

University of Washington  
AUGUST 17, 2023 IACUC Meeting Minutes

Members Present: AB ES KG MRB- 2:33pm  
GL  
AP- 2:33pm JFI MB MS  
SP  
MK- 2:40pm after  
minutes votes  
CC- left at 3:31  
JS  
DT- 2:34pm

Members Absent: DM JPVH MRK  
AW GS

Total count: 14

### Opening Business

- The Floor was opened for public comment at 2:30 pm.
- The IACUC Chair called the meeting to order at 2:36 pm.

### Confirmation of a Quorum and Announcement

- Quorum was confirmed by ZR.

### Approval of the IACUC Meeting Minutes

- The IACUC Chair called for the approval of the JULY 27, 2023 meeting minutes.  
Motion was made and seconded: to approve the minutes as written.  
Further Discussion: none  
Vote: Approved with 11 members voting in favor, 0 against and 2 abstentions.
- The IACUC Chair called for the approval of the AUGUST 8, 2023 special meeting minutes.  
Motion was made and seconded: to approve the minutes as written.  
Further Discussion: none  
Vote: Approved with 9 members voting in favor, 0 against and 4 abstentions.

### Benefit Story – JS

This month's Benefit Story is an update on a story from 2016. That November, I reported on the development of a gene replacement therapy to cure Duchenne muscular dystrophy. Duchenne muscular dystrophy is an inherited disorder affecting about 1 in 3500 boys. It causes severe progressive muscle weakness starting around the age of four, and typically leads to death from cardiac or pulmonary failure within just 10 to 20 years.

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The cause of the muscle weakening is the loss of a protein called dystrophin. The gene therapy aims to replace the defective dystrophin gene with a healthy copy. Working with rodent and canine animal models of Duchenne muscular dystrophy, the Chamberlain lab found that viral vectors can be used to direct the expression of healthy dystrophin in muscle cells that lack dystrophin and thereby restore relatively normal muscle function and extend life span.

In June of 2023, the FDA approved this treatment for boys that are 4 to 5 years old, the age group showing the most benefit in an ongoing clinical trial. This is the 13th gene therapy approved by the FDA and the first to target a common genetic disease in children. The clinical trial is still running and additional results may support expanding the age range of children who are approved for treatment. The treatment is not without risk and further improvements are needed to optimize the benefits, but this is an exciting development that brings hope to many families. A big thank you to the animals that made it possible.

### **Attending Veterinarian's Report – CC**

I have checked with the leadership at all sites, and I have 3 reportable events for the committee at this time.

On 4/10/23, two 3.5 week old mice on protocol 4565-02 were found dead in their cage. There was no food and no gel present when found, and there was no gel/toggle sign on the cage. The water valve was working properly. The animals had been weaned by the research group three days prior. The cage had been checked by the husbandry staff daily but the lack of food was not noted by the husbandry technician. The lab member had previously performed this procedure and, per the PI, has an impeccable record of animal care. The lab member accepted full responsibility for the incident. The lab member was mandated to undergo retraining for weaning and for checking food and water. The husbandry staff member in the room was also retrained on checking food and water. It was also recommended that the lab develop a checklist or other similar mechanism to ensure that all steps are followed when performing weaning.

This has been reported to OLAW.

### **Questions/Discussion:**

The typical procedure is to place gel in cage and toggle the lixit and place a gel/toggle sign on the cage.

The IACUC discussed what kind of letter to send, and decided to send a Letter of Counsel asking for additional information on what the lab is doing to address this issue and prevent it from happening again.

Motion was made and seconded: to send a Letter of Counsel.

Further Discussion: *request more information on steps being taken to prevent a future incident*

Vote: Approved with 13 members voting in favor, 0 against, 0 abstentions.

On July 4<sup>th</sup> the two chillers that control HVAC temps in the SLU 7<sup>th</sup> floor vivarium space malfunctioned. The room temps alarmed as well as the chiller malfunction alarmed (both as they should) however the reporting guide to infocenter (our after-hours call out system) were mislabeled as standard rooms (non-emergency call out) and the engineers were not dispatched right away to fix it. The facility supervisor did call the infocenter to confirm they were responding, but the infocenter operator mistakenly told her the

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engineers HAD been called. This error was not identified until the next morning and overnight the housing room rose to 81.6 at its highest (per The Guide, mouse rooms should be maintained with dry bulb temperatures of 68-79 F). This sensor is located in the ducts so likely the animals did not experience temperatures this high (with the air changes in the IVCs) and there were no sick animal reports the following day. The chillers were repaired first thing on the 5<sup>th</sup> and all has been normal since. We have met with the infocenter management and updated the call tree designation to prevent future issues.

This has been reported to OLAW.

**Questions/Discussion:**

The IACUC discussed informing the person renewing the contract with the company to confirm that they're aware of these issues, and follow-up with the company to ensure we're informed when someone is sent out to do the work. The IACUC decided to get more information about who to follow up with before taking further action.

*There was no vote on this issue.*

On July 3<sup>rd</sup>, a cage of two female 7-month-old mice on protocol 4450-01 was found without food. One mouse had expired, and the remaining mouse was hunched with a ruffled haircoat but stable. The second mouse recovered after supportive care and monitoring. Per the lab, the cage had been moved off of the SSR rack on June 30<sup>th</sup> (where it was fed by lab staff) so the husbandry staff should have resumed responsibility for feeding that cage after that date, but we have been unable to confirm with husbandry staff that the cage was relocated on that date. Both the lab member responsible for that cage and the husbandry staff in the room have undergone retraining.

This has been reported to OLAW.

**Questions/Discussion:**

There have been some incidents in past with this lab, but not with the individuals involved. When proper procedure is followed the cages should have ample food when moved off of the SSR rack by the lab staff. According to the lab's records, this cage was moved on 6/30 and the dead animal was discovered on 7/3. However, there's no way to confirm what happened since moving cages is not documented. IACUC members suggested solutions for tracking cage relocation, including color coding or numbering with an accompanying checklist. Another suggestion, from a member's experience in the fish facility, is to use a pink sticker to identify recently moved animals.

The IACUC discussed sending a Letter of Counsel because animal death was involved. They ask the group to come up with a mechanism for identifying animals that have been recently moved.

The IACUC discussed sending a Letter of Counsel to the lab and a Letter of Acknowledgement to the DCM tech staff.

A member asked if there is an attempt to train all Husbandry staff so this isn't repeated. CC emphasized that there is always discussion among DCM staff to come up with solutions so this type of event isn't repeated.

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Motion was made and seconded: to send a Letter of Counsel to PI and a Letter of Acknowledgement to DCM/Husbandry Staff

Further Discussion: *none*

Vote: Approved with 13 members voting in favor, 0 against, 1 abstention.

**Update on Protocol Monitoring:** In the past month, we discontinued protocol monitoring for one protocol. We added two new rodent protocols to vet monitoring. One of these was added to facilitate the development of a more robust monitoring paradigm following viral challenge in a newly added experiment. The other one was added to follow up on some unexpected clinical impacts after the use of a previously-approved vehicle. We currently have 23 protocols with ongoing enhanced veterinary monitoring. Of these 23 protocols, 17 were placed on monitoring proactively at or near the time of protocol approval due to either the complexity of the project, at the request of the PI for veterinary collaboration, or due to the novelty of a specific procedure. The other six were placed on monitoring after the work began as a result of an unanticipated outcome. Of the 23 protocols, 8 are actively performing the procedure for which they are on monitoring. All labs all continue to work closely with veterinary staff to carry out their work.

### **OAW Director's Report – JFI**

**IACUC metrics** – IACUC metrics are in the meeting folder

On June 2nd 2023, OAW received an animal welfare concern. The concern centered around a specific employee of the primate center and their animal handling technique, describing several instances when appropriate technique and procedure was not followed. A subcommittee of the IACUC appointed by the chair investigated this concern and found it to be substantiated in that the reported instances did occur. The employee had vivarium access removed during this investigation. After interviews and discussion, the subcommittee's decision was to allow highly supervised retraining of the individual, with close oversight by the Attending Veterinarian and designees to evaluate the efficacy of retraining. As of this report, this individual still does not have badge access to the vivarium, but is allowed to enter the vivarium under direct supervision for training purposes. As in all cases, the Attending Veterinarian retains the authority to revoke this individual's privilege to work with animals if warranted. The subcommittee of the IACUC considers this concern resolved, with expectation that the Attending Veterinarian will alert the subcommittee if any future related concerns arise or if there is evidence that retraining is not sufficiently effective.

### **Questions/Discussion:**

The IACUC requested some clarification about the basis of the concern and the plan for retraining and recertification. No further action requested by the committee.

### **Responses to Letters & Other Follow up –**

4489-01 - In July, an incident was reported to the IACUC in which, on the dates of December 1st 2022 and March 6th 2023, approximately 20 mice were euthanized with expired euthanasia solution. As was reported, the presence of expired euthanasia solution was identified during an IACUC inspection of the space in February. The expired solution was used after it was identified by the IACUC, and the bottle was also still present in June. The IACUC voted to send a letter of reprimand to the PI. In that letter the IACUC asked for confirmation that the corrective actions reported to the IACUC were taken, including labeling the bottle as expired, retraining lab staff, and limiting lock box access. The letter also asked for an update on the status of the expired solution, as well as more information about the process and methods for training

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lab staff about management of controlled drugs and expired drugs. In the PI's response, they expressed appreciation for the feedback from the committee, and stated that they understand the importance of responsible animal research and providing training and supervision to that end. The PI also stated that "I also deeply regret that this occurrence has undermined the trust between my lab and the IACUC." The PI confirmed that the reported corrective actions have been taken, and confirmed the bottle has been disposed of, providing a copy of the reverse distribution invoice dated 8/10/23. The PI described that they met with lab members in person to discuss policies for handling controlled substances, which are outlined in a handbook located in the lock box. Expiration dates have also been logged onto his calendar, which will provide notifications 4 weeks prior to expiration so that new drugs can be ordered, the expiring drug can be labeled, logbooks can be updated, and returns can be scheduled. Additionally, the PI will immediately inform lab members of IACUC inspection results. The PI also expressed that he found the reverse distribution process to be confusing, and acknowledged that he should have reached out to the IACUC sooner for assistance. He indicated that he would like to help make information more readily available, given the importance of properly disposing of controlled substances. Since last month, the group has voluntarily suspended animal research pending feedback from the IACUC.

**Questions/Discussion:**

The IACUC acknowledged the serious nature of this incident and appreciates the lab's response and initiative to help prevent a future incident, and additionally educate other labs about expired substances. The lab will continue to receive close supervision under vet monitoring moving forward.

An IACUC member asked if, on a site visit, they should be expected to have the lab label and bag expired substances within view? The chair detailed the plan in place to get rolls of stickers saying "expired" and place stickers on any substances and ask lab to immediately place them in a clearly marked bag and not use until the expired substance can be properly disposed of.

A member commended the lab for doing everything we asked them to do, but feels that the confusion with the reverse distribution process is unconnected to this incident. OAW leadership responded that they believe this is the lab's attempt to work toward improving the system overall. The PI will enter expiration dates of all incoming drugs into their calendar, which is one of many preventative measures the lab has taken.

Training IACUC members on what to look for in terms of expired substances will be the topic of an upcoming IACUC training according to the chair.

The IACUC discussed whether a follow-up letter is necessary to inform the PI that the IACUC is satisfied with their response and is not opposed to the resumption of animal work in the lab.

Motion was made and seconded: to send a Letter of Acknowledgement  
Further Discussion: *acknowledging lab's response to IACUC's Letter of Reprimand*  
Vote: Approved with 9 members voting in favor, 5 against, 0 abstentions.

**Standard Operation Procedures**

- NHP Anesthesia and Sedation Procedures – AS

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- *Statement#1: Language adjusted to align with changes made to related WaNPRC sedation SOP.*

Motion was made and seconded: to approve the standards of procedures as written.

Further Discussion: *none*

Vote: Approved with 13 members voting in favor, 0 against, 1 abstention.

### **IACUC Training**

**Waste Gas Management**— Wes Cochran, Environmental Health and Safety Manager, EH&S

*See presentation in Supporting Documents*

### **Closing Business:**

The Meeting was brought to a close at 3:58 pm.