

July 3, 2019
ANIMAL CARE AND USE COMMITTEE
Meeting Minutes

The meeting was called to order by the Chair in Room 209, at the ORIC, 886 Chestnut Ridge Road on July 3, 2019 at 12:05 pm.

Attendance:

Members: Chair, Attending Vet, 1, 4, 9, 12, 16, 18, 20, 21, 22, 23, 24, 114

Alternates: 114

Absent: 5, 7, 116, 14 (alternate)

Others: 112, 113, 115, 118

A quorum was present and acting.

Chair's Comments

The Chair welcomed and introduced the new IACUC Coordinator.

IACUC Admin Updates

It was noted that microphones are now available for use during the meetings.

Old Business

- a. The minutes from the June 5, 2019 meeting were approved with several members abstaining.
- b. The action item list was reviewed and updated.

New Business

A. Updates

There are no updates at this time.

B. Protocol Review

1608003713_R1: The purpose of this research is to advance knowledge on the effects of brain injury, and how it can be treated, which will improve the lives of patients suffering from traumatic brain injury (TBI) and stroke. The research will test whether treatments are effective in alleviating the deficits associated with these injuries and identify drugs and behavioral therapies. The issues that were discussed by the committee were the investigator did not provide specific information regarding the substances in Appendix C and which experiment they will be used in and the

experiments described are in generalities and no specifics are provided. The committee also expressed concerns regarding the transcranial TBI experiment and its frequency. There are concerns over whether repeated TBI will debilitate the animals and make this experiment a category E. Harm/Benefit analysis was done and deemed appropriate for this Category E study. The committee requests that more information is provided regarding the experiments and sections of the protocol should be edited for clarity. A motion to for the revision of the protocol to go to DMR review was seconded and approved unanimously.

C. Discussion

1. The IACUC committee discussed the dates of approval regarding renewals of protocols. There are concerns that the renewal of the protocol process begins too soon and that a protocol could be approved two months early, effectively losing two months from its original three-year period of research. There are implementation issues concerning changing the renewal process; there are investigators that submit renewals early to add new experiments or increase animal numbers for which the current renewal process works well. The committee discussed the variety of methods to amend the process and provide investigators with the full three-year research period. A motion was made to have OAW draft suggestions for amending the approval proceedings for renewals of protocols.

D. Semiannual Program Review

1. Inspection Report Review:
 - a. OLAR discussed concerns regarding the escort present for the inspection. The escorts were not aware of all issues and there was an assumption that they were aware of everything. Additionally, all issues should be explicitly stated during the inspection.
 - b. A question was posed as to why OLAR was considered the responsible party (RP) for deficiencies in spaces used by a PI within the animal facility. It was expressed that OLAR would like IACUC to raise their concerns with deficiencies in PI spaces with the PIs instead of using OLAR to communicate the issues. Additionally, OLAR is presented with a large list of deficiencies but given a short time frame to resolve the issues.
 - c. OLAR raised concerns with rooms being inspected that are designated as spaces that will not be housing animals within six months. OLAR is unable to maintain these rooms to IACUC standards when they are not designated to have animals during the time. However, there has been instances of the rooms needing to be inspected after the regular inspections have occurred as emergency instances, which places a burden on IACUC committee members.
2. Exemptions List:
 - a. Current exemptions were discussed in June.
3. Semiannual Program Review:

- a. The committee reviewed the draft summary of the Semiannual Program Review. Signatures from members present during the review were collected to indicate approval on the program review.
4. Fall 2019 - Semiannual Program Review
 - a. The committee reviewed the Animal Care and Use Program, Disaster Planning and Emergency Preparedness, and IACUC sections of the Fall 2019 Semiannual Program Review.
 - b. Committee members had questions concerning new satellite facilities and their corresponding disaster plans. Current procedures are that OLAR drafts the disaster plans for the animal facilities; however, the Satellite facilities that are pending approval or unfamiliar to OLAR may be best drafted by the investigator. Additionally, the committee discussed the plausibility of adding a clause to the disaster program to add new satellite facilities as an appendix to the annual Disaster Plan.

E. OLAR Updates

1. OLAR discussed the discontinuation of Carprofen gel cups and presented several alternatives such as a Meloxicam SR subcutaneous injection that lasts for a 72-hour period and edible meloxicam or carprofen tablets that are bacon flavored. OLAR will be providing this information for the investigators using post-operative analgesics.
2. OLAR is in the process of finalizing a hire for a new veterinary technician staff member. That staff member will be added to the OLAR veterinary staff shortly.
3. OLAR has been renovating within the barrier space to provide rabbit housing space. The renovations included moving a door that will now encapsulate two other housing rooms and a procedural space.
4. The parvovirus outbreak that was identified on May 22nd and confirmed by testing, has been remedied. It was found to involve three rows in one rack of cages, affecting animals from two PIs. It was confirmed that OLAR has an outbreak SOP for control measures which includes limited room access, modified room entry order, increased PPE, notification of all PIs with animals in the room, and halting of breeding. All control measures have been resolved and breeding can resume.

F. Occupational Health and Safety Subcommittee Report

1. The OHS subcommittee continued to discuss the revisions for Appendix C. Once the revisions are completed, the subcommittee will submit the Appendix C to the IACUC for review. The subcommittee requests, if approved, the revisions be incorporated immediately.
2. Due to some recent exposure incidents requiring medical attention, access of all Occ Med staff to IACUC protocols was discussed. It was confirmed that one Occ Med representative has access to the protocols, but access is limited to that representative.

3. The subcommittee had raised concerns regarding lapses in the annual renewal of the Occupational Health Questionnaires (OHQ). The questionnaire is due annually while protocols are renewed every three years. This may lead to personnel being cleared only at the start of the protocol and when the protocol is renewed. Committee members pointed out that OHQ renewal reminders are sent out by the Occ Med system, so the capability of Occ Med flagging individuals that have lapsed exists.
4. OHS subcommittee has requested to present an IACUC training as needed every quarter on a hazard that is frequently seen by the Subcommittee.

G. IACUC Training

1. Pertinent to concerns raised by the IACUC regarding access to HVAC records in animal facilities, the OLAR facilities manager (FM) presented information concerning the monitoring of the HSC animal facility.
 - a. The FM discussed how the current monitoring system displays real time monitoring (temperature and humidity) with a floor plan for each zone housing animals. There is access to trending data within the last 24 hours, and once a month an excel spread sheet is compiled with data (temperature readings and set points, humidity values) and sent to the Operations Manager (OM) and Facilities Manager (FM). There are some rooms that are part of the older facility , which are tracked manually from daily measurements of in-room thermometer & hygrometer monitors.
 - b. The set points for humidity and temperature are derived from the Guide and are unique to each species. Additionally, the alarms for humidity and temperature have a range of temperature and humidity levels which are monitored and will set off an alarm once outside the set range.
 - c. Alarms are equipped to notify the on-site HVAC lead and technician, OM, and FM. The alarms are addressed by the HVAC technicians - typically with adjustments within the Building Management System. If remote system adjustments do not correct the problem, the technician examines and replaces failed mechanical components as needed.
 - d. The FM stressed that the HVAC lead and technical support for the system is available 24/7. Fluctuations are a normal part of any animal facility, and there are times when environmental conditions are beyond the design of the system to handle.
 - e. OLAR monitors situations where repeated alarms are occurring and when problems are indentified through communications with WVU maintenance. When continued out of range temperatures and high humidity or systemic HVAC failures occur, OLAR actions include the use of humidifiers, fans, heaters, and moving animals to other areas if needed.
 - f. The committee discussed the possible ways to access and view the out-of-range HVAC records and the alarm records during a facility inspection, such as presenting the data as graphs. Based on questions put forth from

committee members, it was confirmed that the OM or FM would be the point person for PI's to request access to the records if there are concerns about temp/humidity issues affecting experiments. It was also mentioned that additional training will be taking place for HVAC monitoring of the downtown facility and FARF systems. In addition, it was mentioned that alarm notifications repeat hourly and the majority of alarms received are for the automatic watering system rather than HVAC issues.

H. Adverse Events / Possible Non-compliances

Committee member 16 recused himself from discussion as he is listed on the protocol as personnel.

At the last meeting, the committee discussed the adverse event form submitted by the PI to report the death of an ewe on 5/30/19 due to complications from neurosurgery, confirmed by necropsy to be the result of brain bleeding. The committee had discussed the unavoidable complication from this type of surgery and had expressed concerns that the report contained conflicting information regarding the ewe's state of consciousness. The PI submitted a revised adverse event form to clarify the state of consciousness, provide additional details with PI's past experiences of ewes in similar conditions recovering, and to explicitly state the consensus among the clinical veterinarian and the PI. The committee found the revised form acceptable, and no further action was requested.

I. PAM

1. The Post Approval Monitoring Coordinator has recently concluded a PAM review of five protocols and a report was filed to the committee.
 - a. The PAM Coordinator met with the investigator heading three protocols and study personnel to review records, discuss the protocols and standard operating procedures. No surgical procedures were observed, but the training records are comprehensive and up to date. The training procedure for new personnel and animal monitoring procedures are satisfactory and the research records are inclusive and well maintained. The Post Approval Monitoring Report will be closed, but the investigator is able to invite the PAM coordinator to observe a surgical procedure.
 - b. PAM and a lab inspection by an IACUC member were conducted concurrently. The PAM Coordinator met with the investigator and study personnel to review records, discuss the protocols and standard operating procedures. At the meeting with the investigator, training records and the current protocol were not available. Recommendations to the investigator are to develop a SOP outlining the transportation of animals and tamoxifen transportation and to develop a comprehensive training procedure for new personnel. The PAM Coordinator reported to IACUC that recordkeeping and

documentation on the two protocols need to be improved. The PAM Report will remain pending until a surgical procedure is observed.

There being no further business to discuss, the meeting was adjourned at 2:26 pm.

Actions Items

- a. OAW will draft suggestions for amending the approval proceedings for renewals of protocols.

Under Vet Review, DMR Review or In Review Determination (as of 6/28/19)

Protocol #	PI	Type	Vet Reviewer	Reviewer 1	Reviewer 2	Status
1606003173_R1.1	Barbier	Amd	Knapek	Mathers	Cuff	Waiting for PI
1606003177_R1	Simpkins	Renewal	Knapek	Goodman	Mathers	DMR
1604002338_R1	Simpkins	Renewal	Washington	Cuff	Goodman	Waiting for PI
1606003142_R1	J. Du	Renewal	Knapek	Mathers	Connors	DMR
1906025082	Rota	New	Knapek	Wilson	Bowdridge	Waiting for PI
1608003713_R1	Vonder Haar	Renewal	Washington	Goodman	Perone	FCR
1809018212.2	Schreurs	Amd	Washington	Bryner		DMR
1805014087.4	Bennewitz	Amd	Knapek	Kelley	Cuff	DMR
1801012067.14	DeVries	Amd	Washington	Wilson		DMR
1812019923.1	Konat	Amd	Washington	Cuff		DMR
1802012692.6	Hussain	Amd	Knapek	Kelley	Goodman	DMR
1604001894.13	Lockman	Amd	Washington	Wilson	Bryner	DMR
1604002251_R1	Pugacheva	Renewal	Washington	Mathers	Cuff	DMR
1807015826.1	Seftor	Amd	Knapek	Connors		DMR
16080003693_R1.1	Shaffer	Amd	Washington	Minch	Bowdridge	DMR
1605003053_R1	Olfert	Renewal	Knapek	Perone	Goodman	DMR
1608003835_R1	Wilson	Renewal	Knapek	Bowdridge	Minch	DMR
1602000495.12	Goodman	Amd	Knapek			VVC
1604002166_R1	Lieving	Renewal	Washington	Wilson	Perone	DMR
1801012111.10	DeVries	Amd	Washington	Kelley	Wilson	DMR
1711010210.6	Geldenhuys	Amd	Knapek	Anderson	Bryner	DMR
1906025659	Lindsey	New				DMR
1906025667	Yu	New				Waiting for PI
16080003840.6	Pei	Amd				Waiting for PI

DMR or DMR after FCR Approvals – for June 2019

Protocol #	PI	Type	Approved
1604002213_R1	M. Perone	Renewal	6/4/2019
1604002302_R1	E. Tucker	Renewal	6/6/2019
1905023574	J. Boyd	New Protocol	6/21/2019
1905024304	Z. Weil	New Protocol	6/24/2019
1603001012.11	S. Kinsey	Amd	6/3/2019
16080037163.24	C. Vonder Haar	Amd	6/4/2019
1712010982.6	M. Dietz	Amd	6/4/2019
1711010210.5	W. Geldenhuys	Amd	6/11/2019

1901020651.1	P. Mathers	Amd	6/10/2019
1811018889.5	L. Hazlehurst	Amd	6/5/2019
17090093265.7	C. Robinson	Amd	6/12/2019
1801012111.7	C. Devries	Amd	6/13/2019
16090003850.15	E. Wan	Amd	5/31/2019
1701005049.19	W. Du	Amd	6/14/2019
1712010982.7	M. Dietz	Amd	6/14/2019
1602000495.11	R. Goodman	Amd	6/14/2019
1603000971.15	P. Chantler	Amd	6/19/2019
1602000254.4	T. Eubank	Amd	6/24/2019
1803013294.3	M. Dietz	Amd	6/28/2019

VVC and Administrative Approvals – for June 2019

Protocol #	PI	Type	Approved
1811018889.4	L. Hazlehurst	VVC	6/10/2019
1603001702.2	M. Sokolov	VVC	6/18/2019
1708008945.12	C. Anderson	VVC	6/13/2019
1602000254.5	T. Eubank	Admin	6/28/2019

Closed Protocols – for June 2019

Protocol #	Date Closed	PI
1604002115	6/14/2019	Yu
1605003068	6/22/2019	Kotcon

August 7, 2019
Institutional Animal Care and Use Committee
Meeting Minutes

The meeting was called to order by the Chair in Room 209, at the ORIC, 886 Chestnut Ridge Road on August 7, 2019 at 12:05 pm.

Attendance:

Members: Chair, Attending Veterinarian, 1, 4, 5, 7, 9, 12, 16, 18, 22, 24

Alternates: 114

Absent: 20, 21, 23

Others: 112, 118, 115

A quorum was present and acting.

Chair's Comments:

The chair announced the AAALAC reaccreditation status (full accreditation continues).

IACUC Admin Updates:

The OAW/IACUC shared email address has changed from acuc@mail.wvu.edu to iacuc@mail.wvu.edu and will be officially announced during the new website rollout.

Old Business:

- a. The minutes from July 3, 2019 meeting were approved with no changes requested.
- b. The action item list was reviewed and updated.

New business:

1. Updates

1. AAALAC letter:

- a.) The reaccreditation letter covered HSC, LSB, RNI (not visited due to construction), and FARF (not directly referenced but included in the visit), and stated that full accreditation shall continue. The letter also contained a list of items that AAALAC considered are well-done and stated that the Post Site Visit Communication (PSVC) satisfactorily addressed any Suggested Items for Improvement (SFIs) that came up during the exit briefing.
- b.) The SFIs from the exit briefing were reviewed:
 - a. Ensure that the 3R's are addressed in the IACUC protocol review process (section 11 in the protocol form). It was stressed that the IACUC make sure a strong justification is provided and that alternatives are reviewed and deemed not appropriate. In particular, more attention needs to be paid to the 3Rs in teaching protocols as this was brought up

by AAALAC site visitors. The committee discussed whether there is a need to change the wording on the protocol, but no changes will occur at this time. Reviewers would like to be reminded to pay special attention to this particular area when reviewing.

- b. Revise Perioperative Management of analgesia in rodent policy. The clinical vet will update IACUC policy to clarify proper dosages for analgesics (analgesics were not being given as frequently as they should).
 - c. Health monitoring program for fish housed long term. The AV has developed a program for zebrafish and knife fish (All PIs will submit a resident fish 1-2 times a year or when an outbreak is noted).
 - d. Ensure proper function and calibration for euthanasia equipment, including directions posted for neonates. The AV indicated this is complete.
 - e. Consistent labeling and use for multi-use bottle usage. The AV indicated a vet tech is looking into this, but suggested it should also be a universal IACUC policy.
 - f. Develop an SOP for hand-washed experimental equipment that is shared amongst users (ex: metabolic cages and rodent behavior core equipment). The AV has developed a program for sanitation.
- c.) The AV has requested for a timeline for verifying action plans (by next program review), and the Chair agreed.

2. Protocols for Review

1604002075_R1: This is a renewal of a protocol that looks at using 2 different drug compounds to treat arthritis and osteoporosis in 4 different induced/spontaneous models (pain category E). Several reviewers pointed out that animal numbers do not work out, and reviewers believed that too many animals are classified as category E. For example, non-arthritis animals appear to be included but there is no justification for why. It was noted that in the third experiment, there is no timeline or indication of what disease is mimicked. In the last experiment (osteoporosis model) 3 time points are mentioned, but it is unclear what was happening at those time points. Also noted was that the OVH experiment has 3 time points listed for drug administration, but other experiments list the drug administration as daily. Drug administration is listed for 3 routes (time-released pellets, IV injections and osmotic mini-pumps), but it is unclear when mini-pumps are used. Category E justification for the arthritis model was deemed valid, as arthritis is a painful disease that affects many people. Motion to go DMR was approved unanimously.

3. Discussion Items

1. Protocol Approval Dates: The OAW administrator opened up the discussion regarding the procedures for the protocol approval dates. There are 2 outcomes for renewals – those who would like the renewal to be approved ASAP in order to start working and those who want to get the most time out of their 3 years of the current protocol. Should PIs be given the option at the beginning of the process? The question was raised regarding “expedited review”, and one member noted that the review process is “rolling”, so there is no real reason to expedite and it is not allowed by OLAW. Last month, the IACUC tasked OAW with finding a solution. As a first step, OAW has changed the frequency of reminders regarding renewals. Instead of starting reminders at 4 months prior to expiration of the current protocol, reminders would start at 3 months and repeat at 2 months and 1 month. (If animals are present, an additional reminder will be sent prior to the one month date). It was reiterated that the decision to have the approval date align with the expiration date of the

current protocol came directly from senior administration. However, the renewal will be locked, and the PI will need to wait until the start date to make any changes to the renewal. The renewal approval letter will not be sent until the day before the expiration. The Chair suggested that an email be sent to the PI stating that the protocol has been approved and will be effective on “date”, but the official approval letter will not be sent until the day before the start date of the renewal. The Chair and OAW will work together on verbiage. Some discussion occurred regarding submission of renewals vs new protocols. The AV reported that protocol numbers change with renewals, but OAW corrected that the base number does not change (similar to amendments) and the “R1” designation for renewals is just for the review process only. A member suggested that, if a choice of approval date is given, the 3-year expiration date should be the “default” start date. The AV stated that it gives OLAR more certainty regarding when to expect renewals to be approved. The former chair pointed out that he received more feedback that the approval process takes too much time, not that it moves too quickly. The AV posed a question regarding how animal counts are updated once a renewal is approved, and some discussion ensued regarding whether animals currently in the facility at the time of renewal are counted against the new protocol.

2. Appendix C: Since manufacturer/catalog number information is requested in the appendix under the Other/Experimental Drugs section, the Chair raised the question as to whether a PI is out of compliance or needs to submit an amendment if he/she decides to switch to another vender/manufacture. OAW and the Chemical Safety representative reiterated that the manufacturer/catalog number is not required information, but rather is requested for chemical safety review purposes – to help with SDS review. Therefore, it is not a compliance issue. Suggestions included changing “manufacturer” to “vendor”, but it was countered that the manufacture info is needed to find the correct SDS sheets for chemical safety review.
3. Semiannual Inspections: The Chair offered the suggestion that the committee implement “teachable moments” in the comments section of the inspection reports, stressing that those items are important, but not deficiencies. To help implement this, training for the IACUC will take place prior to the Fall 2019 inspections. The AV stated that deficiencies must be addressed, but that comments have no regulatory burden.
4. Satellite Facilities: The Chair posed the question, should all satellites be treated equally? The Chair raised some concerns regarding the veterinary care and monitoring of animals in large capacity Satellites (i.e. 200+ cages), which relies on the lab personnel and the assumption that they have had proper training to identify issues. One member suggested “spot inspections”. Another member mentioned that this isn’t so much an inspection issue as an animal observation/husbandry issue. The AV expressed the opinion that monitoring frequency is the decision of AV and should be decided on a case by case basis (based on the lab’s credentials and training). At present, the veterinary staff (clinical veterinarian) checks on satellites every 6 months, right before the IACUC semiannual inspections. The AV expressed the importance of fostering a good relationship with the PIs and the belief that over surveillance would be an overreach. For new Satellites, the AV stated that she pops in from time to time to check that everything is going ok.

4. Semiannual Program Review (Fall 2019)

The following sections of the Semiannual Program were discussed and deemed acceptable by the IACUC, unless noted otherwise:

1. Section 4. IACUC Protocol Review:

- a.) Humane Endpoints: This item was deemed acceptable, but the AV thinks that humane endpoints should be reviewed more closely. OAW reported that the endpoints will be better defined with the electronic system. It was noted that AAALAC site visitors mentioned this as well.
- b.) Genetically Modified Animals: It was noted that the adverse event form has a section for reporting this issue to the IACUC.
- c.) The toe clipping policy was checked not applicable since no PIs are currently approved to do toe clipping.

2. Section 5. IACUC Membership and Functions: All items were acceptable.

3. Section 6. IACUC Training: All items were acceptable.

4. Section 7. IACUC Records and Reporting Requirements:

- a.) The Semiannual includes a plan and schedule for each deficiency identified: The Chair decided that this is a possible “minor” deficiency because there were some cases in the facility inspection report where the responsible party requested more information rather than providing an action plan.
- b.) Records of IACUC Reviews: It was noted that the IACUC follows the University’s policy on records retention for 3 years after the closure of the protocol, and it was clarified that this pertains to the protocol end date, not the study end date.

5. OLAR Update

The AV reported that a new Registered Veterinary Technician with 6 years- experience in small animal clinics started on August 5th.

6. Occupational Health/Safety Subcommittee Report

- 1. The new Appendix C is not yet ready to be discussed.
- 2. At the last OHSS meeting, the need for better definitions for deficiencies that concern EH&S issues that fall within the realm of the IACUC (i.e. compliance) vs. other non-IACUC EH&S areas was discussed. For example: Over-classification of sharps containers (i.e. placing items in sharps containers that shouldn’t be there, like paper towels) is not a direct personnel or animal safety compliance issue; therefore, is not an IACUC “deficiency”. However, recapped needles would be, although not all members were in agreement. The AV reported that AAALAC is no longer focusing on recapped needles.
- 3. There was also a concern about the origin of the deficiency categories (currently added to the ALFI inspection program). It was clarified that the categories were voted on by the IACUC in the past. The AV requested for them to undergo re-review. There was a motion to develop a method of deficiency review and revision, possibly via a subcommittee.
- 4. The AV suggested that protocol documents access for the Department of Occupational Medicine be brought to the forefront. The Chair expressed concern about giving access to individuals that have not met proper regulatory requirements as protocols may contain sensitive information.

OAW reported that the IO has previously stated that granting additional access to Occ Med is not an action item. However, the AV feels that the IO is in favor of “need to know” access. The issue is that Occ Med has had a couple of situations where there have been exposures (sometimes off-hours), and the person is not aware of what agent they were working with and the medical staff is not able to treat. OAW suggested that there be an informational sheet a person can take with them to the emergency department (ED) with the information specifically needed by Occ Med, as protocols do not contain human treatment information. It was noted that an IBC protocol does have all of the information for biohazards but not for chemicals. If an individual NOT working with animals has a chemical exposure, they take the SDS sheets to the ED. These instructions are provided as part of EH&S training for lab personnel, and one member noted that the ultimate responsibility therefore lies with the laboratory personnel. A member asked about the procedure in the High Containment Area, but the AV doesn’t think that would be sufficient. The AV has also requested that Occ Med be represented within the IACUC, and the former chair stated that the request was extended on multiple occasions in the past and that a representative is already on the IACUC roster. It was recommended that Occ Med be invited to attend IACUC meetings on an as-needed basis. It also may be helpful for them to attend to discuss specific information that is needed from protocols. The AV also brought up that the Occ Med “annual approval” does not match with the IACUC’s 3- year approval. It was also noted that the Occupational Health Questionnaire has been modified to identify more risks.

5. 5-10 minute training sessions on an EH&S topic are to start next month (1st topic: Chemotherapy).

7. Training

The AV presented a training session on adoption and recommended that the IACUC create an adoption policy (a few members recalled that there was an IACUC-reviewed adoption policy at some point). She presented information from AVMA, AAALAM, USDA, OLAW and the IACUC handbook, citing that although there is no regulatory requirement, the overall opinion is that adoption programs are encouraged under the supervision of the AV and IACUC. All programs should follow federal/state/local laws and regulations, and the IACUC should have a policy if an adoption program is considered. Currently, rats, pigeons and lambs are adopted, but there is only an old “WVU policy” and an OLAR SOP that is not on the website. Therefore, there may be a need for an IACUC-approved policy that is up to date and more accessible. A member expressed concern about the committee deciding which species could be adopted. The Chair felt strongly that genetically modified animals should not be included in the adoption policy, due to concerns of them being released into the wild. One member that has documentation regarding the adoption policy for rodents used in teaching will provide this information to OAW, and further discussion of the policy will be revisited later. Input from WVU Legal is also needed to comply with zero tolerance policies on acquiring WVU property.

8. Adverse Events/ Possible Non-Compliances

1. Stewartstown Farm Adverse Event: A calf was noted missing on July 8th, last seen on July 7th. The calf was never recovered, and the cause was not determined. The farm manager reported the incident to the IACUC via the Adverse Event Form. Due to concerns that the calf was stolen, a member asked if the farm manager had called the police (WVUPD). The answer was unknown, but another member will check with the farm manager. The AV asked about closing/locking the gates in the evening. It was clarified that the gates were not a problem or issue, but security for

all of the farms will be explored further. In particular, there is a desire to increase police presence.

2. Protocol Non-Compliance: OLAR veterinary and husbandry staff reported a possible non-compliance to the clinical veterinarian on 2 separate dates. The non-compliance was centered around lack of observation of restrained rats and unapproved restraint devices (DecapiCones with binder clips). The observations did not concur with the restraint information in the PI's protocol, which describes 2 different monitoring plans (continual vs. every 15 minutes) and only one type of restraint device (not DecapiCones). The issues were brought to the attention of the PI immediately by the clinical veterinarian, and a reminder email sent as well. It was noted that the lab personnel did not appear to be responsive to the direction presented by the clinical veterinarian. During the IACUC investigation, it was recommended that the PI submit an amendment to the IACUC to clarify the monitoring of restrained animals and restraint devices used. The Chair also asked OAW to do a pre-review of the new amendment when it is submitted to ensure that the observational discrepancies are resolved. The committee agreed (unanimously) that OLAW should be notified of the non-compliance. The Chair will send letters to OLAW and to the PI instructing the PI and staff to heed instructions from the veterinarians and to follow the restraint procedures on the currently approved protocol until an amendment is approved. The Chair will also set up a meeting with the PI to convey the IACUC's decision.

9. PAM

The PAM Administrator reported on two PAM reviews. One PAM is still in progress (waiting to observe procedures), and a second PAM is being scheduled.

There being no further business to discuss, the meeting was adjourned at 3:15 pm.

Action Items

1. Non-Compliance: OAW/Chair will draft letters to PI and OLAW; Chair will arrange meeting with PI.
2. OAW will work on verbiage for notification to PIs when IACUC review of renewal is completed.

Under Vet Review, DMR Review or In Review Determination (as of 7/31/19)

Protocol #	PI	Type	Vet Reviewer	Reviewer 1	Reviewer 2	Status
1606003142_R1	J. Du	Renewal	Knappek	Mathers	Connors	Waiting for chemical hazard SOP approval
1608003713_R1	Vonder Haar	Renewal	Washington	Goodman	Perone	DMR
1809018212.2	Schreurs	Amendment	Washington	Bryner		Waiting for PI
1604001894.14	Lockman	Amendment	Washington	Wilson	Bryner	Waiting for PI
1604002251_R1	Pugacheva	Renewal	Washington	Mathers	Cuff	Waiting for PI
16080003693_R1.1	Shaffer	Amendment				Waiting for PI
1605003053_R1	Olfert	Renewal	Knappek	Perone	Goodman	DMR
1801012111.10	DeVries	Amendment	Washington	Kelley	Wilson	Waiting for Satellite Approval
1711010210.6	Geldenhuys	Amendment	Knappek	Anderson	Bryner	Waiting for Satellite Inspection
1906025667	H. Yu	New Protocol	Knappek	Connors	Minch	Waiting for PI
1604002265_R1.2	Rajendran	Amendment	Knappek	Perone	Elliott	DMR
1907026540	Lindsey	New Protocol	Knappek	Goodman	Kelley	Waiting for PI
1907026536	Vonder Haar	New Protocol	Washington	Minch	Wilson	Waiting for PI
1803013440.4	Ramamurthy	Amendment	Knappek	Mathers		Waiting for PI
1603000924.5	Huber	Amendment	Knappek	Kelley	Cuff	Waiting for PI
1607003285_R1	Washington	New Protocol				DMR
1907026586	Hazelhurst	New Protocol	Knappek	Kelley	Cuff	DMR
1606003213_R1	Mathers	Renewal				Waiting for PI
1803013068.4	Liu	Amendment	Washington	Cuff	Goodman	DMR
1604002138_R1	Klinke	Renewal	Knappek	Mathers	Cuff	DMR
1604002075_R1	Barnett	Renewal	Knappek	Goodman	Connors	FCR
1609003885_R1	Lituma	Renewal				Pre-Review-Waiting for PI
1609003850_R1	Wan	Renewal				Pre-Review

DMR or DMR after FCR Approvals – for July 2019

Protocol #	PI	Type	Approved
1604002338_R1	J. Simpkins	Renewal	7/10/2019
1608003835_R1	M. Wilson	Renewal	7/10/2019
1604002166_R1	G. Lieving	Renewal	7/10/2019
1906025082	C. Rota	New	7/12/2019

1606003177_R1	K. Simkins	Renewal	7/17/2019
1705006642	B. Li	Annual Review -DoD	7/19/2019
1906025659	B. Lindsey	New	7/23/2019
1907026698	C. Rota	New	7/30/2019
1907026544	M. Barbier	New	7/31/2019
1802012692.6	S. Hussain	Amd	7/1/2019
1807075826.1	R. Seftor	Amd	7/3/2019
1812019923.1	G. Konat	Amd	7/3/2019
1708008945.13	C. Anderson	Amd	7/8/2019
1805014087.4	M. Bennewitz	Amd	7/8/2019
1608003840.6	M. Pei	Amd	7/10/2019
1603001702.30	M. Sokolov	Amd	7/12/2019
1603001552_R1.1	J. Simpkins	Amd	7/22/2019
1801012111.10	C. DeVries	Amd	7/22/2019
1701005049.21	W. Du	Amd	7/22/2019
1811019148.20	H. Damron	Amd	7/25/2019
1606003173_R1.1	M. Barbier	Amd	7/25/2019
1602000797.7	H. Damron	Amd	7/26/2019
1811018889.7	L. Hazlehurst	Amd	7/26/2019
1604002138.7	D. Klinke	Amd	7/29/2019
1811019092.3	L. Hazlehurst	Amd	7/29/2019
1803013440.4	V. Ramamurthy	Amd	7/30/2019
1603001702.3	M. Sokolov	Amd	7/30/2019

VVC and Administrative Approvals – for July 2019

Protocol #	PI	Type	Approved
1602000317.5	S. Hileman	VVC	7/8/2019
1602000495.12	R. Goodman	VVC	7/28/2019
1708008935.90	C. Robinson	VVC	7/30/2019
1811019092.4	L. Hazlehurst	VVC	7/31/2019
1701005049.20	W. Du	Personnel	7/3/2019
1602000317.4	S. Hileman	Personnel	7/8/2019
1604002302_R1.1	E. Tucker	Personnel	7/8/2019
1903013294.4	M. Dietz	Personnel	7/9/2019
181101889.6	L. Hazlehurst	Personnel	7/10/2019
1811019092.2	L. Hazlehurst	Personnel	7/10/2019
1804013715.5	F. Damron	Personnel	7/11/2019
1603000971.16	P. Chantler	Personnel	7/12/2019

1603001209.1	D. Siderovski	Personnel	7/17/2019
1708008945.14	C. Anderson	Personnel	7/17/2019
1604002026.14	R. Leonardi	Personnel	7/18/2019
1809018204.3	B. Boone	Personnel	7/22/2019
1903022662.1	B. Lindsey	Personnel	7/29/2019

Closed Protocols – for July 2019

Protocol #	Date Closed	PI
1605003131	7/5/2019	Barnes
1606003205	7/14/2019	Rota

September 4, 2019
Institutional Animal Care and Use Committee
Meeting Minutes

The meeting was called to order by the Chair in Room 209, at the ORIC, 886 Chestnut Ridge Road on September 4, 2019 at 12:10 pm.

Attendance:

Members: Chair, Attending Veterinarian, 1, 4, 5, 7, 9, 12, 16, 20, 21, 22, 23

Alternates: 114, 25, 26

Absent: 18, 24

Others: 112, 118, 115

A quorum was present and acting.

Chair's Comments:

The Chair welcomed and introduced the new IACUC alternate member and two guests: the new clinical veterinarian and the Assistant Vice President for Research Administration.

IACUC Admin Updates:

1. The signup sheet for the upcoming October Semi-Annual IACUC inspections was distributed.
2. Members were reminded to make sure their enrollment in Occupational Medicine (OHQ) is up to date. The OAW will check on the status for all members.

Old Business:

1. The minutes from the August 7, 2019 meeting were approved unanimously with no changes requested.
2. The action item list was reviewed and updated.

New business:

1. Updates

- a. For the new process to align approval dates of renewals with the expiration date of the current protocol, the IACUC Administrator and Chair have worked on a template email to PIs to provide notification that their IACUC review is complete (prior to releasing the approval letter and approved protocol). This template is now being used, but it is still a work in progress.
- b. Regarding the non-compliance discussed at the previous meeting, the Chair confirmed that a letter was sent to OAW and that he met with the PI to stress the importance of protocol

compliance and appropriate response to veterinarian authority. An amendment to modify restraint monitoring procedures was submitted and is currently waiting on the PI to submit a revision based on IACUC reviewer comments. No additional concerns have been reported by OLAR staff.

- c. Regarding the incident involving a missing calf discussed at the previous meeting, it was confirmed that the WVU police were not contacted. The general consensus was that the police should still be alerted, and both the Chair and OAW Director agreed to ask/follow up with the Farm Manager to make sure this is done.
- d. Regarding the Adoption Policy discussed at the previous meeting, it was confirmed that the member with documents on rat adoptions provided those to the Chair. Concerns were expressed regarding the need for review by legal since it deals with animals that are WVU property. The AV requested that the Adoption Policy remain an action item as it is an ongoing work in progress.
- e. Updated Farm SOPs were sent out to the committee in advance of the meeting. The subcommittee that worked on the SOPs was led by the OLAR clinical veterinarian and representatives from OAW and the farm. The SOPs were also sent to the new farm clinical veterinarian for review. The development of new and improvement of existing SOPs was part of an action plan to address previous farm issues reported to OLAW. The completion of the SOPs will be included in an update letter to OLAW, due September 15th.

2. Protocols for Review

1908027360: This new protocol submission involves research on the effect of obesity on bacterial gut infections, which is being examined using a model of high fat diet-induced obesity in male mice that are then infected with *Salmonella* or *Shigella* (Category E). One reviewer had a major concern that the type of *Shigella* infection proposed would lead to severe morbidity, which did not seem justified based on the harm/benefit analysis. Conversely, the type of *Salmonella* infection proposed would not produce clinical pathology (i.e. is not Category E). In addition, reviewers had concerns regarding the use of breeding to obtain the male subjects needed, resulting in unjustified wastage of female animals. One of the reviewers met with the PI to convey these concerns, and the PI agreed to obtain mice commercially or via transfer from other breeding protocols and to drop the *Shigella* experiments, resubmitting the protocol as Category C with the understanding that any clinical issues would be reported to the IACUC (via the Adverse Event/Unexpected Outcome Form). Other suggestions included improving justification as to why the strain selected is a good model for human obesity (i.e. references to literature), more details on the exact formulations of the high/low fat diets, correction of discrepancies in animal use numbers, clarification of experimental groups, correction of *Salmonella* dose (typo). A motion for the revised protocol to go DMR was seconded and unanimously approved.

1609003850_R1: This Category E protocol renewal involves a mouse model of multiple sclerosis (experimental autoimmune encephalomyelitis or EAE) and inflammatory bowel disease (DSS-induced colitis). Studies are focused largely on the role of STAT5 in controlling/regulating/modulating these diseases. One shared concern among reviewers was that the PI indicated no significant morbidity was

expected for DSS-induced colitis, which was inconsistent with the fact that it causes sickness, thus the designation as Category E. Reviewers felt that the PI was using mortality/morbidity terminology interchangeably rather than distinguishing the terms. Additional reviewer comments included a request for more details in Appendix L- Progress Report and clarification for why one study that did not involve EAE or colitis had animals designated category E. The AV recommended that the PI remove a sentence (repeated across Appendix Bs) indicating that mortality is likely caused by severe paralysis, as elsewhere the PI describes a clearly defined endpoint that should avoid progression to that state. There was a consensus that the proposed use of these Category E disease models was justified based on harm/benefit analysis. A motion for the revised protocol to go DMR was seconded and unanimously approved.

3. Discussion Items

- a. The Chair encouraged member participation in the upcoming Semi-Annual IACUC Inspections
- b. The Chair has tasked a subcommittee to review the standardized deficiencies list for the inspections

4. Semiannual Program Review (Fall 2019)

The following sections of the Semiannual Program were discussed and deemed acceptable by the IACUC, unless noted otherwise:

- a. Section 8. Veterinary Care:
 - 1. Item #2 Veterinary Access: It was noted that the University Police is the fall back to provide veterinary access to all animals.
 - 2. Item #6 regarding Part Time/Consulting Veterinarian was deemed “N/A” since WVU has a full time AV.
- b. Veterinary Care: 1. Clinical Care and Management
- c. Veterinary Care: 2. Animal Procurement and Transportation/Preventive Medicine
 - 1. Item #3 Procurement linked to IACUC review and approval: It was confirmed that the farm has a procedure in place to track animal numbers (animal procurement form and approval agents that review forms).
 - 2. Item #4 Random source dogs and cats inspected: Marked “N/A”
 - 3. Item #5 Population status of wildlife species considered prior to procurement: It was noted that this item is addressed via the required scientific collection permits for wildlife studies.
 - 4. Item #11 Deliveries are planned to ensure receiving personnel are available: This item was marked as a minor deficiency due to a recent case at the farms.
 - 5. Item #16 Quarantined animals from different shipments are handled separately or physically separated: This item was marked as a minor deficiency since a policy is in place but may not always be followed.

5. OLAR Update

- a. Two members of Husbandry staff recently received ALAT certification and additional staff are studying to take the exam in the future.
- b. Most members of the veterinary staff will be attending the National AALAS meeting (October 13th -17th). Coverage in their absence will be provided by the NIOSH veterinarian, and protocol/amendment reviews can continue to be sent to the AV during this time.

6. Occupational Health/Safety Subcommittee Report

- a. A second revised draft of Appendix C- Use of Substances was shown to the committee.
 1. A new addition to the Anesthesia section is a check mark to indicate SOPs are followed for use of isoflurane, MS-222, and/or urethane. One question asked was whether euthanasia was included, and it was confirmed that it would be included as the SOPs are meant to cover “from cradle to grave” for the substance.
 2. Committee suggestions from the previous review at the June meeting were incorporated and included a change in title for the “Other” section, “Manufacturer” was changed to “Vendor” in the chart column, and NFPA Rating was added as a column. It was noted that there is no website link for NFPA Rating, but the column title does specify that it can be found on the (M)SDS or via Google search. Underneath the chart is a section that can be checked for following the SOPs for formaldehyde/formalin. A definition of “pharmaceutical grade” has now been provided under the chart with instructions on what should be provided if non-pharm grade is being used.
 3. Committee members felt it was confusing whether PIs were expected to provide further justification when a pharmaceutical-grade drug is not being used because it is not available. In addition, there were concerns about the amount of information being requested, with the Chair reiterating that the committee has previously discussed holding off until OLAW/FDA/USDA completes their updating of federal guidelines for the use of non-pharm compounds in animals. An additional concern expressed was that there was some duplication between what a PI must provide on the animal protocol and what they already provided to EH&S as part of lab audits. Additional discussion centered on the key information the committee wants PIs to provide (pH, sterility, purity) and the need to clarify that the PI does not need to provide ALL the information listed as it would be excessively burdensome. It was clarified that the current guidelines give the IACUC “factors to consider” in evaluating non-pharm substances, which leaves it open for the IACUC to decide what MUST be provided. Members also felt it was important to provide PIs with a background for why this information is important (i.e. to ensure compounds will not cause adverse/toxic effects in animals).
- b. The Chemical Safety representative gave the first part of a 2-part presentation on chemotherapy drugs. Topics included Classification of Chemotherapy Drugs (Alkylating Agents, Plant Alkaloids, Antitumor Antibiotics, Antimetabolites, Topoisomerase Inhibitors, Misc. Antineoplastics), Common Chemotherapy Drugs used in IACUC Protocols (Cisplatin, Paclitaxel/Docetaxel, Doxorubicin, Mitomycin, Belomycin), and Chemotherapy Drug Hazards (carcinogenic, mutagenic, teratogenic, organ toxicity).

7. Training Animal Lab and Facility Inspection (ALFI) Demo

- a. An ITS representative for ALFI demonstrated the current version of ALFI software that will be used for the upcoming October IACUC semiannual inspections.
- b. An overview of the download function for areas outside of WIFI range was presented.
- c. Inspector and Responsible Party (RP) views were demonstrated. One new feature highlighted was a button to mark that a deficiency was addressed/fixed at the time of inspection.
- d. Member suggestions included the ability to have multiple RPs (currently can only have one), requiring RPs to respond to all deficiencies (major and minor) but not to recommendations/comments, add drop down list of some common default responses that RPs could select, prompts for the RP to submit an action plan if deficiency not already addressed.

8. Adverse Events/ Possible Non-Compliances

Potomac State: Just prior to Labor Day, OAW received a report of a horse that died as a result of seizures, which was later clarified as "acute respiratory muscle paralysis" Additionally, the day before the IACUC meeting, the OAW received a second report of a personnel issue that revealed an allegation of horse abuse. A connection between the two reports is unknown at this time. An investigation is being opened to collect more information. The AV expressed concern as to why notification was not received at the same time as OAW.

9. PAM

- a. A procedure observation for a lab is scheduled this week, as part of a continuation of an ongoing PAM.
- b. Additional routine PAMs on two PIs from the Orthopedics group (covering 5 protocols) are scheduled for this month.

There being no further business to discuss, the meeting was adjourned at 2:13 pm.

Action Items

- 1. Check OHQ for all Committee Members.
- 2. Request that farm administration ensure WVU Police are contacted regarding calf incident.
- 3. Update letter to OLAW concerning the Institution's resolutions regarding previous issues at the Stewartstown and Organic farms.
- 4. Development of Adoption Policy

Under Vet Review, DMR Review or In Review Determination (as of 08/29/19)

Protocol #	PI	Type	Vet Reviewer	Reviewer 1	Reviewer 2	Status
1608003769_R1	Meares	Renewal	Washington	Perone	Connors	DMR
1607003285_R1	Washington	Renewal				DMR
1609003850_R1	Wan	Renewal	Washington	Cuff	Connors	FCR
1604002026_R1	Leonardi	Renewal	Washington	Mathers	Kelley	Waiting for PI
1604002138_R1	Klinke	Renewal	Knappek	Mathers	Cuff	Processing Revision
1609003885_R1	Lituma	Renewal	Washington	Wilson	Bowdridge	DMR
1604002075_R1	Barnett	Renewal	Knappek	Mathers	Cuff	DMR
1908027682	Geldenhuys	New Protocol	Washington	Goodman	Perone	DMR
1908027360	Robinson	New Protocol	Knappek	Kelley	Cuff	FCR
1907026536	Vonder Haar	New Protocol	Washington	Minch	Wilson	Processing Revision
1907026586	Hazlehurst	New Protocol	Knappek	Kelley	Cuff	Waiting for PI
1607003257.7	Kelley	Amendment				DMR
1603000924.5	Huber	Amendment	Knappek	Kelley	Cuff	DMR
1606003142_R1.1	J. Du	Amendment	Knappek	Connors	Bryner	DMR
1708008935.10	Robinson	Amendment	Knappek	Cuff	Connors	DMR
1903022662.2	Lindsey	Amendment	Kessler	Connors	Bryner	DMR
1604001894.14	Lockman	Amendment	Washington	Wilson	Bryner	DMR
1803013068.5	Liu	Amendment	Kessler	Perone	Ringer	Waiting for PI
1811019148.4	Damron	Amendment	Washington	Minch		Waiting for PI
1608003693_R1.1	Shaffer	Amendment				Waiting for PI
1711010210.6	Geldenhuys	Amendment	Knappek	Anderson	Bryner	Waiting for Satellite Inspection
1708008945.16	Anderson	Amendment				Pre-Review
1811019092.5	Hazlehurst	Amendment				Pre-Review

August 2019 Approvals (as of 08/29/19)

Protocol #	PI	Type	Approved
1606003213_R1	Mathers	Renewal	8/10/2019
1606003142_R1	J. Du	Renewal	8/14/2019
1605003053_R1	Olfert	Renewal	8/15/2019
1907026540	Lindsey	New Protocol	8/15/2019
1604002251_R1	Pugacheva	Renewal	8/21/2019
1906025667	Yu	New Protocol	8/22/2019
1604002265_R1.2	Rajendran	Amendment	8/5/2019
1801002067.15	Devries	Amendment	8/13/2019
1803013068.4	Liu	Amendment	8/14/2019
1604002138.8	Klinke	Amendment	8/15/2019
1608003840.7	Pei	Amendment	8/20/2019

1602000317.6	Hileman	Amendment	8/23/2019
1604002265_R1.3	Rajendran	Amendment	8/23/2019
1801012067.16	DeVries	Amendment	8/26/2019
1901020171.1	Geldenhuis	Amendment	8/28/2019
1701005049.22	J. Du	Personnel	8/6/2019
181109148.3	Damron	Personnel	8/8/2019
1608003713.25	Vonder Haar	Personnel	8/13/2019
1602000486.8	K. Anderson	Personnel	8/14/2019
1602000495.13	Goodman	Personnel	8/15/2019
1602000686.4	Kestner	Personnel	8/15/2019
1603001124.9	Pistilli	Personnel	8/27/2019
1905024304.1	Weil	Personnel	8/27/2019
1708008945.15	C. Anderson	Personnel	8/29/2019
1602000511.3	Pugacheva	Personnel	8/29/2019
1604002251_R1.1	Pugacheva	Personnel	8/29/2019

**October 2, 2019
Institutional Animal Care and Use Committee
Meeting Minutes**

The meeting was called to order by the Chair in Room 209, at the Office of Research Administration, 886 Chestnut Ridge Road on October 3, 2019 at 12:00 pm.

Attendance:

Members: Chair, Attending Veterinarian, 1, 4, 5, 7, 9, 12, 16, 20, 21, 22, 23

Alternates: 114, 25

Absent: 18, 26

Others: 112, 115, 118

A quorum was present and acting.

Chair's Comments:

1. The Chair recently attended the Scientists Center for Animal Welfare (SCAW) IACUC Training Workshop and will be attending IACUC 201 and 301 in November.
2. The two new alternate IACUC members were announced (clinical vet and a scientist). Moving forward, they are to be included as tertiary reviewers as part of their IACUC training.

IACUC Admin Updates:

Semiannual IACUC inspections are underway and towards the end of October, information on surgical lab inspection scheduling will begin.

Old Business:

1. The minutes from the August 7, 2019 meeting were approved unanimously with no changes requested.
2. The action item list was reviewed and updated.
 - a. The OHQ for all members has been checked and all members are up to date.
 - b. A request was directed to the Farm Manager to contact WVU police regarding the missing calf incident.
 - c. A final update letter to OLAW regarding previous concerns at the farm was sent out, and a response was received from OLAW indicating that they have now closed the case.
 - d. The AV sent a draft of the updated Adoption Policy to the Chair, and it was made available to IACUC members prior to the meeting. The Chair also sent the policy to legal (Associate General Counsel for WVU) for review. One member had a question concerning whether the language in the policy should allow more flexibility as to who can perform the physical examination on the

animal prior to release. The AV expressed that she feels the examination should be under the purview of the AV and pointed out that the language states “Attending Veterinarian *or designee*”. The Chair encouraged the committee to read the draft and be ready to discuss at the next meeting.

New business:

1. Protocols for Review

- a. No protocols or amendments at this time

2. Discussion Items

- a. Renewal Approval Dates:

1. The Chair reiterated that the IACUC should have a policy whereby PIs have the option to align renewal start dates with the expiration date of the current protocol. The IACUC Administrator described the implementation of this new process thus far, which includes the alignment of the renewal start date with the expiration date as the default option. The PI gets sent an “IACUC Decision” email that states the IACUC review is complete and no further revisions are requested, which also notifies the PI that they will receive official approval documents (approval letter & approved protocol) on the business day prior to the renewal start date, unless they request a sooner start date. The Chair mentioned that there have already been some issues in implementing this policy, such as PIs requesting immediate approval (prior to receiving the IACUC decision email) and PIs submitting an amendment to the current protocol requesting changes that were not included in the already submitted renewal. One question about the process was whether this IACUC decision email should be delayed if there are other factors holding up approval, such as incomplete training requirements of personnel on the protocol. It was suggested that the decision email should still be sent after IACUC review is complete but should mention if there are any extenuating factors that may hold up approval.
2. Additional discussion ensued regarding whether a “renewal” is reviewed as a new protocol. It was clarified that the regulations regarding 3 year de novo reviews indicate that a complete review of the entire protocol should be done, not that the protocol itself is thought of as “new”. The ability to carry over sections of the protocol that have not changed is a requirement item for the electronic system under development.

- b. IACUC Annual Review – USDA Protocols: In the interest of reducing administrative burden, the AV suggested that the annual IACUC protocol review align with the same reporting period for the USDA Report (fiscal year Oct 1 – Sept 30). The OAW Director recommended that the annual reviews should be based on the initial approval date, rather than all be done in October as it may require some PIs to do an additional annual review (i.e. if a protocol is approved August 2019, it will undergo annual review three times prior to the renewal -Oct 2019, 2020, AND 2021). The suggestion was made that for future annual reviews, the PIs should turn in one report (due ~ October 15th) that captures all the information needed for both the annual review and the USDA

report. The OAW Director reiterated, however, that the numbers are not always the same for the two separate processes. For example, if the protocol was renewed in July 2019, the only numbers needed for the annual review in October would be the animal use that occurred since last reviewed (i.e. July 2019 – Sept 30, 2019) whereas the USDA report would require animal use information for the entire fiscal year. No consensus was reached on the best approach.

- c. Co-Housing Exception to the Guide (FARF): A requested exception to the Guide's recommendation that different species be housed separately was discussed. The exception involved the co-housing of sheep and pigs in the same room, but in separate pens, at the FARF. Housing space requirements for larger pig breeds could be met by housing them in an area that is also used to house sheep. The clinical veterinarian stated that there should be no problems with co-housing in the same area as long as the pigs come from an approved vender and are certified pathogen-free. Also, no behavioral issues would be expected. A motion to approve the exception was seconded and approved unanimously by the committee.
- d. Exception to the Acclimation Policy: A recent renewal submission for a protocol (1604002146_R1) involving special livestock events requested an exception to the IACUC policy on Acclimation of Newly Acquired Animals. Since the animals are procured and brought to the farm just for the purposes of judging contests and then immediately removed, the PI felt it would be beneficial to the animals if they did not have to be acquired in advance and have their diets changed. One committee member clarified that the exception was not for quarantine, as the animals will not be housed with those already at the farm. The AV did not have any concerns for this exception as the defined acclimation period is intended to preserve biological data for experimental procedures, which does not apply to this case. A motion to approve the exception was seconded and approved unanimously by the committee.
- e. A member brought up concerns about difficulties obtaining some common veterinary drugs due to manufacturer back order. The AV added that they were having problems obtaining heparin for the same reason. The Chair acknowledged that this may become a serious issue moving forward.
- f. Two members provided information regarding an upcoming across-campus forum on reducing administrative burden in animal research (Oct 7th at LSB, Oct 9th Ag Sciences, Oct 16th HSC 4-5 pm). The three former IACUC Chairs (one currently not on the committee) were tasked by the IO to hold these forums to collect feedback and suggestions from the research community. A short presentation on the changes that have already been made and information from the Committee on Governmental Regulations will be presented.

3. Semiannual Program Review (Fall 2019)

The following sections of the Veterinary Care portion of the Semiannual Program were discussed and deemed acceptable by the IACUC, unless noted otherwise:

- a. Surgery

1. In regards to the item on researchers having appropriate training to ensure good technique, the Chair reminded members to check training records during the upcoming surgical lab inspections.
2. For the item concerning categorizing surgical procedures as minor or major, the Chair pointed out that there is now an updated protocol form appendix (Appendix A- Surgical Procedures) that asks PIs to specify minor/major procedures.
3. For the item regarding effective procedures for monitoring expiration dates on surgery packs, it was noted that a written guideline is needed to provide clear guidance to PIs on how to determine expiration dates.

b. Pain, Distress, Anesthesia, and Analgesia

1. In regards to the item concerning regular review of guidelines for analgesic and anesthetics, it was noted by the AV that the clinical veterinarian has just recently updated the guidelines, and they will be reviewed by the committee. In response to a member's question concerning how reviews of guidelines are documented, the OAW director pointed out that the top header of the policy/guidelines/SOP document shows the version it is and date at which last reviewed.

c. Euthanasia

1. In regards to the item on standardized methods that consider age and species, the AV clarified that for rodents, age consideration is needed for differing acceptable methods for neonates vs adults.
2. For the item on whether euthanasia training considers the psychological stress to personnel, several members as well as the AV (in regards to OLAR staff) commented that only personnel that are comfortable performing euthanasia or a particular method of euthanasia are asked to perform it. The AV also brought up "Compassion Fatigue" and expressed that it may be beneficial to provide OLAR staff and the researchers working with animals an informational session on this topic.

d. Drug Storage and Control – all items were acceptable.

- e. Semi-Annual Inspections**- The IACUC Administrator pointed out that the OLAW Checklist (sent out to committee members prior to the meeting) also contains a Semiannual Facility Inspection Checklist, which is a good resource for inspectors. The Checklist contains links to relevant areas of the Guide and also has a special section on Aquatic Housing and Support Areas that is relevant for those inspectors that will be looking at the zebra/knifefish areas. The Chair mentioned that at his SCAW training, one institution discussed how they have facility managers submit a "dings and dents" report prior to inspections, so brick and mortar types of deficiencies are already recorded, allowing IACUC inspectors to focus on the animal welfare. The Chair suggested this be a discussion point for another meeting, to consider whether the committee would want to implement something similar for future inspections.

5. OLAR Update

- a. The new veterinary technician has been on the job for about a month and has come up to task quickly. She will be the only vet tech on staff during the National AALAS meeting (week of October 14th).
- b. A new husbandry staff member is starting soon as a replacement for a former staff member that has moved up to a research technician position.
- c. A member inquired if there were any problems during the planned power outage that took place in HSC on 9/22/19. The AV reported that the facility manager was present and monitoring the rooms during the outage. The backup power system came online, and no major issues came up, although a humidity increase was noted in the 600 corridor.

6. Occupational Health/Safety Subcommittee Report - The Chemical Safety representative gave the second part of the 2-part presentation on chemotherapy drugs. The main topic was the Safety Review of Chemotherapy Drugs and Other Substances in IACUC Protocols, which touched upon the procedures the Safety Officer uses to review protocols. One point highlighted was that PIs can initiate a service request for EH&S to conduct a “waste determination” for their use of a hazardous substance in animals. For example, this can help determine if the bedding would need to be classified as hazardous and/or may require a special disposal method. Another topic discussed was the information that is requested from PIs if hazards are identified. Such information includes a lab-specific SOP, for which a generic template SOP is provided for the PI to fill out. The SOP is then reviewed by chemical safety, with revisions requested if needed. The current generic SOP form was then presented and explained.

7. Training- Semi Annual Inspections- The IACUC Administrator gave a slide presentation on what to look for during facility inspections, which also covered inspection of surgical areas. The presentation touched on PPE availability & proper use, Occupational Health and emergency contact signage, macroenvironment (temp/humidity, lighting, etc.), microenvironment (condition of cages/pens, access to food & water, proper cage labeling for special treatments, socialization, enrichment, space recommendations), husbandry (proper food storage & bin labeling, species appropriate bedding, testing automatic watering systems, cleaning/sanitation records, proper waste storage, pest control), cage ID cards, review of clinical records, and proper drug storage and checks of expiration dates. For surgical areas, inspectors should examine surgical equipment (anesthesia machines, tools, etc.), view surgical records, and feel free to ask questions about surgical procedures. One member inquired about the non-survival surgery procedure, and it was clarified that instruments need to be clean, but are not required to be sterile.

8. Adverse Events/ Possible Non-Compliances

- a. Potomac State – Two adverse events were recently reported regarding horses at Potomac State. The Chair assigned a team which included the farm clinical veterinarian that traveled to Potomac State to investigate and meet with their new Director of Farm Operations and clinical veterinarian. The first event concerned the death of horse that died of acute respiratory paralysis, the result of an inherited condition called Hyperkalemic Periodic Paralysis Disease (HYPP). The second event was an allegation of horse abuse. The investigators found no signs of abuse in the horses, including the horse in question, and the clinical farm veterinarian found the horses appeared to be in good health. Recommendations included better clinical management of the HYPP horses. Guidance regarding a report was requested to OLAW, and OLAW responded that this was not a reportable incident. The Chair sent letters summarizing the findings of the investigation and the IACUC recommendations to the Potomac State Farm Director, Clinical Veterinarian, and Potomac State's Dean of Academic Affairs and their President . After the investigation, a welfare call came in from a private party that claimed there was an excessive amount of ticks on a horse recently purchased from Potomac State. A Clinical veterinarian examined horses currently at the college's farm and found little to no ticks. The Chair and investigators felt that there may be an underlying personnel issue/vendetta behind some of the unsubstantiated allegations. The AV expressed frustration that she has not been receiving reports from the Davis College clinical veterinarian, despite having requested them, and concern for the lack of individual medical records for the horses. The AV has spoken to the President of the college and has a meeting scheduled.
- b. 16020000686 – An adverse event form was submitted by a PI with a teaching protocol involving conditioning studies in rats. Two rats experienced weight loss and reduced appetite over a three day period where behavioral training was not taking place, which was found to be a result of lack of access to water due to misplaced water bottles. Once corrected, the rats appeared to recover quickly and gain back the weight. A detailed action plan was submitted, and included retraining via written instructions as well as in-person. The IACUC Administrator confirmed that the personnel were following the weight monitoring schedule in the protocol (weights taken on training days only). OLAR staff did not notice the misplacement during their daily checks, and the AV indicated that the oversight has been addressed with the husbandry staff. There was a consensus that this should be reported to OLAW. No further action is requested of the PI at this time.
- c. 1712010982 – An adverse event was reported by a PI on the IACUC annual review form (for USDA-species protocols). The adverse event involved the development of a Grade IV infection and subsequent euthanasia in two sheep that were part of an experimental group. The PI indicated they worked with vet staff to treat the animals once they reached a Grade III infection. The protocol states clear endpoints, with animals euthanized at Grade III; however, the consensus of the committee was that this was not a non-compliance since treatment intervention was a clinical decision of the veterinarian. The committee recommended that the PI amend the protocol to update the defined endpoints to reflect what is actually done in practice, clarify how progression from Grade III to Grade IV is assessed, update the expected morbidity/mortality if needed, and provide details on how these complications will be addressed or prevented in the future (such as change in exposure dose). The members were in agreement that this does not need to be reported to OLAW or the USDA. In addition, since the

animals were receiving analgesics, they remained within their designated pain category (D).

- d. 1602000495- Prior to discussion, two members with a conflict of interest recused themselves. The adverse event occurred during a routine ovariectomy in a ewe and involved the discovery of large masses from a previous unsuccessful pregnancy. With guidance from the clinical veterinarian, the decision was made to euthanize the animal as there was also evidence of a significant uterine infection, confirmed by pathology. The AV felt that the decision to euthanize was an appropriate response for animal welfare reasons. Due to this being a culled ewe, the consensus was that this was an adverse event that could not be anticipated since it was a complication from events occurring prior to arrival that were not detectable by pre-surgery bloodwork (progesterone assay).

9. PAM

- a. To complete an ongoing PAM, the PAM Administrator visited a lab to observe a PI's 30 minute non-surgical procedure with anesthesia in mice. Some concerns noted were related to cleanliness of area, which included cloth drapes and cardboard present in the room, improper heat source for the isoflurane induction box, lack of monitoring records, only gloves used for PPE – no lab coat, and no disinfectants or paper towels available for cleaning equipment after use. Recommendations were to remove or clean drapes and cardboard, use a more appropriate heat source, cleansing of equipment after use, and to maintain monitoring records.
- b. As part of a group of PAM reviews encompassing a group of PIs working in orthopedics, the PAM Administrator observed a euthanasia procedure for one PI working with a USDA-covered species (rabbit). The PAM Administrator noted that the PI and staff are well organized and have well maintained surgical, post-operative, and DEA records. Proper handling and technique in conducting the euthanasia was also noted. Some issues identified were that F-Air canisters on the anesthesia machine had not been weighed, and improper transport of the rabbit between rooms (carried in a towel). Recommendations were to record the weight of the F-Air canister prior to use and to transport the animal in a covered container or carrier. Additional observation will be scheduled for a second PI in this research group at a later date.

There being no further business to discuss, the meeting was adjourned at 2:47 pm.

Action Items

1. Adoption Policy
2. OLAW Letter concerning adverse event on #16020000686.
3. Memo to PI to submit amendment for #1712010982.

**November 6, 2019
Institutional Animal Care and Use Committee
Meeting Minutes**

The meeting was called to order by the Chair in Room 209, at the Office of Research Administration, 886 Chestnut Ridge Road on November 6, 2019 at 12:00 pm.

Attendance:

Members: Chair, 1, 4, 5, 7, 14, 16, 18, 20, 21, 22, 23, 24

Alternates: 114, 25, 26

Absent: Attending Veterinarian, 12

Others: 112, 113, 115, 118, 119

A quorum was present and acting.

Chair's Comments:

1. The Chair will be attending IACUC 201 and 301 in Houston this month.

IACUC Admin Updates:

1. The OAW Director introduced two new OAW staff members: the IACUC Administrative Assistant/Coordinator and new second PAM Administrator who will mainly focus on farms, Davis college, and wildlife, and will also be working on evaluating policies and guidelines on the OAW website.

Old Business:

1. The minutes from the October 2, 2019 meeting were approved unanimously with no changes requested.
2. Action list was reviewed and updated
 - a. Adoption Policy- has gone through WVU Legal and given their blessing. See further discussion below.
 - b. OLAW letter concerning adverse event on #1602000686 – Letter and plan of action was acceptable by OLAW.
 - c. Memo sent to PI to submit amendment on #1712010982- Letter was sent, but at this point there has not been a response, a reminder should be sent to the PI.

New Business:

1. **Updates:**
 - a. The three forums on reducing administrative burden were completed; however, there has yet to be a debriefing regarding the outcomes. One of the committee members tasked by the IO to head the forums reported that next steps have yet to be determined but hopes to have a discussion ready for the December meeting. The Chair will be updated.

2. Protocols / Amendments Review

- a. No protocols or amendments to review this month.

3. Discussion:

- a. Adoption Policy- Policy has gone through WVU legal and has been given their endorsement. The final policy needs to go out for comments for thirty days to faculty/PIs with IACUC protocols. Committee input included a request to put the policy on IACUC letterhead. Members expressed concern about the policy creating an issue with agricultural animals by dictating adoption over other final disposition options, such as market sale. The suggested resolution was to make a minor adjustment to the language, changing “authorizes” to “permits”, making it less authoritative.
- b. Anesthesia and Analgesia in Mice and Rats Policy - Two current mice and rats policies were updated and consolidated by the clinical veterinarian. It was suggested by a committee member to make it a guideline rather than a policy. The OAW Director confirmed that is a guideline and noted that if a PI would want to make changes to his/her protocol within these guidelines, it can go through VVC. Exceptions to the guideline would be approved through protocol review and assessed on an individual basis. A motion was made to vote to approve new guideline, seconded, and approved unanimously. The next step is to update the OAW website to make it accessible to PI’s.
- c. Occupational Health Program- The Chair had a discussion with the Director of Occupational Medicine regarding access to protocols and current representation on the committee. Discussion included the option to have an Occ Health representative be able to phone into the IACUC meeting when needed to discuss Occ Health relevant issues or a specific protocol. The committee had no objections to having an Occ Health representative call in when requested by the committee.

Also discussed were issues with the OHQ questionnaire automatically not clearing individuals who have any animal exposure and allergies. This leads to a mandatory review, even for those who are renewing their OHQ with no changes since last being cleared. The Chair asked if it would be possible to have the questionnaire show what was entered the previous year and have the option to indicate no changes, so the individual would automatically be reapproved for the current year. The Director of OM indicated this was possible, but it was noted that former Chairs made similar requests with no results. The committee understands that the Occ Health group will address the issue within their group and with IT to assess the possibility of the renewal change. However, it was pointed out that this may not help with first time students who need to take the questionnaire for classes. One member detailed the issue with students working with sheep getting automatically rejected, requiring the student to call to get clearance. Requests have been made in the past to change the questionnaire to make it different for PI’s and students. The OAW Director pointed out that there is no OSHA requirement for the OHQ to be reviewed annually and therefore has advocated (along with the former Chairs) for having it valid for 3-years, similar to CITI training or when an individual changes employment tasks.

The next question discussed was how the committee can make it easier for Occ Med to figure out exposure when the individual is not conscious or able to describe the exposure event. Occ Health has previously requested access to all protocols, but this creates confidentiality issues. One possibility was to make appendix C's and appendix I's accessible, but problems expressed by committee were how to tie to individuals to the proper protocol when they are not the PI, and with multiple hazard items on the appendices, how would one know what the exposure was. Is it helpful or practical to create a way to communicate possible exposures without making full protocols available and keeping information up to date with amendments and personnel additions?

Finally, the committee discussed whether there is a way to do remote Occ Health testing for all off campus locations that are a significant distance from Morgantown. Options included sending Occ Health staff to those locations to conduct testing or having local clinics near the remote sites to conduct testing. Sending staff would be best since the clinics may not have the trained staff to conduct specialized testing, such as an audiologist. The Chair proposed to provide a list of the facilities and the number of people who need testing and having Occ health staff go to locations to conduct necessary testing. Notification to managers would need to be made to ensure attendance during these on-site testing visits.

4. Semiannual Program Review:

The following sections of the Semiannual Program were discussed and deemed acceptable by the IACUC, unless noted otherwise:

- a. Personnel Qualifications and Training
 - 1. Regarding "Continuing education for program and research staff provided to ensure high quality care and reinforce training:"- The clinical veterinarian noted that OLAR offers twice a month training for research personnel and also per request, citing a recent example of a lab that is scheduled for aseptic surgery training. There is a special email address (olartraining@hsc.wvu.edu) where this training can be requested via email. However, this item was deemed a Minor Deficiency based on possible lack of continuing education availability at the FARF and farms. It was noted that the FARF is under the purview of OLAR now, so CE would be provided via OLAR. For the farms, historically training came from farm manager and the previous clinical veterinarian. The new clinical farm veterinarian has started some informal training. There was a discussion on Quality Assurance Training offered by external organizations such as the National Cattleman's Beef Association, but it is unknown if these are utilized currently.
- b. Occupational Health and Safety of Personnel
 - 1. "Program for medical evaluation and preventive medicine for personnel includes: pre-employment evaluation including health history:" After referring to the Guide and discussing confidentiality and HIPPA issues with asking health history questions prior to employment, this item was deemed Not Applicable.
- c. Personnel security
 - 1. In regards to "Preventive measures in place include pre-employment screening, and physical and IT security", members deemed the item acceptable but did note that

background checks would not cover whether an individual was involved in an animal rights organization.

d. Revisited items previously marked as minor deficiencies in current review and previous Spring 2019 program review:

1. Under spring review under IACUC Protocol Review: Major versus minor Surgical procedure evaluation was deemed a minor deficiency and is now acceptable since Appendix A- Surgical Procedures was updated to make a clear designation and identification of major vs minor surgeries.
2. From current review under IACUC Records and Reporting Requirements: A minor deficiency was identified for “Includes a plan and schedule of each deficiency identified”. Discussion was about how some of the responses from responsible parties in the inspections did not have action plans, but rather requested more information regarding the deficiency.
3. From current review under Veterinary Care -Animal Procurement and Transportation/Preventive Medicine: A minor deficiency was noted regarding “movement of animals as planned to minimize transit time and deliveries are planned ensuring personnel are available”. The deficiency was related to an issue at the farm. Since the deficiency was noted, a new SOP that only allows calves to be brought in on Monday, Tuesday or Wednesday, avoiding holiday weekends and ensuring enough staff is available and the veterinarian has time to treat if an animal is ill.
4. From current review also under Veterinary Care – Animal Procurement: “Quarantine animals from different shipments are handled separately or physically separated” was acceptable because there is a policy in place. For the farms, there are approved exceptions to the policy such as for animals arriving for performance tests.
5. From spring review under Veterinary Care- Surgery: There was a minor deficiency for “effective procedures for sterilizing instruments and monitoring expiration dates on sterile packs are in place”. A guideline is being developed by OLAR for standardized dates for sterilized packs. However, it was noted that reputable sources are varied as to how to determine expiration dates, so they are looking at WVU hospital’s policy to determine what source to follow. Vet techs currently routinely go through all the OLAR rooms, and if they find any kind of expiration date past due, they contact the PI.
6. From spring review under Veterinary Care- Drug Storage and Control: A minor deficiency was marked for “procedures are in place to ensure analgesics and anesthetics are used within date”. Past discussion was centered around mixed drugs or dilutions. It was confirmed that OLAR is working on a guideline for how to determine the best way to regulate expiration dates, taking into consideration the limits on the efficacy of drugs after being diluted or mixed.

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

- a. Several members of OLAR vet and husbandry staff attended the AALAS national meeting last month and presented one paper and one poster presentation. The paper looked at humidity and temperature monitoring across multiple different cages and tested ranges in an IVC rack versus a static rack. The poster concerned behavioral training in undomesticated pigeons.
- b. Personnel: A new animal health technologist came on board last month. AALAS certification test preparations are ongoing for about 5 of the current animal health techs. Three technicians have submitted paperwork to take the LAT and ALAT exams.
- c. Working on two policies: the multiple use vials and drug mixtures and one on sterilized pack shelf life.
- d. Compassion fatigue: Possibility of a presentation at one of the branch meetings of AALAS.
- e. Since the new AVMA is being published soon, OLAR may consider making changes to procedures for euthanasia with CO2 among others. Protocols will not need amended as the IACUC can make a statement to cover all the protocols using CO2.

6. IACUC training

- a. The IACUC Administrator gave a slide presentation on “Avoiding the pitfalls of an inadequate Semi-Annual Review” which includes a program review, facility inspection and a review of animal care and use “activities” that might not be otherwise addressed in program review or inspections. The first component is covered by the committee’s review of the OLAW checklist. For the second component, facility inspections, the IACUC needs to ensure all facilities are included in the inspection, which encompasses the facility, surgical areas and satellites. The ultimate goal is to improve the animal care and use program and get honest feedback by investing the time to educate staff/personnel on the purpose of inspections, using a non-confrontational approach. The third component should include things such as routine laboratory inspections and the current list of exceptions to the guide and institutional policies. The committee should participate to prevent the same people doing the same tasks. Also, there should be follow up on deficiencies, addressed currently by the ability to see previous inspection deficiencies during inspections (via ALFI program). Additional follow up can be conducted by OAW staff. Finally, it is important to look at trends, to address deficiencies being repeated over several cycles, etc. Discussion following the presentation included comments on how to train/educate PIs to better distinguish between semiannual inspections versus PAM reviews as the PAM’s are not “inspections” and are meant to be non-punitive. Suggestions included clearer language in emails and clear objectives of PAM’s. Basically, it will take time for PI’s to get used to PAM’s versus inspections.

7. Adverse events/ Possible non- compliances

- a. 1602000280- A cow was found deceased in the pasture, which upon veterinarian examination appeared to be due to a ventral mammary laceration that resulted in significant blood loss. It was mentioned that the field had been recently brush-hogged, and a small, young tree trunk with rough edge was discovered, which may have been one potential cause of the laceration.

The completed action plan in the report involved moving the cows to a different pasture. The committee consensus was that this was an unfortunate and unavoidable accident and was not a reportable event to OLAW.

- b. 1602000495- Two committee members recused themselves from the discussion due to a conflict of interest. The reported adverse event involved a neurosurgery procedure in which unexpected head movement during an intra-brain drug injection caused subsequent shifting of the drug cannula, resulting in brain inflammation which complicated the ewe's recovery after the procedure. The clinical veterinarian was consulted, and the ewe's condition stabilized after receiving the recommended treatments. The committee requested that the clinical veterinarian work with the PI to help update adverse event form to clarify the language in the report and was subsequently tabled for further discussion at the next IACUC meeting.
- c. 1608003713- The PI reported a higher than expected mortality from TBI surgeries being done by a student in training. The PI took over remaining surgeries, and the submitted action plan involved continued, additional training with the student on pilot animals, as it is the only way to gain experience on managing the brain bleeding risk that only occurs in live surgeries. The committee's recommendations were to consider amending the protocol to increase mortality rate during training and to clarify how additional practice animals would be procured. The committee determined that this was not a reportable event to OLAW.

8. PAM

- a. The PAM Administrator completed an Orthopedics visit on October 17th. The PI is taking a brief hiatus from animal work (until Spring 2020), but the PAM Administrator did a review of surgical records, training records, and DEA records. All records are up to date and look good. The laboratory staff had a lot of questions regarding the Non-Pharmaceutical policy, which was reviewed with them during the visit. They also had questions regarding the policy for care of rodents undergoing survival surgery, and this was discussed during the visit and the policy was sent to them.

There being no further business to discuss, meeting was adjourned at 2:27 pm.

Action Items:

- 1. Send reminder to PI to submit amendment on #1712010982.
- 2. Adverse event tabled for #1602000495: continued discussion pending revision of reporting form.
- 3. Chair will follow-up on request for changes to Occ Health questionnaire information and procedure.
- 4. Request a list of off-site locations and their personnel that need testing for Occ Health.
- 5. Send Adoption Policy out for 30-day comment to the PIs.
- 6. Update OAW website with new Anesthesia and Analgesia in Mice and Rats Guideline.
- 7. A new Guideline for standardized expiration dates on sterile packs will be submitted by OLAR.
- 8. A new Guideline to determine expiration dates/ efficaciousness on drugs, particularly dilutions and mixed drugs will be submitted by OLAR.

**December 4, 2019
Institutional Animal Care and Use Committee
Meeting Minutes**

The meeting was called to order by the Chair in Room 209, at the Office of Research Administration, 886 Chestnut Ridge Road on December 4, 2019 at 12:00 pm.

Attendance:

Members: Chair, Attending Veterinarian, 4, 5, 7, 9, 12, 16, 18, 20, 22, 23

Alternates: 114, 25, 26

Absent: 1, 21

Others: 112, 113, 115, 116, 118, 119

A quorum was present and acting.

Chair's Comments:

1. The Associate Vice President for Research Administration made an announcement regarding a change in OAW Directors. The new OAW Director will start on January 13, 2020. The current director will stay on in a consulting role to assist with continuing development of the Kualii animal module, ALFI, and OAW website.
2. Due to the New Year Holiday, the committee agreed to move the next IACUC meeting from January 1st to the 8th.
3. The IO's committee working on reducing regulatory burden for the Animal Care and Use program has been invited to the January 2020 meeting to present the forum results and request further information/input from the committee. The IO's committee will then prepare a report of their recommendations to the IO.
4. The IACUC Post Approval Monitoring staff have been enlisted to review and update procedures, policies, guidelines and SOPs to bring them all up to date and consistent in style. Specific committee members will be assigned as reviewers for scientific, veterinary or safety input. Once updated they will be presented to the full committee for review.
5. One clinical veterinarian has left the university and therefore will no longer be serving on committee.

IACUC Admin Updates:

1. There were no IACUC Administrative updates for this meeting.

Old Business:

1. The minutes from the November 6, 2019 meeting were approved with no changes requested. Three members abstained.
2. The action item list was reviewed and updated.
 - a. A reminder was sent to the PI on protocol #1712010982 to submit an amendment to address an

unexpected outcome reported on their annual review form. The lab manager expressed they will submit an amendment but are waiting, as they will not be performing further surgeries on animals until spring or summer and are taking that time to analyze the data already collected. The PI will submit an amendment once they have more information.

- b. The Chair contacted Occ Health with an email, stating there was no need for their participation (via phone) in today's meeting and also reiterating a list of requests made to Occ Health. As of yet, no response has been received.
- c. The committee has requested offsite locations and personnel to conduct Occ Health testing for personnel working in locations far from the main campus.
- d. The adoption policy was sent out to PIs for review and no comments have been returned thus far. Once the 30-day review period has passed, the policy will be posted on the OAW website.
- e. Guidelines for expiration of sterile packs ("WVU IACUC Sterile Pack Policy") was submitted by OLAR and sent to the committee for review.
- f. Guidelines for expiration dates of mixed drugs has also been submitted for committee review.

New business:

1. Protocols for Review

- a. Protocol #1910030520 was initially reviewed as a DMR, however, the reviewers requested that the protocol be discussed at the full committee due to a possible category E designation for a surgical procedure involving intracoelomic telemetry implants in fish, which utilizes electro-sedation rather than anesthetics/analgesics since the fish will be released back into the field shortly after the procedure and are potential sources of human consumption. The committee discussed possible general/local anesthetics and analgesic alternatives that could potentially be utilized in the field. The importance of FDA-approval of drugs used in fish for human consumption was noted by the PI in the protocol and reiterated by one of the members during the discussion. A motion was made, seconded, and approved to return the protocol to DMR if it can be amended to include an anesthetic and/or analgesic that would justify it as a category D rather than category E. The consensus was that the committee cannot evaluate the protocol as a Category E at this time until all options for anesthetics/analgesics are explored by the PI, with justification provided as to why none can be used. The committee's review comments will be provided to the PI to guide the amendment of the protocol for further review.

2. Discussion Items

- a. The Sterile Pack Policy was reviewed by the committee. Based on the available evidence, the policy will allow for polyethylene wrapped packs to have two year expiration dates and cloth wrapped packs to have expiration dates of one year. Requested changes included addition of information about the use of sterilization indicators, clarification that cloth wrapped items are only considered sterile if the wrap is undamaged, and a typo correction. All edits and clarifications suggested by the committee were made to the policy. The policy will now go out to animal research PIs for a 30-day review.

3. Semiannual Program Review (Fall 2019)

a. Facility Inspections: The inspection report in ALFI was reviewed by the committee, with a focus on repeat deficiencies and new deficiencies. It was noted that there were no significant deficiencies reported, only minor. Discussion ensued regarding whether some deficiencies should be removed since they are outside the realm of animal care. Examples included re-capped needles in Sharps (which is not considered good practice but allowed if proper technique used) and other EH&S issues like trash in Sharps, improper storage of items in the flammable cabinet, and incorrect labeling of chemical containers. The Chair stressed that Occupational Health and Safety is part of the program review, and it was noted that the deficiency list that is currently in the ALFI inspection software was previously approved by the committee. A subcommittee is currently working on updating the list and timelines for correction, which will then be presented to the whole committee to review and approve. The Chair expressed that a reasonable approach is to leave those deficiencies in the current report, with the understanding that the list will be updated for the next round of semiannual inspections. For one of the repeat deficiencies concerning a missing outlet cover, there was a discussion regarding whether a PI or OLAR is responsible for room/structural deficiencies (i.e. missing outlet cover, hole in ceiling) if the PI's lab space is within the vivarium. The OLAR Director confirmed that the PI's can request work orders without going through OLAR. For a repeat deficiency concerning inadequate record keeping, the Responsible Party response was unclear as to how the issue was addressed, and it was noted that a follow-up is therefore needed. Under the facility-wide comment section of the report, the OAW director pointed out the comment concerning an eyewash/shower station in the FARF with brown water despite regular flushing, as this is a health and safety concern. Further discussion ensued concerning other eyewash stations that have not been fixed, despite work order submissions. The Chair stressed that these repeated issues will be brought to the attention of the IO.

b. Surgical Inspections: Only two minor deficiencies were reported, one of which concerned the lack of access to a hard copy of a protocol, although an electronic version was accessible. It was clarified that this is not a deficiency as the requirement is that the protocol is available, regardless of the format. The deficiency will be removed from the report.

c. Program Review Summary- The summary of the Semiannual Program Review, compiled from committee discussions guided by the OLAW Checklist across the past five meetings, was presented. The committee requested a typo correction and had no other comments or corrections.

d. Exceptions List – The Exceptions list, which includes currently active exceptions to the Guide and exceptions to WVU Policies/Guidelines, was presented. The committee requested an abbreviation be spelled out, and had no additional comments or corrections.

e. The AV requested that her minority view (that heartbeat rather than respiration should be used to verify death for euthanasia via exsanguination on protocols #1602000495 and 1602000317) be included in the Semiannual Report).

4. OLAR Update

- a.** An OLAR veterinary technician presented the new OLAR website that she developed to the committee, covering the flow of the website, which includes tabs for Training & Education (includes Training videos, drug formulary, etc), online Forms (with upload ability to submit to OLAR, which

requires SOLE access), Services & Rates, Animal Import/Export, FAQs, and Contact info. The committee requests included having the option to submit forms without using SOLE, clarifying FAQs for new personnel, and making some items facility-specific to avoid confusion.

- b. The AV reiterated that one of the clinical veterinarians has left OLAR and will be returning to small animal practice. A search for another clinical veterinarian is ongoing.

5. Occupational Health/Safety Subcommittee Report –

- a. Regarding the IACUC requests for Occupational Health Questionnaire changes, including the request to have it completed every three years rather than annually, the response from Occ Med was that the department did not have the funding to make updates to the OHQ questionnaire. A member of the reducing burden committee mentioned that the OHQ changes will probably be one of their recommendations for reducing burden, which may lead to the availability of funds to make those changes.
- b. Occ Med are in favor of the plan for the IACUC Committee to notify Occ Med if there is a need for meeting attendance by a representative via phone. Occ Med also inquired whether they can gain access to protocols if they sign a nondisclosure agreement. Several members of the committee stated the access to the IACUC protocols would not help the medical staff directly as there may be multiple agents and drugs on any given protocol. Other methods should be considered.
- c. The Biosafety Officer reported some recent incidents involving OLAR staff getting needle sticks when collecting biohazard bags in the ABSL-2 hallway. Several small group meetings were arranged with research personnel working in this hallway to go over proper needle disposal in Sharps containers. In addition, OLAR husbandry staff will no longer be collecting the biohazard bags since they would not be able to identify what they are exposed to as these areas are used by multiple PIs with multiple protocols. Part of the corridor will be taped off and designated a biohazard area so that staff can go between housing and procedure rooms without changing PPE.

6. Adverse Events/ Possible Non-Compliances

Two committee members recused themselves from the discussion due to a conflict of interest.

- a. The Adverse Event Form for protocol #160200049, previously discussed at the last meeting, was revisited by the committee. The PI submitted a revised form with help from the clinical veterinarian, which was accepted by the committee. The consensus was that the event did not need to be reported to OLAW. The AV expressed Occupational Health and Safety-related concerns about the surgery table being used by the PI. EH&S is already looking into improvements that can be made.
- b. A new adverse event recently reported on the same protocol was then reviewed by the committee. The adverse event concerned an animal that received a control treatment during a neurosurgery. Twelve days post-surgery, the animal had issues standing which progressively got worse despite treatments given in consultation with the clinical veterinarian, resulting in the eventual decision to euthanize the animal. The PI reported that other animals from this vendor had leg issues, albeit not as severe, and he will not be using the vendor in the future. One lay committee member expressed concern that vendors are allowing animals that are more appropriate for agricultural purposes to be sold for biomedical research. Other members, including the clinical farm veterinarian, stressed that these were “culled” sheep, sold because they were deemed unproductive by their owner, and that

“vendor” is not really the appropriate word for the source of the sheep. The AV confirmed that there is no OLAR-approved vendor/source list for sheep procurement. The committee deemed this was an unavoidable event and not reportable to OLAW.

7. PAM

- a. The new PAM Administrator conducted a PAM for a PI in FARF. She reviewed records, training documentation, and SOPs, which showed everything was in order and up to date. The PI and his senior graduate student were reminded to review their documents periodically, including posted contact information. It was discussed if there are ways to expedite students’ training for classes. Also, the PAM Admin reviewed the PI’s protocols and discussed amending some protocols (upon renewal) to provide more details on health assessments and create consistency in method of euthanasia to ensure compliance across all protocols. For one protocol, a room used for the final processing of the animals is not currently on the protocol and is not currently on the inspection list. This is being remedied. It was recommended that an SOP be created for the processing procedure, as it is only verbally conveyed to students. It was also recommended that the anesthesia machine be serviced prior to resuming surgeries conducted under a different protocol, and the PI was provided with information on surgical instrument services (cleaning/sharpening) and use of a hot bead sterilizer for batch surgeries.
- b. There was a PAM conducted for a PI’s protocol who has both a research and teaching protocol conducting behavioral experiments with rodents. Graduate students assist with research and the laboratory portion of the class, and undergraduates taking the class are trained by the PI on animal research ethics, PPE and animal handling. All record keeping is up to date and complete. The PAM Admin provided the PI with updated signage and training documents. For cases when students need additional training to get comfortable with handling animals, the PAM Admin recommended that OLAR be contacted to schedule additional animal handling training. The AV stated there is a video for students working with animals in a classroom setting in Life Sciences that should be available, and a contact for this video was provided to the PAM Admin for follow up.
- c. A second PAM was conducted for another PI. The laboratory is in a level 2 containment area as it involves tick research, and the PAM Admin and PI discussed logistics of animal transport. The PI’s other protocol involves the use of Rickettsia, which takes place in the high containment area (HCA) in HSC. Animal records, including animal health scoring records, for those studies are stored in the HCA. Personnel records were accessible and up to date, and training forms were provided per the PI’s request. The PI also made a request for guidance on record retention and a follow up will be made.

There being no further business to discuss, the meeting was adjourned at 2:35 pm.

Action Items

1. Post Adoption Policy on website once 30-day review period passed.
2. Multi-Dose and Mixed Substance Labeling, Use, and Expiration Dates Policy to be reviewed at next meeting
3. Send Sterile Pack Policy out for 30-day comment period.
4. Semiannual inspection report list of follow ups.