Memorandum

To: Animal Care & Use Committee
From: Vaughn C. Kowahl, Chief Technical Officer
Date: January 1, 2013
Re: Protocol updates for compliance with the new “Guide” (8th edition)

The following updates and enhancement to the University of Virginia’s Institutional Animal Care & Use Committee online protocol submission system were put online 1/1/2013.

New & Modified Questions Added to Protocol (screenshots of the questions as they appear online can been seen at the end of this memo)

1. Breeding and Weaning Policy Exemption
   a. Shown only on Mouse or Rat species procedures either must have a Breeding Colony
   b. Yes/No required, with justification text box required if Yes
   c. View “help” at this URL

2. Environmental Enrichment (other than social housing) Exemption
   a. Shown on all species procedures
   b. Yes/No required, with justification text box required if Yes
   c. View “help” at this URL

3. Non-Pharmaceutical Grade Drugs
   a. Shown on all species procedures
   b. Yes/No required, with justification text box required if Yes
   c. View “help” at this URL

4. Restraint Devices
   a. Shown on all species procedures
   b. Yes/No required, if Yes user is directed to add justification to Main Procedure Description
   c. No additional “help” URL

5. Social Housing Policy Exemption
   a. Shown on all species procedures
   b. Yes/No required, with justification text box required if Yes
   c. View “help” at this URL

6. Main Procedure Description (Which of the following procedures will be performed on any animals used in this procedure section?)
   a. Shown on all species procedures
   b. Select all that apply checkboxes (Required)
   c. No additional “help” URL
7. Post-Procedural and/or Post-Operative Plans  
   a. Shown on all species procedures  
   b. This is only a modification to the instructions, no change in data gathering  
   c. No additional “help” URL  

8. Humane Endpoints and Criteria for Euthanasia  
   a. Shown only for Category E species procedures or if any of the specific procedures are checked in the Main Procedure Description  
   b. Required text box if shown  
   c. No additional “help” URL  

Other Protocol modifications  
1. When a user chooses to use Avertin (Tribromoethanol) or Methoxyflurane, they are required to include a Non-Pharmaceutical Grade Drugs justification.  

Committee Review online:  
1. Comment fields have been added for new questions #1, #2, #5, and #8.  
2. If an Exemption is being requested (“Yes” for questions #1, #2, #3, or #5) the words “Exemptions in” will precede the Species Procedure Title in the Outline of Review Comments. This will allow the committee members to quickly and easily see if there are exemption requests contained in the protocol being reviewed.  

The new questions and other Protocol modifications are NOT required for “Minor Modification only” protocols or “Animal Handlers edits ONLY”  
If the user selects the Protocol Submittal Type to be “Minor Modification only” the following will happen:  
- The new questions will appear when editing an individual Species Procedure, but the “(REQUIRED)” field indicator will not be displayed to the user. Exceptions to this, are for questions that have YES/NO (i.e. #1, #2, #3, and #5) and if a user selects YES to one of these, then the additional text becomes required and is displayed as such.  
- The user will be able to submit the protocol without completing the new questions.  
- The user can make changes to the new fields if needed (e.g. if a user needs to do a “Minor Modification only” change to one of the new fields).  
- The protocol “print out” and the committee’s “comparison/comment/review feature” will display “User has not yet entered required data” OR “<will show blank space>” for the incomplete fields.  

Added protocol business logic and enhancements  
1. Protocol system will prevent protocol submittal if there are 1-digit years in literature searches (this will force/require 2-digit years prior to protocol submittal)  
2. System will alert user, but not prevent protocol submittal, if literature year search endpoint entered by user is not the same as current year (this will hopefully help to remind people to update their search dates, when appropriate)  
3. Enhanced the user experience for the addition and removal of Animal Handlers from Species Procedures.
Screenshots
Breeding and Weaning Policy Exemption

Federal regulations establish the density of animals permitted in rodent cages. The ACUC has a Policy on Breeding and Weaning of Rats and Mice to further clarify standards of allowable cage densities, breeding paradigms, and weaning ages.

Does the nature of the research require an exemption to the Breeding and Weaning Policy?

(REQUIRED)

- YES
- NO

If YES, provide the nature of the exemption being requested and the strain(s) of animal(s). Provide any supporting data or references to justify this request.
Species-specific physical and psychological enrichment is an accepted standard of care to enhance animal well-being and will be provided for animals unless an exemption is approved.

Does the nature of the research require an exemption for Environmental Enrichment? *(REQUIRED)*
- YES
- NO

If YES, a scientific justification must be provided. Be specific!
Are you requesting an exemption to a specific form of enrichment or to all enrichment? Include which group(s) of animals, the duration, and the scientific rationale.
Non-Pharmaceutical Grade Drugs

[HELP]

Pharmaceutical grade drugs must be used when available. Cost is not an acceptable justification for requesting chemical grade alternatives. The use of pharmaceutical-grade drugs ensures potency, stability, and sterility of drugs that are administered to experimental animals. ACUC Policy on Use of Pharmaceutical Grade Compounds

Does the nature of the research require the use of Non-Pharmaceutical Grade Drugs? (REQUIRED)

- YES
- NO

If YES, describe the compound, the justification for its use, how many animals will receive it, what groups of animals will receive it, at what dosage and for how long.
If a pharmaceutical grade alternative is available, explain why it cannot be used.
How is the non-pharmaceutical compound made?
How do you ensure its sterility and stability?
Restraint Devices

Will any animals be kept in a restraint device during the course of these experiments for more than momentary procedures (longer than 5 minutes)? *(REQUIRED)*

- YES
- NO

- If you answer YES, please note that restraint devices must be justified in the Main Procedure Description below. This includes animals that are chronically tethered (i.e., normal behaviors and movement are limited in some manner). Veterinary care must be provided, and possible removal from the restraint, if lesions, illnesses, or severe behavioral changes are observed.
Social Housing Policy Exemption

Social Housing Policy Exemption

[HELP]

Social housing will be provided for all social species.

Examples of situations where singly housing animals does NOT require an exemption include veterinary medical concerns, aggressive animals, short-term use of metabolic cages, and post-operative recovery with return to conspecifics upon healing. Examples of reasons that WILL require an exemption to social housing include long-term tethering, behavioral experiments requiring long-term individual housing, etc.

Does the nature of the research require an exemption for Social Housing? (REQUIRED)

☐ YES
☐ NO

If yes, a scientific justification must be provided.
Be specific - Are you requesting an exemption for a specific group of animals or all animals?
How many animals will be involved?
What is the duration of the exemption?
Main Procedure Description (Which of the following procedures will be performed on any animals used in this procedure section?)

Main Procedure Description

All procedures to the same animal must be in the same species procedure section.

Provide a clear, concise, sequential description of the procedures involving the use of animals from arrival and acclimation through euthanasia and disposition of the animal. This must be easily understood by all members of the committee. Discuss what the impact will be (both transient and permanent) of any and all proposed procedures on the animal's well-being.

Include details of:

1. Acclimation
2. Anesthesia and monitoring
3. Surgical preparation
4. Surgical procedure
5. Wound closure
6. Include the identity, frequency, amount, and location of any chemical or biological substance injected or sampled
7. Include any necessary changes in housing or husbandry requirements
8. Behavioral studies
9. Indicate the length of the experiment and describe the end point of the experiment
10. Other pertinent information

Which of the following procedures will be performed on any animals used in this procedure section? (select all that apply OR select NONE) (REQUIRED)

- NONE
- assessment of toxicologic effects
- infectious disease
- models of cardiovascular shock
- myocardial ischemia
- organ or system failure
- pain modeling
- production of monoclonal antibodies
- trauma
- tumor models
- vaccine challenge

Main Procedure Description (REQUIRED):

The main procedure text box below will accept 32,000 characters (including "whitespace"). "whitespace" = "spaces" + "line-breaks generated by the Return/Enter key". Information entered beyond this limit will not be retained!
Post-Procedural and/or Post-Operative Plans

Describe in detail plans for monitoring and caring for animals in the post-procedural and/or post-surgical periods. Should several studies be described, provide post-procedural details for each study or manipulation in an easy to follow format. The ACUC Policy on Recognition and Assessment of Pain, Stress, and Distress of Laboratory Animals provides useful species-specific behavioral expression of pain and distress and includes recommendations for analgesics and anxiolytics.

Include such items as:

1. Treatment, if any, for post-procedural pain and distress
2. Administration of antibiotics/analgesics (type, rate, dose, frequency)
3. Frequency of observation
4. Monitoring parameters that will be recorded, especially those used to monitor for pain and/or distress
5. Timing of suture removal, if applicable

Post-Procedural and/or Post-Operative Plans (REQUIRED):

These are my Post-Procedural and/or Post-Operative Plans
Humane Endpoints and Criteria for Euthanasia

For all studies, the IACUC must weigh the potential benefit of the study objectives against the magnitude of potential physical and psychological harm to the animal (animal welfare impact). This includes both anticipated (due to experimental design) and unanticipated adverse events. The experimental endpoint of a study occurs when the scientific aims and objectives have been reached. The humane endpoint is the point at which pain or distress is prevented, terminated, or relieved. NIH Guidelines require that study endpoints occur prior to, or coincident with, humane endpoints whenever possible.

Please describe how humane endpoints were established for your study by addressing the 4 questions in the section below.

1. What is your definition of humane endpoint(s) as it applies to these studies? To guide you in determining suitable criteria for euthanasia, refer to the ACUC Policy on Determination of Humane Endpoints. Be specific, e.g. greater than 15% weight loss from baseline or age matched controls, lack of food and/or water consumption for more than 48 hours, extreme lethargy, hindlimb paralysis, neurologic signs, etc?
2. How frequently will animals be observed and assessed for these criteria? If the frequency of observations will change over time (e.g., once weekly until tumor size reaches 1 cm², then every other day for duration), this information must be provided?
3. How will your staff be trained to recognize these specific humane endpoints? How are laboratory personnel trained to recognize and respond to unanticipated outcomes?
4. What is the required action to be taken when an endpoint is reached?

NOTE. A clinical monitoring or pain scoring sheet is highly recommended for any study where development of pain or distress over time is anticipated, and is required for all Category E procedures. Sample clinical scoring sheets can be found in the ACUC Policy on Determination of Humane Endpoints, and additional examples are available from the Office of Animal Welfare.

Humane Endpoints and Criteria for Euthanasia (REQUIRED):

These are my Humane Endpoints and Criteria for Euthanasia