

**August 5, 2020
Institutional Animal Care and Use Committee
Meeting Minutes**

The meeting was called to order by the Chair via Zoom on August 5, 2020 at 12:00 pm.

Attendance:

Members: Chair, Attending Veterinarian, 1, 9, 16, 18, 21, 22, 23, 24, 25, 26, 114

Alternates:

Absent: 4, 7, 20

Others: 112, 113, 115, 118, 119

A quorum was present and acting.

Chair's Comments:

1. The IACUC Chair announced an alternate member that has been appointed to full member (114) and two new alternate members, one from the School of Medicine, Department of Physiology and Pharmacology and the other from the School of Medicine, Department of Biochemistry.

IACUC Admin Updates:

1. The OAW Director announced a go live date of August 31st for the Kuali electronic protocol system. Up until this date, wholesale changes to the form can be made in the system. Directions and access to the Kuali system has been provided to committee members to test the system. After go live, large updates will be more difficult, so committee feedback is essential at this time.
2. The first OAW newsletter has been released, and the plan is to have quarterly issues, with the option of additional special issues when there are significant changes/updates to announce to the research community. The Chair inquired if there is a method to track web traffic to evaluate the impact of the newsletter.

Old Business:

1. **Action Items were reviewed and updated.**
 - a. Media Policy- draft revisions once Legal and Communications input received.
 - i. The OAW Director had not received feedback from legal at time of the meeting.
 - b. Send updated Hazardous Chemicals and Superovulation policies out for 30-day review.

- i. These policies have been sent out without any feedback received at time of the meeting.
 - c. OAW/IACUC newsletter preparation.
 - i. See discussion above in IACUC Admin updates.
 - d. Continued review of OLAW Assurance.
 - i. See discussion below in Semi-Annual Program review.
 - e. Committee Member Kuali testing.
 - i. The Chair reiterated the importance of committee members to test the system and provide feedback. See discussion above in IACUC Admin updates.
 - f. Follow up on possible non-compliance for protocol 1701005049 and Erma Byrd 146
 - i. See discussion below in Adverse Events/ Possible Non-compliance issues.
2. The minutes from the July 1, 2020 meeting were reviewed and approved unanimously by the committee.

New Business:

1. Updates

- a. One committee member has resigned, as they will be retiring at the end of the year. Another member has renewed their term for one year.

2. Discussion

- a. The OAW Director spoke with the IO regarding tentative plans for completing the fall semiannual inspections and offered some strategies to the committee. In order of priority, regulations must be met, but considering COVID-19, there is a need to put personnel safety above best practices. This could be accomplished by allowing people to inspect their own spaces using the ALFI system. Another option would be to do video chat inspections. Any in person inspections will require planning to allow for proper PPE and social distancing guidelines. It was noted that USDA-covered areas will still require two inspectors. The veterinarians on the committee can help cover inspections, and the Attending Veterinarian wants to do as many inspections as possible to become more familiar with all the facilities. Importantly, committee members will not be dissuaded from participation if they want to be involved. Inspections will likely start mid to late October. The OAW Director asked the committee to reach out to him with concerns or comments regarding the plans for conducting the semi-annual inspections.

3. Policies/ Guidelines/ SOPs:

- a. Prolonged Restraint in Animals
 - i. The policy was discussed, and there were no changes requested by the committee. A motion was made and seconded to put the policy out for 30-

day review with contingent approval in absence of significant changes requested. Committee approved with a unanimous vote.

4. Protocols/ Amendments Review

a. IACUC Protocol 1603000971_R1

- i. This protocol renewal proposes to continue the study of chronic stress and clinical depression as severe risk factors for cardiovascular disease and early onset of cognitive dysfunction and dementia. In addition, the study proposes to look at the link between chronic stress and e-cig exposure and further cerebrovascular dysfunction. The protocol receives a Category E designation as it uses Unpredictable Chronic Mild Stress (UCMS) to achieve chronic stress/ depressive symptoms in the animals. The committee discussed the protocol and its Category E designation and determined it was appropriately justified. A motion was made and seconded to move the protocol from FCR to DMR, and approved with one member who recused themselves due to conflict of interest.

b. IAUC Protocol 1708008935_R1

- i. This protocol renewal proposes to continue to study neonatal sepsis models using *Streptococcus agalactiae* and *Escherichia coli* and treatment approaches aimed to combat interleukin-27 and myeloid-derived suppressor cells effects on neonatal immunity. This protocol has a Category E designation because of the induction of sepsis. The committee discussed the protocol and Category E designation and determined it was appropriately justified. A motion was made and seconded to move protocol from FCR to DMR, and the committee approved with a unanimous vote.

c. IAUC Protocol 1805014293.13

- i. This protocol covers studies on the effects of major depressive disorder and the immune system with a focus on B-cells. The proposed amendment adds several new Category E stress induction paradigms. The committee reviewed the amendment and Category E justification and determined it was appropriately justified. A motion was made and seconded to move the review of the protocol from FCR to DMR with a unanimous vote.

d. IACUC Protocol 1901020171.3

- i. This protocol covers studies on the role of mitochondria on neurodegeneration, with the goal that understanding this role will lead to better therapies for stroke and Parkinson's disease. The amendment is to add an experiment with a new stroke model (photothrombotic stroke), designated as Category D. The Attending Veterinarian requested the

amendment go FCR due to concerns the endpoint determinations as described would be considered Category E. After discussion, the committee determined that the procedure could remain as Category D if the PI revised the endpoints appropriately. To assist the PI in further refinement of analgesics used for the surgical stroke procedure, the Attending Veterinarian wants to examine animals post-opt to assess pain levels. A motion was made to move to the review to DMR contingent upon the PI adjustment's of endpoints. If not adjusted to meet the Category D definition, the PI will need to provide further justification of the endpoints, and the amendment will return to FCR at the next meeting. The motion was seconded and approved with a unanimous vote.

5. Semiannual Program Review

- a. OLAW Assurance Review
 - i. The OAW Director presented the OLAW Assurance Sections III D and III 4 and discussed recommended updates/revisions. The committee had no further comments or questions.

6. OLAR: Discussion of clinical concerns, training, staff and PI concerns

- a. For the open position of clinical veterinarian, two qualified applicants were interviewed, and an offer has been extended to one candidate. The OLAR Director is awaiting a response.
- b. The OLAR Facility Manager is leaving. An interim manager has been appointed, who will be assisted by two support staff, and the position has been posted.
- c. There is still an open vet tech position, but there have yet to be applicants.
- d. There have been some challenges getting certain PPE due to COVID-19. A one to two month supply has been kept on hand, but some changes may need to be made to PPE policies to adjust to any future shortages.

7. Occupational Health and Safety Subcommittee Report

- a. The subcommittee met to go over the current Q-Fever Policy, which is up for 3 year review. Their discussions centered on how to best capture personnel at risk for Q-fever and medical monitoring of those exposed.
- b. The Chair questioned if there is still a need for regular monthly meetings of the subcommittee. This was a point of discussion at the subcommittee's meeting as well, and the consensus was that meetings can be reduced to an as-needed frequency. A motion was made to sunset the standing monthly report and move to an ad hoc basis. The motion was seconded and approved unanimously by the committee.

8. IACUC Training

- a. There was no IACUC Training for this meeting.

9. Adverse Events/ Possible Non-Compliances

- a. IACUC Protocol 1604001894

- i. The committee resumed the July 2020 meeting discussion regarding this non-compliance involving a cage of animals left over a weekend in a room outside the animal facilities that is not an IACUC-approved Satellite. A Chair-appointed subcommittee completed their investigation, which included Zoom interviews with the relevant parties. The incident was determined to be a result of miscommunication regarding exchange of the animals between laboratory personnel. The conclusion was that this incident was a protocol non-compliance, but not an animal welfare issue since animals had access to food and water and did not appear to suffer adverse consequences. However, the committee acknowledged the potential for this to be a serious welfare violation if circumstances had been different. A preliminary report was submitted to OLAW, and the OLAW representative indicated an official report was only needed if federal funding was impacted. Since the animals in question were not supported by PHS funding, a motion was made to not report and to send a letter to the PI stressing the potential seriousness of this type of non-compliance, with recommendations on how to improve communications between lab personnel. The motion was seconded and unanimously approved.

- b. IACUC Protocol 1701005049

- i. The committee resumed discussion from the July 2020 meeting regarding inappropriate placement of two male breeders in a cage. The Chair sent a letter to the PI soliciting an action plan for how the incident was/will be addressed to prevent future occurrences. The committee reviewed the action plan submitted by the PI, which included continued group and individual discussions with laboratory personnel, plans to seek re-training from OLAR, and additional checks post-weaning to confirm proper sex identification. The committee deemed the action plan sufficient, and a motion was made to send a letter to the PI to thank them for submitting their response. The motion was seconded and unanimously approved by the committee.

- c. IACUC Protocol 1608003693_R1

- i. The event reported by the PI on this protocol involved an adverse, unexpected outcome from administration of chromic oxide. The veterinarian was consulted after animals were observed as lethargic, and five animals did not survive despite veterinary treatment. Additional administrations of

chromic oxide were immediately stopped. It was determined that the wrong form of chromic oxide (CrO_3) was erroneously used and was also listed on the approved protocol. Necropsy was conducted and samples were sent out to two institutions for independent testing. One pathology report supported toxic levels of chromium and a second report is pending. A motion was made and seconded to send a letter of recommendation to the PI to amend the protocol with the correct compound. When the committee voted, there was one abstention and two no votes. The dissenting opinion was that more information was needed on the toxicity of the two formulas of chromium, and the overall impact on all animals that received the wrong form of chromium. A new motion to table the discussion until more information is gathered was seconded and approved with a unanimous vote.

d. IACUC Protocol 1807016518

- i. The adverse event reported on the above protocol involved three animals that had presented with blindness, unresolved at the time of the report. It was indicated that animals were being treated for Polioencephalomalacia, cause unknown. Feed was pulled and sent for analysis. In what was believed to be an unrelated incident, an additional animal was found outside the electric fence, exhausted from either trying to get back in and/or from being chased. The animal received veterinary treatment, but was euthanized after failing to improve. Necropsy did not provide any additional information. The clinical farm veterinarian provided an update on the blind animals, indicating that they had recovered but were not yet introduced back to the herd. Results from the feed analysis were still pending. A motion to table the discussion until the feed analysis comes back was seconded and approved unanimously by the committee.

e. IACUC Protocol 1602000486

- i. The event reported on the above protocol involved four animals receiving daily experimental and control IP injections that suffered adverse consequences and later died or required euthanasia. The PI consulted with the Attending Veterinarian who determined the cause as likely to be from improper injection technique, based on the clinical symptoms and necropsy findings. The PI terminated the experiment and remaining animals were euthanized. The PI's action plan involved re-training all staff on injection procedures. While the committee consensus was that this was an animal welfare issue, the committee determined it was not a reportable event. A motion was made for the Chair to send a letter thanking the PI for the report, reiterating that the retraining should be scheduled now that OLAR has

resumed training sessions. The motion was seconded and was unanimously approved by committee.

f. IACUC Protocol 1809018212

- i. The unexpected outcome reported on the above protocol involved animals transitioning to a high cholesterol diet that developed complications from cessation of eating and reduced to no fecal output. Veterinary clinical care interventions were not successful, and the decision to place rabbits back on regular chow was made after further veterinary consultation. The diet transition difficulties may have been the result of a prolonged period on regular chow after arrival, as the study was delayed due to the university's directive to reduce research activities during the pandemic. An amendment to the protocol to allow animals to continue in the study on regular chow was submitted and subsequently approved. A motion was made and seconded to send a letter to the PI thanking them for the report and was unanimously approved by the committee.

g. IACUC Protocol 1602000495

- i. The first adverse event reported on the above protocol involved a hoof-injury resulting from the animal catching its foot between flooring slats. Per the recommendation of the clinical veterinarian, the animal was euthanized due to deteriorating condition. It was noted during discussion that the OLAR facilities manager is working on obtaining rubber floor mats and looking into ordering pens with slats closer together to prevent future occurrences of this issue. The committee determined this was an adverse event unrelated to protocol study activities. A motion was made and seconded to send a letter to the PI thanking them for the report. The motion was unanimously approved by the committee. One member recused themselves from the discussion and vote due to conflict of interest.
- ii. The second adverse event involved surgical complications following ovariectomies. One animal did not recover and was found to have a hernia upon necropsy. The clinical farm veterinarian conducted exploratory surgery on the remaining two animals and did not find evidence of hernia, but did treat signs of infection at the incision sites. Animals subsequently recovered and continued with the study. Since hernia is acknowledged on the protocol as a potential cause of morbidity/mortality and the anticipated rate of occurrence was not exceeded, the IACUC felt the response to the event was appropriate. It was noted that the veterinarians will continue to conduct health vetting for procured animals and continue to assist the PI in refining surgical technique. A motion was made to thank the PI for their report and

highlight the need to continue to work with veterinary staff to make improvements in surgical technique. The motion was seconded and approved with a unanimous vote from the committee. One member recused themselves from the discussion and vote due to conflict of interest.

10. PAM

- a. IACUC Protocols 1705006733 & 1809018212
 - i. A PAM was conducted via Zoom with the PI and research staff on the above referenced biomedical protocols, which involve animal models of Alzheimer's Disease and trauma disorders. The PAM Administrator (#115) presented the PAM report, which included a checklist, recommendations/assessments, and information requests by PI/lab staff. In addition, the PAM session included a discussion with the research group about their recently reported adverse event on 1809018212. The research group expressed concerns over the sound frequency of the fire alarm interfering with their behavioral training as well as the functioning of a downdraft table. The PAM Administrator is working with PI and OLAR facility management on possible resolutions to concerns.
- b. IACUC Protocol 1910029794
 - i. A PAM was conducted on the above referenced agricultural protocol studying a novel vaccine candidate's efficacy on *Haemonchus contortus* infection. The report was initially started in person and completed via Zoom. The PAM Administrator (#119) presented the PAM report, which included a checklist, observations conducted, recommendations/assessments, and information requests by PI/lab staff. The IACUC reviewed the report, and no animal welfare issues were identified.

There being no further business to discuss the meeting was adjourned at 3:10pm.

Action Items:

1. Media Policy- draft revisions once Legal and Communications input received.
2. Inquire with IT about measuring OAW website traffic.
3. Post Hazardous Chemicals and Superovulation policies to website.
4. Send Prolonged Restraint in Animals for 30-day review.
5. Continued development of plan for completion of Semi-Annual Inspections.
6. Continued discussion and evaluation of Adverse Event on protocol 1807016518.
7. Continued discussion and evaluation of Adverse Event on protocol 1608003693_R1.

September 2, 2020
Institutional Animal Care and Use Committee
Meeting Minutes

The meeting was called to order by the Chair via Zoom on September 2, 2020 at 12:00 pm.

Attendance:

Members: Chair, Attending Veterinarian, 1, 4, 7, 9, 16, 20, 21, 22, 24, 25, 26, 114

Alternates: 27, 28

Absent: 18, 23

Others: 112, 113, 115, 118, 119

A quorum was present and acting.

Chair's Comments:

1. The IACUC Chair introduced new alternate IACUC committee members 27 and 28 followed by a round of introductions from committee members and OAW staff. The Chair then reiterated role and voting status of alternates and how voting is conducted via Zoom meeting.

IACUC Admin Updates:

1. The OAW Director announced that the Kuali electronic protocol system moved into production on Monday August 31, 2020. The OAW will make edits based on feedback on the go as real data is put into the system during production. The IACUC is still encouraged to provide feedback. The OAW goal is to have final product ready within the next couple months. WVU internal IT is now able to fix issues with the system and able to consult with Kuali developers as needed.

Old Business:

1. Action Items were reviewed and updated.

- a. Media Policy – draft revisions once Legal and Communications input received.
 - i. WVU Legal's only input was to make sure Communications (University Relations) was aware of policy. The OAW director will meet later with Communications to review the policy coverage once there is a finalized, IACUC-approved version. The AV was consulted on a revised draft which is discussed further below.
- b. Inquire with IT about measuring OAW website traffic
 - i. The OAW will be getting monthly reports on hits for the website and for the newsletter. There will not be historical data but will have information moving forward.

- c. Post Hazardous Chemicals and Superovulation policies to website.
 - i. These policies have been posted
 - d. Post Prolonged Restraint in Animals policy for 30-day review.
 - i. Policy has been sent out for review comments. There has been no feedback yet, but 30-day window has not yet expired.
 - e. Continued development of plan for completion of Semi-Annual Inspections.
 - i. See discussion below.
 - f. Continued discussion and evaluation of Adverse Event on protocol 1807016518.
 - i. See discussion below.
 - g. Continued discussion and evaluation of Adverse Event on protocol 1608003693_R1.
 - i. See discussion below.
2. The minutes from the August 5, 2020 meeting were reviewed and approved by the committee with three abstentions.

New Business:

1. Discussion

- a. Fall 2020 Inspections
 - i. An initial schedule has been put together for inspections of the OLAR and farm managed areas by the AV and clinical farm veterinarian, respectively. Per OLAW's recommendation that persons managing an area not be the sole inspector, a PAM inspector will accompany the veterinarians and also assist with use of the ALFI inspection software. The Chair, Vice Chair, and Chemical Safety Officer will also be involved in inspections of areas requiring special considerations. It was reiterated that IACUC members are welcome to participate in any inspections. Guidelines for safely conducting in-person inspections, developed in consultation with the Biosafety Officer, were reviewed. Plans for surgical lab inspections, which will take place after facility inspections are done, are ongoing and will be discussed further at the next meeting. Should there be any changes in university guidelines concerning COVID-19, one alternative plan is to have inspectors that are not already on site participate via video. The AV suggested to begin inspections earlier, due to COVID concerns; however, the Chair pointed out that this would then move up the spring inspections, possibly causing winter-weather related travel issues to the remote farm locations in the spring. The consensus was to focus on starting facility inspections early, but to place more consideration on the timing for remote site inspections. The OAW will work with inspectors to finalize a schedule.
- b. Pharmaceutical-grade Drugs
 - i. The Chair requested this be discussed at the meeting due to questions regarding the definition of pharmaceutical grade drugs. The IACUC

Committee reviewed the definitions given by NIH and OLAW. Historically the WVU IACUC has considered any USP-designated drugs as pharmaceutical grade. The main concern brought up by the AV is whether it is acceptable to use USP-certified drugs sold by a chemical supply company rather than a pharmaceutical supplier (i.e. drugs manufactured for medical/veterinary use). After discussion, the Chair decided to put together a subcommittee to review the issue and work on solutions to bring to the committee for further discussion.

c. Student Training Policy

- i. The AV discussed options for a student training policy, applicable to temporary students rotating in the lab for less than a semester, undergraduates participating in summer research programs, etc. In order to reduce burden and be compatible with COVID social distancing guidelines, these students would not have to be added to the protocol and could work with animals inside the animal facilities under the supervision of a trained person in the lab (rather than face-to-face training with OLAR personnel) as long as they are only conducting minor, non-surgical procedures. Similar to teaching protocols, students would still have to complete regulatory training (CITI, OHQ). It was stressed that this would be an optional policy, as some investigators would prefer to add temporary personnel to the protocol so they can conduct more advanced procedures and work independently. A motion was made and seconded to develop an official policy and was approved unanimously by committee.

d. Approval Process – Procedure Library SOPs

- i. The OAW Director discussed options for the process of IACUC approval for procedures added into the future Kuali procedure library. The suggested process was initial verification by a veterinarian and expert in the relevant field, followed by a two-week IACUC review. If approved, it would then be added to the library. Also discussed was the pending CUSP Initiative to create a national, standardized procedure library for shared use across institutions.

2. Policies/ Guidelines/ SOPs:

a. Use of Media Policy

- i. The updated Use of Media policy was reviewed and discussed by the committee. The committee had some minor edit suggestions. A motion to approve the policy (pending the minor edits and no significant comments received during a 30-day investigator comment period) was motioned and seconded with a unanimous vote by the committee.

b. Q Fever Policy

- i. The Q Fever policy underwent a subcommittee review, and minor edits were made along with information updated to reflect that the state of West Virginia

is now considered high risk. After discussion, the Chair requested the FAQ section of the policy be separated, especially on the website. Approval of the policy was motioned and seconded with a unanimous vote by the committee. The updated policy will be sent out to researchers and personnel working with sheep/goats.

c. Euthanasia by Cervical Dislocation/Decapitation Policy

- i. This existing policy received some minor edits after subcommittee review. The committee discussed the new version and defined areas that need further detail (e.g. sharpening standards) with possible input from PIs using the policy. A motion was made to table the discussion until more information is gathered and edits have been made. The motion was seconded and approved unanimously by the committee.

d. Social Housing Policy

- i. After subcommittee review, this existing policy received some minor edits as well as additional agricultural and species considerations information added by the AV. After discussion, the committee made a motion to approve the policy pending no significant comments received after a 30-day investigator comment period. The motion was made, seconded, and approved unanimously.

3. Protocols/ Amendments Review

a. IACUC Protocol 1709009365_R1

- i. This protocol renewal proposes to continue research of the host cytokine environment and its effects on the efficacy of a tuberculosis (TB) vaccine. This protocol has a Category E designation due to the TB infection model. After discussion, the IACUC determined the Category E designation was appropriate, and the research was scientifically justified. A motion was made and seconded to move the review from FCR to DMR and was approved unanimously by the committee.

b. IACUC Protocol 2008035833

- i. This new protocol proposes to research the effects of stressors in puberty as predictors of affective disorder in women. This protocol has a Category E designation due to use of the chronic variable stress paradigm. The IACUC discussed the protocol and determined the Category E designation was appropriate, and the research was scientifically justified. A motion was made and seconded to move the review from FCR to DMR, and the motion was approved unanimously.

4. Semiannual Program Review

a. OLAW Assurance Review

- i. The OAW Director discussed and reviewed suggestions for changes to be made to the OLAW Assurance Sections 7 and 8 on IACUC review of protocols and amendments. After discussion and clarifications, the IACUC had no further updates.

5. OLAR: Discussion of clinical concerns, training, staff and PI concerns

- a. The position of Clinical Veterinarian has been filled, and the individual will be starting at the end of September. For the open positions of Facility Manager and Veterinary Technician, there are individuals identified to send offers to and the OLAR Director hopes to have those positions filled by the end of September.
- b. OLAR identified an issue with an animal care technician making mistakes in documentation of care provided and in filling food receptacles during a recent weekend shift. The mistakes were corrected, and there were no ongoing animal welfare concerns. Resolution in the short term is to have that person's work double checked by senior staff with possible disciplinary actions if issues continue.
- c. There was an HVAC issue in one animal housing area the weekend of August 18th. The issue was brought to the AV's attention via the research staff rather than OLAR staff or system alerts. The interim OLAR facilities manager is investigating why the monitoring system and backup system failed. The AV plans to make improvements to the environmental monitoring systems and will be developing an SOP for how OLAR staff should manage/alert for facility issues. Also, lists of weekend on-call OLAR husbandry supervisors will be distributed to building managers to facilitate communication of any issues on weekends.

6. IACUC Training

- a. The IACUC Administrator provided a demonstration on how IACUC members will perform reviews in the new Quali protocol submission and review system. The OAW Director discussed the roll out of transferring to the Quali system. The OAW will be accepting new protocols in the system on October 19th, 2020 and renewals in late November. The OAW staff will begin working with PIs one-on-one to transfer all protocols into the system over a nine-month period.

7. Adverse Events/ Possible Non-Compliances

- a. IACUC Protocol 1608003693_R1
 - i. This adverse event was tabled from the last meeting, pending acquisition of more information. The adverse event involved an unexpected outcome from the administration of chromic oxide. The Chair had two committee members investigate the issue. The IACUC is still awaiting information on the chromium oxide utilized and responses for questions posed to the PI. There is also a pending report to determine if these animals can be offered for future sale. The Chair made a motion to table the discussion of the adverse event until pending information is received. The motion was seconded and approved unanimously by the committee.

b. IACUC Protocol 1807016518

- i. This was a continued discussion from the August 5th meeting due to a pending feed analysis, which was a suspected culprit of temporary blindness in several animals (now resolved). The lab result has come back, but it showed nothing unusual in the feed sample. Additional feed samples were sent to another lab to do more extensive vitamin and mineral analysis. A motion was made to table the rest of the discussion until the new feed analysis is received. The motion was seconded and approved unanimously by the committee.

c. IACUC Protocol 1809018212

- i. This adverse event was revisited after an update on further clinical complications in animals having difficulties transitioning to and from a high cholesterol diet. Despite clinical care provided, one animal was found deceased, and another was euthanized per recommendation of the AV. Remaining animals are now stable and eating a regular diet and cleared to move on to other aspects of the protocol research. A preliminary report was submitted to the USDA by the AV, but a full report was not requested. All issues with this adverse event have now been resolved, and there are no additional animal welfare concerns. The committee decision was to send the (updated) letter to the PI that was approved at the last meeting.

d. IAUC Protocol 1710009866

- i. This adverse event involved a chiller system failure in a satellite fish facility over a weekend. Due to a possible COVID-19 exposure of personnel involved in daily weekend checks, the system failure and subsequent loss of fish were not discovered until the following Monday. The Chair and AV expressed that there is a need for remote environmental monitoring sensors to alert investigators to issues with their Satellites. The AV is looking into some cost-effective options. A motion was made to request the PI to develop a better disaster plan and system of notifications for this satellite facility. The motion was seconded and approved unanimously by the committee. A motion was also made to recommend the IO report the incident to OLAW, as it was deemed a programmatic issue. The motion was seconded and approved unanimously the committee.

8. PAM

- a. There were no PAM reviews conducted in August 2020.

There being no further business to discuss, the meeting was adjourned at 3:39 pm.

Action Items:

1. Finalize plan and schedule for Fall Inspections
2. Further discussion on definition of Pharmaceutical-grade Compounds (subcommittee)
3. Drafting of a Student Training Policy
4. Post Use of Media Policy for 30-day review
5. Post Prolonged Restraint in Animals Policy to website
6. Send Q-Fever Policy to Researchers and Personnel and post to website
7. Revision of Euthanasia Cervical Dislocation/Decapitation policy
8. Send Social Housing Policy out for 30-day review
9. Continued discussion of Adverse Event IACUC Protocol 1608003693_R1
10. Continued discussion of Adverse Event IACUC Protocol 1807016518
11. Follow up on Adverse Event 1710009866.

October 7, 2020
Institutional Animal Care and Use Committee
Meeting Minutes

The meeting was called to order by the Chair via Zoom on October 7, 2020 at 12:00 pm.

Attendance:

Members: Chair, Attending Veterinarian, 4, 7, 9, 16, 18, 20, 21, 22, 23, 24, 25, 26, 114

Alternates: 27, 28

Absent: 1

Others: 112, 113, 115, 118, 119

Guest: New OLAR Clinical Veterinarian

A quorum was present and acting.

Chair's Comments:

1. The Chair had the AV introduce the new OLAR Clinical Veterinarian.
2. The Chair thanked everyone for their participation in the Fall 2020 inspections.

IACUC Admin Updates:

1. The OAW Director discussed the new USDA draft policy for Field Research that is up for public comment. One proposed change of concern is that surgery performed in the field would make the animals USDA-covered species, with no clear definition of "surgery" provided (does not distinguish between minor vs major). Field researchers on the committee were encouraged to share the draft policy with their peers and submit any comments to the USDA.
2. The OAW Director discussed a recent FOIA from PETA and WVU's response. The request was for information regarding euthanasia of animals in response to COVID-19.
3. The OAW Director also reported that the New England Anti-Vivisection Society has rebranded their mission, which is now elimination of all animal research.
4. The OAW Director reported that during testing of the Kuali electronic protocol system, a bug was discovered, which is waiting on IT to resolve.
5. The IACUC Administrator announced that the amended Rodent Behavior Core SOP has completed review and an updated version has been posted to the OAW website.

Old Business:

1. **Action Items were reviewed and updated.**
 - a. Finalize plan and schedule for Fall Inspections

- i. All but one inspection has been scheduled (RNI). No animals are currently being housed there.
 - b. Further discussion on definition of Pharmaceutical-grade Compounds (subcommittee)
 - i. The subcommittee had a meeting a week ago and are in the process of drafting a document to define Pharmaceutical-Grade Compounds and provide some examples. The subcommittee hopes to have a draft for review at November meeting.
 - c. Drafting of a Student Training Policy
 - i. The AV has created a draft that has been sent out to the Chair and OAW for initial comments.
 - d. Post the Use of Media Policy for 30-day review
 - i. Some comments on the policy were received which were resolved by providing clarification to the PIs on how their questions were already addressed within the policy as written. The policy has now been finalized and posted.
 - e. Post the Prolonged Restraint in Animals Policy to website
 - i. This policy has now been posted.
 - f. Send Q-Fever Policy to Researchers and Personnel and post to website
 - i. This policy has now been sent and posted.
 - g. Revision of Euthanasia Cervical Dislocation/Decapitation policy
 - i. The OAW Director reported that the revision is still in process.
 - h. Send Social Housing Policy out for 30-day review
 - i. This policy has now been posted.
 - i. Continued discussion of Adverse Event IACUC Protocol 1608003693_R1
 - i. See discussion below.
 - j. Continued discussion of Adverse Event IACUC Protocol 1807016518
 - i. See discussion below.
 - k. Follow up on Adverse Event 1710009866
 - i. An IACUC response letter was submitted to the PI, requesting an updated disaster plan. The PI had not submitted the updated disaster plan at time of the meeting but has been in contact with OAW regarding updating contact information.
2. The minutes from the September 2, 2020 meeting were reviewed and approved by the committee with one abstention.

New Business:

1. Discussion

- a. Clinical Emergency Procedures
 - i. This discussion came about due to a recent incident where a researcher performed a clinical intervention on an animal without first contacting veterinary staff. This raised the question as to whether research personnel understand the proper procedure to follow for clinical issues with animals and if they are aware that veterinary staff are available 24/7 to handle such issues when they arise. The AV requested the PI submit an Adverse Event Form,

which had not been received at the time of the meeting. It was noted that clinical emergency procedures have been incorporated into a draft update of the Adverse Event policy. There was a suggestion that a statement could be added to the veterinary contact sheets posted in animal use areas, to reiterate that veterinary staff should be contacted to provide clinical care if it is not an approved procedure on the protocol. The Chair inquired if there is a way to highlight this in the new Kuali system, and OAW Director stated that this could be easily added as a policy the PI acknowledges/agrees to in the system.

- b. IACUC expectation – PIs not working with animals
 - i. The question at hand is what are the expectations and regulatory training requirements for protocol PIs who indicate that they do not work directly with animals? After discussion, the IACUC concluded that the best practice was to continue with the current status quo of requiring PIs to complete the regulatory CITI training and OHQ and holding them to the responsibilities of overseeing their research staff even if they are not conducting any procedures in animals. A motion was made and seconded with a unanimous vote by the committee.

2. Policies/ Guidelines/ SOPs:

- a. Blood Collection SOP
 - i. The OAW Director stated this should be a guideline not an SOP. After discussion, there were some revision comments and clarifications requested from the committee. A motion was made and seconded to table the review and discuss a revised version at the November meeting and was approved unanimously.
- b. Adverse Event/ Unexpected Outcome Reporting Form
 - i. The IACUC Administrator updated the form to be more user friendly and to add new questions and rephrase/consolidate existing ones. The committee discussed the changes and had suggestions for further edits to include a definition of reasonable reporting times, clarification of the reporting chain, and the method of reporting (phone call, email, etc.). The consensus was that a reasonable timeframe would be to report through a chain of command within 48 hours of discovery of the event, with the form submitted within a week. The form will be revised and resubmitted to the committee along with an updated Adverse Event policy.

3. Protocols/ Amendments Review

- a. IACUC Protocol 2009036460
 - i. This IACUC protocol was called to FCR due to a concern that the proposed SARS-CoV2 infection/vaccine model should be Category E instead of C. The committee decided that the PI must clarify endpoints further to make a final determination of pain category, but that the Category E justification provided by the PI was scientifically sound and appropriate given the importance of the work in light of the current COVID-19 health crisis. A motion was made and seconded to move the review of the revision to DMR and unanimously approved.

4. Semiannual Program Review

- a. OLAW Assurance Review
 - i. The OAW Director discussed and reviewed suggestions for changes to be made to the OLAW Assurance Section 9 regarding continuing reviews of ongoing protocol activities, including post-approval monitoring. A final, full draft document will be shared with entire committee and IO.
 - b. As part of the semiannual program review, a subcommittee headed by the AV will conduct a separate review of the Agricultural program based on the FASS Guide. This review will be included in the semiannual report to the IO and also in preparation of the AAALAC description in the future accreditation renewal.

5. Veterinarian Reports

- a. OLAR/AV
 - i. Staffing update: The new OLAR Clinical Veterinarian began on September 29th. The Facility Manager position is currently still open; however, HR is doing background checks, and the goal is to be able to extend an offer this week. There is still an open veterinarian technician position posting with currently no applicants.
 - ii. During mid-September two rooms in OLAR were missed for daily checks due to a schedule change not being communicated to personnel. The AV reported no welfare issues from the missed checks, and schedule changes will now be emailed to staff.
 - iii. Two weeks ago, there was a ceiling leak in an animal room that required relocation of the animals. There were no animal welfare issues reported, and the room was repaired and cleaned up within a week.
- b. Clinical Veterinarian Report
 - i. There have been problems with severe parasitism in one set of animals at the farm. Two animals under supportive veterinary care subsequently passed away. The Clinical Farm Veterinarian expressed that this rate was not out of the norm for the affected animal group size.
 - ii. The Clinical Farm Veterinarian discovered suspected signs of foreign animal disease in a group of animals. It was reported to the USDA and state veterinarian, who came to conduct sampling, and animals were placed under quarantine. All testing came back negative; however, the Clinical Farm Veterinarian feels that the samples may have been taken too late in the disease to have enough viral load to yield positive results. The issue is considered to now be resolved.

6. IACUC Training

- a. There was no IACUC Training scheduled for this month's meeting.

7. Adverse Events/ Possible Non-Compliances

- a. IACUC Protocol 1807016518

- i. This was a continued discussion from the August 5th and September 2nd meetings due to a pending feed analysis, which was a suspected culprit of temporary blindness in several animals (now resolved). Feed samples were sent for more extensive vitamin and mineral analysis. Report from testing has yet to be received. A motion was made to table the rest of the discussion until the feed analysis is received. The motion was seconded and approved unanimously by the committee.
- b. IACUC Protocol 1902022202
 - i. The event involved two separate incidents where daily feeding/weight recordings were missed in animals undergoing behavioral training with food regulation. Both incidents involved only a single missed day of feeding/weight recording, which was quickly remedied the next day with no adverse consequences other than a modest initial weight loss. The PI's identified action plan was to retrain students and have all work double checked by a supervisor. A motion was made to accept this action plan, which was seconded and unanimously approved by the committee.
- c. IAUC Protocol 1602000083
 - i. This adverse event happened on one of the farms and involved an animal that was able to hang itself on a halter left in the animal holding area overnight. The event was reported to the Clinical Farm Veterinarian, who arrived promptly and assisted the PI with inspecting the area for any additional hanging risks. The veterinarian recommended that halters have a specific storage location away from animals, and a storage solution has subsequently been identified. The PI's action plan involved education of all students and farm staff on hanging risks in an upcoming lab meeting. A motion was made to thank the PI for the report and have them proceed with the action plan. Motion was seconded and unanimously approved by the committee.
- d. IACUC Protocol 1608003693_R1
 - i. This adverse event was tabled from previous meetings, pending acquisition of more information. The adverse event involved an unexpected outcome from the administration of chromic oxide. The Chair had two committee members investigate the issue. The PI provided responses to the follow up questions from the committee members and also clarified that all animals exposed will be euthanized and buried and not sold to market. The investigation report concluded that a series of missteps led to the purchase and administration of the wrong form of chromic oxide. The committee expressed serious health and safety concerns for the personnel exposed to the toxic CrO₃ through its preparation or administration as well as any additional individuals that may have been exposed via entering the room in which it was prepared. EHS and Occupational Medicine will be enlisted to help with chemical cleanup and health monitoring. Actions that the committee wants the PI to take include

ensuring that personnel review the (M)SDS sheets and wear proper PPE when preparing and/or administering compounds in the future, submitting an amendment to clarify the form of chromic oxide used on the protocol, add all individuals involved in drug administration as personnel, and contacting EHS to arrange a hazardous waste pick up of the remaining compound. A motion to request this action plan was seconded and approved unanimously by the committee.

8. PAM

- a. There were no PAM reviews conducted in September 2020.
- b. The Post-Approval Monitors reported on the ongoing Fall Semi-annual Inspections, which are going well and running smoothly with the ALFI inspection program.
- c. It was announced that surgical space inspections are to be completed in November. In the past, inspections were spread across about seven IACUC committee members, but the process may need to be modified to accommodate the university's pandemic guidelines. The Chair and OAW Director will meet to discuss this prior to the November IACUC meeting.

There being no further business to discuss, the meeting was adjourned at 2:42 pm.

Action Items:

1. Pharmaceutical-Grade Substances definition document
2. Student Training Policy
3. Revision of Euthanasia Cervical Dislocation/Decapitation policy
4. Follow up on Adverse Event 1710009866: Disaster Plan receipt
5. Receipt of Adverse event form for emergency surgical procedure performed without consultation of clinical veterinarians
6. Blood Collection SOP revision
7. Adverse Event Form revision and policy discussion
8. Send final OLAW Assurance document to committee and IO
9. Adverse Event Protocol 1807016518: Feed analysis
10. Adverse Event on Protocol 1608003693_R1: Follow up
11. Plan for November Surgical Space Inspections

November 4, 2020
Institutional Animal Care and Use Committee
Meeting Minutes

The meeting was called to order by the Chair via Zoom on November 4, 2020 at 12:00 pm.

Attendance:

Members: Chair, Attending Veterinarian (in at 12:30), 4, 7 (in at 12:10), 9, 16, 18, 20, 21, 22, 23, 24, 25, 26, 114 (out at 2:30)

Alternates: 27

Absent: 25, 28

Others: 112, 113, 115, 118, 119

A quorum was present and acting.

Chair's Comments:

1. There were no comments from the Chair this month.

IACUC Admin Updates:

1. The OAW Director gave an update on the KUALI electronic protocol system. OAW has begun the transfer of existing protocols into the new system. Three wildlife protocols have been transferred and are ready for IACUC review. The OAW Director explained that since there is information not previously requested with the old system, IACUC review of transferred protocols is required. The OAW Director informed the committee that they will be receiving emails soon regarding review of transferred protocols and available training options include a short instructional video and/or in person Zoom training with the OAW.
2. The Assurance for OLAW has been submitted and the nine-month (shorter period due to changing reporting dates) OLAW report has been completed and will be provided to the IO.
3. The OAW is in the process of gathering animal use numbers for the USDA Report due December 1st.

Old Business:

1. **Action Items were reviewed and updated.**
 - a. Pharmaceutical-Grade Substances definition document
 - i. On agenda, see discussion below.
 - b. Student Training Policy
 - i. On agenda, see discussion below.
 - c. Revision of Euthanasia Cervical Dislocation/Decapitation policy
 - i. On agenda, see discussion below.

- d. Follow up on Adverse Event 1710009866: Disaster Plan receipt
 - i. PI updated his Disaster Plan in the Satellite SOP included in the recently renewed protocol.
 - e. Receipt of Adverse event form for emergency surgical procedure performed without consultation of clinical veterinarians
 - i. Adverse event was received, see discussion below.
 - f. Blood Collection SOP revision
 - i. On agenda, see discussion below.
 - g. Adverse Event Form revision and policy discussion
 - i. Action Item still in process and will be discussed in the December meeting.
 - h. Send final OLAW Assurance document to committee and IO
 - i. Has been submitted to IO and OLAW.
 - i. Adverse Event Protocol 1807016518: Feed analysis
 - i. On agenda, see discussion below.
 - j. Adverse Event on Protocol 1608003693_R1: Follow up
 - i. On agenda, see discussion below.
 - k. Plan for November Surgical Space Inspections
 - i. All inspections have been scheduled and are underway.
2. The minutes from the October 7, 2020 meeting were reviewed and approved by the committee unanimously.

New Business:

1. Discussion

- a. Pre-review: Expectations for PIs
 - i. This discussion regarded expectations of PIs for responding to pre-review comments prior to the protocol going to IACUC review. The Chair stated the issues at hand are ease of review for IACUC reviewers and roadblocks in turnaround time if revision after pre-review is a requirement. The consensus was that pre-review makes the IACUC review easier overall and does not necessarily delay approval, and the IACUC Administrator can use discretion in deciding when protocols get pushed through without pre-review, depending on the extent of the corrections that need to be made. Also, the Chair recommended there be stronger language in emails to indicate that the PI needs to address significant issues found during pre-review before the protocol will be sent out for IACUC review.
- b. Personnel involved with Food/Drug prep
 - i. This discussion surrounded the question of when personnel need to be on a protocol. Currently, only personnel with direct animal contact are required to be on a protocol, while those only doing food or drug prep are not required to be added. The OAW Director pointed out that it is not typically in the purview

of the IACUC to require personnel not directly involved with live animals to be on the protocol. After some discussion, the Chair moved to table further discussion to allow the committee time to consider other ways to identify when there could be potential for hazards with feed or drug prep and pass the information along to the appropriate group/department such as Chemical Safety or Occupational Health.

2. Policies/ Guidelines/ SOPs:

- a. Euthanasia by CD/Decap
 - i. The committee continued review of this policy since edits had been made after the last discussion. No further edits were suggested, and a motion was made and seconded to send the policy out for 30-day review with pending approval if no significant comments received. The motion was approved with one abstention.
- b. Blood Collection SOP
 - i. The SOP had edits made after further veterinary review. The significant changes regarded collection percentages and volume calculations. A motion was made and seconded to send the SOP out for 30-day review with pending approval, which was approved unanimously.
- c. Training Requirements for Research Personnel, Visitors, or Students
 - i. This is a new policy drafted by the AV to allow temporary personnel, such as rotating students, to not have to be added to a protocol. Temporary personnel are required to be supervised and cannot conduct surgeries among other restrictions. PIs can still add these people to protocols if desired or if temporary stipulations do not allow for personnel to complete designated roles. Temporary personnel would still be required to complete regulatory training which the PI would have to track rather than OAW, and those records would have to be made available during inspections. After discussion, there were no further comments and only minor edits suggested to the policy. A motion was made and seconded to post the policy for 30-day review with pending approval, and the motion was approved unanimously.
- d. Non-Pharm Use in Animals
 - i. A subcommittee has been working on the update of this existing policy. During discussion it was suggested that the background section was too long and should be edited and possibly moved to the end of document, with the policy starting with definitions instead. This policy was tabled to be sent back to the subcommittee for edits based on discussion.

3. Protocols/ Amendments Review

- a. IACUC Protocol 1603001209_R1
 - i. This IACUC protocol renewal involves research on the role of the RGS12 protein in complex behavior processes related to neuropsychiatric disorders, with a focus on studying drug treatments and genetic manipulations that affect the function of this protein. The protocol is designated Category E due to

behavior tests with inescapable stressors (forced swim, tail suspension). All reviewers agreed that the use of the behavior tests was necessary for studying the role of the RGS12 protein and was well justified in the protocol. Other corrections that needed to be made were summarized by reviewers. A motion was made and seconded to move from review of the revision to DMR, and the motion was unanimously approved.

4. Semiannual Program Review

- a. Spring 2020 Deficiencies:
 - i. Program review deficiencies from the Spring 2020 Semiannual Report were re-reviewed to identify if there were any repeat deficiencies. One past deficiency was identified as a repeat minor deficiency: “Procedures are in place to address: Veterinary review and oversight of medical and animal use records”, as it was noted that records were not available at one of three sites at the farm that was involved in the previous deficiency.

5. Veterinarian Reports

- a. OLAR/AV
 - i. A new OLAR facility manager has been hired and started this week.
 - ii. On a Saturday in October, husbandry staff missed a room due to an error on a check sheet, but there were no animal welfare issues. Moving forward everything will now be double checked.
- b. Clinical Veterinarian Report
 - i. OLAR Clinical Report:
 - 1. The AV discussed a recent case of complications developing in an animal that underwent neurosurgery. The animal was under veterinary care but continued to decline and was subsequently euthanized. The necropsy indicated brain herniation and pericardial effusion. The AV considered this a clinical issue that was within the anticipated potential complications for this type of procedure, with no deviation from approved procedures.
 - 2. A recent set of orthopedic surgeries involved three animals that crashed during the surgery (out of 24 animals). The same regimen was followed from past successful surgeries, and either a veterinary technician or veterinarian was present during this recent set. The exact cause is not clear but may be related to a vendor issue. Further troubleshooting will be conducted and a preliminary report submitted to the USDA.
 - ii. Agriculture Clinical Report:
 - 1. The Agricultural Veterinarian reported rectal prolapses in a few animals, which were treated. Another animal underwent surgery for urolithiasis but did not recover from the procedure.
 - 2. Recent TB testing on a herd came back with 30% “suspect”, which is a normal finding for the number of animals tested. The USDA came to

conduct further tests, and all animals tested negative. The USDA suspects that the initial results may have been due to the presence of birds in the area where the animals are housed.

6. IACUC Training

- a. There was no IACUC Training scheduled for this month's meeting.

7. Adverse Events/ Possible Non-Compliances

a. IACUC Protocol 1807016518

- i. This was a continued discussion from past meetings due to a pending feed analysis, which was a suspected culprit of temporary blindness in several animals (now resolved). This second report, which included more extensive vitamin and mineral analysis, also came back inconclusive. Since there is no clear connection of the blindness with protocol activities, this was deemed a clinical issue with unknown cause.

b. IACUC Protocol 1608003713

- i. The event involved an off-hours incident where a student accidentally clipped an animal's tail while replacing a cage lid. Research personnel performed an amputation of the damaged part of the tail (under anesthesia, with analgesics and antibiotics provided) without prior veterinary consultation but did contact veterinary staff the next morning. Upon examination, veterinary staff determined the procedure would need to be re-done to promote proper healing. The animal was subsequently euthanized by research staff for other clinical reasons, unrelated to the tail injury. The AV had a discussion with the PI, stressing that on-call veterinary staff must be contacted and consulted prior to treating a clinical emergency. The AV felt this event was indicative of a programmatic issue, as it suggests researchers are not aware of the proper procedures to follow for clinical emergencies. There was a motion to recommend reporting to OLAW and request a remediation plan from the PI that addresses steps to ensure proper clinical emergency reporting. The motion was seconded and approved unanimously.
- ii. To address the programmatic issue, an update to the Adverse Event/Unexpected Outcome Reporting Policy is already being drafted, which includes a definition of clinical emergency and guidelines for reporting. This will be discussed at the next meeting.

c. IACUC Protocol 1902022202

- i. This adverse event involved an experimenter error whereby equipment used to deliver electrical pulses during behavioral training was accidentally set to a higher output due to a flipped switch. At the end of the testing session, the animal was observed to have a nose injury and some movement issues with its hind legs. Veterinary staff was immediately contacted and examined the animal, finding no external signs of leg injury and no pain response upon palpitation. The animal showed improvement and displayed normal mobility in follow-up examinations. The PI's resolution in the short term is to tape the

switch, and the long-term resolution is to disable the switch circuitry. A motion was made to recommend not reporting the event to OLAW, which was approved by a majority vote with two dissenting votes. One member was absent from the discussion and vote due to a conflict of interest.

d. IACUC Protocol 1608003693_R1

- i. This previously discussed adverse event was revisited to provide an update and have a new discussion regarding embargoing data from publication. The exposed students were contacted by EHS and Occupational Health and were provided the option for health monitoring. Any remaining chemical residue in the workspace was cleaned by EHS. Legal Counsel has also been consulted. Since the last meeting, the PI has submitted an amendment to the protocol that includes clarification of the form of chromium being used.
- ii. After discussion regarding data publication, it was determined that the committee could not prevent the toxicologist from publishing a case study. However, the committee voted unanimously to embargo the data collected from animals exposed to the wrong chromium formulation from publication by the PI.
- iii. The committee had remaining serious concerns about the lack of PI oversight that led to the series of missteps in the incident and felt that remediation should go beyond just a letter to the PI, pushing for change at the programmatic level. After a long discussion, a motion was made and seconded to suspend the protocol. The motion did not pass, as the vote was split 50/50, with three abstentions. One member was absent from the discussion and vote due to a conflict of interest. The Chair will discuss committee concerns with the IO.

8. PAM

- a. There were no PAM reviews conducted in October 2020.
- b. Fall 2020 Semiannual Inspections:
 - i. Everything has gone well with inspections, and there is one additional facility location to complete (RNI). Surgical space inspections are underway.
 - ii. Topics to consider for the Spring 2021 inspections:
 1. Response deadlines per report rather than each individual deficiency. The PAM Administrator will have to consult with IT as to how this could be handled in the ALFI inspection software.
 2. Spaces outside the vivarium where euthanasia and non-survival surgeries are performed. Does the committee want those spaces inspected annually, semiannually or on a routine basis? The Chair suggested annually.
- c. The OAW Director brought up the topic of tracking progress on deficiencies. The Chair recommended including a link to an ongoing progress report as part of the Items for Review email sent out before every monthly IACUC meeting.

There being no further business to discuss, the meeting was adjourned at 2:57 pm.

Action Items:

1. Adverse Event Form revision and updated policy -OAW
2. Continued discussion of personnel involved with Food/Drug prep and protocol requirements- IACUC
3. Euthanasia by CD/Decap Policy – send out for 30-day review (post if no comments) -OAW
4. Blood Collection SOP - send out for 30-day review (post if no comments) -OAW
5. Training Requirements for Research Personnel, Visitors, or Students - send out for 30-day review (post if no comments) -OAW
6. Revision of Non-Pharm Use in Animals – IACUC Subcommittee
7. Report to OLAW Adverse Event on IACUC Protocol 1608003713 - OAW
8. Adverse Event IACUC Protocol 1608003693_R1 communicate IACUC's discussion with IO for further resolution – Chair

December 2, 2020
Institutional Animal Care and Use Committee
Meeting Minutes

The meeting was called to order by the Chair via Zoom on December 2, 2020 at 12:00 pm.

Attendance:

Members: Chair, 1, 4, 7, 9, 16, 18, 20, 21, 23, 24, 25, 29, 114

Alternates: 27, 28

Absent: AV, 22, 26

Others: 112, 113, 115, 118, 119

A quorum was present and acting.

Chair's Comments:

1. The IACUC Chair discussed the rising cases of COVID-19 and disaster plans which are in place should they be needed. Disaster plans have recently been reviewed and updated to ensure COVID-19 related issues and staffing have been addressed.

IACUC Admin Updates:

1. The OAW Director reported that annual reports (USDA, OLAW) have been submitted.
2. USDA APHIS had some public listening sessions to get feedback on developing AWA standards for birds not bred for use in research; however, topics covered are not applicable to any of WVU's current research projects.
3. In the interest of reducing burden, APHIS has proposed an AWA amendment to change from the annual review of USDA research activities to a 3-year review in addition to eliminating the 3-year registration renewal requirement for research facilities.

Old Business:

1. Action Items were reviewed and updated.

- a. Adverse Event form and updated policy -OAW
 - i. On agenda, see discussion below.
- b. Continued discussion of personnel involved with Food/Drug prep and protocol requirements - IACUC
 - i. The Chair received no comments from IACUC for suggested changes to current policy. The current policy of only having personnel with direct animal contact on protocols will stand.
- c. Euthanasia by CD/ Decap Policy – send out for 30-day review (post if no comments)

- i. This policy did not go out for 30-day review, as it was noted there needed to be more information regarding chickens. OAW reached out to a PI with experience and are still awaiting their feedback to finalize the draft.
 - d. Blood Collection SOP – send out for 30-day review (post if no comments)
 - i. No comments have been received, will be posted once 30-day period has expired.
 - e. Training Requirements for Research Personnel, Visitors or Students – send out for 30-day review (post if no comments)
 - i. No comments have been received, will be posted once 30-day period has expired.
 - f. Revision of Non-Pharm Use in Animals
 - i. On agenda, see discussion below.
 - g. Report to OLAW Adverse Event on IACUC Protocol 1608003713
 - i. The report is pending.
 - h. Adverse Event IACUC Protocol 1608003693_R1 communicate IACUC's discussion with IO for further resolution
 - i. The Chair had a meeting with the IO and pertinent parties to relay the IACUC's concerns.
2. The minutes from the November 4, 2020 meeting were reviewed and approved by the committee unanimously.

New Business:

1. Discussion

- a. Adverse Event Classification and Reporting
 - i. A revised policy on adverse event reporting underwent initial review with the OAW, AV, and Chair. Previous IACUC discussion on the reporting form resulted in a consensus that the form should be submitted within a week of initial report of the event, but the fundamental question brought up for current discussion was whether all adverse events and unexpected outcomes *must* be submitted on the form. For example, some may be better categorized as clinical issues that can be discussed via veterinary reports. After further discussion on categorization of events and criteria/decision trees for requesting form submission, the topic was tabled so that the AV, who was absent from the meeting, could be included in the discussion. In addition, a member stressed that legal should be consulted for clarification on what information could be subject to FOIA requests.

2. Policies/ Guidelines/ SOPs:

- a. Non-Pharm Use in Animals
 - i. Revisions to the policy suggested at the last meeting have been made. With no further comments from the IACUC, a motion was made and seconded to send out for 30-day review with pending approval if no significant comments received. The motion was approved unanimously.
- b. Autoclave Validation and Sterile Pack Processing

- i. The original policy was updated to include information on testing and validating autoclaves and expand information on sterile pack preparation. There were no further suggestions or comments from the IACUC. A motion was made and seconded to send the policy out for 30-day review with pending approval. The motion was approved unanimously.
- c. Euthanasia Guidelines
 - i. This is a new document which summarizes acceptable methods of euthanasia per species, based on AVMA guidelines. It was noted that one section on laboratory fish was missing information (acceptable and secondary methods). A motion was made and seconded to have the veterinarians complete the fish section, after which the guidelines will be sent out for 30-day review with pending approval. The motion was approved unanimously.

3. Protocols/ Amendments Review

- a. IACUC Protocol 1604002026_R1.4
 - i. This protocol amendment adds a Category E procedure (colitis model) to test a therapeutic target for the treatment of inflammatory conditions. The reviewers were in agreement that the Category E justification was appropriate and justified for the important research goals. Minor concerns and veterinary comments were summarized. A motion was made and seconded to move the revision from FCR to DMR and was unanimously approved.

4. Semiannual Program Review

- a. Program Deficiencies
 - i. The OAW Director went over the summary report of the program deficiencies for the Fall 2020 program review. The committee discussed the deficiencies (all minor) and the planned resolutions for each, and information was added/updated as needed.
 - ii. The OAW Director inquired as to how the committee would like to do future program reviews- go over the checklists within a meeting (past approach) or assign subcommittees to review certain sections and summarize the deficiencies and areas for improvement to the committee (current approach). The committee did not object to continuing with the new method for program reviews.
- b. Facility Deficiencies
 - i. Topic was tabled until the next meeting when the full report will be complete.

5. Veterinarian Reports

- a. OLAR/AV
 - i. The clinical OLAR veterinarian gave an overview of OLAR's Husbandry Continuity of Care Plan to address potential COVID-19 issues. The document covers critical supplies, preventive measures to reduce COVID transmission, and backup and staff reduction plans.

b. Clinical Veterinarian Report

i. OLAR:

1. Two ewes presented with nasal and ocular discharge. One of the cultures taken indicated multi-drug resistant *Pseudomonas*, and antibiotic treatment was provided to both animals. Despite supportive care, one animal continued to decline and was euthanized. Final necropsy results are pending, but initial observations point to pneumonia leading to sepsis. The second animal was able to complete the study.

ii. Agricultural:

1. Calves at one of the farms had an outbreak of respiratory disease, and antibiotics and NSAIDs were provided. Diagnostic tests are pending.
2. There was a single case of inappetence in recently purchased sheep at one of the farms. Supportive care and antibiotics were provided, and the animal is being monitored and is improving.
3. Dairy calves are healthy and were weaned the week of Thanksgiving.
4. A guard llama (for sheep) search has begun in efforts to replace the donkeys at one farm, and a guard llama may be considered for another farm location as well.
5. At a sister campus, a horse was treated for lacerations sustained from fencing that someone cut in the night/early morning hours. The animal is healing and showing improvement as supportive care continues. University police were notified of the incident.

6. IACUC Training

- a. The OAW Director reported that moving forward, the OAW will use a hybrid of current IACUC protocol review procedures and new KUALI procedures to ensure all members have ease of access to protocols for review determination. Different ways of approaching this procedure were discussed.

7. Adverse Events/ Possible Non-Compliances

- a. There were no adverse events or possible non-compliances to discuss this month.

8. PAM

- a. There were no PAM reviews conducted in November 2020.
- b. Surgical Inspections Update:
 - i. One location is left to complete and is scheduled for the day after the meeting (12/3).
 - ii. During this round of inspections, several spaces were discovered as being no longer in use for survival surgeries.

There being no further business to discuss, the meeting was adjourned at 2:24 pm.

Action Items:

1. Euthanasia by CD/Decap Policy Edits (awaiting feedback)-OAW
2. Non-Pharm Use in Animals: send out for 30-day review and post – OAW
3. Autoclave Validation and Sterile Pack Processing: send out for 30-day review and post – OAW
4. Euthanasia Guidelines: Minor edits from discussion then send out for 30-day review and post – OAW
5. IACUC Discussion – Should CITI's Aseptic Surgery be a mandatory training rather than recommended.
6. IACUC Discussion - Adverse Event Classification and Reporting