast tracked the plan. [Redacted by] (OACU) thinks this is an OLAW reportable since the guidance for reporting to OLAW states that if a mechanical failure leads to death or harm of animal, it should be reported. Dr. Ascher mentions that whenever OLAW is asked, they always want the incident to be reported. [Redacted by] re-reads the section of the guidance that states that conditions that jeopardize the health or wellbeing of animals including natural disasters, accidents, or mechanical failures. Mr. Green thinks that the initial vote from everyone should be reconsidered after hearing what [Redacted by] shared about accidents being included, since everyone deemed this incident an accident. [Redacted by] and Mr. Green changed their votes to yes. [Redacted by] asked if there were any exceptions. [Redacted by] replied that the exception for incidents of drowning or manipulations are ones that fall within parameters of a protocol. [Redacted by] clarified drowning as caused by flooding due to valve jams from bedding. [Redacted by] then change their votes to yes. [Redacted by] also changed vote to yes. [Redacted by] mentioned there are past incidents that probably should have been reported since the committee was unaware of this clause. Dr. Ascher says it's ok, we're learning and developing as a group. [Redacted by] still is not sure if she would consider it a reportable because it wasn't a failure of any equipment or accident on the staff's behalf. [Redacted by] stated we will make note of that in the letter that the staff was not at fault. A report will be prepared and submitted to OACU with the majority voting that this is a reportable incident.

- **COVID19 actions with staff scheduling**

Dr. Ascher gives an overview of the current staff scheduling. We went to a split schedule where each facility has an A and B team working different schedules; 7-day work week. [Redacted by] has 3 teams. Everyone has staggered lunch breaks. People disinfect their areas before and after they eat in the break rooms. During primate and rabbit procedures, PPE has been ramped up to include face shields in addition to face masks. Mr. Green mentioned that this is so that if someone comes up positive the whole staff won't get quarantined. Dr. Ascher states that fortunately, we have not had to quarantine whole teams due to staggered staffing within the team as well; there is still the theoretical possibility that a whole team might have to go out. Management has

been addressed about possible staff burnout. Mr. Green mentioned that animal resources team has daily call-in at 10am about news on different facilities; check up on staff and get feedback on different things. These meetings have been cut back to twice a week now; sharing ideas and making sure everyone is on the same page. Dr. Ascher mentioned that there used to be daily COVID 19 updates meetings, but then brought down to 3 or 4 times a week. [Redacted] mentioned that all animal tech groups are working together to get through this time [Redacted] is impressed by people working in animal facility; originally worried about supply of PPE, but it doesn't seem to be an issue; very happy to see that. Dr. Ascher asked staff to check-in with other staff to see if there are any concerns, so she is glad to hear it seems to be working out.

- **NCATS amendments**

Mr. Green mentioned that a few amendments have gone through for COVID 19 protocol that [Redacted] is working on. They were reviewed and approved by Safety and Dr. Ascher.

- **Follow-up list**

Mr. Green listed follow up items for next meeting [Redacted by agreement] on training for expired items update and update on reporting primate incident; Dr. Ascher might have update on long-term studies. He doesn't think there are any ASPs for review next month either, but will check on that.

A motion to adjourn was made by Dr. Ascher and seconded by [Redacted by agreement] The motion passed unanimously. The meeting was adjourned at 1:54pm.

Office of Research Services
Animal Care and Use Committee
Minutes of June 16, 2020

Members Present:

Redacted by agreement

Mr. Scott Green, Dr. Jill Ascher,

Redacted by agreement

Redacted by agreement

Members Absent:

ACUC Coordinator:

Visitors:

The meeting was called to order at 1:03 pm.

- **Review Minutes from the May 19, 2019 meeting**

The May 19, 2020 minutes were reviewed. There were two changes made to the minutes. The indication that the NIAID letter was 'drafted' changed to 'sent'. Redacted by agreement vote on the guinea pig incident was changed from 'no' to 'yes'. A motion was made by Dr. Ascher and seconded by Redacted by to approve the minutes with corrections. The motion passed unanimously.

- **Redacted NHP Incident**

Redacted by led the discussion reviewing an incident involving two macaques on May 21, 2020.

A mispairing resulting in traumatic injury occurred after TB testing and physical examinations had been conducted. A group of veterinary technicians were assisting the facility veterinarian with sedating primates for physicals. After the veterinarian performed the physicals the two macaques were inadvertently pair housed by contract staff resulting in severe injuries to the non-dominant primate. The two animals involved were housed in adjacent cages in the same quad and were not meant to be paired with each other. Several factors have been taken into consideration upon further investigation of the incident from Facility and Contract Management. One main issue was that veterinary technicians with minimal DVR experience had not been properly supervised by a task manager or trainer. The proper procedures for verifying cage tags and room layouts were also not followed. The contractor provided a response to DVR management with a corrective action plan. Dr. Ascher provided clarification that the primates were not meant to be pair housed and that inadequate training had occurred for the veterinary technicians involved. There are a handful of other factors to consider as well given the current COVID-19 pandemic staff are operating at 50% capacity, are procedures being scheduled to accommodate staffing and the contractor has only been on-site since January 2020. Scott indicated there had been a similar incident at Redacted by a year or two prior where a lock was missed resulting in an escaped primate and injury to another. The concern is whether OLAW will consider this a repeat offense if it is raised as a reportable incident from the committee. Further discussion on the manner occurred and Redacted by agreement and Mr. Green will discuss further whether the incidents were in fact similar if further action is taken by the committee. Redacted by agreement asked whether the incident affected the scientific

research or not and Dr. Ascher responded that in fact the animal suffered significant inflammatory response and has been receiving medicated treatment and thus will result in a variable to the study results; however no formal response has been given by the institute conducting the study. [Redacted by agreement] also questioned inadvertent virus transmission to the injured animal; [Redacted by agreement] indicated they were both on the same study. Mr. Green called for a vote from the committee on whether the incident was reportable to OLAW, the committee agreed unanimously. Mr. Green and [Redacted by agreement] will draft a letter to OACU for delivery to OLAW. Dr. Ascher would like to review the draft prior to submission.

- **Welcome** [Redacted by agreement]
[Redacted by agreement] has joined the ACUC committee as a non-affiliated member. She was introduced to committee members during her first meeting today.
- **Training for Guidance for Reporting to OLAW**
Information received from the OACU was shared with the committee regarding what types of incidents needed to be reported to OLAW. Guidance was provided after confusion over an incident being discussed at the last ACUC meeting regarding a potential reportable incident. Dr. Ascher reminded the committee that this would be an excellent opportunity to conduct training for the committee members. Mr. Green indicated that [Redacted by agreement] from the office of OACU will provide additional training to the committee from [Redacted by agreement] in addition to reviewing the guidance. [Redacted by agreement] asked for clarification of the OLAW acronym and [Redacted by agreement] provided a general overview of OLAW, PHS Policy and various regulations along with compliance monitoring.
- **Expired Items Training Update**
[Redacted by agreement] indicated this training had previously occurred. He resubmitted the attendance roster for confirmation. Mr. Green indicated training with staff occurred because of numerous expired items found during the semi-annual inspection. This will be an item of interest for the fall semi-annual inspection.
- **Update on discussion of NHPs at [Redacted by agreement] on long term holding, not on active studies**
Mr. Green asked Dr. Ascher if DVR had received a response from NIAID over the [Redacted by agreement] primate concern. Dr. Ascher provided a quick recap of the concern over 9 singly housed primates and that no reply had been received from NIAID. [Redacted by agreement] asked when the committee had originally reached out to NIAID and Mr. Green responded an initial reply came on May 18, 2020 that NIAID would be discussing the concern. [Redacted by agreement] recommended reaching out to the NIAID group again, Mr. Green will contact [Redacted by agreement] Dr. Green asked about the previous concern with NIAID regarding a lack of communication with veterinarians, contract staff and management. [Redacted by agreement] indicated communication has improved via email and phone. All issues are being reported immediately to the appropriate contacts. Dr. Ascher will continue to monitor communication and assist as needed.
- **NCATS amendments**
Regarding recently submitted amendments Mr. Green provided a quick synopsis of the process for [Redacted by agreement] and indicated they are under designated review by the committee.
- **AAALAC Site Visit Update**

An announcement has been made that the official AAALAC site visit for NIH was postponed one full year until June 2021. The updated Program Description will be due in April 2020.

- **Semi-Annual Review Briefing**

Mr. Green has scheduled the review briefing with the ORS Director for June 29, 2020. Mr. Green, Dr. Ascher, [Redacted by agreement] and [Redacted by agreement] will represent the committee at the review meeting.

- **Fall Semi-Annual Review**

Mr. Green tasked the committee to begin thinking about the fall ACUC inspections and how we will conduct them given the current operations of NIH during the COVID-19 pandemic. Dr. Ascher will bring the discussion forward to all APD's at their next meeting. We will also consult OACU regarding this issue.

- **Clarification on COVID-19 Research Restrictions**

[Redacted by agreement] asked for clarification on when restrictions for research will be lifted upon the return of Group A to campus. Dr. Ascher indicated all information regarding research comes from [Redacted by agreement] and [Redacted by agreement] and the IC Scientific Directors. If clarification is needed regarding Technical Service Requests [Redacted by agreement] encouraged [Redacted by agreement] to reach out directly to the facility managers. Research support will be provided based on the capabilities of the current staffing levels.

- **Announcements**

The next ACUC committee meeting will be July 21, 2020

A motion to adjourn was made by Dr. Ascher and seconded by [Redacted by agreement]. The motion passed unanimously. The meeting adjourned at 2:04 pm.

Office of Research Services
Animal Care and Use Committee
Minutes of July 21, 2020

Members Present: Redacted by agreement Mr. Scott Green, Dr. Jill Ascher, Redacted by agreement
Redacted by agreement

Members Absent: Redacted by agreement

ACUC Coordinator:

Visitors:

The meeting was called to order at 1:01 pm.

- **Review Minutes from the June 16, 2020 meeting**

The June 16, 2020 minutes were reviewed. Redacted by agreement moved to approve the minutes as written, Redacted by agreement seconded the motion. The minutes were approved by the committee.

- **Update on Semi Annual Report to ORS Director**

Mr. Green provided a recap to the committee on the presentation given to Redacted by agreement. The presentation was well received with one suggestion. Redacted by agreement would like to receive the information on findings categorized by building or location and prefers a visual graph or chart. This will allow her to better identify trends that may develop and help with obtaining corrective actions.

- Redacted by agreement **NHP Incident**

Redacted by agreement completed the investigation into the incident and submitted her report to Mr. Green and Dr. Ascher for review. A letter was drafted on behalf of the committee and sent to Dr. Denny with OACU on July 21, 2020 for approval prior to sending to OLAW for review and feedback.

- **Guinea Pig Pup Incident**

OLAW reviewed the report submitted by the committee for the incident that occurred in May. OLAW agreed with the response provided by DVR. Mr. Green announced that new guinea pig caging is currently in the procurement process and will mitigate potential future concerns.

- **Update on discussion of NHPs at Redacted by agreement on long term holding, not on active studies**

The committee recapped this ongoing concern and reached out again to NIAID's ACUC committee. NIAID is currently working with the Principal Investigator of the study to develop an SOP and guidance on social housing NHP's. Dr. Ascher is happy with the current attention being given to the situation and asked the committee not to lose sight of the original concern.

- **NCATS amendments**

No additional updates on recently approved amendment to Redacted by agreement protocol.

- **AVMA Guidelines**

AVMA guidelines were officially published. Clarifications are below:

Clarification #1: These Guidelines were designed for use by members of the veterinary profession who carry out or oversee the euthanasia of animals.

- Euthanasia for scientific purposes is under the purview of the Institutional Animal Care and Use Committee or Oversight Body (IACUC/OB). In these situations, “The IACUC[/OB] has mandatory veterinary input and considers animal welfare, requirements for postmortem tissue specimens, and interference of euthanasia agents or methods with study results.”

Clarification #2: The Guidelines apply to methods of euthanasia which are strictly defined, such that “while some methods of slaughter and depopulation might meet the criteria for euthanasia identified by the Panel on Euthanasia (POE), others will not and comments in this document are limited to methods used for euthanasia.”

- With regard to free-ranging wildlife, the Guidelines acknowledge that “... the quickest and most humane means of terminating the life of free-ranging wildlife in a given situation may not always meet all criteria established for euthanasia (i.e., distinguishes between euthanasia and methods that are more accurately characterized as humane killing).”
- These limitations in application of the guidelines notwithstanding, AAALAC International emphasizes that death of animals for scientific purposes, including the method of death, is under the purview of the Institutional Animal Care and Use Committee or Oversight Body (IACUC/OB). For additional information regarding free-ranging animals refer to the AAALAC International Species-Specific Reference Resources ([https://www.aaalac.org/resources/resources-list/#Species Specific](https://www.aaalac.org/resources/resources-list/#Species%20Specific)) with attention to their appended clarifying caveats.

[Redacted by] reviewed the changes with the committee, DVR SOP’s on euthanasia of rodents have already been updated and no significant changes were made for large animals.

- **Fall Semi-Annual Review**

Mr. Green informed the committee that [Redacted by], Dr. Ascher and he had met to discuss options for fall inspections while under restrictions due to COVID-19. [Redacted by] from OACU offered three suggestions to the committee including using video to conduct inspections, having only one inspector for non-regulated species or tasking ad-hoc members to represent the ACUC committee. Mr. Green indicated after their discussion that the committee would be leaning towards utilizing ad-hoc members based on the number of regulated species housed in DVR facilities. [Redacted by] indicated we would still need one member of the committee to attend as several members of the committee are currently assigned to facilities and we prefer that they not inspect their own location. [Redacted by] requested clarification of the three options and Mr. Green explained the concern and difficulties with filming video for the inspection. Dr. [Redacted by agreement] agreed with the suggested approach, it will help to limit the number of individuals in areas and utilize current facility experts. The only concern Mr. Green foresees is the [Redacted by] inspection given the size of the operation. Dr. Ascher indicated [Redacted by] is currently operation as three separate teams and could be inspected as such. [Redacted by agreement]

suggested contacting current onsite teams and facility managers to determine individuals willing to serve as ad-hoc members and join one committee member for the inspection. This appears to be the approach several other IC's are using according to Dr. Ascher and [Redacted by agreement]. Mr. Green polled the committee for current access to NIH and will assign teams with the ACUC Coordinator [Redacted by agreement]. There are concerns over restricted access on campus, but the committee will work with each facility accordingly. Mr. Green indicated the inspection would need to be initiated during August and completed by the beginning of September to allow time for review of findings. ACUC members unable to serve as inspectors will review all findings for the semiannual fall report.

- **Pig Housing Exemption**

In the past Clinical Center oversized pigs could be housed in [Redacted by agreement] with an understanding that pens were slightly smaller than the guide requires however the pigs were provided access to outdoor pens weather permitting. [Redacted by agreement] drafted a new exemption for the pigs as a previous version of an exemption was written five years ago under the previous director. Dr. Ascher requested [Redacted by agreement] to assist [Redacted by agreement] with review of the draft prior to submitting it to her for approval. [Redacted by agreement] is also working to have these animals adopted out as soon as possible.

- **Veterinary Staff/DVR Support Changes**

Dr. Ascher announced the current DVR Behaviorist would be leaving and [Redacted by agreement] is going to step in temporarily with other DVR veterinarians assisting with behavior rechecks. Dr. Ascher is seeking a veterinarian for [Redacted by agreement] will have a new Facility Manager joining us from the FDA. [Redacted by agreement] accepted a new position with DVR focusing on data analysis and collection. She will assist in training the new [Redacted by agreement] Manager. A new Program Analyst will be starting to support Dr. Ascher directly and a Facility Specialist position will soon be open in [Redacted by agreement].

- **Training Opportunities**

[Redacted by agreement] provided an OACU update to the committee including an attachment with resources and a summary of what was presented at [Redacted by agreement]. These included the 21st Century Cures Act, a goal to harmonize current regulations for various agencies, guidance on minutes for ACUC meetings and updates to VVC, FCR and DMR review.

Dr. Ascher reminded everyone that training is very important. A reminder to all committee members to email [Redacted by agreement] any and all training reviewed for tracking purposes. Mr. Green inquired about the SCAW meeting; [Redacted by agreement] replied in an email that it has been postponed until further notice.

- **Training Animal Discussion**

[Redacted by agreement] provided a summary to the committee of what the DVR Veterinarians discussed regarding the use of training animals on [Redacted by agreement] and [Redacted by agreement]. For small animals it is best to use cull animals unless performing procedures like tattooing which needs to be verified days later. The goal of using large animals in the future is for temporary transfers to the training protocol. All animals used for training should be on the training protocols [Redacted by agreement] clarified that for large animal transfers the same animal would only be counted once. Also, if animals

are utilized on more than one ASP, they should be counted on the ASP with the higher pain classification. This topic will be discussed further in the August ACUC committee meeting.

- **Concerns**

[Redacted by] brought a concern regarding the ORS Director posting a summary of staff shearing sheep at [Redacted by]. She was concerned about whether the post was appropriate and if the animals should have been on the training protocol and were the staff properly trained? Dr. Ascher indicated the sheep shearing went well and that no animals were injured. Mr. Green and Dr. Ascher indicated the animals did not need to be transferred to the training protocol because the shearing was a routine husbandry task. Dr. Ascher also indicated several of the participants routinely shear at their own off-site farms. Dr. Ascher submitted the article for the ORS Director to share as it was a successful team building event.

- **Announcements**

The next ACUC committee meeting will be August 18, 2020

A motion to adjourn was made by [Redacted by agreement] and seconded by Dr. Ascher. The motion passed unanimously. The meeting adjourned at 2:07 pm.

Office of Research Services
Animal Care and Use Committee
Minutes of August 24, 2020

Members Present:

Redacted by agreement	Mr. Scott Green, Dr. Jill Ascher,	Redacted by agreement
Redacted by agreement		

Members Absent:

Redacted by agreement

ACUC Coordinator:

Visitors:

The meeting was called to order at 3:18 pm.

- **Review Minutes from the July, 21 2020 meeting**

Review of the July ACUC meeting minutes have been postponed until the September ACUC committee meeting. Today's meeting will address an abbreviated agenda.

- **Update on discussion of NHPs at [Redacted by] on long term holding, not on active studies**

The committee reviewed a draft SOP from LMM and opened the call for discussion. Mr. Green requested input from the members of the committee working directly with NHP's. Both Dr. [Redacted by] and [Redacted by] provided input. [Redacted by] felt as though scientific studies were taken into consideration and [Redacted by] agreed. One concern raised was regarding the suppression of viral loads in [Redacted by] experience it is okay to pair NHP's once they have been suppressed, especially if both NHP's are on therapies. Dr. Ascher would like the committee to present recommendations to the NIAID ACUC for consideration. Dr. Ascher was concerned regarding the last sentence of the document: 'Should be reevaluated by DVR or NIAID facility veterinarian' this statement needs to be clarified that a DVR veterinarian will be the one to make the change at their discretion. [Redacted by] inquired if the DVR Behaviorist should also be consulted in the decision. Dr. Ascher believes leaving it at DVR should be fine as it covers both the Behaviorist and Facility Veterinarian. [Redacted by] mentioned to split the responsibilities to include consideration by both veterinarians of the institutes but with final say by the DVR Veterinarian. [Redacted by] will draft the committee's recommendations for review by Dr. Ascher and Mr. Green prior to submitting to NIAID.

- **[Redacted by] NHP Burn Incident**

Concerns were brought to Dr. Ascher's attention by [Redacted by] over a gel pack burn to an NHP after a dental procedure at [Redacted by]. The NHP was having a tooth extracted but was unable to maintain proper temperature, the veterinarian asked for an additional heat source to be provided to the NHP and the assisting veterinary technician placed an unwrapped small gel heating pack onto the animal. The veterinarian asked whether it should be wrapped first, but the veterinary technician informed the veterinarian that it was not necessary. A few days after the procedure a burn was apparent, the wound was cleaned and debrided, it is currently healing well and down to the size of a quarter. The animal had already been receiving antibiotics due

to the tooth extraction and was not on study at the time. There has been a subsequent retraining of veterinary technicians and veterinarians to discuss the oversight and how to treat animals with heat packs. [Redacted by agreement] would also like for her staff to participate in the training as well. [Redacted by agreement] was not familiar with the use of gel packs at the time of the investigation. Moving forward additional heat sources have been ordered. Dr. Ascher also reminded everyone that this is not an uncommon injury but that all attempts should be made to minimize an occurrence. The incident should serve as a reminder to all to pay attention to training as there has been a fair amount of turnover on the DVR contracts. One correction in the report per [Redacted by agreement] is that it was an NIA NHP and not an NIH NHP. Mr. Green inquired how hot the gel pack could become, [Redacted by agreement] tested with a thermometer and determined at least 108 degrees. Dr. Ascher requested clarification regarding the status of the animal not being on the protocol. Dr. [Redacted by agreement] indicated the animal is not currently on an active study. [Redacted by agreement] indicated it was not on an active study, but these animals do stay around for a time period due to the NIA need for aged animals. Mr. Green inquired about the status of the returning veterinary technician for an interview. [Redacted by agreement] clarified that the veterinary technician had returned to work and will coordinate with [Redacted by agreement] for [Redacted by agreement] and [Redacted by agreement] to follow up. Mr. Green inquired if we would be able to accommodate the training for the PI's group. It was also suggested for [Redacted by agreement] to submit a request for new equipment ASAP a procurement deadline is fast approaching. Mr. Green said we would need to wait to vote on whether this is a reportable until after the investigation is complete. [Redacted by agreement] and [Redacted by agreement] completed most of the investigation into the incident and submitted their preliminary report to Mr. Green, Dr. Ascher and the committee for review. A final report will be completed after the final interview is conducted this coming week and will be submitted for review to the committee. The preliminary report is attached.

- **Fall Semi-Annual Inspections**

Mr. Green asked if there were any concerns thus far with scheduling and conducting the semiannual inspections. Dr. Ascher addressed the discomfort of some individuals in conducting the walk thru's given some positive COVID cases in DVR. A brief discussion on safety protocols ensued.

- **Announcements**

The next ACUC committee meeting will be September 15, 2020

A motion to adjourn was made by [Redacted by agreement] and seconded by [Redacted by agreement]. The motion passed unanimously. The meeting adjourned at 3:55pm.

Office of Research Services
Animal Care and Use Committee
Minutes of September 29, 2020

Members Present: Mr. Scott Green, [Redacted by agreement]

[Redacted by agreement]

[Redacted by agreement]

Dr. Jill Ascher

Members Absent: N/A

ACUC Coordinator: [Redacted by agreement]

Visitors: [Redacted by agreement]

Call to Order:

The meeting was called to order at 1:05 pm.

Review of Meeting Minutes:

- **Review Minutes from July 21, 2020 & August 24, 2020 Meetings**

The July 21 and August 24, 2020 minutes were reviewed. A motion was made to approve the July 21, 2020 minutes by [Redacted by agreement] and seconded by [Redacted by agreement]. The motion was approved by the committee. The motion to approve the August 22, 2020 minutes was made by [Redacted by agreement] and seconded by [Redacted by agreement]. The motion was approved by the committee.

Incident Reports:

- **Follow up OLAW Response to NHP Pair Housing Incident**

OLAW accepted our report and had no further questions or concerns regarding the incident.

- **Follow up NIHAC Burn Incident**

[Redacted by agreement] provided an update to the incident reported to the committee from 7/13/20. She provided a summary again to the committee regarding the animal that was burned by a heat pack directly placed onto the animal without being wrapped. Unfortunately, this action was not caught prior to the animal being burned. Several corrective actions have since been taken by the staff at [Redacted by agreement] to mitigate future adverse events. Mr. Green asked the committee for questions or comments regarding the incident. Mr. Green requested a vote from the committee on whether the incident should be reported to OLAW and the committee subsequently determined that it should be considered a reportable incident. [Redacted by agreement] will finalize the report for submission to OLAW on behalf of the committee.

- **Non-Medicated SIB NHP Incident**

Mr. Green summarized an incident involving an NHP that did not receive a dose of SIB medication which subsequently resulted in an injury. Since the incident, the animal has been identified for euthanasia due to its SIB history. The animal had successfully responded to daily dosage of medication before the incident. The assigned veterinary technician did not administer the appropriate dose as assigned. After interviewing several contract employees and the facility veterinarian it was determined the animal did not receive its medication because the veterinary technician had been called to assist with an emergency in another building. It was requested that another technician provide the treatment, but the technician did not arrive at the animal room to administer the treatment until after cage changing had begun and the animal had already started to self-injure. The contract management team subsequently implemented several safeguards to avoid future incidents. [Redacted by agreement] made a comment regarding the incident and indicated the animal had been on treatment for several years and had not injured itself for only 4 months prior. She wondered if the animal may have potentially injured itself regardless. [Redacted by agreement] indicated the animal was scheduled for euthanasia today due to ongoing SIB. He does not know that one could conclude the animal injured itself that day due to one missed dose of medication. Mr. Green indicated the veterinarian overseeing the animal did believe the missed dose was a factor. [Redacted by agreement] inquired how long after the medication is given does it take affect? [Redacted by agreement] indicated standard practice is to receive medication an hour prior to procedures occurring. He indicated a quick search showed the medication has onset of approximately 1-2 hours after oral dosage. Mr. Green asked the committee if this was a reportable incident and no committee members believed it was reportable. [Redacted by agreement] does not believe it was a direct result of one missed dose and [Redacted] also believed that the animal was chronically dosed and missing one dose by a few hours for a BID orally administered drug shouldn't cause a drastic change on the efficacy, unless the animal was not on an effective dose to begin with. Dr. [Redacted by agreement] indicated the animal belonged to NIAID and was an SIV animal since 2015. Mr. [Redacted by agreement] asked why the animal was being maintained under the protocol with an SIV status. [Redacted by agreement] indicated the animal was being followed long term for virus detection. [Redacted by agreement] said the committee must consider whether there was a failure to follow through with veterinary directive. [Redacted by agreement] indicated it was a tricky point because it did not appear a specific time point was assigned to the animal and that one veterinary technician was pulled away due to an emergency and the other was following orders as expected and by room entry order by the time this technician was able to administer the medication to the animal injuries were observed. Mr. Green indicated the records did not indicate when the treatment needed to be given, just that it is typically given early in the morning. [Redacted by agreement] asked what time the medication was given. [Redacted by agreement] suggested a review of treatments and ensuring times are clarified on medical records. Dr. [Redacted] does not believe the adjustment of time based off half-life of the drug would make a difference unless it was an IV dosage based on pharmacological assessment. Dr. Ascher requested we have [Redacted] notes written in the minutes as her input is very important. She also would like to make sure we review the SOP and retrain the staff. Additional discussion ensued with [Redacted by agreement] and Mr. Green as to whether there was a failure to follow veterinary orders or not based off an established timeframe. The committee would like to defer a vote until the dosage time point is confirmed by the veterinarian.

Further discussion regarding time points for treatments should be considered. Dr. Ascher indicated whether the vote occurs now or later she would still vote no based off [Redacted] assessment. She indicated if it was a continual problem her vote may differ. [Redacted by agreement] [Redacted by agreement] and [Redacted by agreement] agreed with Dr. Ascher's assessment as well. Mr. [Redacted by agreement] believes it is a reportable and [Redacted by agreement] would like additional information on whether the veterinarian's orders were followed correctly. Mr. Green requested Dr. [Redacted by agreement] to follow up on this animal's DVMAX records for further clarification prior to a committee vote by email.

Follow Up to Mr. Green's request for DVMAX information and SOP review:

- 1) There was no specific time identified in DVMAX as to when the animal should receive the treatments. It only mentioned BID.
- 2) There is no DVR SOP on administering BID treatments, although it has now been suggested that one be created.

This information was sent to the members of the ACUC committee via email with a request for vote on whether this incident was a reportable incident to OLAW. The final vote from the committee was that the incident was not a reportable one; however, it included one dissent from the community representative who felt the incident was still reportable. [Redacted by agreement] felt that there was a loss in the chain of care or custody of the animal during husbandry procedures regardless of its medical history or predictable euthanasia. He felt there should have been a back up plan put into place.

- **Buprenorphine SR use past expiration date and past use by date Incidents**

[Redacted by agreement] informed the committee that during the fall ACUC inspection there were several instances of dosing of Buprenorphine after the use by date. This occurred in both [Redacted by agreement] and [Redacted by agreement]. There is an existing ARAC guideline from 4/2016 that indicates the medication must be labeled if it is a preservative free pharmaceutical. The guideline is to use within 28 days. The US Pharmacopeia and the product manufacturer indicates the drug should be discarded after the 28-day. [Redacted by agreement] believes this is a minor deficiency and should be grouped by building. [Redacted by agreement] indicated that Dr. [Redacted by agreement] reported the deficiency to the ACUC for [Redacted by agreement] and then [Redacted by agreement] followed up at [Redacted by agreement] and found the deficiency there as well. Dr. Ascher questioned whether an SOP was necessary or could the ARAC guideline be followed? [Redacted by agreement] stated that not all IC's follow ARAC guidelines so an SOP may be appropriate. [Redacted by agreement] and [Redacted by agreement] reviewed all clinical records for animals that had been dosed after the use by date and the records indicated that the animals receiving pain relief from the medication. [Redacted by agreement] also indicated the directive is not clear regarding use by date of date labeled or date the bottle was punctured for first use. Mr. Green asked the committee whether they felt this was a reportable incident. All committee members agreed it was a minor deficiency and not a reportable incident.

- **NHLBI Pig Incident**

Dr. Ascher summarized an incident with an anesthetized pig from [Redacted by agreement] to ICU. The veterinary technician in the transport vehicle was not a seasoned technician. The animal went into cardiac arrest quickly after the endotracheal tube was removed. NHLBI was very concerned with the incident. Upon investigation [Redacted by agreement] found that about 50% of pigs being transported back to DVR do have the endotracheal tube removed during transport. Dr. Ascher found that several staff members from DVR and NHLBI were not familiar with oxygen levels and when to extubate an anesthetized pig. [Redacted by agreement] and Dr. [Redacted by agreement] are working with the staff members from NHLBI on setting up a training. Dr. [Redacted by agreement] performed a necropsy on the animal and it appeared the animal had fluid and gastric contents in the lungs as well as pneumonia, he believes the aspiration occurred after extubating and was not previously existing. He also informed the committee that there had been a band placed in the heart during the initial procedure although this likely had no effect on the low oxygen level of the animal while under anesthesia. Dr. Ascher indicated post incident follow up and procedures need to be determined on how to consistently approach the handling of anesthetized pigs returning to ICU after procedure. [Redacted by agreement] asked for clarification on procedures prior to extubating and [Redacted by agreement] agreed that the tube is generally removed once the pig begins chewing on the tube. Dr. Ascher would like to discuss further with veterinarians off committee to determine best practices as she was concerned the pig could have possibly been aroused prior to returning to a sedated state in the transport vehicle. Mr. Green asked the committee whether this is a reportable incident and Dr. Ascher wanted to know if the committee had enough information to vote. Dr. Ascher, [Redacted by agreement] and [Redacted by agreement] believe it is reportable. Dr. [Redacted by agreement] asked for clarification on what part of the incident is reportable and [Redacted by agreement] indicated a lack of veterinary technician response and training. Dr. Ascher believes the individual in the transport vehicle was not trained appropriately and that it is not just a concern for DVR staff but NHLBI staff as well. [Redacted by agreement] mentioned several animals are necropsied every year that have died after anesthesia exposure after a veterinary technician thought it was waking up appropriately. He is not sure that the aspiration was a direct cause of death and suggested possibly waiting for histology reports prior to making a final decision. He indicated that these deaths have not previously been considered reportable. [Redacted by agreement] agreed that the conversation would not be the same had the pig died on the surgical table as opposed to the transport vehicle. Mr. Green asked if the committee should wait on the vote and [Redacted by agreement] indicated it would be a good idea. [Redacted by agreement] asked for further detail from the veterinary technician and Dr. Ascher described the subsequent steps taken but that we could request additional follow up on the incident. A follow up discussion should occur within the next week to ensure DVR staff and NHLBI staff members understand anesthesia and monitoring appropriately. We also need to adapt a consistent approach and response to future scenarios. [Redacted by agreement] does not believe this is a reportable as an opinion from OACU unless there is absolute proof that procedures were not correctly followed by the veterinary technician.

Semi Annual Program Review

The committee reviewed the findings presented on the excel spreadsheet. At the next meeting, the committee will review checklists for future use during inspections.

Old Business

- Update on Spring ACUC Findings report
The ORS Director requested a breakdown of the findings and to present them graphically to make identifying trends easier.
- Update on NIAID Group Housing Response to DVR ACUC Committee
Mr. Green indicated that we had not received a response from NIAID after presenting comments to their ACUC for review. Dr. Ascher suggested reaching back out to the NIAID ACUC again to finalize the guidelines.

New Business

- Recording of meetings:
Dr. Ascher inquired whether we have been recording meetings either by audio or video. We are not currently doing so only providing written minutes. Mr. Green clarified we are not and if we were to record, we would need to notify everyone at the meeting.

Review of ASP's & Amendments

- NCATS amendments:
[Redacted] has had several amendments approved and are listed below:
[Redacted by agreement]

- DVR Amendments:
N/A

Reviews:

Due to COVID there has been no activity on [Redacted] during the past year. The animal numbers have not changed. The committee will reach back out to [Redacted by] regarding her response to question number 5 which appeared to be incorrect.. Mr. Green asked whether [Redacted by agreement] thought the study would proceed moving forward and she was unsure.

[Redacted] animal numbers are lower due to COVID. The committee has no comments.

[Redacted by agreement] Mr. Green had a question regarding total animals on ASP, the committee will reach back out to [Redacted by agreement] for clarification.

SOP Review & Policy Review

- N/A

Continuing Education

- Shrews are now being used for research at [Redacted] It was suggested a brief overview be provided to the committee regarding the husbandry care of the animals. [Redacted by] asked whether the committee would like to have training on Shrews. Mr. Green, [Redacted by agreement] and [Redacted by] were in favor of a presentation for the ACUC committee.

[Redacted by agreement] and [Redacted by agreement] will reach out to the staff and PI at [Redacted by agreement] for a possible presentation in November or December.

- ICARE announcement from OLAW provides seminars for ACUC Committees. [Redacted by agreement] indicated the sessions fill up quickly, but it is available as a resource. Please send Ms. [Redacted by agreement] all attendance to trainings for tracking purposes.

Announcements:

- Congratulations [Redacted by agreement] on receiving an ORS Director's award. [Redacted by agreement] thanked the committee for their support especially that of the staff at DVR.
- [Redacted by agreement] had to step down from the ACUC committee. If you have any suggestions for outside members please send them to [Redacted by agreement], Dr. Ascher or to Mr. Green.
- The next ACUC Committee meeting will be held on October 20, 2020.

Adjournment:

- A motion to adjourn was made by Dr. Ascher and was seconded by [Redacted by agreement]. The motion passed and the meeting was adjourned at 3:15 pm.