

Monday September 29, 2008

Protocol Assessment Liaison BULLETIN

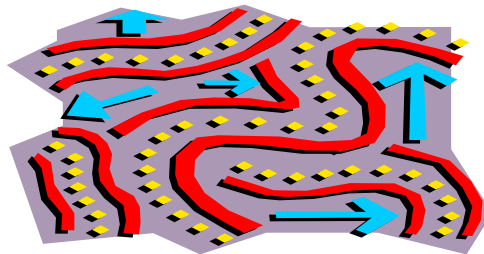
This Educational Information has been brought to you by Traci Clemons, Protocol Facilitation Program for the Vice Chancellor for Research, in cooperation with the UNMC Institutional Animal Care and Use Committee, and Comparative Medicine.

For additional information please contact:

Traci Clemons; tclemons@unmc.edu or Extension 98560

**IACUC NEWS: CHANGE IS HERE...
CONTINUING REVIEW,
A NEW LOOK ON FORMS,
AND MORE!**

HERE IS YOUR ROAD MAP



AND IF ALL ELSE FAILS... ASK FOR DIRECTIONS!

CHANGES TO IACUC SUBMISSION REQUIREMENTS

1. All **IACUC forms** have been modified effective 10/01/08. Please submit all documents to the IACUC on the updated forms. After November 1, 2008, submissions on the old forms will not be accepted.
2. The **Pain Classification system** (section II.1 Category of Research) will be changed to reflect the current USDA system. All current protocols will have the pain classification automatically changed. This change will not impact the IACUC review process but will allow for accurate reporting of numbers of animals used in each pain category to the USDA and AAALAC.
 - a. If your current protocol is Category A it will become a Category C.
 - b. Category B protocols will become Category D1.
 - c. Category C protocols will become Category D2.
 - d. Category D protocols will become Category E.
3. The **Request for Change** submission requirements have changed effective 10/01/08. To request a change in the protocol title and/or study personnel, a Request for Change form should be submitted. For any other change(s), the following must be submitted:
 - A completed Request for Change form. This form should include a brief narrative which describes the proposed change(s) and discussion of any potential impact of the proposed change(s) on animal well-being.

AND

 - A revised version of the entire approved protocol (including all previously approved changes) in which the proposed change(s) have been incorporated and underlined in all applicable sections. In the revised version, please indicate the date the change was submitted.
4. The **3 Year De Novo Review** submission requirements have changed effective 10/01/08. The six year resubmission is no longer required. An approved protocol must be reviewed every 3 years by the IACUC to ensure the project is being conducted in accordance with current policies and regulations. The following must be submitted:
 - A completed 3 Year De Novo Review form.

AND

 - The latest approved version of the entire protocol including all related addendums. The protocol should include all previously approved modifications. **NO CHANGES ARE TO BE REQUESTED AT THIS TIME.**
5. An Addendum, **Addendum A- Protocol Specific Breeding**, has been created. This addendum, when applicable, should be completed and attached to the IACUC Application for Animal Research. This addendum should be completed when the experimental design includes the need to breed animals because (not an all-inclusive list):
 - a. You need to generate pregnant females to collect embryonic/fetal tissue.
 - b. Experimental procedures will be performed on the pregnant females.
 - c. You need to generate suckling pups to perform experimental work.
 - d. You need to generate suckling pups for tissue/blood collection.

IACUC APPLICATION (PROTOCOL) SUBMISSION INSTRUCTIONS

New Protocol Submission: Four (4) protocol forms are available. The choice of which form to use is determined as follows:

- You are a faculty member at UNMC or UNO that plans on performing research on either campus, then an IACUC Application for Faculty Animal Research is to be submitted.
- You are a faculty member at UNMC or UNO that plans on maintaining a breeding colony to produce weaned pups to transfer to an IACUC approved research protocol, then an IACUC Application for Faculty Breeding Colony is to be submitted.
- You are a student at UNMC or UNO that plans on performing research on either campus, then an IACUC Application for Student Animal Research is to be submitted.
- You are a faculty member at UNMC or UNO that plans on using animals on either campus that is part of a course you are teaching, then an IACUC Application for Use of Animals in Education and Training is to be submitted.

Request for Change: Any change in a previously approved protocol must undergo review and approval prior to implementation of the change. Submission requirements depend on the type of request as follows:

- You are requesting to add and/or delete personnel, a Request for Change form is to be used.
- You are requesting to change the title of your protocol, a Request for Change form is to be used.
- You are requesting any change, other than personnel or title changes, a Request for Change form is to be used **AND** submission of a revised version* of entire protocol in which the proposed changes have been incorporated and underlined is required. *This revised version must include all previously approved changes and it will become the only approved version of the protocol.

Continuing Review: The continuing review process ensures that the protocol is being conducted in accordance with current policies and regulations. **NO NEW CHANGES IN PROTOCOL ARE TO BE REQUESTED AT THIS TIME.** The frequency of review and submission requirements depends on the species of animals used and the length of the time that the protocol has been active.

If you are **using USDA covered animals** in your research, submission requirements are as follows:

- Year 1, a USDA Annual Continuing Review form is to be submitted.
- Year 2, a USDA Annual Continuing Review form is to be submitted.
- Year 3, a 3 Year De Novo Review form **AND** the latest approved version of the complete IACUC protocol (including all previously approved changes and related addenda) submitted on the current IACUC form is required.
- Repeat the above schedule as applicable.

If you are **NOT using USDA covered animals** in your research, submission requirements are as follows:

- Every 3rd year (triennially), a 3 Year De Novo Review form **AND** the latest approved version of the complete IACUC protocol (including all previously approved changes and related addenda) submitted on the current IACUC form is required.

IACUC APPLICATION FOR ANIMAL RESEARCH CONDUCTED BY UNMC/UNO FACULTY

Revision: 9/2008

You complete this form to apply for approval of research using animals if:

- You are a faculty member at UNMC or UNO that are proposing to use animals in research other than educational or training purposes
- This is a new project or one that is due for triennial review (3 Year De Novo Review)

ADDENDUM A-PROTOCOL SPECIFIC BREEDING

Revision: 9/2008

- You should complete this form and attach it to the IACUC Application for Animal Research when the experimental design includes the need to breed animals.

ADDENDUM B-REQUEST FOR EXPIRED MATERIALS OR DEVICES IN ANIMALS

Revision: 9/2008

- You should complete this form and attach it to the IACUC Application for Animal Research when you are requesting to use expired materials.

Paper color: blue

IACUC APPLICATION FOR FACULTY BREEDING COLONY

Revision: 5/2008

You complete this form to apply for approval of research for the establishment of a breeding colony if:

- You are a faculty member at UNMC or UNO
- You will be breeding animals to produce weaned pups to transfer to an IACUC approved research protocol(s)
- This is a new project or one that is due for triennial review (3 Year De Novo Review)

ADDENDUM TO THE BREEDING COLONY PROTOCOL

Revision 5/2008

- You complete and attach this form to the Breeding Colony Protocol if maintaining the breeding colony involves procedures not listed on the main application.

Paper color: white

IACUC APPLICATION FOR USE OF ANIMALS IN EDUCATION AND TRAINING

Revision: 9/2008

You complete this form to apply for approval of research using animals if:

- You are a faculty member at UNMC or UNO
- This is a new project or one that is due for triennial review (3 Year De Novo Review)
- The project is part of a course you are teaching

Paper color: pewter gray

IACUC APPLICATION FOR ANIMAL RESEARCH CONDUCTED BY UNMC/UNO STUDENTS

Revision: 9/2008

You complete this form to apply for approval of research using animals if:

- You are a student at UNMC or UNO that is going to conduct the research
- This is a new project or one that is due for triennial review (3 Year De Novo Review)

ADDENDUM A-PROTOCOL SPECIFIC BREEDING

Revision: 9/2008

- You complete this form and attach it to the IACUC Application for Animal Research when the experimental design includes the need to breed animals.

Paper color: canary

REQUEST FOR CHANGE

Revision: 9/2008

You complete this form to apply for approval of research using animals if:

- You already have a protocol approved by the IACUC to do the research
- You would like to make a change in the title, the procedure, the number or kind of animals or the participating personnel

NOTE: A change in protocol other than change in study title or study personnel requires submission of a **revised IACUC application** that incorporates the changes in all appropriate Sections. Submissions without a revised IACUC application will be returned without review.

Paper color: goldenrod

USDA ANNUAL CONTINUING REVIEW

Revision: 9/2008

You complete this form to apply for approval of research using animals if:

- You already have a protocol approved by the IACUC to do the research
- Your protocol involves the use of USDA covered species
- The project has already been underway for one, two, four, five, seven, etc years.

Paper color: canary vellum

3 Year (Triennial) De Novo Review

Revision: 9/2008

You complete this form to apply for approval of research using animals if:

- You already have a protocol approved by the IACUC to do the research
- The research has been underway for multiples of 3 years (i.e., 3, 6, 9, years)

NOTE: In addition to the review form, you must submit the latest approved version of the complete IACUC Protocol and any related Addendums on the current IACUC form. The protocol should include all previously approved modifications. The de novo review process ensures that the protocol is being conducted in accordance with current policies and regulations. **NO NEW CHANGES IN PROTOCOL ARE TO BE REQUESTED AT THIS TIME.** If you need to make a change in your currently approved protocol, you must submit a separate Request for Change form for review.

Paper color: green

DOCUMENTATION OF TRAINING

Use this form to document that study personnel have completed all training requirements.



In order to facilitate timely review of the protocols, the deadlines for submission are:

- The last working day of the month for protocols that require Full committee Review.
- Every Monday for protocols that qualify for the Designated Member Review.



For assistance in choosing the correct IACUC Application or for assistance in completing the forms please contact:

IACUC – Dr. Turpen 94388, Beth 96046, or Rebecca 93573

PAL – Traci Clemons 98560, Cell 650-4351



*TO AVOID COMPLIANCE ISSUES PLEASE KEEP AN UPDATED VERSION
OF THE APPROVED PROTOCOL ON FILE
&
ALLOW PERSONNEL LISTED ON THE PROTOCOL ACCESS TO THE
UPDATED VERSION*

NEW POLICIES IN IACUC GUIDELINES ON THE WEBSITE:

1. *Appendix P – IACUC policy for the Conditional Use of Expired Medical Materials in Animals*
2. *Appendix Z – Policy on the Use of Non-Pharmaceutical Grade Compounds in Animals*
3. *Appendix AA – Breeding Protocol*

If you have any comments pertaining to previous editions of PAL Bulletins, New Ideas, or Suggestions for topics please contact tclemons@unmc.edu !

***As always please check the IACUC and CM Websites for new forms and updates.**

***Book Mark these sites for quick access:**

[IACUC Home](#) [UNMC Comparative Medicine](#)