

Institutional Animal Care and Use Committee (IACUC) September 17, 2020

Meeting Held: 9:30 AM, Zoom teleconference

Members Present: 123229, 123212, 123125, 123244, 123201, 123203, 123243, 123247,

123242, 123192, 123230, 123245

Guest/alternates: 123211, 123143, 123251, 123197

Executive Members: 123140

123229, IACUC Chair, called the meeting to order at 9:31 AM on September 17, 2020, with a guorum present (XXX).

Conflict of Interest Disclosure: None noted

OLD BUSINESS:

Consent Agenda:

- Minutes from: July 16, 2020
- Annual Reviews (Attachment 2)
- Actions since last Meeting (Attachment 3)
 - Annual updates approved
 - o Annual updates resulting in terminated protocols
 - New protocols approved
 - Changes in protocol approved
 - o Protocols terminated
- IACUC Incident Reports

MOTION: To approve consent agenda (123201/123192). VOTE: For: 11, Opposed: 0,

Recused: 0, Abstained: 0.

Status of previous reviewed: One protocol is waiting for funding, if none, will pull in October

NEW BUSINESS:

Review of New Protocols:

None at this time

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Changes in Protocols

None at this time

Guiding Principles:

None at this time

Any concerns with the new DR method of review for Category D? None, seems to be a more rigorous review

Adverse Event/Protocol Deviation Reports:

Researchers didn't obtain smear and bloodwork at project initiation as listed in protocol.
 Filed the deviation report followed by an amendment. Samples were obtained once amendment was approved.

Compliance Administrator Report:

- 123140 and123125 met with Facilities Management concerning access to animal facilities. This had been noted as a deficiency in our semi-annual report. Will send them information on animal locations, contact information and animal numbers at least semi-annually.
- USDA Notice-asking for criteria for field studies
- SOP page is up on the website and requires a login. Information has gone out in RCA update
- Novelution-the discovery phase has started. Please let 123140 know of any changes you would like to see to the forms
 - Deviation/AE will now be part of the protocol file
 - CITI training will download automatically every night. Unable to do this with Blackboard therefore training will need to be updated
- USDA is proposing a change to animal welfare with the CARES Act. Not necessary to renew registration every 3 years if your inspections are okay. Proposing to eliminate annual updates.
- Occupation Health-our 2014 assurance was on probation because of our low participation percentage at that time. Participation is now a requirement. Challenges arise since the program is managed by another department. What can we do to make this a better program and less frustrating for researchers.

9:48 123245 joined meeting

- A problem with the "reason" for declining a vaccine. Would like that rationale removed. People can decline but there is always a concern if we swing too far with non-participation. Can we have "Optional"-no reason necessary?
- Rabies and tetanus are the primary recommendations, some recommendations are not directly related to the animal work being done
- Fees are the biggest issues
- International students may have the necessary vaccines but are unable to show proof of this
- Looking into seeing if the fees can be written into a grant budget

9:55 123242 exited

• Animal researchers are held to a different standard than other researchers on campus but not different to other animal researchers at other institutions.

9:59 123201 and 123251 exited

Work on revising the letter sent to those who need Occ Health

Update with your primary care physician before starting animal research
 10:05 123201 returned
 123197 exited

Attending Veterinarian Report:

- No research has been stopped but there have been some delays. There are training and space problems
- New PIs with minimal animal experience but are now needing to use animals-this is a problem. Often their graduate students are also inexperienced in animal work.
 - AV and 123201 have discussed having upper class Vet Tech students help with this. They would have taken laboratory animal classes and would have animal handling and ward care experience.
 - Would still need to complete all training and would be compensated
 - o Would give them experience and exposure to another career direction
 - o How do you match the students to a PI?
 - May be an issue since they would still have classes and some research time points are sensitive
 - What about undergrads who are not vet techs and are also on the protocol?
 Would need to be a distinction between the two
 - o Who would supervise them? Probably AV
 - Would look at on a protocol by protocol basis
 - Should we try a trial run? Yes
- Sudro facility manager is still trying to set aside time blocks for training help
- Space issues-for now there are 2 relatively short studies that will be conducted in Van Es. This is a short term fix. There is a challenge finding space for animal work.
 Protocols may be declined due to lack of space, even if funded and approved
 - Do we want to push for a centralized facility? Is this a discussion for VPR top bring to upper administration?
 - Our current system is not designed to help those with minimal animal experience
 - o AV and 123140 are working on a white paper about the space issue
 - Be thinking of how to address this issue
- Had a virtual USDA inspection
 - o He looked at 2 Vet Tech protocols and had no comments
 - He carefully reviews AE reports
 - o All USDA reports are now electronic
 - o NDSU still on 'more frequent' inspections
 - Every 3 years is a full inspection, others are 'focused'

Meeting adjourned @ 10:42 a.m. The next IACUC meeting is on October 15, 9:30 AM Zoom, teleconference.



Institutional Animal Care and Use Committee (IACUC)
October 15, 2020

Meeting Held: 9:30 AM, Zoom teleconference

Members Present: 123229, 123242, 123203, 123245, 123125, 123201, 123249, 123247, 123212,

123192, 123230, 123180 (alternate for 123250)

Guest/alternates: 123211, 123143, 123251, 123246, 123197

Executive Members: 123140

123229, IACUC Chair, called the meeting to order at 9:31 AM on October 15, 2020, with a quorum present 10/14).

Conflict of Interest Disclosure: None noted

OLD BUSINESS:

Consent Agenda:

- Minutes from: September 17, 2020
- Annual Reviews (Attachment 2)
- Actions since last Meeting (Attachment 3)
 - Annual updates approved
 - o Annual updates resulting in terminated protocols
 - New protocols approved
 - o Changes in protocol approved
 - o Protocols terminated
- IACUC Incident Reports (No incidents reported)

MOTION: to approve as presented (123125/123242). <u>Discussion</u>: no changes noted. VOTE: For: 10, Opposed: 0, Recused: 0, Abstained: 0.

9:32am 123192 entered the meeting

Continuing Education – An article "Everything You Need to Know about Satisfying IACUC Protocol Requirements". This may be a good review for experienced reviewers and a good starting guide for new reviewers. Will be posted on the website.

9:32 123246 entered the meeting

The status of previously reviewed protocols were reviewed. Still waiting on funding, this protocol has been on hold long enough that there have been some regulation changes since first submitted. Administrator wants to pull and require resubmission if funding becomes available. Members agreed withdrawing the protocol from review would be appropriate.

9:35 123246 exited the meeting

9:36 123230 entered the meeting

9:37 123251 entered the meeting

NEW BUSINESS:

Review of New Protocols

None at this time

Changes in Protocols

None at this time

Guiding Principles

• Humane Endpoints - Swine unit is following the Guiding Principle but realized there needs to be a comment added for lactating animals, their body condition score may drop below the indicated standards, but this wouldn't indicate an endpoint for these animals. The updated Guiding Principle reflects that.

MOTION: to approve this change (123125/123245) Vote: 12; For: 12, Opposed: 0, Recused: 0, Abstained: 0

• Euthanasia - 2020 AVMA Guidelines came out. While making some necessary changes to the GP, the AV cleaned up our document, removed some methods which he believed were not commonly used and added others. Asked the committee if anything needed to be added. Member indicated that reptiles are not mentioned. 123242 will send references and edits to the AV for inclusion. Member indicated that some of the methods that have been removed from the GP are commonly used in the field, may make sense to keep in the SOP even though we do not currently have anyone using them at this time. The AV will incorporate the necessary changes, and the document will come back to committee.

9:48 123246 entered the meeting

• Training Requirements - Administrator is preparing for Novelution which doesn't recognize training completed through Blackboard but will automatically check CITI Training. The GP has been modified to reflect the shift toward exclusively using CITI for online delivered species-specific training.

MOTION: to approve this change (123242/123245). Vote: 12; For: 12, Opposed: 0, Recused: 0, Abstained: 0.

Adverse Event Reports:

Should receive a report next month on a sheep flock experiencing low iodine levels.

Compliance Administrator Report:

- USDA registration is due soon and have not yet received the form. Have been told that our registration will not expire even if the forms are not received in time.
- OLAW and UDSA Annual reports are due December 1-animal numbers should be submitted
- A reminder email sent to Animal Facilities about winter storm protocols to maintain access to building/animals.

• Discussed implementing a COVID-related project initiation form. Sudro Hall requires a protocol initiation form asking if personnel, supplies, back-up are adequate to begin the protocol. This would be a COVID-specific resource checklist.

9:59 123242 exited the meeting

• This would be a good reminder to have enough of everything. Committee will not require the form, but will add it to the website for voluntary use.

Attending Veterinarian Report:

- The Sheep study (A20037) is wrapping up.
- Will be going to Hettinger and Dickinson on Monday for inspections.

Discussion Topics:

- An "Event Form" request has been received. Used when REC personnel are working with the public. Some outreach activities may utilize animals when personnel are not comfortable handling animals.
 - o If using NDSU Animals, NDSU facilities, or NDSU personnel: if 2 out of 3 yes then need a protocol.
 - o Can add "Extension agent" CITI training
 - Need a 'light" version of the IACUC protocol form
 - o Should be routed through Ag Administration
 - o Who would complete the form?
 - o Do I need a protocol for outreach/extension? Maybe
 - Question of training, currently protocol not reviewed until all training is complete. Training won't be necessary if no protocol
 - Need to work on form more and involve extension agents and livestock specialists at REC in this discussion. Don't want to add another layer of bureaucracy

10:29 123192 exited.

- OHS –a follow-up from last month
 - Contacted Safety Office and GCA
 - o Do we want to put OHS guidance on our website?
 - o Most recommendations coming from provider are to meet general health guidelines and are not specific to working with animals.
 - o Still working on if this cost can be charged to a grant.
- Addition of Personnel in Novelution
 - o Currently this is done by Administrator
 - o Depending on category, does committee want to see these? No.

Meeting adjourned @ 10:38 AM. The next IACUC meeting is November 19, 2020 9:30 AM on Zoom.

Respectfully submitted by: 123211/123143



Institutional Animal Care and Use Committee (IACUC) November 19, 2020

Meeting Held: 9:30 AM, Zoom teleconference

Members Present: 123229, 123201, 123125, 123243, 123242, 123245, 123192, 123212, 123249,

123250, 123203,

Guest/alternates: 123211, 123143, 123180, 123246, 123197 (voting member at 9:51)

Executive Members: 123140

123229, IACUC Chair, called the meeting to order at 9:31 AM on November 19, 2020, with a quorum present (10/13).

Conflict of Interest Disclosure: None noted

OLD BUSINESS:

Consent Agenda:

- Minutes from: October 15, 2020
- Annual Reviews (Attachment 2)
- Actions since last Meeting (Attachment 3)
 - Annual updates approved
 - o Annual updates resulting in terminated protocols
 - New protocols approved
 - o Changes in protocol approved
 - o Protocols terminated
- IACUC Incident Reports

MOTION: To approve (123192/123212). VOTE: For: 10, Opposed: 0, Recused: 0, Abstained: 0.

Continuing Education - None at this time

Status of previously reviewed protocols: One has been withdrawn and will be resubmitted if funding received

NEW BUSINESS:

Review of New Protocols:

Protocol A21012 "Role of placental and fetal pregnancies and their metabolites in parturition and extra uterine survival" Category D

Section 4-language too technical, lay explanation to be added.

9:34 123203 and 123246 entered.

- What success rate are you anticipating? Are there enough animals to be statistically significant and not too many?
- What contingencies are there if there are multiple failures?
- Need criteria for removal of animals from the study
- The number of ewes seems high.
- How long will animals remain in the metabolism crate? Need justification.
- Will the catheter be inserted into both femoral veins?
- Page 5 should be dorsal not ventral
- When monitoring after surgery indicate actual number of days and what will be monitored
- Procedures for birthing should be clarified. Will ewes be in metabolism crates? How will the research team monitor the animals to ensure that someone is present during the birth?
- Euthanasia procedures should be clarified.
- Pentobarbital will be given; will this interfere with the blood tests?
- Will these slaughtered animals enter the food chain?
- On page 8 of 18, Experiment 3-what volume of maternal blood will be drawn and in what time frame?
- Clarify the drug dosages
- Does PR mean the same as PRG?
- Experiment 1-Please address concerns about trauma during blunt dissection.
- Referenced articles need to be provided, there are discrepancies between the references and the protocol.
- These surgeries will take 2-4 hours to animals will need IV fluid.
- Should be given Banamine or other NDSAID for pain relief.
- Need a timeline from the PI. This is a lot of surgical hours and need to visualize how this will all take place.
- Clarification on length of time ewes will be in metabolic crates and the justification for their use is needed.

9:50 Matt exited the meeting

- Training-gas anesthesia, fetal euthanasia (confirmed death) and surgery training all necessary.
- Long-term catheter care will be necessary.

MOTION: Return to Full Committee after requested revisions (123212/123245) Vote: 11 For: 11, Opposed: 0, Recused: 0, Abstained: 0.

Changes in Protocols

None at this time

Guiding Principles-Euthanasia

- Sections from the AVMA Guidelines were added back after the last meeting
- Still need to add a few more items and have a review and feedback from a member

Adverse Event/Protocol Deviation Reports:

- Lamb abortions in a sheep flock at ANPC. They were iodine deficient. This deficiency takes a while to develop so is not noticeable until it is too late.
- They were immediately supplemented with iodine.
- Had a meeting with ANPC and Animal Science, learned that the feed mix had been made with non-iodized salt. While this likely contributed to the issue, it was likely not the sole cause.
- Spontaneous abortions were reported that were likely related.
- Will there be any long-term affects to research projects? This flock only used for production. Most of the animals will be removed from the herd and potentially sold at market.

• There are no regulatory reporting requirements related to these sheep as they are not used in research, but are production animals.

Compliance Administrator Report:

- OLAW report has been submitted
- USDA report is in progress. Have been communicating with the USDA due to a problem with the system.
- FOIA request from SAEN. Another state university only provides Section 4 during an open records request. Why do we release all? VPR is talking to the Chief of Staff about this difference.
- December will be the program review.

Attending Veterinarian Report:

- The Manager of the COBRE and Core animal facility has left NDSU. COBRE and Pharmaceutical Sciences looking to replace her. Have a temporary replacement for the manager role, but she also served as the Director of the COBRE.
- The technician serving the COBRE is also leaving. One of the PIs under the COBRE is currently seeking a temporary replacement for this position to be trained.
- Would like training completed and paperwork located before the technician leaves.
- This area has approximately 30 protocols and 1000 animals.
- AV will schedule a meeting with users of Sudro 207 to outline responsibilities
- For the time being, there will be two time-slip employees filling these roles.
- The previous manager also served as the director. This will again be split into two positions. 123229 has been asked to be the director. This will be a potential conflict of interest (COIC) with the current role in the IACUC.
- Two main issues of concern in ensuring continuity: maintenance and experimental surgical expertise
- May need to 'slow down' protocols
- With regards to the potential dual role of 123229, he would not be involved in COBRE research reviews. He will have no oversight of pharmacy animals, only those projects funded by the COBRE.
- Concern about existing SOPS will revisit on a case by case basis. Some may not be able to be performed at this time.
- The COBRE is being resubmitted for Phase 2, if renewed, likely that 123229 would continue in this role.

Discussion Topics:

- Exhibition application: a request from the VP of Ag. Personnel are told "if in doubt, submit a protocol".
- Have received a few. Are using the current submission form and marking NA when necessary.
- Will wait and develop a new form in Novelution.

Meeting adjourned @ 10:41 a.m. The next IACUC meeting is on January 21, 2021, 9:30 AM by Zoom teleconference

Respectfully submitted by: 123211/123143.



Institutional Animal Care and Use Committee (IACUC) December 17, 2020

Meeting Held: 9:15 AM, Loftsgard 260

Members Present: 123244, 123242, 123229, 123125 123242, 123180 (for 123250), 123247, 123249,

123203, 123201, 123251 (for 123230 until 10:00 AM), 123212, 123230

Guest/alternates: 123197, 123211, 123143

Executive Members: 123140

J. Wilkinson, IACUC Chair, called the meeting to order at 9:30 AM on December 17, 2020, with a quorum present (8/13).

Conflict of Interest Disclosure: None noted

OLD BUSINESS:

Consent Agenda:

- Minutes from: November 19, 2020
- Annual Reviews (Attachment 2)
- Actions since last Meeting (Attachment 3)
 - Annual updates approved
 - o Annual updates resulting in terminated protocols
 - o New protocols approved
 - o Changes in protocol approved
 - o Protocols terminated
- IACUC Incident Reports

MOTION: to approve as presented (123125/123203). <u>Discussion</u>: no changes noted. VOTE: For: 7, Opposed: 0, Recused: 0, Abstained: 1.

Continuing Education - Nothing at this time

Status of previously reviewed protocols: Nothing at this time.

NEW BUSINESS:

Review of New Protocols:

Protocol A21012 "Role of Placental and Fetal Pregnancies and Their Metabolites in Parturition and Extra Uterine Survival" Category D

The PI seems to have sufficiently address many of the issues that just needed clarification.

There are 4 more major issues -

1. **Metabolism crates** - Are we satisfied with their response on the use of the Metabolism crates? It feels that they need to use them for an extended period of time, or the rigor of the study could suffer. The problem is with the external access to the catheters. You wish you could give them more room, but it seems like there's no way to conduct the study without using the crates to restrict movement. If ewes are allowed to move around, it could impact the stability of the catheter. Is the duration that they are requesting excessive? Given what they want to do, shortening the length of time in the crate would mean they likely couldn't meet the aims of the study.

123201 joined the meeting at 9:38 AM.

- 2. **Fetal fluid loss** The PI indicated that the group has done this before, is "pretty good at it", and can manage it. The committee determined that since they have incorporated a couple of training surgeries into the protocol, we should be better able to assess the ability to manage fetal fluid loss during the training surgeries. This offers a reasonable level of safety.
- 3. **Number of surgeries per day** PI indicates can complete up to 2 surgeries per day. Two per day for two hours per surgery seems reasonable, but have concern that it will take 20 days for them to complete all the surgeries necessary for the study. Concern about the variability that this will bring into the study.

123251 (for 123230) entered the meeting at 9:42 AM.

The 20 days will make after care more problematic. It will be staged as far as how they are going to handle everything. It's still do-able as long as you keep everything lined up and organized. Based on the AV's experience with these surgeries –should avoid Friday surgeries because staff availability to monitor recovering animals is less consistent. Also should avoid holidays and pay attention to weather circumstances so that they can ensure that the animals have adequate post-surgical care.

What is the committee's feedback on the 70% success rate? It seems that they are expecting that 3 out of 10 would not be successful. What does this mean? The committee needs more information on what is considered an unsuccessful outcome before they can determine if this is an acceptable success rate.

How much variation in gestation days does a typical herd have? In other words, can they get 40 GD 135 ewes over the course of 20-30 days? This doesn't seem to be addressed within the protocol. If they have to spread the surgeries over the course of several weeks, will they be able to ensure they have ewes at the appropriate gestational period?

4. **Blunt Dissection approach** – Is their justification for the use of this procedure acceptable? The veterinarian members were satisfied with this approach.

123201 disconnected at 9:49 AM and reconnected at 9:50 AM.

Additional questions -

- Will be monitoring the sheep for signs of parturition should clarify what are they monitoring for.
 Is there enough leeway that they don't need to be monitored 24 hours per day? >> There are still
 outward signs in sheep that will show that they are close to lambing. You can make an educated
 guess about if it will be that night or that day. If you were fairly certain of the timing, , you would
 need to be watching fairly closely.
- In experiments 2 and 3, what is happening with the femoral catheter that is in the fetus during birth? >> This should be clarified in the protocol.
- When they state for Experiment 3 slaughter will occur immediately after delivery. Will this happen at ANPC, or are they going to the meat lab? Member noted it states they are being slaughtered at ANPC and not entering the food chain.

Summary of remaining questions for investigator -

- 1. How will they time the gestational date of the surgery?
- 2. Success Rate Please define an unsuccessful outcome.
- 3. How are they going to monitor for signs of parturition?
- 4. What is the status of (or what happens with) the fetal catheter at parturition?

MOTION: to move to designated review pending a revised submission addressing the above questions (123125/123242), Vote: 11; For: 11, Opposed: 0, Recused: 0, Abstained: 0.

Changes in Protocols

None at this time

Adverse Events/Protocol Deviations

Nothing to report at this time. A report came in yesterday, but the AV is still gathering details and will update the committee in January.

Guiding Principles

None at this time

Semi-Annual Program Review:

We previously had issues with HVAC in on-campus buildings leaving animals in less than desirable conditions – which the committee noted as a minor deficiency at the last meeting. Since then IACUC representatives met with facilities and issues seem to have been resolved. Increased communication has helped with this. IACUC administrator will send an update again to the facilities housing animals.

123230 connected at 10:00 AM.

Section on Veterinary Care and Surgery -

The chair indicated that he would like to discuss the section on Veterinary Care and Surgery. He reported that the history here is that there is one protocol involving a very delicate survival surgery. During the review process, we asked them to scale it back to a pilot study. During the training (which occurred first on cadavers, later with live animals) – the AV found that the research team did not have the necessary surgical skills to conduct the research. The PI will need to find alternative ways to conduct the research.

Puts a lot of pressure on the AV to be on top of things when PI's are intent on using novel surgical techniques or techniques with which they don't have prior experience. This is not a deficiency in the program, but is something that we need to address. The AV and IACUC do not have the

resources to train PIs that don't have prior animal experience to be able to conduct successful types of these surgeries.

The concern is that we need to be able to identify these types of situations when they come up. If the research team does not have the appropriate skill set, this might mean requiring outside surgical assistance or training.

In this case, it was good that the committee had required the PI to scale back the initially proposed protocol. We need to be rigorous in asking questions about the skill level of the personnel involved in the procedures. The AV and IACUC administrator are meeting with Sponsored Programs to find a mechanism to find out about proposed research involving novel or complex surgeries at the time of proposal rather than at award or IACUC protocol submission. A section could be added to the Surgery Guiding Principle addressing this issue.

A member indicated that in the past she has received training through an external expert in the procedure. AV reported that companies such as Charles River can be contracted with to conduct some surgical procedures. PIs should consider training costs as part of the proposal budget.

Looking through the checklist, the committee determined that all areas are currently acceptable and no deficiencies were noted.

USDA Report - The IACUC Administrator reported that she has not yet submitted the USDA report due to technical difficulties which the USDA has not been able to resolve. Suggested a note in the report that this is not submitted but include explanation of why.

123212 joined the meeting at 10:13 AM.

Compliance Administrator Report:

- Adverse event reports from October to present were given to SAEN due to open records request. Before it was sent out, the IO scheduled a meeting with a Chief of Staff and the Asst. Attorney General assigned to NDSU. There is an exemption in the Century Code that exempts research data - we tried to argue that the AEs were research data, but the exemption states that Administrative records (which the Asst. AG and CoS determined the reports to be), were not exempted. The IO will continue the conversations with the Asst. AG and CoS.
 - o UND is not currently consulting with their Asst. AG when responding to open records requests.
- Novelution is moving forward. Hope to be online by April.
- Meeting packets were sent out via OneDrive. Does this work for everyone? Yes.

Attending Veterinarian Report:

- Doing a weekly check in with the new facility manager for Sudro 207. It has been very helpful. Are able to keep pace with how the transition is going. She has a half-time worker helping out, but could likely use full-time support. All things considered, things are going well.
- During a recent inspection found that a facility that used CO2 as a euthanasia agent did not have a CO2 Tank. There were no methods of euthanasia available. If they would have had to conduct emergency euthanasia, they would not have been able to do so. Our protocols do ask for PIs to list an emergency form of euthanasia. How do we handle issues where methods are not always readily accessible at a facility? (e.g. captive bolt is at main farm shop, but this is not always accessible). Should we have a secondary or alternate form approved with each protocol? –

Member asked why didn't they have a CO2 tank. AV reported there was a gasket on the tank that was not installed so the CO2 leaked, and they were supposed to have a second tank that was also unavailable for unknown reasons.

o Do we have a list of what types of euthanasia methods are available at each facility? May be helpful to have a list of what is available when members are reviewing protocols.

Discussion Topics:

- A member thanked the AV, IACUC administrator and IACUC chair for keeping things together.
- The AV and chair thanked the committee for all of the work they've done over the past year.

Meeting adjourned @ 10:29 AM. The next IACUC meeting is on January 21, 2021, 9:30 AM via Zoom.

Respectfully submitted by: 123143/123211