Veterinary Verification and Consultation (VVC) in Real Life

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What the heck is VVC?

• A recent addition to the possible routes of review for a change to an IACUC protocol
• Only used for already approved protocols—this route is NOT used for new protocols
• Only used in select circumstances outlined by the OLAW Guidance.
• USDA concurs with this Guidance (we think).
What is the purpose of VVC?

- Make everyone’s life more difficult?
  - NO!!! Make it easier!

- Allows for the possibility of immediate changes to a protocol/procedure that would have previously required IACUC review
  - “Real time” changes made by contacting AV or delegates at time of/during the procedure.
  - “Quick time” changes made by submitting an Amendment that then gets routed to the AV or delegates.
What’s the Catch?

• There are rules...
  – Must have an IACUC authorized vet (our AV/delegates)
  – Must have IACUC reviewed and approved policies already in place!
  – The veterinarian is NOT making a unilateral decision on the change-the veterinarian is VERIFYING that the change requested falls within the IACUC policies already in place.
How Does It Work?

• Imminent/current changes-call Lon or Jessica or James and they can confirm in person that you can make the change immediately.
  – Submit Amendment in eProtocol afterwards
  – It will get routed to VVC and confirmed officially
How Else Does It Work?

- Upcoming changes-submit an Amendment in eProtocol
  - It will get routed to VVC and the change confirmed by Lon, James, or Jessica
  - This should only take 2-3 days
What Changes Will Go To VVC?

• Depends on each Institutions’ Decision and the Policies they put in place

• At CSU-2 main documents guide our VVC Process
  – Protocol Review Process [https://drive.google.com/file/d/0B-Q7fFcWeihxMU4xUFRU21UQmc/view](https://drive.google.com/file/d/0B-Q7fFcWeihxMU4xUFRU21UQmc/view)
  – Performance of Repeat Procedures [https://drive.google.com/file/d/0B-Q7fFcWeihxY3IaNTIFb1hrRTQ/view](https://drive.google.com/file/d/0B-Q7fFcWeihxY3IaNTIFb1hrRTQ/view)
Protocol Review Process

• Added a section defining the types of changes that can be done via the VVC Process:
  – Anesthesia, analgesia, or sedation that follow referenced dosages for the species
  – Substance administration that does not exceed guidelines set by *Diehl, et al* (A published article)
  – Type of experimental substance to a similar class of substance
  – Euthanasia within the AVMA Guidelines
  – Final disposition of the animal, if not more invasive than original
  – Duration, frequency, and type of procedure
  – Number of procedures performed on an animal, excluding surgical procedures
  – Additional strains/sources of animals
  – Changes in space requirements or bedding type, if justified and not excessive
  – Change in diet or water composition as long as continues to meet nutritional needs
Performance of Repeat Procedures

• Outlines common procedures being done at CSU and specifies limits for repeated use.
  – Total blood volume withdrawn based on weight and time period.
  – Gavage volumes
  – Administration sites/volumes/frequency
  – CSF collection sites/volumes/frequency
  – Dietary changes
How Do I Remember All of That?

• You don’t have to!
• Just call the AV, or submit your Amendment as normal
• The IACUC office/vets will route it to VVC if it qualifies!
Scenario 1

• You anesthetize a mouse as described in your approved protocol (injectable anesthetic), but the mouse starts to recover before your procedure is finished and you want to use Isoflurane or a second dose of injectable drug, but this is not in your protocol.
  – Does this qualify for VVC?
    • Yes!
  – What should you do?
Scenario 1

• Call Lon or Jessica or James!
  – Can approve or suggest immediate actions for you to take
  – Later, submit an Amendment with the additional doses/anesthetics for official notification in the protocol.
  – Will go through VVC process
*What if issue is too imminent to allow for calling first??
Scenario 2

• Your protocol involves testing 3 novel antibiotics for a disease, sponsor wants to change one of the antibiotics to a different one.
  – Does this qualify for VVC?
    • YES!
  – What should you do?
Scenario 2

• Since this is a future need, you submit an Amendment.

• VVC Vet will verify that this type of change is present in the approved Policy/Guidelines and the change will be made officially in the protocol.
Scenario 3

• Your approved protocol has SQ implantation of tumor cells, but you decide that you need to surgically implant tumor tissue instead.
  – Does this qualify for VVC?
    • No 😞
  – Why not?
Scenario 3

- This is a new procedure (non-surgery to surgery) AND an increase in pain level
- Neither of these instances will qualify for VVC
Scenario 4

• You want to add three new staff members to your protocol.
  – Does this qualify for VVC?
    • Trick Question!
  – Adding personnel other than PI is administrative and is handled directly by the IACUC Coordinator
Scenario 5

• Your protocol lists blood sampling at 0, 4, 8 and 12 hours, but based on initial results, you want to add a 2 and 24 h time point.
  – VVC?
    • Yes, if the extra collections still fall within the guidelines for maximum sample volumes for the species/size.
    • If the two extra collections caused the total volume to exceed 10% TBV, then this would not qualify for VVC.
Scenario 6

- You have a MRI procedure listed in your protocol and decide that a second MRI at a later time point would give you valuable information.
  - VVC?
    - Yes-adding more of the same procedure would qualify, unless it is a surgical procedure.
  - Submit an Amendment!
Scenario 7

• The current method of euthanasia in your protocol is CO2, but the CO2 machine is broken when you go to use it so you need to use the Isoflurane machine that is available.
  – What are your options?
Scenario 7

• Use the Isoflurane without consulting anyone?
  – No—this would be protocol non-compliance!
• Call the AV?
  – Yes! The AV can approve this change immediately since both are AVMA approved methods.
  – If you want to continue to use Isoflurane in the future, submit an Amendment!
Summary

• If you need immediate answers about a change to a protocol, call a LAR vet
• If you need to make a protocol change for the future, submit an Amendment, IACUC Office will route it the correct way.
• If it qualifies for VVC, it will go through much faster than the regular IACUC processes of designated member review or full committee review.