

Significant Changes: Development and Implementation of Policies and Guidance Documents for Principal Investigators

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April 2, 2016

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Learning Objectives

1. Briefly review the guidance
2. Provide insight on the process of developing policies and guidance documents and how to implement the guidance
3. Share strategies that can be used to change protocols while also meeting the documentation standard of the guidance document
4. Discuss how to create standard operating procedures for common experimental procedures, including the pros and cons of having pre-approved procedures

Disclosure:

Patricia Brown

Emily Clark

Melinda Hollander

Elaine Kim

*have no relevant personal/professional/financial
relationship(s) with respect to this educational
activity.*

Guidance on Significant Changes to Animal Activities

Notice Number: NOT-OD-14-126

Release Date: August 26, 2014



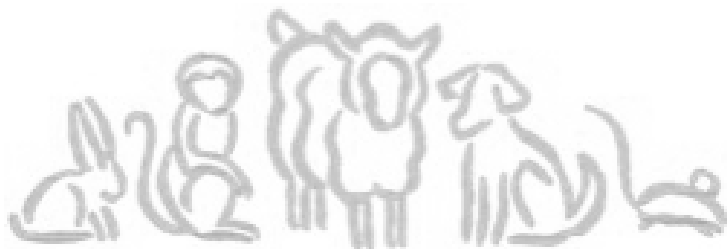
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Resources: Significant Changes

- NIH Guide Notice NOT-OD-14-126
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-126.html>
- OLAW Webpage Significant Changes
http://grants.nih.gov/grants/olaw/significant_changes.htm
- OLAW Special Seminars: Guidance on Significant Changes to Animal Activities
http://grants.nih.gov/grants/olaweducational_resources.htm#a_08212014



Major Points

Significant changes to animal activities may now be handled by several methods as per NOT-OD-14-126.

1. Certain specific significant changes **MUST** be reviewed and approved by either FCR or DMR.
2. Other specific significant changes **MAY** be **administratively handled** using an IACUC-established mechanism of veterinary verification and consultation (**VVC**) when there is an IACUC approved policy that addresses the specific significant change.
3. Requests for increases in **animal numbers MAY** be **administratively handled** using an IACUC established mechanism for doing so and according to an IACUC policy describing allowable increases.

Also Permitted

Other allowed activities:

4. Minor changes **MAY** be **administrative handled** by institutional personnel who support the IACUC without IACUC approval, policies, consultation, or notification.
5. Use of fewer animals than approved by the IACUC does **NOT** require administrative handling, IACUC approval, policies, consultation, or notification.

Review

IACUCs now have 3 methods for handling significant changes to previously approved animal activities:

1. Classic handling of specified or all significant changes: FCR or DMR by IACUC.
2. Administrative handling of procedures performed on animals through veterinary verification and consultation (VVC) by IACUC-designated veterinarian.
3. Administrative handling of increases in animal numbers.

1: Classic

Significant changes that can **ONLY** be approved by FCR or DMR

- from nonsurvival to survival surgery;
- resulting in greater pain, distress, or degree of invasiveness;
 - If USDA regulated, literature review is required
- in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC;
- in species;
- in study objectives;
- in Principal Investigator (PI); and
- that impact personnel safety.

The IACUC **MAY** choose to **require** review of other significant changes by FCR or DMR.

1. OLAW USDA Expectations

- Some significant changes require FCR or DMR and may **NOT** be approved by VVC or administrative handling.
- The IACUC may not develop and approve policies regarding administrative changes to these activities.

2: Veterinary Verification & Consult (VVC)

Some significant changes may be administratively handled according to IACUC-approved policies with verification by and in consultation with an IACUC-authorized veterinarian:

- anesthesia, analgesia, sedation, or experimental substances;
- euthanasia to any AVMA approved method including those approved with conditions as long as the conditions are met,
 - not permitted to have a policy that allows change to a euthanasia method that is not approved in AVMA Guidelines;
- duration, frequency, type, or number of procedures performed on an animal.

2. Advantages of VVC

- Permits research team to immediately apply some significant changes to all animals under the protocol.
- Avoids delays associated with writing and submitting an amendment for IACUC review and approval and reduces the risk of compromising an ongoing research activity.
- Reduces regulatory burden.

2. OLAW & USDA Expectations of VVC

- IACUC policies (guidance documents, SOPs and formularies) that address significant changes must be written, reviewed, and approved **before** they are implemented.
- IACUC policies must be reviewed and approved by consensus **at least** every 3 years by methods that include:
 - FCR or DMR;
 - polling by telephone calls or email; or
 - posting policies in an electronic format for IACUC member review.
- IACUC members are expected to understand and be familiar with their policies.

2. IACUC Responsibilities of VVC

- **Designate:** The IACUC must authorize veterinarian(s) to administratively handle significant changes by VVC.
 - Vet must understand IACUC policies and have lab animal training or experience.
 - Does not have to be AV or IACUC member.
 - May be identified by title, role, or name.
- **Document and record:** IACUC must establish a mechanism for documenting significant changes handled by VVC.

2. Vet Responsibilities of VVC

- **Verify:**
 - Certify that an IACUC policy covers the requested significant change.
 - Determine if the change is appropriate for the specific circumstances.
- **Consult:** Recommend modifications if appropriate and within the scope of the policy.
- **Defer:** Refer the significant change for FCR or DMR by the IACUC, if indicated.

2. IACUC Policy Does Not Apply

What if a significant change is requested, but not covered under an IACUC policy?

- The PI sends an amendment to the IACUC for review and approval.
- IACUC modifies an existing policy to include the requested change according to the IACUC-established mechanisms for making modifications to IACUC policies.
- IACUC develops a new policy that addresses the requested change, according to the IACUC established mechanisms for developing, reviewing, and approving IACUC policies.

3. Administrative Handling of Animal Numbers Increase

An increase in previously approved animal numbers may be handled administratively according to an existing IACUC reviewed and approved policy **WITHOUT** additional consultation or IACUC-notification

3. Expectations of Administrative Handling of Animal Numbers Increase

- IACUC must have a policy that describes increases in animals numbers that can be handled administratively, permitted changes (e.g., percentage, range, or number), and who may approve the change (e.g., IACUC administrator).
- IACUC policy may be written broadly for all species or may be written specifically by species (e.g., rodents, dogs, NHPs).
- The original rationale for the numbers of animals should continue to support the increase in number, range or percent being requested. ***If not, a revised rationale is required.***

4. Administrative Changes

Administrative changes may be managed without IACUC-approved policies, consultations, or notifications:

- correction of typographical errors;
- correction of grammar;
- contact information updates; and
- change in personnel, other than the PI*

*An administrative review must be conducted to ensure that all such personnel are appropriately identified, adequately trained and qualified, enrolled in occupational health and safety programs, and meet other criteria as required by the IACUC.

5. Administrative Change

The use of fewer animals than approved may be handled without IACUC policy, approval, notification, consultation, or administrative handling.

Questions?

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Significant Changes: Development and Implementation of Policies and Guidance Documents for Principal Investigators

Emily W. Clark, PhD

April 2, 2016



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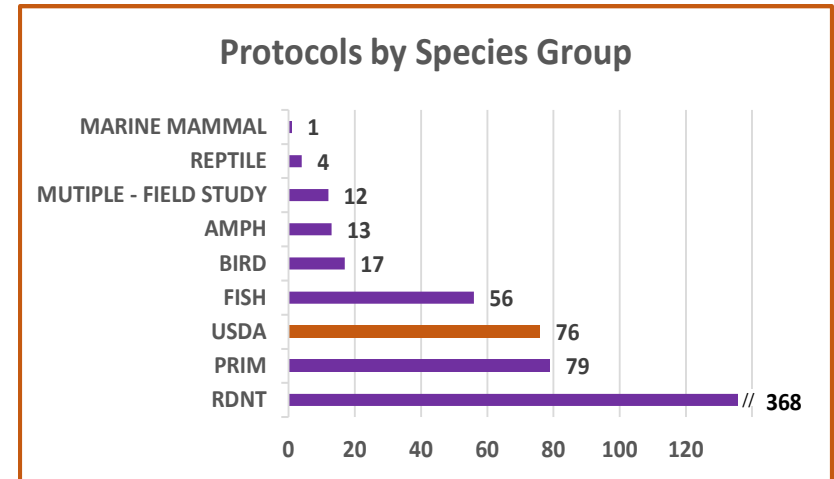
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Disclosure: Emily Clark

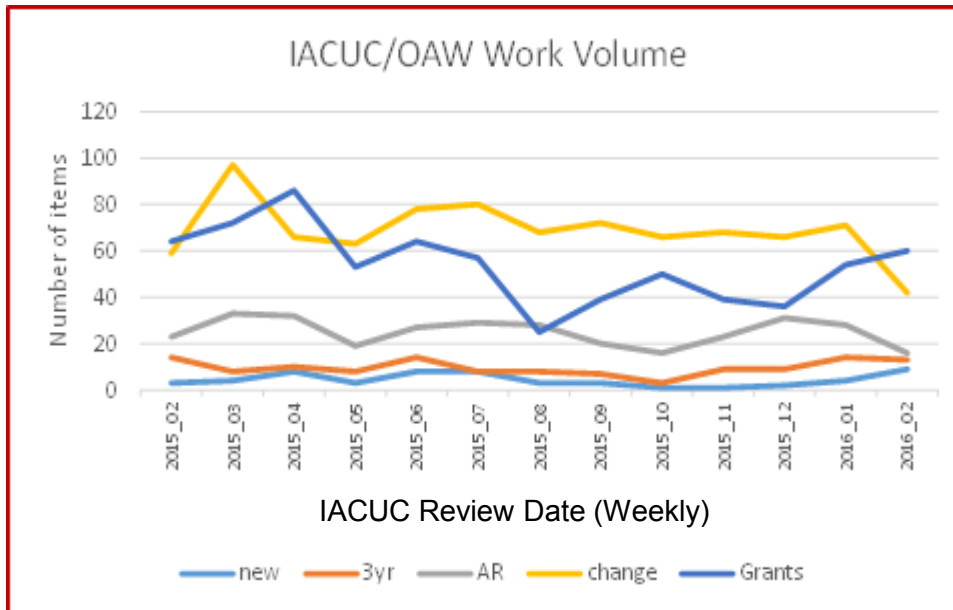
I have no relevant personal/professional/financial relationship(s) with respect to this educational activity

UW Demographics

Protocols and People	UW Protocols	Partner institution protocols	total
Active Protocols	440	41	481
Principal Investigators	336	30	364
Personnel on Protocols	2375	186	2544



Current count = 43 species
Multi-species protocols = 21%



IACUC Review = 95% DMR / 5% FCR

Protocol Items past 12 months

New protocols	54
3-year reviews	111
Annual renewals	302
Significant Changes	837
Grant concurrence reviews	635

UW Significant Change Policy

- Approved on 10/16/2014
- Policy mirrors NOT-OD-14-126
 - Significant Changes requiring review/approval via DMR or FCR
 - Significant Changes that may be handled through Veterinary Verification and Consultation (VVC)
 - changes in anesthesia, analgesia, sedation, or experimental substance that do not result in greater pain, distress, or degree of invasiveness
 - changes in euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals
 - changes in duration, frequency, type, or number of procedures performed on an animal that do not result in greater pain, distress, or degree of invasiveness
 - Significant Changes to increase animal numbers
 - No more than 10% of the number of animals initially approved
 - Administrative Changes: typos, new personnel other than PI, minor clarifications, etc.
 - No review/approval: Use of fewer animals than approved

UW VVC Documents

- In addition to policy, 4 approved VVC SOPs:
 1. VVC of Changes in Timing and Procedures
 2. VVC of Changes in Strain
 - Rodents
 3. VVC of Agents
 - IACUC-approved formularies
 - Other UW IACUC-approved protocols: same species, dose, route, etc.
 4. VVC of Anesthetic Protocols
 - Includes analgesics
 - IACUC-approved formularies
- Guidelines and caveats for verification of each type of change
- Used by AV and 8 designees
 - IACUC-approved SOP for training/authorizing designees

UW VVC Process

1. Vet/investigator determines a change needs to be made to an existing protocol
2. Vet/investigator describes the change (must be clear enough to understand the change without the rest of the protocol)
3. Vet verifies the change is in alignment with IACUC-approved policies/SOPs
4. Vet fills out VVC form within 24 hours and emails:
 - VVC form and description of change to OAW (IACUC office)
 - MUST copy the investigator, the Attending Vet
 - AV: “If you don’t write it down, it didn’t happen”
5. VVCs included with weekly IACUC protocol review items

UW VVC Example 1

In our current protocol, rats may receive some combination of survival surgeries, including spinal cord injury, electrode implants, and neural tracer injections. Currently, we are approved to perform the neural tracer injections as a separate survival surgery. We would like to be able to combine the neural tracer injections with the brain and/or muscle implants in a single survival surgery under isoflurane anesthesia (as approved in the protocol).

UW VVC Example 1 Form

- **Date:** XX/XX/XX
- **Protocol #** XXXX-XX
- **PI:** XXXXXX
- **Request:** This request is to combine two survival surgical procedures into one. Neural tracer surgeries may be combined with other surgeries on this protocol and done in one surgical session instead of two surgical sessions.
- **IACUC Policy:** SOP: VVC of Change in Timing and Procedures
- **Considerations:** I believe this change would be in accordance with all approved IACUC policies and would not increase the pain or distress the animal experiences. Thus, I consider this a request that meets the VVC Guidelines.
- **Veterinarian:** XXXXXX

UW VVC Example 2

We are requesting the addition of isoflurane as an anesthetic for our already approved survival surgeries. Currently, we are approved to use ketamine/xylazine for these surgeries and would like to have the option to use either. In conjunction with this, we would also like to adjust the dosing schedule for buprenorphine. When using isoflurane, we would like to give the first dose of buprenorphine pre-operatively. Buprenorphine will otherwise be administered as currently approved in the protocol. We are not adding any new experiments at this time, or changing the sequence of events. It is a change in anesthesia/analgesia combination only.

UW VVC Example 2 Form

- **Date:** XX/XX/XX
- **Protocol #** XXXX-XX
- **PI:** XXXXX
- **Request:** This is a change to add the use of isoflurane as an anesthetic option for survival surgeries already approved on this protocol. The protocol already lists isoflurane use for other procedures and thus has already had Occupational Health review of isoflurane and the lab members are already familiar with using isoflurane.
- **IACUC Policy:** SOP: VVC of Change in Anesthetics
- **Considerations:** I believe this change would be in accordance with all approved IACUC policies and would not increase the pain or distress the animal experiences. Isoflurane is already being used by these investigators on this protocol, therefore I do not believe there are any training issues. Thus, I consider this a request that meets the VVC Guidelines.
- **Veterinarian:** XXXXX

UW VVC Example 3

We are requesting to extend the timing of our blood draws for our pilot kinetic study. This change is needed because our data to date indicate that the half life of our experimental drug in these monkeys is longer than anticipated, even for the 24 hour sampling time-frame. We will be dropping the 30 minute draw and adding a 48 hour draw, so the number of blood draws and restraint will remain the same.

The current blood draw schedule is: 5 min before dosing and 30 min, 1hr, 1.5hrs, 2hrs, 3hrs, 5hrs, 8hrs, 12hrs, 16hrs and 24hrs after the dose.

The new blood draw schedule will be: 5 min before dosing and 1hr, 1.5hrs, 2hrs, 3hrs, 5hrs, 8hrs, 12hrs, 16hrs and 24hrs and 48 hrs after the dose.

UW VVC Example 3 Form

- **Date:** XX/XX/XX
- **Protocol #** XXXX-XX
- **PI:** XXXXX
- **Request:** Change timing of blood sample collection to add 48 hours and drop 30 minute collection.
- **IACUC Policy:** SOP: VVC of Change in Timing and Procedures.
- **Considerations:** I believe this change would be in accordance with all approved IACUC policies and would not increase the pain or distress the animal experiences, nor does it increase restraint. Thus, I consider this request to meet the VVC Guidelines.
- **Veterinarian:** XXXXX

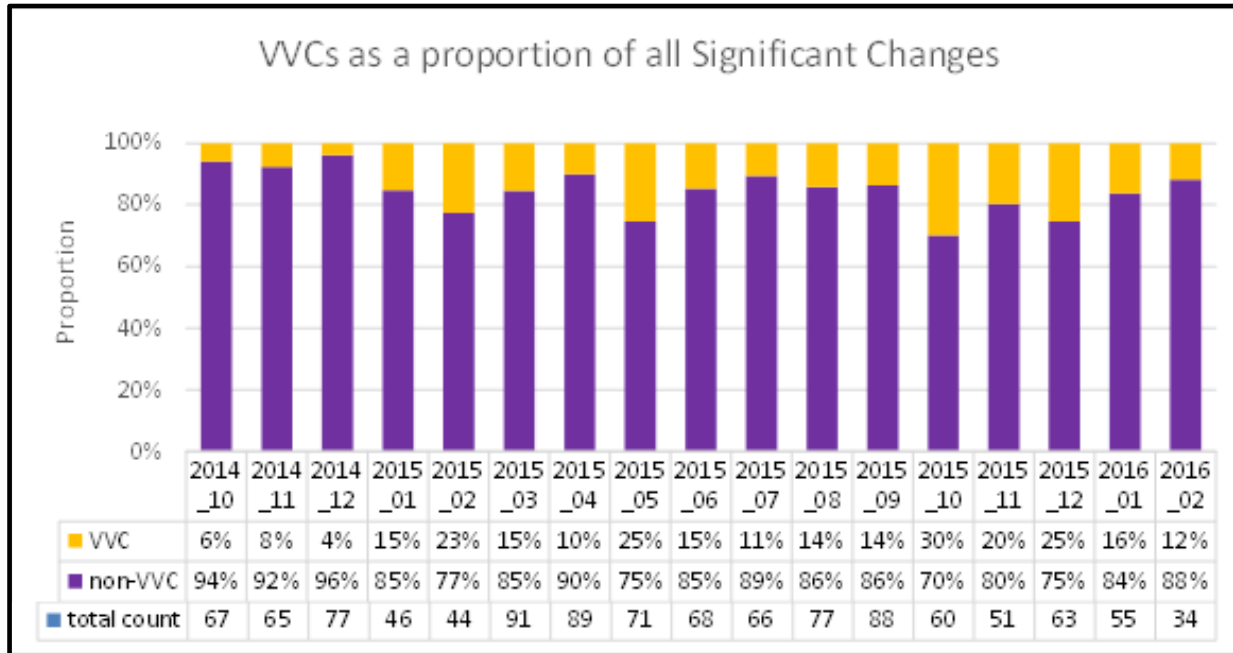
UW (Not Quite) VVC Example

For some of our zebrafish studies we induce specific transgenes through heat shock. Short term exposure to high temperatures does not increase morbidity or mortality at the stages being examined. We would like to modify our previously approved heat shock procedure, as we have learned that some zebrafish lines require higher temperatures, 40–42° C rather than 37–38° C for induction. We request to increase the maximum temperature to be used from 38° C to 42° C.

UW (Not Quite) VVC Example

- Temperature ranges for heat shock of zebrafish **not** specified in any UW IACUC policies or SOPs
- But, other UW IACUC-approved zebrafish protocols use heat shock...
- Maximum temperature on other protocols < 42° C
- Significant Change sent to IACUC for review

UW VVC Metrics



1071 Significant Changes since 10/16/2014:

- 37 FCR = 4%
- 861 DMR = 80%
- 173 VVC = 16%

- Impact on approval time
 - VVCs approved immediately or within 2-4 days
 - Depends on if vet is contacted directly or suggests change
 - DMR turn-around time is 3-5 weeks (including pre-review)

UW VVC Takeaways

- Reduced administrative burden; fewer delays of ongoing research
 - Greater investigator satisfaction
 - Frustration if change does not qualify for VVC
- Policies and SOPs do not cover everything, especially changes in study objectives or aims
- Many nuances and caveats; vets err on the side of caution
 - When in doubt, send change to the IACUC for review
- Encourage investigators to build flexibility into protocol where possible



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Questions?

Thank you:

UW Office of Animal Welfare

Thea Brabb, UW AV

UW Research Community

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Significant Changes: Development and Implementation of Policies and Guidance Documents for Principal Investigators

Mindy Hollander, MS, CPIA



April 2, 2016

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Disclosure: Mindy Hollander



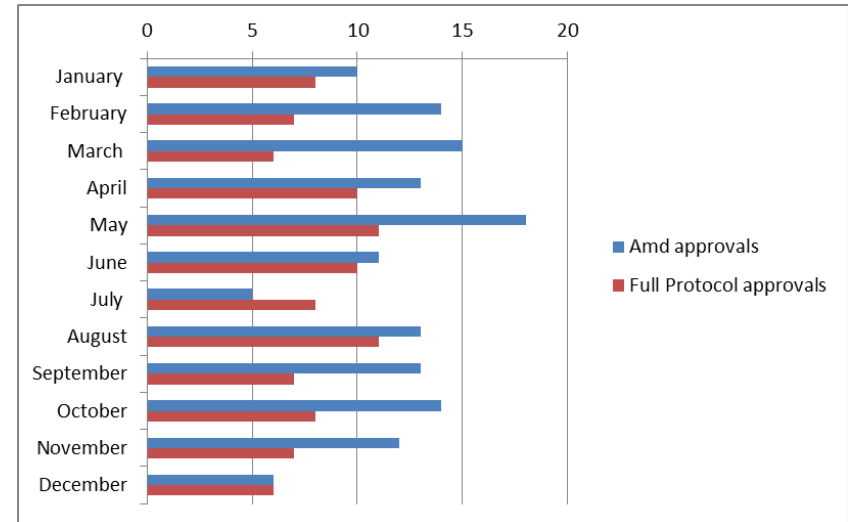
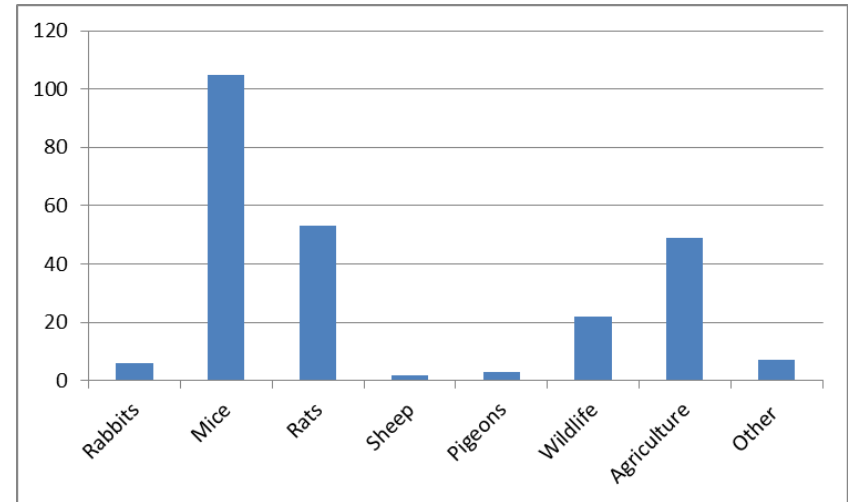
I have relevant personal/professional/financial relationship(s) with respect to this educational activity with the following organization(s)

*West Virginia University
as the IACUC Administrator/Animal Compliance
and Training Officer*

WVU IACUC Info



- 223 Active Protocols
- 115 Principal Investigators
- Average approvals per month
 - 22 Amendments
 - 8 Full Protocols



WVU VVC Policy



- Approved June 2015
- Attending Veterinarian + 3 veterinarian designees
- ADMINISTRATIVE approval
- Does NOT apply to veterinary emergencies
- A written amendment from the PI MUST be submitted (i.e., cannot be worked out between PI and vet then added to protocol after the fact)

WVU VVC Policy



- **WVU IACUC Policy:**

- “Specified Significant Changes to IACUC Protocols to be Approved after Veterinary Verification and Consultation (VVC)”

- **Policy:**

- Specified significant changes that may be approved with veterinary consultation and verification, include changes that are covered under a current IACUC-reviewed and -approved policy, SOP or guideline (found on the ORIC website) and meet the criteria described below under “Significant Changes”. **Principal investigators (PI) will submit all amendments via the IACUC-approved SOP for Amendment Submission** to the Animal Compliance and Training Officer (ACTO). The ACTO will submit the amendment for VVC to a veterinarian who has been approved to conduct the VVC procedures, if it meets the criteria listed below under “Significant Changes”.

WVU VVC Policy (cont.)



- **Veterinary Authority:**

- The consulting veterinarian has the authority to request designated member review (DMR) or full committee review (FCR) of proposed changes for any reason, and must request DMR or FCR for any changes which do not meet the parameters of this policy. The consulting veterinarian is the individual who determines that the change meets IACUC policies and does not require committee review. **NOTE:** The veterinarian is not conducting an IACUC Designated Member Review (DMR), but is serving as a subject matter expert to verify that the changes requested meet the criteria listed below under “Significant Changes” and are appropriate for the animal(s) in a particular circumstance.



■ Significant Changes

- Significant changes that may be approved without designated member review or full committee review, but with VVC include:
 - Changes to compounds or dosage or anesthesia, analgesia, or sedation. Examples of changes which may be approved under this category are:
 - A change in dosage, frequency, route or duration within acceptable and known veterinary parameters.
 - Switching from one approved analgesic, anesthetic or sedative agent to another.
 - Changing the euthanasia method to any method approved in the AVMA guidelines.
 - Changes in duration, frequency, and number of procedures performed that will not adversely affect the animal or will decrease pain / distress. Typical examples under this category may include, but are not limited to:
 - Changing a surgery from survival to non-survival.
 - Adding a procedure which will reduce animal discomfort or potential complications.
 - Changing from a more invasive to a less invasive procedure.

WVU VVC Policy (cont.)



- **Approval of Significant Changes via VVC**

- The ACTO will process the approval for the amendment administratively, after the consulting veterinarian has verified that the required change is consistent with IACUC-approved policies, SOPs and guidelines in the same way all other amendments are processed and approved. An approval letter stating the VVC was completed and approved will be sent to the PI. Consultation with the veterinarian will be documented and saved in the corresponding protocol amendment file.

- **IACUC Notification of Approval of Significant Changes via VVC**

- All approved significant changes via VVC will be listed on the agenda of the IACUC meetings to inform the IACUC members of approvals.

WVU Associated Documents



- SOPs
 - Significant and Minor Protocol Modifications
 - Submission of an IACUC Protocol Amendment

- IACUC-approved formularies (currently rats and mice only)
 - Anesthetics
 - Analgesics

- Approval letter specific for VVC
 - “The above referenced protocol amendment has been approved. Approval was based on verification that the requested amendment is consistent with the WVU IACUC Policy “Specified Significant Changes to IACUC Protocols to be approved after Veterinary Verification and Consultation”.

WVU Process for using VVC



- PI submits an amendment per SOP
 - May or may not have consulted vet

- Administrative review
 - Determines if change is consistent with the VVC policy
 - If not, the amendment will go to the DMR or FCR process for review
 - If so, the amendment will be sent to a veterinarian



WVU Process for using VVC (cont.)



- Amendment is sent to veterinarian for “review”, Chair is cc’d

Dr. Veterinarian

Attached is an amendment from Dr. XXXX, XX-XXXX, where (s)he is asking to XXXXX.

This amendment appears to be consistent with the OLAW Notice NOT-OD-14-126 and the WVU IACUC Policy “Specified Significant Changes to IACUC Protocols to be Approved after Veterinary Verification and Consultation (VVC).

Please let me know if you can verify this, if you require additional information or if you would like to refer it to DMR or FCR.

Cheers
Mindy

WVU Process for using VVC (cont.)



- Veterinarian sends an email stating
 - I verify that this amendment is consistent with XXX SOP / Policy / Guideline
 - I need this additional information, XXX
 - I am referring this to DMR or FCR

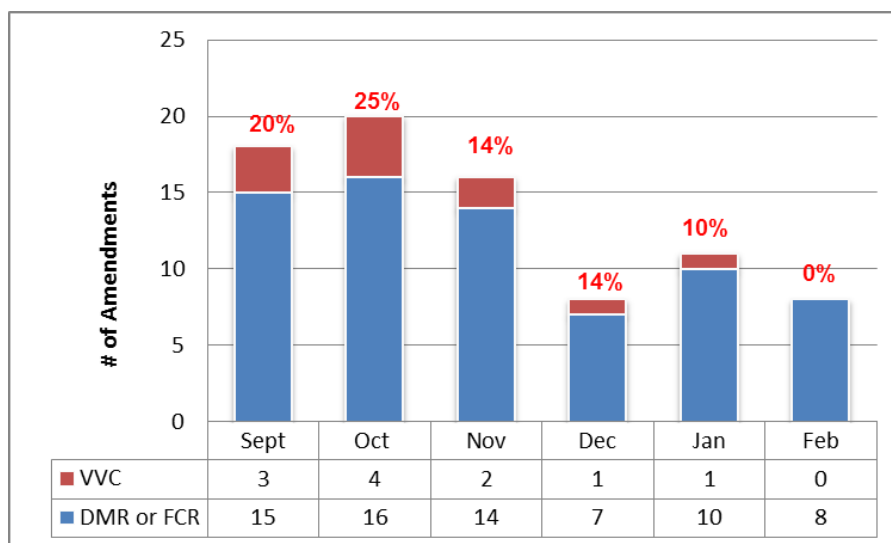
- If the amendment is verified and approved
 - PI gets approval letter
 - Approvals via VVC are included in the monthly reports to the IACUC



WVU use of VVC for amendments



- Average about 14% of our amendments are reviewed using this process
- Turn-around time of amendments
 - VVC average – 0.7 days (*my record = 18 minutes*)
 - DMR / FCR average – 1.9 weeks



Benefits of using VVC




- Happy PIs 😊
 - ↓ delay of research due to faster turn-around time
- Happy IACUC members 😊
 - ↓ the number of reviews that they need to do
- Happy IACUC administrators 😊
 - Less time processing, only deal with one “reviewer”




Drawbacks of using VVC




- Unhappy PIs 
 - They want ALL of their amendments to go through this process

SOLUTION – Don't let the PIs know about this process

- Unhappy Vets 
 - They feel like they are getting extra burden

SOLUTION – Remind them this is why they make the big bucks

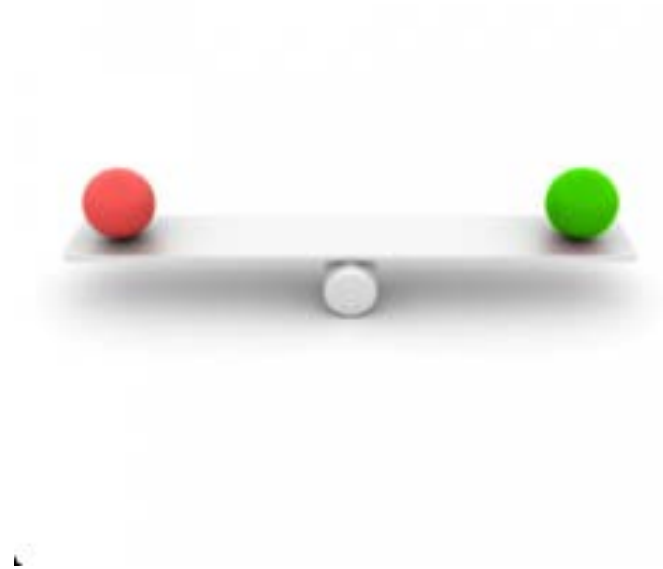
- Unhappy IACUC administrators 
 - If vets decide to go rouge and approve amendments without going through the entire VVC process, sometimes the amendment never makes it into the protocol
 - Vets often will be cautious and send to DMR / FCR

SOLUTION – 1) Suck it up & 2) Be sure vets are trained re: policy

Is it worth it?



- Institution specific
- Weigh the benefits vs drawbacks (conduct a harm-benefit analysis 😊)
- Get IACUC buy-in
- Have all information before presenting to IACUC for consideration



Standard Operating Procedures



- Help PIs
 - They don't have to re-write standard procedures
 - They know what the IACUC is expecting
 - *BUT the PIs need to READ and FOLLOW the SOPs!!*

- Help Vets with VVC
 - Approved procedures are in writing and can be directly compared
 - *BUT if there is any interpretation required, vets may err on side of caution (CYA)*

Standard Operating Procedures



- PIs must READ and FOLLOW
- Step by step
- Simple!
- Must be USEFUL!
- Not every procedure
- Get input from PIs
- Review every ~3 years
- If changes are made NOTIFY PIs 😊



Intent of VVC



- The intent of the significant change guidance from OLAW is to HELP and reduce burden
- May be some extra work up front to write policies, SOPs, etc.
 - Ask your friends at other institutions for their policies, SOPs, etc.

Don't reinvent the wheel!!!

- Decrease overall work long-term AND speed time for significant changes approval

WVU IACUC Policies / SOPs

<http://oric.research.wvu.edu/services/iacuc/iacuc-policies/wvu-iacuc>

Questions?



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Scenarios:

1. PI approved for use of ketamine/xylazine anesthesia; wants to expand the dose range listed in the protocol.
2. PI approved for final disposition of euthanasia; wants to add transfer to another approved IACUC protocol.
3. PI approved for euthanasia of mice via isoflurane overdose + cervical dislocation; wants to add secondary method of exsanguination.
4. PI approved for monthly blood collection in cats; wants to decrease the time between blood collections (collect every 2 weeks), same amount of blood collected.
5. PI to add 2 rats (Genus Rattus) to the protocol (total n=30 rats).
6. PI to change housing location of aquatic species to personal lab space.
7. PI to add transfer to another approved IACUC protocol as final disposition:
 - a. Recipient protocol has at least one pain category D procedure
 - b. Original protocol has pain category C procedures only.
8. Original protocol has 2 procedures: survival surgery and euthanasia with tissue collection. Now PI wants to amend to do tissue collection under general anesthesia and then euthanize under same anesthetic episode (e.g. non-survival surgery).
9. Amendment to increase drug dose, add jugular catheterization procedure (C to D).
10. AV wants to increase drug dose range for an analgesic within published ranges.

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April 2, 2016

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Disclosure: Elaine Kim

I have no relevant personal/professional/financial relationship(s) with respect to this educational activity

Veterinary Verification and Consultation (VVC)

- Implementation of NOT-OD-14-126 at CSU: Should we do it? If so, how?
- VVC Process developed by IACUC—2 documents:
 - Protocol Review Process
 - Performance of Repeat Procedures
- Included items identified in NOT-OD-14-126
 - Anesthesia, analgesia, sedation
 - Euthanasia method
 - Duration, frequency, type and number of procedures
- Additional considerations:
 - Experimental substance administration
 - Animal disposition
 - Source of animals
 - Space requirements



Administrative Review

- Updated contact information
- Typographical errors
- Change funding information
- Change in personnel (not PI)
- Increase in animal numbers of non-USDA covered species, not to exceed 10% of the approved protocol number
- Change in housing location within an IACUC approved facility



CSU Metrics

- CSU ACUP: ~530 protocols
 - Infectious disease, biomedical research, veterinary school, veterinary clinical studies, no medical school, ag satellite facilities, increasing private sponsors, and FDA regulated work
- DR/FCR amendments vs. VVC amendments:
 - Average turnaround time: 3-4 weeks vs. 6-7 days
 - Percentage of total amendments from January-December 2015:
 - 44 out of 240 = 18%
 - DR amendments = ~75% now (~90% before VVC)
- Type of amendments submitted influence past and future revisions of the “Protocol Review Process,” as well as “Performance of Repeat Procedures”



Review Documentation & Administrative Burden

- eProtocol—online protocol system:
 - VVC Panel
 - Protocol Notes section
 - AV comments on rationale, e.g. reference to SOP documents
- Included in monthly meeting minutes → allows entire IACUC to review.
- Any question about DR/FCR vs. VVC → AV sends for IACUC DR Determination.
- Administrative Burden: has it increased or not?





Questions?



**Thank you:
CSU RICRO Staff
Lon Kendall, CSU AV
CSU Researchers**

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