University of Washington March 18, 2021 IACUC Meeting Minutes

Members Present:	JA	KM	KS
	CM	JPVH	MB
	JS	MK	FRR
	KG	SRH	GS

SL JM

Members Absent: AB DM AW

MRK

Opening Business

• The IACUC Chair called the meeting to order at 2:33 pm.

Confirmation of a Quorum and Announcement

• Quorum was confirmed by ZR.

IACUC Training

• The Guide's "Must" versus "Should" - EWC

The presentation reviewed the differences between "must" and "should" in the Guide.

Approval of the IACUC Meeting Minutes

• The IACUC Chair called for the approval of the February 18, 2021 meeting minutes.

Motion was made and seconded: to approve the minutes as written.

Further Discussion: None.

<u>Vote</u>: Approved with 13 members voting in favor, 0 against and 0 abstentions.

Attending Veterinarian's/OAW Director's Report - KS

- HBAS meeting Pain category E discussion around spontaneous death as it relates to aging and lifespan studies. There is close monitoring and well-defined humane endpoints on these studies. As these studies center on lifespan and aging, the principal endpoints are age at death (for mice found dead) or age at euthanasia. >90% of animals enrolled in these studies are humanely euthanized using surrogate endpoints, although a small percentage will die spontaneously despite daily monitoring. Aging complications are not considered painful, but could cause distress. After subcommittee discussion, it was decided that if pain relief (including euthanasia) is not provided when animals seem to be in pain or distress, then it would be considered category E.
- IACUC metrics- see meeting documents
- Facility issues: None
- Protocol Monitoring:

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- Nineteen total protocols. Of the protocols, eight involve surgery, one restraint (and sx), 2 tumor modeling, 8 miscellaneous (tape skirt, infection, water quality, prolonged anesthesia).
 Ten are inactive right now. One protocol was added by the AV for observation and assessment of mobility after refinement of a hot plate analgesia behavioral assay.
- Follow-up on previously reported events:
 - o 4452-01: PI response to Letter of Reprimand:

The PI wants the committee to know that the lab takes animal welfare very seriously, and the nature of their research on the neurobiological basis of animal behavior makes them very sensitive to these matters. When the PI met with IACUC Chair and AV, the two adverse events were discussed more in depth, and they acknowledge that these were the fault of the laboratory, and mistakes were made with animal cages.

Corrective Actions:

The same lab member was involved in both events and the PI has met formally with them twice, explained the severity of these issues, and has implemented a new training and supervisory plan for them. They will now have more direct oversight and reporting of all animal activity to the senior post-docs, lab manager, and PI. They will also take the Engaging the Cages into a Rack on-line training lesson.

The PI has had a general lab meeting dedicated to discussing the adverse events and ensuring that all lab members follow the already established laboratory policies. There will also be a re-training on lab SOPs and special service requests (SSRs).

The lab will also work to improve the team's communications with DCM Vet Services in order to ensure better compliance, training, oversight, and implementation. The PI and lab manager plan to meet directly with the Vet Service to discuss the lab's procedures and research, as well as discuss methods for effective communication related to the mouse colony and experimental mice.

The IACUC Chair and Attending Vet believe that the corrective actions are sufficient and they are hopeful that improved communication will lead to a better outcome with the corrective action plans in place. The lab's protocol has been placed on vet monitoring, so there will be frequent opportunities for checking in with the lab.

ODCM husbandry non-compliance involving rabbits: Discussion of this event was tabled at last month's meeting because an investigation was underway. Based on what has been learned so far, DCM has taken the following corrective action: DCM has revised their twice daily room check procedure such that a different technician will perform the AM and PM checks whenever possible. If this is not possible, then a comment will be added to the room log explaining why that was not possible. HR is still investigating to determine any personnel actions to be taken.

The IACUC Chair stated DCM has been very proactive with implementing different individual staff doing AM and PM checks, and this seems like a good new process. The IACUC would like to hear back from DCM in a few months about how this new process is going.

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• Adverse Events:

o 4397-01- Self-reported to OAW. Four mice received tamoxifen via oral gavage daily. On the fourth day of dosing, one mouse became lethargic immediately following tamoxifen administration but recovered, and a second mouse also showed clinical signs of distress and died shortly after dosing. The remaining 2 mice were not dosed. The researcher self-reported this adverse event to Vet Services, and based on gross necropsy findings on these mice, it appears that oral gavage was not done correctly. During Vet Services follow up with the researcher, it was determined that tamoxifen administration was not described in the protocol. Corrective Actions: The group suspended tamoxifen administration, reported the non-compliance to OAW, submitted an amendment to add tamoxifen administration, and the researcher requested oral gavage re-training with AUTS. Reported to OLAW.

The Attending Veterinarian stated this group does not have a history of this behavior and has shown remorse over this event. IACUC members discussed the type of letter to send to the lab.

IACUC Member Entered 3:08PM

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

Further Discussion: None.

<u>Vote</u>: Approved with 13 members voting in favor, 0 against, 1 abstention.

o DCM: Two cages containing a total of eight mice were found with no food. One mouse was found dead and another one died later in the day despite supportive care. The remaining 6 mice recovered. These mice arrived from the vendor 3 days prior and were unpacked and housed by the room's animal technician who should have provided food, gel, and toggled the lixit in these cages. The research group had not handled these mice at any point. The same animal technician did the daily cage checks on the 2 days before the animal was found dead. The technician in question completed their Health Check refresher training in November 2020 and will receive counseling with DCM HR. Reported to OLAW. IACUC members discussed the history of the DCM technician and prior adverse events that led to the refresher training in 2020. IACUC members discussed the type of letter to send to DCM.

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

Further Discussion: None.

Vote: Approved with 14 members voting in favor, 0 against, 0 abstentions.

- From Arizona
 - o Facilities items: No items to report.
 - o Adverse events: No adverse events to report.

Protocol Review

• Standard procedure reviews – **KS**Another formulation of the substance with added to these standard procedures.

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Motion was made and seconded: to approve the 6 new standard procedures as written.

Further Discussion: None.

<u>Vote</u>: Approved with 14 members voting in favor, 0 against, 0 abstentions.

Other Business

• Update on the RCA subcommittee – KG

A sub-committee (SC) comprised of KG, PVH, SH and LM was formed to review the adverse events that were reported in 2020. The IACUC Chair, AV and DCM Chair were advisors to the SC's process.

The Committee reviewed the adverse event reports from 2020 for commonalities or root causes with a view to providing information as to the how such events could have been mitigated. We did not find commonalities or consistent root causes. In essence each of the events was unique and there was no systemic intervention that the SC could see that would have prevented the events.

The SC also reviewed adverse events for the five prior years to determine whether the numbers of events reported were significantly different to prior years. No clear pattern was found that would suggest that 2020 was an outlier year.

In addition to the reported adverse events, there was a discussion of near-misses. Near-misses were situations where, due to the observation skills, and diligence of staff, an intervention was taken that avoided an adverse event that otherwise might have occurred. This SC will to continue to research what can be learned from near-misses as a means to potentially avoid future adverse events.

Closing Business:

The Meeting was brought to a close at 3:27 pm. The floor was opened to public comment.