**University of Delaware**

**Institutional Animal Care and Use Committee**

**Request to Amend an Animal Use Protocol**

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| **Title of Protocol:** Click here to enter text. | |
| **AUP Number:** Click here to enter text. | **🡨 (4 digits only)** |
| **Principal Investigator**: Click here to enter text. | |
| **Requested Changes**  **I am requesting a change to: *(Check all that apply)***  Animal Species *(Complete Section 1)*  Animal Numbers *(Complete Section 2)*  Animal Procedures *(Complete Section 3)*  Therapeutic or Experimental Agents *(Complete Section 4)*  Pain Category *(Complete Section 5)*  Use of Biological Material, Hazardous Agents or Radiation *(Complete Sections 4 & 6)*  Other *(Specify)* Click here to enter text.  *(Complete Section 7)* | |
| **Changes MUST NOT be initiated until IACUC approval is granted** | |

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| **Official Use Only**  IACUC Approval Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date of Approval: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Principal Investigator Assurance**

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| 1. I agree to abide by all applicable federal, state, and local laws and regulations, and UD policies and procedures. |
| 1. I understand that deviations from an approved protocol or violations of applicable policies, guidelines, or laws could result in immediate suspension of the protocol and may be reportable to the Office of Laboratory Animal Welfare (OLAW). |
| 1. I understand that the Attending Veterinarian or his/her designee must be consulted in the planning of any research or procedural changes that may cause more than momentary or slight pain or distress to the animals. |
| 1. I declare that all experiments involving live animals will be performed under my supervision or that of another qualified scientist listed on this AUP. All listed personnel will be trained and certified in the proper humane methods of animal care and use prior to conducting experimentation. |
| 1. I understand that emergency veterinary care will be administered to animals showing evidence of discomfort, ailment, or illness. |
| 1. I declare that the information provided in this application is accurate to the best of my knowledge. If this project is funded by an extramural source, I certify that this application accurately reflects all currently planned procedures involving animals described in the proposal to the funding agency. |
| 1. I assure that any modifications to the protocol will be submitted to the UD-IACUC and I understand that they must be approved by the IACUC prior to initiation of such changes. |
| 1. I understand that the approval of this project is for a maximum of one year from the date of UD-IACUC approval and that I must re-apply to continue the project beyond that period. |
| 1. I understand that any unanticipated adverse events, morbidity, or mortality must be reported to the UD-IACUC immediately. |
| 1. I assure that the experimental design has been developed with **consideration of the three Rs: reduction, refinement, and replacement, to reduce animal pain and/or distress and the number of animals used in the laboratory.** |
| 1. I assure that the proposed research does not unnecessarily duplicate previous experiments. *(Teaching Protocols Exempt)* |
| 1. I understand that by signing, I agree to these assurances.   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Principal Investigator Date |
| **Signature(s) of All Persons Listed on This Protocol**  I certify that I have read this protocol, accept my responsibility and will  perform only the procedures that have been approved by the IACUC.   |  |  | | --- | --- | | **Name** | **Signature** | | 1. Click here to enter text. |  | | 2. Click here to enter text. |  | | 3. Click here to enter text. |  | | 4. Click here to enter text. |  | | 5. Click here to enter text. |  | | 6. Click here to enter text. |  | | 7. Click here to enter text. |  | | 8. Click here to enter text. |  | | 9. Click here to enter text. |  | | 10. Click here to enter text. |  | | 11. Click here to enter text. |  | | 12. Click here to enter text. |  | | 13. Click here to enter text. |  | | 14. Click here to enter text. |  | | 15. Click here to enter text. |  | |

**Proposed Changes to an Existing Protocol**

**Complete all boxes below that correspond to the changes requested.**

***Note:* All Addenda associated with the requested changes (Survival Surgery, Terminal Surgery, Polyclonal Antibody, Monoclonal Antibody, Wildlife) must be completed and submitted to the IACUC along with this Amendment**

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**Is Funding Source the same as on original, approved AUP?**

**Yes**   **No**

**If no, please state Funding Source and Award Number:** Click here to enter text.

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| |  | | --- | | **Section 1: Change in Animal Species** | | 1. Genus species requested: Click here to enter text. | | 1. Common name: Click here to enter text. | | 1. Justification for additional species: Click here to enter text. | | 1. Determination that the new species is the most appropriate:   ***(Check all that apply and explain)***:   1. A large database exists, allowing comparisons with previous data: ***(Explain)***: Click here to enter text. | | 1. The anatomy or physiology is uniquely suited to the study proposed: ***(Explain)***: Click here to enter text. | | 1. This is the lowest species on the phylogenic scale suitable to the proposed study: ***(Explain)***: Click here to enter text. 2. Other: ***(Explain)***: Click here to enter text. | |
| |  | | --- | | **Section 2: Change in Number of Animals** | | 1. Number requested: Click here to enter text. | | 1. Genus species: Click here to enter text. | | 1. Justification for additional animals: Click here to enter text. | | 1. Explanation of how this number was derived, preferably by the use of power analysis:   ***(Check all that apply and explain)***:   1. Pilot study or preliminary project where group variances are unknown at the present time. Describe the information used to estimate how many animals will be needed: (Only a limited number of animals will be permitted.)   ***(Explain):*** Click here to enter text. | | 1. Group sizes are determined statistically. Describe the statistical analysis used to estimate the number (N) of animals needed: N may be estimated from a power analysis for the most important measurement in the study, usually based on the expected size of the treatment effect, the standard error associated with the measurement, and the desired statistical power (e.g. P < 0.05). Data analysis methods should not be submitted unless directly applicable to the estimate of N.   *An online calculator may be found at:*  <http://www.math.uiowa.edu/~rlenth/Power/>  *or a* *stand-alone calculator that can be downloaded from:*  <http://www.psycho.uni-duesseldorf.de/abteilungen/aap/gpower3>  ***(Explain):*** Click here to enter text. | | 1. Group sizes are based on the quantity of harvested cells or the amount of tissue required for *in vitro* studies. Explain how much tissue is needed based on the number of experiments to be conducted and the amount of tissue you expect to obtain from each animal (e.g., 10g of tissues are needed: Each animal can provide 2g. 10g /2g per animal = 5 animals needed.)   ***(Explain):*** Click here to enter text. | | 1. Teaching protocol. Specify the number of students in the class, the student to animal ratio and how that ratio was determined: Animal numbers should be minimized to the fullest extent possible without compromising the quality of the hands-on teaching experience for students or the health and welfare of the animals.   ***(Explain):*** Click here to enter text. | | 1. Study involving feral or wild animals. Animals will be captured and released in an attempt to maximize the sample size within logistical constraints. Describe the process by which you estimate these numbers and estimate the precision needed:   ***(Explain):*** Click here to enter text. | | 1. Observational, non-manipulative study. Animals will not be captured, their behavior will not be interfered with, and exact animal numbers cannot be predicted:   ***(Explain):*** Click here to enter text. | | 1. Product testing. The number of animals needed is based on FDA guidelines. Provide the citation from the regulations, the IND tracking number, or relevant FDA correspondence:   ***(Explain):*** Click here to enter text. | | 1. Other. Elaborate, indicating the method used to determine the group size.   ***(Explain):*** Click here to enter text. | |

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| |  | | --- | | **Section 3: Change in Animal Procedures\*** | | 1. Complete description of change in procedure: Click here to enter text.   Are humane endpoints the same as approved in the original protocol? Yes  No  If no, please describe: Click here to enter text. | | 1. Why the change is being requested: Click here to enter text. | | 1. How the change relates to the work previously approved: Click here to enter text. | | 1. List who will be performing the procedure: Click here to enter text. | | 1. Provide details on each person’s training to perform the procedures: Click here to enter text. |   ***\*Procedural changes which differ significantly from your previously approved AUP, require completion of Section 8.***  ***\*Procedural changes which may cause pain or distress (even if fully alleviated) and are not already described in your previously approved AUP, require completion of Section 9.***  ***\*Procedural changes that involve surgery require completion of the appropriate surgical addendum.*** |

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| **Section 4: Change in Therapeutic or Experimental Agents\***   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | 1. Agent information:  |  |  | | --- | --- | | Agent: | Click here to enter text. | | Dose (mg/kg): | Click here to enter text. | | Route: | Click here to enter text. | | Volume: | Click here to enter text. | | First administered: | Click here to enter text. | | Frequency: | Click here to enter text. | | Duration or # Doses: | Click here to enter text. | | | 1. Justification for the change: Click here to enter text. 2. If a compound is injected, is it pharmaceutical-grade? Yes  No   If no, please explain why a non pharmaceutical-grade drug is used, and describe how it is prepared so that it is sterile. : Click here to enter text. |   ***\*Agents which differ significantly from those described in your previously approved AUP require completion of Section 8.***  *\*A****gents which may cause pain or distress (even if fully alleviated) and are not already described in your previously approved AUP require completion of Section 9.*** |

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| **Section 5: Change in Pain/Distress Category\***   |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | 1. Pain Category Previously Approved: *(please mark one)*  |  |  | | --- | --- | | USDA PAIN CATEGORY: ***(Note change of categories from previous form)*** | | | Category | Description | | B | Breeding or holding where NO research is conducted | | C | Procedure involving momentary or no pain or distress | | D | Procedure where pain or distress is alleviated by appropriate means (analgesics, tranquilizers, euthanasia etc.) | | E | Procedure where pain or distress cannot be alleviated, as this would adversely affect the procedures, results or interpretation | |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | 1. New Pain Category Requested: *(please mark one)*  |  |  | | --- | --- | | USDA PAIN CATEGORY: ***(Note change of categories from previous form)*** | | | Category | Description | | B | Breeding or holding where NO research is conducted | | C | Procedure involving momentary or no pain or distress | | D | Procedure where pain or distress is alleviated by appropriate means (analgesics, tranquilizers, euthanasia etc.) | | E | Procedure where pain or distress cannot be alleviated, as this would adversely affect the procedures, results or interpretation | |  |  | | --- | | 1. Justification for the change in the Pain Category: Click here to enter text. |   ***\* Change to a more painful/distressful category requires completion of******Section 3 and Section 9.*** |

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| **Section 6: Use of Biological Material, Potentially Hazardous Agents, or Radiation\***   |  | | --- | | 1. List the biological material, potentially hazardous agent, or radioactive material to be used.   (This includes the use of cell lines, bacteria, viruses, prions, pathogens, carcinogens, teratogens, nanoparticles, irradiation, radioactive materials, etc.) If you are uncertain whether a substance or procedure requires EHS approval, please contact EHS. Click here to enter text. | | 1. Do you have approval from EHS?   Yes  No  (If you checked “yes”, please attach a copy of the approval form) |   *\*****Requires completion of Section 4.*** |

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| **Section 7: Other Changes**   |  | | --- | | 1. Describe in detail any other changes you wish to make to your previously approved AUP: Click here to enter text. | | |
| **Section 8: Unnecessary Duplication of Work**  ***Note:*** *If any of these changes that are part of this amendment differ significantly from those described in your previously approved AUP; you must conduct searches to show that these changes are not duplicating previous work.* |
| Activities involving animals must not unnecessarily duplicate previous experiments performed by you or others. Provide a written narrative that assures that the activities of this project comply with this requirement and support this assurance by performing a literature search.  The search should return, at minimum, the related previous work from your laboratory.  **You must conduct at least two (2) searches.**  ***(Not Required for Teaching Protocols)*** |
| Database Used:  Medline  Agricola  Toxline  CAB Abstracts  Biosis  Other *(Specify)*: Click here to enter text. |
| Date of Search: Click here to enter text. |
| Years Covered: Click here to enter text. |
| Keywords Used: Click here to enter text. |
| Number of Papers Found: Click here to enter text. |
| Discussion of the Relevancy of the Papers Found: Click here to enter text. |
| Database Used:  Medline  Agricola  Toxline  CAB Abstracts  Biosis  Other *(Specify)*: Click here to enter text. |
| Date of Search: Click here to enter text. |
| Years Covered: Click here to enter text. |
| Keywords Used: Click here to enter text. |
| Number of Papers Found: Click here to enter text. |
| Discussion of the Relevancy of the Papers Found: Click here to enter text. |

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| **Section 9: Alternatives to Procedures that May Cause Pain or Distress**  ***Note:*** *If any of these changes that are part of this amendment will cause pain or distress, even if fully alleviated, and are not described in your previously approved AUP, you must conduct searches for alternatives to these procedure(s).* |
| I have considered alternatives to procedures that may cause more than momentary pain or distress. Alternatives refer to methods or approaches which result in refinement of procedures which lessen pain and/or distress; reduction in numbers of animals required; or replacement of animals with non-whole-animal systems or replacement of one animal species with another, particularly if the substituted species is non-mammalian or invertebrate. I have used the following methods and sources to search for alternatives:  **You must conduct at least two (2) searches.** |
| Database Used:  Medline  Agricola  Toxline  CAB Abstracts  Biosis  Other *(Specify)*: Click here to enter text. |
| Date of Search: Click here to enter text. |
| Years Covered: Click here to enter text. |
| Keywords Used: *(must include the word “alternative”)* Click here to enter text. |
| Number of Papers Found: Click here to enter text. |
| Discussion of the Relevancy of the Papers Found: Click here to enter text. |
| Database Used:  Medline  Agricola  Toxline  CAB Abstracts  Biosis  Other *(Specify)*:Click here to enter text. |
| Date of Search: Click here to enter text. |
| Years Covered: Click here to enter text. |
| Keywords Used: *(must include the word “alternative”)* Click here to enter text. |
| Number of Papers Found: Click here to enter text. |
| Discussion of the Relevancy of the Papers Found: Click here to enter text. |