

SUBJECT: Animal Care and Use Program Review for Washington State University

DATES: August 31- September 1, 2016

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Introduction

We were commissioned by WSU to evaluate the animal care and use program of the university to perform the following functions:

Assess investigator /animal care staff knowledge and understanding of University requirements and expectations for animal care and use compliance

Assess oversight systems designed to ensure compliance and expectations

Identify challenges or barriers inhibiting compliant research

Recommend best practices for continuous improvement of the animal use program

Develop management plan and recommend resources to implement best practices

Our evaluation included interviews of the senior leadership, faculty, veterinarians, research lab managers & technical staff, graduate students and animal care managers & staff in the College of Veterinary Medicine (CVM), College of Agriculture, Human and Natural Resource Sciences (CAHNRS), College of Arts and Sciences (CAS) and the College of Medicine, Nursing and Pharmacy in Spokane. We visited and reviewed representative areas of the vivaria in the respective departments. We also met with members of the IACUC and Office of the Campus Veterinarian (OCV). These discussions took place in groups and one-on-one sessions, as necessary. We intentionally did not review the grizzly bear program since we felt it had been inspected and reviewed thoroughly due to the recent USDA inspections. The previous AAALAC program description, the recently implemented animal health database and various IACUC policies were also available for review.

Visit Logistics

Dr Keane and Mr. Kluzik coordinated the schedule and meeting times for the respective Colleges and provided transportation between the respective areas. Time was allotted after each faculty meeting to tour facilities, labs and to talk with staff and animal care managers and personnel. One member of the team travelled to Spokane to perform the review and interviews at the Colleges of Medicine, Nursing and Pharmacy. Working lunches on both days included video teleconferences with personnel in Spokane to discuss IACUC and OCV programs. Time was allotted on the second day for one-on-one discussions with personnel that requested it. Approximately 6 people requested one-on-one meetings either because

they could not make the initial meetings or had additional information that they wished to express. At the end of the second day of the visit, the team presented preliminary findings in a PowerPoint format.

General Comments

The animal care and use program is well run and is generally in compliance with all applicable laws and regulations. As with any large University, there are areas which could be improved, but WSU has a good animal care and use program which is supported by the recent AAALAC accreditation and multiple USDA inspections in past years. The research faculty and staff and animal facility managers and animal care staff we interviewed were open, honest and dedicated to staying in compliance. They were frustrated with some aspects of the program, especially the IACUC processes, that will be discussed below but a culture of compliance was evident across the campus. Across all colleges, there was good rapport and communication with the Office of the Campus Veterinarian (OCV) and excellent usage of the animal health database to keep the OCV informed of animal health issues. The findings and recommendations will be discussed as bullet points below in large thematic areas. We refrained from identifying individual labs, colleges or individuals and based findings and recommendations on the overall programmatic evaluations.

IACUC Function

- Improve protocol and amendment review process to speed up approvals and promote a culture of compliance.
 - Across the Colleges there was frustration in the Animal Use Protocol (AUP) approval process from taking too long (i.e., months) to approve protocols and amendments. Many faculty across departments and colleges described receiving inconsistent answers to questions depending on who in the administration they asked (OCV vs ORA) for guidance. They appreciated how overworked and short staffed the ORA office was but felt in general that the veterinarians gave more useful information which was often inconsistent with ORA guidance resulting in further delays.
 - Across the Colleges, many research faculty described a scenario where ORA referred them to a web site to find their most current approved protocol only to find that the protocol was not the most current version. They were first made aware that they started with an outdated protocol when it was rejected by ORA after spending time on modifications or renewal application. They were frustrated about their wasted time and the need to start over again. Many have stopped looking on the web site for their protocol and surrendered to just calling the ORA requesting an e-mail providing the most current version as an attachment.
 - Across the Colleges, many research faculty perceived that ORA office was inconsistently responsive depending upon office staff vacations and seasonal schedules contributing to rate limiting steps in all ORA activities.
 - According to research faculty, the amendment process seems to be overly cumbersome without a good way to identify what has been changed in the protocol. This leads to additional work for the reviewers and increased scrutiny (re-review) of the protocols after original approval. Investigators are also unclear on what types of changes are required to be reported to the IACUC and/or to funding agencies and which changes may indeed be

reviewed administratively by ORA. Investigators also do not understand when a new reviewer receives a modified or amended protocol proposal, that he or she has the opportunity to review the entire protocol possibly bringing up new questions related or unrelated to the modification/amendment. The amendment or modification process takes several weeks per research faculty leading to frustration and the likelihood of moving forward with a protocol modification without IACUC approval.

- It is our understanding that a new IACUC protocol form and approval process are under development that will help to correct the problem of delayed approvals. Research faculty indicated value in implementing a standardized electronic submission and review of research proposals.
 - The IACUC should keep PIs informed of the progress of this project and get input from them on how it will work from their end.
 - Identify changes made in amendment process to speed review and avoid total re-review of the entire approved protocol.
 - The addition or deletion of personnel, other than a change in PI, should be done quickly by administrative approval to minimize the lag time between addition of new personnel and approval.
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- Educate PIs on reporting requirements to outside agencies (i.e., OLAW). A reporting noncompliance policy has been approved by the IACUC and sent to investigators, but this information would be better handled by “town hall” type meetings to explain why it is being done.
 - Increase staffing in ORA. Some of the bottleneck and problems with compliance deal with an understaffing of the ORA promoting the temptation for research faculty to perform unapproved procedures (especially gathering pilot data) rather than wait for a “prolonged” IACUC approval. A time in motion study and an analysis of the number of personnel, responsibilities and titles should be performed to identify gaps in staffing and bottlenecks to AUP review.
 - The ORA needs to develop a culture and reputation as a helpful entity rather than an impediment. The ORA needs to develop an identity that it is not the “IACUC”. We routinely heard investigators refer to the ORA as the IACUC. Investigators need to understand the distinction between the administrative support office and the decision making body.
 - The ORA and OCV need to educate the investigators as to the function and use of the Veterinary Verification and Consultation (VVC) process which will help speed up approval of minor changes to the AUPs using IACUC pre-approved formularies, SOPs and references.
 - According to many research faculty across Colleges, tracking the progress of a submitted protocol or amendment is very difficult once it is assigned to a reviewer. The ORA should develop a protocol tracking process within the review process in order to:
 - Identify members who take a long time to review and re-assign protocols after a set number of days.
 - Identify research faculty who cause delays in their protocol approval due to prolonged duration responding to reviewers’ questions. Principal Investigators must understand

their responsibilities in submitting timely responses to reviewers' questions so as not to contribute to delays in approval of their proposals..

- Determine a reasonable time frame from submission to approval. For example, how much time will you allot for initial processing of a protocol in the ORA office? How many days will you allow reviewers to review the protocol and return comments? How many days does the ORA have to return a letter to the PI with comments? Identifying these metrics will help determine what is a reasonable time to get a protocol approved. This information must be provided to the investigators in order to manage expectations and for them to plan for future studies.
- Develop training for *new* faculty on the protocol approval process. This will help take the mystery out of how to submit a protocol for the first time. Many faculty indicated the value in the OCV or ORA or IACUC working pro-actively especially with new PIs at the “front end” of protocol development. The faculty found great value in “pre-review” of their protocol, especially by the veterinarians to identify low hanging fruit or frequently found obstacles for more trouble-free protocol approval.
- Update and improve website. The website was a major problem with all investigators. It is not user friendly and it is very difficult to find information including the most recently approved protocol or the personnel training requirements.
- Researchers indicated a need for a better way to track IACUC protocol approved animal numbers used annually, be they feedlot cattle or breeding mice. If PIs are asking for this, it seems they see it as complicated and a potential risk for noncompliance.
- According to many faculty across Colleges, too many “global list-serve” e-mails are sent out by the ORA (over 300 per year?) resulting in low interest in opening and reading. This may lead to noncompliance especially if changes in program expectations are communicated by e-mail.
- Several veterinary research faculty indicated frustration with, in their mind, irrelevant training especially in areas like aseptic technique if for example, they are a board certified surgeon. Alternate routes to meeting training requirements may include specialty certifications with surgical and clinical appointments in the veterinary school.
- Decrease inconsistencies in replies to PIs. Many investigators complained about receiving different answers to the same questions based on who they asked.
 - OCV, ORA and IACUC chair should meet on a regular basis to discuss issues and insure they are consistent in their approaches to questions.
 - The ORA should delegate questions to specific individuals (i.e., veterinary questions go to the AV, science questions to the Chair, hazardous substance questions to IBC, IACUC process & policy questions go to??).
 - Develop policies to answer FAQs so the ORA can handle many queries efficiently and consistently regardless who answers the phone.
- Perform protocol reviews while training is being completed. The current practice of holding up protocol review until training is completed, delays the approval process. The ORA should review

this policy and determine if the two processes can be done simultaneously. The final approval letter should not be sent out until all the training is accomplished, but the training could be performed while the protocol is under review.

- Research faculty indicated frustration with receiving mixed, unclear or inconsistent direction on formally enrolling students participating in IACUC approved teaching protocols (e.g., 200 students in Introductory Animal Science courses) specific to training & occupational health requirements. Possibly standardizing all veterinary and animal science students' occupational health program at entry to the University across all WSU species encountered in teaching protocols and delegating training to the instructors would simplify the process.
- Some research faculty perceived a lack of Agricultural Animal relevance specific to the IACUC proposal and IACUC membership. They perceived the protocol and reviewer questions were more mouse-centric and not applicable to agricultural animals. Possibly the IACUC should have primarily the IACUC members with agricultural expertise review AG protocols as well as build relationships with this users' group.
- Link approval of the animal use protocol with approval by an EH&S Specialist or appropriate committee screening hazards and making recommendations for safely working with infectious, chemical or physical (radiation) hazards. The current practice of protocol approval without EH&S Specialist approval is problematic. If a protocol using a hazard or biohazard is approved by the IACUC but has not been approved by the Specialist or the appropriate oversight body, the IACUC is essentially providing conditional approval of a protocol which is against OLAW requirements. Hypothetically, under the current process an investigator could start work on a protocol prior to obtaining EH&S approval.
- Across all of the Colleges' animal facilities, the managers described the common scenario where research faculty would dose an animal with a hazard, write an unintelligible acronym on the cage card and not tell the manager that hazards were present. Faculty are not following the institutional requirement of contacting the facility manager well in advance of dosing animals with hazards.
 - Faculty must be retrained on this requirement given animal care staff's legal right to know when they are exposed to hazards. In addition to meeting with faculty well in advance of dosing animals, the written guidance on how specifically animal care staff should work safely with hazard-dosed animals, their carcasses, cages and bedding already distributed to PIs at IACUC approval should also be sent directly to the facility managers for training their staff.
- Many research faculty believed that the ORA Office was understaffed – which is true. Washington State University should benchmark with other institutions of similar size and scope.

Post-Approval Review/Monitoring (PAR)

- Most PIs were complimentary of the review process and felt it helped them identify inconsistencies/drift between their protocol and what was happening in the lab and found it to be a “straight forward” and constructive process especially when planned in advance.
- Research faculty were confused on who (OCV, ORA, IACUC) does post approval monitoring. This role typically resides at other institutions in the IACUC office with the Post Approval Monitoring staff reporting directly to the IACUC or IO.

- While almost all interviewed were complimentary of the PAR staff member, some encouraged the program to have more staff trained and experienced with agricultural animals.
- Some research faculty found value in sharing their approved research protocol with all laboratory staff as one of their best post-approval means of ensuring compliance. Some labs require staff members “sign off” that they have indeed read and understand the research protocol as an effective tool in assuring compliance. This best practice should be standardized.
- Animal facility managers across all colleges wanted better access to all approved research protocols in their vivarium to promote compliance, be aware of modifications and heighten awareness of protocol activities impacting the animals and staff (e.g., hazards to potential adverse effects).
- Several long-term, research lab managers appeared disgruntled with the “intrusion” of post-approval monitoring singing the praises of a previous post-approval monitoring program which was “friendlier” but also apparently not effective at changing poor lab practices or addressing chronic, non-compliant activities which became apparent after further discussion.
- It is a difficult job to develop working rapport with the PIs and not be seen as police or just another inspection. According to some PIs, this perception is alleviated when the PAR person explains the purpose of the visits at the start. Also, encouraging research staff found in non-compliance during a lab visit to “self-report” to the IACUC impresses the IACUC and also helps the PAR staff be more helpful and collaborative than appear adversarial.
- The current PAR process is performed within 90 days of approval, however with a protocol that is approved for 3 years, performing them at a later date as well would help identify drift that may happen over time. Research staff indicated value in both early and repeated PAR visits.
- A process to identify “high risk” protocols that need to undergo post approval monitoring would be important as well as identifying a metric to achieve (i.e., 10% of the protocols reviewed each year).

Animal Care/Office of the Attending Veterinarian

- All research faculty interviewed described very positive experiences approaching the veterinary staff for problem solving across many areas but felt the ORA/IACUC office was not supportive. “Be careful who you call” claimed one PI. Select researchers’ negative impressions of the ORA Office may be changed if the ORA Office discusses successful problem solving approaches and guidance offered by the OCV given researchers’ apparently positive experiences with OCV.
- Animal Facility managers indicated value and an interest in having veterinarians visit their facilities more often for building relationships and enhanced, direct oversight.
- Research lab staff enjoyed “hands-on” training by the OCV and would welcome much more additional training opportunities, especially with new hires.
- While all staff interviewed were highly complimentary of the OCV, there were a few recommendations that the OCV staff should rely more on the Vet Teaching Hospital clinicians for treating the agricultural animals, especially for emergencies.

- Confusion was demonstrated as to why the change occurred in Attending Veterinarian and if this was permanent. While the OCV staff all appeared incredibly collegial and collaborative, this may need to be discussed individually with each or all OCV members together for long-term team building and sustainability.
- Review the tasks performed by the OCV and ORA. It appears that over a period of time, due to staffing shortages, the OCV has assumed roles that are more suited to the ORA. Specifically, the online IACUC required training is managed and tracked by the OCV. This function is traditionally part of the ORA. The PAR program is currently under the OCV. Depending on the focus and intent of the program, we have seen it under the ORA or the OCV. The annual reports to OLAW, AAALAC and USDA are currently performed by the OCV, and these are normally functions performed by the ORA. Writing the IACUC semiannual program review and facility inspection documents should not be done by the OCV office even though the OCV staff excel at meeting that need. The ORA office staff must take over this administrative function so the veterinary staff skillset may be used more appropriately where needed. Veterinarians should also not take the “stand-alone” lead on fact finding (e.g., interviewing researchers and staff) when non-compliances are suspected or being investigated. This sets the veterinary staff up for an adversarial relationship where the research staff may become reluctant to discuss anything with the veterinary staff potentially leading to serious institutional risk related to noncompliant activities. The Attending Veterinarian (and veterinary members of the IACUC) certainly play a leadership role, but the IACUC should be represented at the front-line investigating noncompliances.
- Many believed that the OCV was understaffed which is true. The institution should benchmark with other institutions considering animal census, core programs and number of veterinary staff members (faculty, residents, technicians).
- WSU has a very, decentralized animal care program with multiple per diems and support based solely on Departmental support. There is no centralized program for capital improvements or shared equipment; and the investigators feel that the upper administration (President and VPR) do not value the animal research endeavors as evidenced in their view by lack of support and funding for the program. On reviewing the various vivaria this lack of strategic planning became evident with the array of caging types, per diem rates and minimal funding to upgrade or improve facilities.
- WSU should consider developing a centralized vivaria management process. Centralization under the VPR would help to:
 - Decrease redundant staff which is duplicated at each department.
 - Increase daily reporting and informational flow to the OCV.
 - Provide consistent, daily oversight to the animal care program by centrally trained, qualified staff reporting to one Animal Resource Director, typically the Attending Veterinarian.
 - Allow for more consistent, standardized, animal care across the campus and better utilization of resources.
 - Centralize support in the VPR/IO office for capital improvements, core programming, strategic planning and space utilization across all Colleges.

Investigators

- Ensure all personnel in the lab have access, have read and understand the animal use protocols. It was evident during the interviews that only selected personnel in the labs and vivarium had access to the protocols or understood what procedures had been approved. It is critical that all personnel involved in a protocol understand their roles and responsibilities. It significantly minimizes risk of noncompliance if everyone in the lab knows what is in the protocol. A fairly simple tenet to follow is “Know what is in the protocol and follow what is in the protocol”.
- Encourage the PIs to have the ORA or OCV perform a pre-review of the protocol prior to submission to improve approval times.

Conclusion

It was both an honor and a pleasure to be invited to Washington State University for review and comment on the Animal Care and Use Program. The staff and skill sets that are represented at WSU are impressive and their desire to voluntarily undergo this review, demonstrates their commitment to compliance and continuous improvement. Finding the most effective, efficient and cost-effective way to work together to provide the best possible animal care and provide an atmosphere of compliance while pushing the boundaries of science is a challenge that will not be solved in a short time and is an ever changing, ongoing process. We believe the OCV, ORA and VPR are at a significant juncture in the development of the program. With the addition of key personnel and programmatic restructuring, WSU could easily improve on their already outstanding program.