

**NCSU IACUC Meeting**  
**Thursday, September 17, 2020**  
**Meeting held Via Zoom Online Meeting Platform**  
**1:00 p.m.**

**Present:** K. Anderson, D. Sloop, R. Elder, J. Dew, P. DeLong, G. McKeon, W. Flowers, J. Gadsby, N. George, C. Morales, S. Suter, S. Tonkonogy

**Others:** M. Jung, T. Olagbaju

**Absent:** C. DePerno, P. Siciliano

**Call to Order at 1:00 pm**

**Review minutes of the July 16, 2020 meeting**

The minutes of the July 16, 2020 monthly meeting were reviewed. A motion was made and seconded to approve the minutes as submitted. The motion to approve the minutes was approved unanimously.

**General Report and Updates from Dr. McKeon**

The USDA accepted the two animal concern reports presented at the July IACUC meeting. Nothing further is needed at this time and the USDA will contact the NCSU AV if further information is needed.

The USDA will conduct a virtual records inspection this year. The IACUC office is working to compile records in an accessible and secure format for inspection.

An EthicsPoint report was received regarding an individual working with animals in the [REDACTED] that was not listed on the IACUC approved protocol. The PI submitted an amendment to add the person which has been approved. Leadership at the facility has taken initiative in educating the PI to prevent re-occurrence, and no further action is needed at this time by the IACUC.

After reviewing AAALAC FAQ's following inspections, the AV and the IACUC Director have determined that multiple species housed in the same room should be considered an exception to standards. Several papers appear to indicate that this housing set up may influence animal behavior. The question was raised if this should be an exception described in each protocol for which it applies, or if it should be an IACUC policy. It was decided that the IACUC Director and clinical veterinarians will explore how to best address the housing situations and report back to the committee at the next meeting.

A PI conducting an agricultural study at the [REDACTED] [REDACTED] reported that several pigs died as a result of a common swine disease, as determined by veterinary necropsy. The pigs came from a source outside the university. The pigs are being treated appropriately and biosecurity practices are being followed to prevent transmission to other units.

Update on [REDACTED] from IACUC chair: Following the last inspection, the IACUC chair requested SOPs from PI's regarding use of the unit, including cleaning procedures and a plan for when frequent rain prevents regular flushing into the lagoon. The PI's that use the unit will send these SOP's to the unit manager, who will send the SOPs to the IACUC.

## **IACUC office updates**

### **Semiannual inspections update**

The IACUC office is continuing with in person and Zoom inspections following university social distancing guidelines. Members are encouraged to participate if they are available for inspections.

### **AAALAC visit-College of Sciences**

The site visit is scheduled for late October, the week of the 26<sup>th</sup>. A lunch "Zoom" date will be set up with the site visitors, and members are encouraged to attend if possible. The IACUC office will update committee members as more information becomes available.

### **Draft policies discussion:**

The IACUC Director suggested that the IACUC formulate some policies to guide Principal Investigators in certain areas, for example blood collection or aquatic species care. The member veterinarians agreed with this idea but requested that any policies on drug formularies be avoided since these guidelines change frequently. Members agreed that guidelines may be beneficial but suggested avoiding calling anything a "policy" as these tend to involve stricter enforcement and may be interpreted as administrative burden to researchers. The question of which areas to focus on first was discussed, and which research groups would benefit the most from additional guidance. The IACUC Director will continue to work on identifying areas which may benefit from written guidelines and bring any new guidelines to the committee for review and discussion.

### **Member Training Discussion:**

In follow up to previous program review suggestion to incorporate more training into the IACUC meetings, additional opportunities are being explored. Videos shared by the CVM investigators providing an overview of their work will be shared on a routine basis, IACUC members and investigators will be encouraged to share their science with the committee, and reference articles will be shared for group discussion.

For the September meeting the committee reviewed the following ILAR article for discussion "Everything You Need to Know About Satisfying IACUC Protocol Requirements"

Members felt that the following areas are well covered by the committee: Blanket protocols, numbers justification, and pain category classification.

Topics/ areas that could be improved in protocol review and the program: Description of study in non-scientific terms, key words used in literature searches, and providing more post-approval monitoring.

Members agreed the above paper may be beneficial to post online as guidance to researchers when drafting their protocols.

Meeting adjourned at 2:41 pm.

Recorded and submitted by Candace Morales, IACUC Compliance Coordinator  
and Jennifer Dew, IACUC Director

**NCSU IACUC Meeting**  
**Thursday, October 15, 2020**  
**Meeting held Via Zoom Online Meeting Platform**  
**1:00 p.m.**

**Present:** R. Elder, J. Dew, P. DeLong, G. McKeon, W. Flowers, N. George, C. Morales, S. Tonkonogy, J. Gadsby (left at 2:05pm)

**Others:** M. Jung, T. Olagbaju, K. Kretchman, A. Jindal, E. Pedone

**Absent:** C. DePerno, P. Siciliano, K. Anderson, D. Sloop, S. Suter

**Call to Order at 1:00 pm**

**Review minutes of the September 17, 2020 meeting**

The minutes of the September monthly meeting were reviewed. A motion was made and seconded to approve the minutes as submitted. The motion to approve the minutes was approved unanimously.

**Protocol Review**

**20-246-A**

Summary: This study focuses on the development of a vaccine for gut edema in pigs. Gut edema is caused by bacterial imbalances due to sudden diet changes, most often after birth or weaning. The primary reviewer stated that the clinical signs of disease are variable, and range from severe to mild depending on the case. The reason this is a category E protocol is because one group will be vaccinated and the control group will receive no vaccination. Because the pigs will receive no vaccine, there is the potential for category E use. The vaccine is approved for use in Europe, and one reviewer noted that in order to receive FDA approval in the U.S, an untreated control group would be needed for the study.

Discussion: The following items were discussed and need to be addressed in the protocol

- Update the animal number justification with the primary reviewer's suggested wording
- Confirm is the BUA approved for the toxin?
- For the toxin IV administration in the control group, please include that there is previous experience dosing this agent to include a timeframe for seeing clinical issues associated with the substance and extra details to describe when the 3 times a day monitoring is conducted. Is there a window of time where monitoring should be increased?
- Pain/ distress question 3, please update the first bullet to say at the discretion of the clinical veterinarian (with approval from the study director) to be consistent with the end paragraph.
- Health and safety question 11, please address this question from the BUA, the current answer doesn't answer the question.

- Clarify who on the protocol will perform the injections and their experience with performing the injections

Action: Modifications required for approval with subsequent DMR review

#### 20-451-B

Summary: This protocol involves the pain mechanisms associated with radiation treatment. In the long term, this research is poised to reveal potential targets to prevent or treat acute orofacial radiation associated pain. Category E use is necessary to study these pain mechanisms.

Discussion: The following items were discussed and need to be addressed in the protocol

- Animal care and use page, question 2, please describe the diptheria toxin ablation procedure and when it is performed
- BUA is needed for the diptheria use, please work with EHS to obtain approval. Also, please clarify work restrictions for staff for the cisplatin use.
- For the animals listed in category B, if any of those animals are genotyped or euthanized, they should be moved to category C
- Tail tip for genotyping should be <21 days for no anesthesia and use anesthesia for over 21 days. It currently states 25 days, please update.
- Blood collection: Please clarify methods and volumes taken

Action: Modifications required for approval with subsequent DMR review.

#### 20-390-B

Summary: This protocol focuses on the association between circadian rhythms and skin cancer incidence. Mice will be exposed to UV lights at different intervals and light cycles will be manipulated to achieve the research goals. The study is considered category E due to inflammation expected from sunburn, which is expected following UV exposure and is necessary to achieve the research objectives.

Discussion: The following items were discussed and need to be addressed in the protocol

- Include strain of mouse to be used
- Add description of altered light cycles to be used
- Refine clinical monitoring and state the total size if multiple tumors develop.
- Check with EHS to ensure no safety precautions required for UV light use.

Action: Modifications required for approval with subsequent DMR review

### **General Report and Updates from the Attending Veterinarian**

Self-report IACUC protocol 20-137-B: An emailed report was received from a PI stating an expired medical catheter was used for a surgery involving a biomedical pig. The lab conducts heart surgery and requires multiple sizes of balloon catheters due to the variability in length of the vessels in the pig model. The size required for this animal was in sterile packaging but past the expiration date listed by the manufacturer. During the surgery there were other complications and the procedure was non survival.

As information shared by the AV, in a previous surgery the prior month, a similar situation arose and the AV in consultation with the IACUC director allowed a catheter past the expiration date by one month to be used. That surgery went as expected and the pig is doing well post operatively with no issues.

The IACUC had a long deliberation on what guidance should be given to PIs regarding the use of expired catheters. The NIH guidance on this topic was shared as a part of the discussion. It was decided more information is needed to determine how the IACUC would like to proceed and to gather information from manufacturers on how long items may be considered sterile and what is expected patency of the device (no loss of integrity of the plastic) after the listed expiration date. The topic will be discussed further at the November IACUC meeting.

Self-report IACUC protocol 17-156-B: A PI conducting a study with intrathecal injections in pigs reported that several pigs were euthanized while still under anesthesia due to neurological signs. The PI is waiting to determine the cause of the event and will file an adverse incident report to the IACUC once they have more details.

### **IACUC office updates**

#### **AAALAC visit-College of Sciences**

The site visit is scheduled for October 27-28, 2020. The IACUC zoom lunch is scheduled for October 27<sup>th</sup> at 11:30.

#### **SOP discussion:**

The committee discussed how to handle inclusion of SOPs on farm/ag unit protocols. SOPs for animal husbandry and veterinary care are maintained at the units. The IACUC reviews the SOPs during semiannual inspections. The committee discussed several options and decided to continue with monitoring the SOPs at the semiannual inspections and for the coming visits to notify the facility managers to ensure the SOP books are up to date and provided for the inspections for review. When SOPs are mentioned in an IACUC protocols it should state that "SOPs are maintained onsite and viewed during inspections."

#### **NCDA facilities inspections:**

The IACUC reviewed the current list of all the NCDA facilities and the corresponding IACUC protocols. Sites that have IACUC protocols covering animals that do not belong to NC State in facilities that are not NC State are treated as commercial farms and are not

not inspected by the IACUC. Sites with NC State animals or paid personnel or with PHS funded studies are inspected by the NC State IACUC.

**Discuss [REDACTED] Inspections:**

These are [REDACTED] protocols that the IACUC approved visiting on a two year rotation with self-evaluations conducted in between. Due to COVID restrictions, the IACUC agreed that a zoom inspection will be conducted for the fall 2020 visit and in person inspection will be scheduled for 2021.

**Discuss vet logs at [REDACTED]**

We discussed the current process for recording/ noting that the AV or a designee visits the site for a health related reason. There should be a log maintained at each site and a contact list with the clinical veterinarian for that site.

**Reminder:** Program review is going to be conducted at the November 19th meeting.

**Member Training Discussion:**

Training was tabled to the November meeting.

Meeting adjourned at 3:07pm.

Recorded and submitted by Candace Morales, IACUC Compliance Coordinator  
and Jennifer Dew, IACUC Director

**NCSU IACUC Meeting**  
**Thursday, November 19, 2020**  
**Meeting held Via Zoom Online Meeting Platform**  
**1:00 p.m.**

**Present:** K. Anderson, R. Elder, J. Dew, P. DeLong, G. McKeon, W. Flowers, N. George, C. Morales, S. Tonkonogy, J. Gadsby, P. Siciliano, D. Sloop, S. Suter

**Others:** K. Kretchman

**Absent:** C. DePerno

**Call to Order at 1:04 pm**

**Review minutes of the October 15, 2020 meeting**

The minutes of the October monthly meeting were reviewed. A motion was made and seconded to approve the minutes as submitted. The motion to approve the minutes was approved unanimously.

**Semi-annual Program Review**

The IACUC Director sent out the checklists for the IACUC to review this month. The below items on the checklists were discussed. The program review will be finalized and signed at the December meeting or by email.

**1. Institutional Policies and Responsibilities**

There were only four meetings since the last program review due to Covid-19 restrictions and lower volume of protocols during the spring and summer months. Work seems to be picking back up again recently.

Inspections using the Zoom format have been very well received by the research community.

Committee membership was discussed following the recent AAALAC site visit for the College of Sciences that it would be beneficial to recruit new members for colleges that are not currently represented.

New guidelines for PIs are still being drafted and will be circulated for committee review in early 2021.

**2. Institutional Policies and Responsibilities (Veterinary Care)**

The IACUC is working with a PI regarding potential use of expired sterile medical materials (not medications) and the PI is developing a plan to provide more information regarding sterility and integrity of the equipment for the IACUC's review.

**3. Institutional Policies and Responsibilities (Training, Occupational Health & Safety)**

Training information is presented at IACUC meetings and continues to be well received. Training opportunities were shared with the members and all members are encouraged to participate.



Post approval monitoring is still pending for one lab as we are awaiting a new group of rodent surgeries to be scheduled. All lab members performing rodent survival surgery have completed the AALAS training module in response to the requirement detailed on the September 2020 Biomedical Partnership building IACUC semiannual inspection report.

The OHS review plan for the college of veterinary medicine has been submitted for HR review and the next step is to use a smart form and send that out to users to collect and track yearly OHS updates.

### **Other meeting discussions:**

The AV presented the topic of expired items discussion.

This is in relation to the amendment request on protocol 20-137-B. The work on this protocol is conducted at the CVM. A proposed plan was submitted by the PI for how verification of sterility will be studied per the request to use materials after their expiration date. The amendment submitted to protocol 20-137 will be withdrawn and resubmitted pending this information.

The committee had the following question that they would like the PI to clarify in the plan:

1. What is the length of time after expiration that will be tested? It was suggested to use the longest period that may be used, which was defined as potentially products that are 2 years expired. If products 2 years past expiration don't hold up for integrity or sterility, then it is suggested that the PI work backwards to provide the range that is acceptable, potentially 1 year to 6 months.
2. Please update the plan to provide more details, and under point #2 of the plan, please correct the typo to say "check".
3. Include a group size, 3-5 per group as a pilot to determine sterility and tensile strength.
4. For Sterility testing, the committee felt that no growth would be the only acceptable outcome.
5. Could bacteriology testing be done at the Vet school lab rather than outsourced?
6. Recommend that both re-sterilization methods mentioned (ETO and hydrogen peroxide gas) be tested for tensile strength changes. Please indicate in the plan that the original packaging will not be opened or removed prior to re-sterilization.

### **College of Sciences AAALAC Site visit:**

An overview of the 5 AAALAC suggestions for improvement were discussed along with the proposed responses.

OHS response to handling fish without gloves was discussed. During the AAALAC site visit, a suggestion for improvement was given to clarify the safety training for staff handling fish at [REDACTED] without gloves. There was discussion and staff are trained generally for safety precautions, but the missing piece may be materials related to Mycobacterium marinum as a zoonotic risk. The AV will share materials with the PI and this will be included in all future training sessions with staff.

**IACUC Office updates:** The current IO is scheduled to retire in December 2020 and the university is in the process of interviewing potential candidates. Updates will be provided to the IACUC and regulatory agencies as more details are known.

**Training session related to fish euthanasia methods:**

A video was shared by CVM staff who performed studies for adequate fish euthanasia methods. A letter will be drafted and sent to the PI and staff from the IACUC to thank them for their work done exploring alternatives and refinements to reduce any distress related to this process.

Meeting adjourned at 2:27pm.

Recorded and submitted by Candace Morales, IACUC Compliance Coordinator  
and Jennifer Dew, IACUC Director

**NCSU IACUC Meeting**  
**Wednesday, December 9, 2020**  
**Meeting held Via Zoom Online Meeting Platform**  
**1:00 p.m.**

**Present:** R. Elder, J. Dew, P. DeLong, G. McKeon, W. Flowers, C. Morales, S. Tonkonogy, J. Gadsby, D. Sloop

**Others:** M. Jung

**Absent:** K. Anderson, C. DePerno, N. George, P. Siciliano, S. Suter

**Call to Order at 1:00 pm**

**Review minutes of the November 19, 2020 meeting**

The minutes of the November monthly meeting were reviewed. A motion was made and seconded to approve the minutes as submitted. The motion to approve the minutes was approved unanimously.

**General Report and Updates from Attending Veterinarian**

The CVM is preparing for the next AAALAC site visit which is scheduled to occur sometime in early 2021. There were no other items to report.

**Semi-annual Program Review**

A motion was made and seconded to approve the Program Review as written. The motion to approve the Semi-annual Program Review was approved unanimously. The report will be sent to the IO to sign and signatures from IACUC members will be collected electronically following the meeting via email.

**Protocol Review**

20-137 amendment [REDACTED]

Summary: An IACUC member requested full committee discussion of this amendment. The amendment requests the addition of 40 pigs for a new agent to be dosed after a surgery already approved on the protocol.

Discussion: The VR requested more information on the agent to be dosed. The same agent is to be dosed in rats on a separate protocol for this PI. The reviewer advises that the PI first dose the agent in rats prior to moving the study to pigs. The IACUC agreed that the PI should dose only a few pigs to begin the study, not the full 40 requested.

Action: Modifications required for approval with subsequent DMR review. The IACUC will request that the PI report back following the dosing of the first group pigs.

19-041 amendment [REDACTED]

Summary: This amendment requests the addition of a new species (mice) for maximum tolerated dose (MTD) studies. These studies were previously planned in rats on this protocol.

Discussion: The reviewers are still awaiting revisions. The reviewers are working with the PI to justify the proposed changes. The amendment is still under review and awaiting the PI's response to reviewer comments.

Action: Modifications required for approval with subsequent DMR review

20-391 new protocol [REDACTED]

Summary: This protocol was brought to the committee for discussion with the potential for category E use. The PI listed the animals in category D, however due to the nature and description of the studies the IACUC office felt the category E designation may be more appropriate. The goal of this project is to determine whether the circadian clock has an influence on DNA damage induced by ionizing radiation. Mice will undergo irradiation, tumor cell injection, and an altered light cycle to study these effects.

Discussion: The pre-reviewer presented this protocol for discussion. They had no major comments, but multiple points of clarification. One member noted that the protocol states that mice may develop adverse clinical signs, and will be euthanized within 24 hours of developing the adverse clinical signs. The PI stated in a response to a reviewer comment that due to circadian rhythms, the mice may need to be euthanized at a certain time of day which is the reason they may not be euthanized immediately. The IACUC agreed that due to this description, the pain category E designation is appropriate. The following questions will be sent to the PI for clarification:

- Clarify if all animals will be in pain category E, or if some will fall into pain category C
- Request a scientific reference for the link between circadian rhythm and tissue analysis to further justify need to extend euthanasia beyond the humane endpoint
- Confirm BUA approval is needed

Action: Modifications required for approval with subsequent DMR review and EHS approvals.

**IACUC Office updates:** RED system will be down for maintenance beginning at 4:00 pm, Friday December 18<sup>th</sup> through the weekend.

Inspection plans for 2021 were discussed. The IACUC office is currently scheduling inspections for January 2021 and will keep members informed on inspection dates. Some inspections may need to be conducted virtually or postponed depending on local pandemic restrictions in place at that time. All inspections will be conducted with the minimum number of inspectors required following university social distancing guidelines.

Meeting adjourned at 1:49pm.

Recorded and submitted by Candace Morales, IACUC Compliance Coordinator  
and Jennifer Dew, IACUC Director