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Protocol Assessment Liaison
BULLETIN

This Educational Information has been brought to you by Traci Clemons, Protocol Facilitation Program for the Vice Chancellor for Research, in cooperation with the UNMC/UNO Institutional Animal Care and Use Committee, and Comparative Medicine.

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KNOW YOUR PROTOCOL



**THE SIMPLE TRUTH ABOUT
IACUC PROTOCOLS, WHY THEY
EXIST, AND WHAT CAN HAPPEN
IF YOU FAIL TO FOLLOW THEM.**

The Purpose of the Protocol



- To ensure the animal use portion of the grant is approved by the institution's IACUC.
- To obtain IACUC approval of the protocol prior to animal use.
- To ensure that the PI and all lab personnel are conducting research in accordance with the IACUC approved protocol.
- To assure the NIH Office of Laboratory Animal Welfare (OLAW) that all animal procedures comply with 1) the Public Health Service (PHS), 2) United States Department of Agriculture (USDA) Regulations, 3) UNMC Institutional policies, and 4) AAALAC International requirements.

So What can happen when you don't follow your Protocol?



- Research could be compromised because procedures are inconsistent.
- Personnel may not be appropriately prepared or trained to perform a procedure.
- Animal welfare is jeopardized if unapproved procedures cause potential pain, discomfort, or death of animals.
- The protocol may have to be suspended.
- The PI's reputation could be jeopardized.
- Grant awards could be revoked or the NIH may require pay back of funding.
- The USDA may fine the institution.
- The institution's reputation may be damaged and funding could be affected.
- The institution's AAALAC International accreditation could be jeopardized.
- The institution may be more likely to become a target of animal rights groups.



Why does this happen?

Science is experimental investigation, and this requires testing multiple hypotheses, which are not always evident from the start.

We are always looking for ways to improve or modify procedures.

Time is of the essence.

Having multiple related protocols can get confusing.

- It has recently become apparent that there are re-occurring issues of noncompliance due to personnel not following the approved protocol.
- It is the UNMC/UNO IACUC's responsibility to address, correct, and provide education to our research community to prevent noncompliance from happening.
- The UNMC/UNO IACUC is required to report incidents of noncompliance and corrective action plans to NIH/OLAW. OLAW and the USDA expect us to take the necessary steps to minimize noncompliance.

What can we do to fix it?

- Ideas to help make sure that lab personnel are familiar with the IACUC approved protocol:



- ✦ Keep a copy of the IACUC approved protocol on a server that all lab personnel have access to. (The most sensible because you can keep it updated with the latest changes.)
- ✦ Print a hard copy and keep it in the laboratory.
- ✦ Review the protocol with new personnel including all procedures that they will be responsible for.
- ✦ Create SOP's for standard procedures performed in the protocol.
- ✦ Create calendars and schedules with laundry lists of the procedures.

Ways to minimize changes to your approved Protocol:

- **Standard Operating Procedures:**

- **Build in options:**

- **Be more general where you can:**

- **Try a having a new protocol for each experiment:**

- Write simple SOP's for the procedures that you do on a regular basis, and use the same SOP in all protocols.

- "Don't Box Yourself In": 1) Write in choices of acceptable procedures that may be used.
2) List all possible procedures that lab personnel will perform and include proposed training for the procedures that they may be trained for down the road.
3) Include procedures for pilot studies or training personnel.

- Try to be more general when it is appropriate e.g. will use either anesthetic X or Y; will remove sutures between 10-14 days; use acceptable drug dose ranges and routes of administration; etc.

- Short concise protocols for each experiment can be beneficial, and can make things much simpler then trying to keep up with changes from a protocol that was written in the 90's.

It is Time to be Proactive



Review

- Review Current Protocols with your lab personnel.
- Submit changes if necessary.
- Make sure personnel are trained for their listed responsibilities.

Update

- Update all previously approved changes into your saved/current copy of the protocol.
- Include the date changes were submitted and underline them.

Consult

- Ask for guidance on policies, procedures, regulations, forms, or applications from IACUC, CM, or PAL.
- Visit the IACUC website for the most current forms and information.