**

**COVER PAGE - Checklist for Significant Change Application**

|  |  |
| --- | --- |
| **PI Name:** |  |
| **Protocol Number:** |  |
| **Protocol Title:**  |  |

**Check (“x”) the categories that are relevant to this application:**

|  |  |
| --- | --- |
| **For projects supported by a federal granting agency:** * I have attached an appendix file that includes the grant cover page, abstract, and vertebrate animal section with this application.
* I avow that this significant change does not constitute a “change in scope” to the funded research project that must be reported to the funding agency.
 |  |
|  |
|  |
| The significant change involves the use of **hazardous chemicals, biological hazards, or recombinant DNA** in live animals *that was not listed in the original approved protocol* and I have approved relevant SOPs, or have submitted new SOPs for new hazardous materials: |  |
| **New personnel** listed on this protocol application have completed enrollment in the occupational health and safety program, including a medical evaluation. The new individuals are: |  |
| The significant change includes the use of **controlled substance/s** in the live animal *that was not listed* in the original protocol approved by IACUC. **This includes:**  |  |
| The significant change involves the use of **radioactive materials** or **irradiation** with live animals *that was not listed* in the original protocol approved by IACUC; I have attached a copy of the approval from the radiation safety officer to this application. |  |
| The significant change includes the use of a **laser** in the live animal *that was not listed* in the original protocol and I have submitted a copy of the approved laser registration form. |  |
| This project is the subject of a Conflict of Interest (COI) committee **management plan** and I have submitted a copy of the plan with this application. |  |
| ***I have checked the attestation box on the last page of the application and typed my name as an electronic signature.*** |  |

**

***APPLICATION FOR SIGNIFICANT CHANGE TO ANIMAL PROTOCOL***

**I. ADMINISTRATIVE INFORMATION:**

**Principal Investigator (PI):**

|  |  |
| --- | --- |
| Name: |  |
| Degree/Title: |  |
| Dept. / Institute: |  |
| Email: |  |
| Phone: |  |

**Protocol Information:**

|  |  |
| --- | --- |
| Title of Protocol: |  |
| Funding Agency\*: |  |
| Date of Initial Submission: |  |
| Date of this Revision (*if applicable*): |  |

*\* For federal grants attach the abstract and vertebrate animal section (VAS) of the grant.*

**II. The Following Significant Changes ARE PROPOSED:**

*Check all that apply and complete only those sections of the application./*

|  |  |
| --- | --- |
|  | Change in Study Objectives *[Complete Item #2]* |
|  | Change in Animal Subjects: **[ ]** species **[ ]**  number *[Complete Item #3]* |
|  | Change in Surgical Procedures *[Complete Items #4 & #6]* |
|  | Change in Non-Surgical Procedures *[Complete Items #5 & #6]* |
|  | Change in Pain/Distress Levels *[Complete Item #6]*  |
|  | Change in Anesthetic/Analgesic regimen *[Complete Item #7]* |
|  | Change in Animal Monitoring or Humane Endpoints *[Complete Item #8]* |
|  | Change in Method of Euthanasia  *[Complete Item #9]* |
|  | Change in Use of Hazardous Agents in Animals  *[Complete Item #10 and submit relevant new safety approval documents from EHS]* |
|  | Other Significant Change in Activity *[Complete Item #11]* |
|  | Change in PI *[Complete Item #12]* |

*NOTE: The IACUC may request that you submit a new protocol application instead of this form if the number or the magnitude of changes proposed are deemed substantial, or if numerous previous significant amendments have been made. If you have questions, contact the IACUC Chair before proceeding.*

***ITEM #1 MUST BE COMPLETED ON ALL APPLICATIONS***

**1. Nontechnical Summary of Proposed Significant Change(s):**

*This should be written in language that a non-scientist (e.g. high school student) can understand. Be sure to include the species and the new types of activities that will done with animals.*

|  |
| --- |
|  |

**2. Change In Study Objectives:**

*Provide the rationale for the changes and explain how the new objectives relate to the purpose of the study as described in the approved protocol.**Be sure to include the species and the new types of activities that will done with animals.*

|  |
| --- |
|  |

**3. Change in Number of Animals or Addition of Animal Species:**

*Increases greater than 20% of the originally approved number of animals require this form; insert the species and animal numbers in the relevant column.*

Original Species: New Species:

|  |  |  |
| --- | --- | --- |
| # additional animals needed |  | # animals needed |
|  |  |  |

 Justification for additional animals:

|  |
| --- |
|  |

Justification for adding new species of animal:

|  |
| --- |
|  |

**4. Change in Surgical Procedures:**

 a. Describe proposed changes in *non-survival* surgical procedures in detail:

|  |
| --- |
|  |

 b. Describe proposed changes in *survival* surgical procedures in detail:

|  |
| --- |
|  |

 c. Describe proposed changes in *multiple major survival* *surgery* procedures in detail:

|  |
| --- |
|  |

 d. If proposing to ADD multiple major survival surgery (*not previously approved*), provide strong scientific justification:

|  |
| --- |
|  |

e. For all surgery categories above indicate whether:

 Post-surgical Monitoring will be:

|  |  |
| --- | --- |
|  | as described in the approved protocol |
|  | modified as described in Section # 8 |

 Humane Endpoints will be:

|  |  |
| --- | --- |
|  | as described in the approved protocol |
|  | modified as described in Section # 8 |

f. New Surgeon/Qualifications: *(List any new individuals who will be conducting surgeries and their qualifications and whether the PI has confirmed that they are trained to competency)*

|  |
| --- |
|  |

**5. Change in Non-Surgical Procedures:**  *(This includes changes in the duration, intensity, frequency, degree of invasiveness, or other features of a non-surgical procedure with animals.)*

 a. Describe proposed changes in non-surgical procedures in detail:

|  |
| --- |
|  |

 b. For new non-surgical procedures:

Monitoring will be:

|  |  |
| --- | --- |
|  | as described in the approved protocol |
|  | modified as described in Section # 8 |

Humane Endpoints will be:

|  |  |
| --- | --- |
|  | as described in the approved protocol |
|  | modified as described in Section # 8 |

**6. Change in Pain/Distress Levels:**

*If the proposed changes do not affect the status of other animals listed in the original protocol, include only new animals requested in Item 3 above. If changes add new animals or move already approved animals into Category E, complete Section 6b. If changes involve adding new animals to pain/distress categories D or E, complete Section 6c.*

 a. Categorize the level of pain or distress that animals might experience as a result of proposed changed procedures in the protocol:

|  |  |
| --- | --- |
|  | No changes will result  |
|  | Proposed changes will alter the pain/distress levels |

|  |  |
| --- | --- |
| **Species:** | **# of animals** |
| Pain Category C *(\*No or momentary Pain or Distress)* |  |
| Pain Category D *(\*\*Alleviated Pain or Distress)* |  |
| Pain Category E *(\*\*\*Unalleviated Pain or Distress)* |  |

 b. If animals are listed in Pain Category E above, provide strong scientific justification here; including your Harm-Benefit assessment of this work:

|  |
| --- |
|  |

c. Updated Search for Alternatives for potentially painful or distressful procedures. *Complete ONLY if your proposed changes will add/move any animals into pain/distress categories D or E.*

 Specific Databases that were searched *(include at least 2)*:

|  |
| --- |
|  |

 Years Covered by Searches:

|  |
| --- |
|  |

 Key Words / Search Strategies Used:

|  |
| --- |
|  |

 Date of New Search(s):

|  |
| --- |
|  |

 Narrative of Findings from Literature Searches: *Be sure to include responses to EACH of the 3 “Rs” in your narrative (Reduce, Replace, Refine).*

|  |
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|  |

**7. Change in Anesthesia/Analgesia Regimen:**

**a. ANESTHESIA**

|  |  |
| --- | --- |
|  | No Changes Will Result  |
|  | Proposed Changes Involve: |

|  |  |  |
| --- | --- | --- |
|  | Species 1 | Species 2 |
| Name of agent\*  |  |  |
| Dose *(mg/kg or % concentration)*  |  |  |
| Route of administration |  |  |

\*If volatile anesthetic drugs will now be used, please address how safety/scavenging issues will be addressed:

|  |
| --- |
|  |

 Reason for Change:

|  |
| --- |
|  |

 **b. ANALGESIA/SEDATION**

|  |  |
| --- | --- |
|  | No Changes Will Result  |
|  | Proposed Changes Involve: |

|  |  |  |
| --- | --- | --- |
|  | Species 1 | Species 2 |
| Name of agent  |  |  |
| Dose *(mg/kg or % concentration)*  |  |  |
| Route of administration |  |  |
| Frequency |  |  |

 Reason for Change:

|  |
| --- |
|  |

 If changes involve withholding analgesia after surgical procedures (not previously approved), provide scientific justification:

|  |
| --- |
|  |

**8. Change in Animal Monitoring or Humane Endpoints.**

a. Describe changes in **Post-Procedural Care and Monitoring** that relate to this amendment:

|  |
| --- |
|  |

 b. Describe changes in **Humane Endpoints** that will be used to terminate animals from the study early to avoid unnecessary pain or distress:

|  |  |
| --- | --- |
|  | Moderate to severe clinical signs of pain and distress that is unalleviated by appropriate analgesics |
|  | Anorexia (inability to eat or drink) |
|  | Emaciation (weight loss > 20% of normal weight |
|  | Mutilation of operative site |
|  | Depression/lethargy > 48 hours |
|  | Non-weight bearing/paralysis |
|  | Infection not resolved with antimicrobial therapy |
|  | Diarrhea |
|  | Moribund – lack of righting reflex |
|  | Cyanotic, difficulty breathing |
|  | CNS signs (seizures, circling) |
|  | Hypothermia |
|  | Other *(describe):* |  |

 If you are NOT using humane endpoints, provide strong scientific justification. *Be sure to explain what essential information will be obtained between the interval when an animal becomes moribund and when death occurs that cannot be obtained in another way in your studies*

|  |
| --- |
|  |

**9. Change in Euthanasia Method**

**Indicate whether the method(s) to be used for euthanizing the animals is/are consistent with current AVMA Guidelines on Euthanasia and IACUC guidelines:**

|  |  |
| --- | --- |
| **Yes\*** |  **No** |
|  |  |

*\*Complete Section 9a if “Yes” is checked; Complete Section 9b if “No” is checked.*

*(In some cases, both may be checked).*

**a. AVMA ACCEPTABLE EUTHANASIA METHODS (2020 Guidelines) that will be used:**

***(Check all that apply)***

 **Species 1:**  **Species 2:**

|  |  |  |
| --- | --- | --- |
| \*CO2 exposure  |  |  |
| Overdose using anesthetic agent\*\* by injection or inhalation\*\*\* |  |  |
| Cervical dislocation under anesthesia |  |  |
| Decapitation under anesthesia |  |  |
| Exsanguination under anesthesia |  |  |
| KCl (Potassium chloride) injection intravenous or intracardiac under general anesthesia |  |  |

**\*If CO2 or anesthetic drug inhalation will be used, check which secondary method(s) will be used to confirm death? *(required)***

|  |  |
| --- | --- |
|  | Decapitation |
|  | Cervical Dislocation |
|  | Opening Thorax |
|  | Exsanquination or Major Organ Removal (e.g. brain, heart) |

\*\***If anesthetic drugs will be used for/during euthanasia, provide the**

**following information:**

 **Species 1:**  **Species 2:**

|  |  |  |
| --- | --- | --- |
| Name of agent  |  |  |
| Dose mg/kg or % |  |  |
| Route of administration |  |  |

***NOTE: If volatile anesthetic drugs will be used for euthanasia, be sure to also complete Section VI.B. of this application form to addresses safety/ scavenging issues.***

**b. AVMA CONDITIONALLY ACCEPTABLE OR NONACCEPTABLE\* EUTHANASIA METHODS (2020 Guidelines) that will be used (*requiring further scientific justification*):**

 **Species 1:**   **Species 2:**

|  |  |  |
| --- | --- | --- |
| Cervical dislocation *without general anesthesia*(**Note:** *rodents only*) |  |  |
| Decapitation *without general anesthesia* (**Note:** *rodents only*) |  |  |

**\*Provide scientific justification for the proposed deviation from the AVMA and IACUC recommended euthanasia methods.** *(If only a portion of the experimental animals will be euthanized by non-recommended methods, provide an estimate of how many animals will be euthanized in that manner.)*

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**\*Additionally, provide information about the specialized training of the personnel who will carry out the non-recommended euthanasia procedures (*required*).**

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10. Change in Use of Hazardous Agents in Live Animals:

 a. Indicate the type of change:

|  |  |
| --- | --- |
|  | **Biological** *(infectious agents, tumor cells, viral agents, recombinant DNA)*  |
|  | **Chemical** *(toxins, carcinogens or other hazardous chemicals)* |
|  | **Radioactivity** *(isotopes or ionizing radiation)* |

 b. Describe the proposed changes in detail:

|  |
| --- |
|  |

*Note: If you are making changes in any of these categories, you must also attach copies of the relevant approvals from the Office of Environmental Health and Safety and appropriate for the agents listed. It is recommended you discuss the changes with IACUC Chair to determine exactly what may be needed!*

**11. Other Significant Change:**

|  |
| --- |
|  |

**12. Change in Principal Investigator (Pi):**

 a. Identify new PI and discuss reasons for change:

|  |
| --- |
|  |

 b. Discuss the relevant experience/training/qualifications of new PI here *(attach CV to application)*:

|  |
| --- |
|  |

***Assurances:***

 *I certify that the approved animal use protocol in conjunction with the Significant Change(s) in this application accurately describes all aspects of the proposed animal usage. I further certify that the use of animals will be in accord with U.S. Department of Agriculture Animal Welfare regulations (Code of Federal Regulations, Title 9, Chapter 1, Subchapter A, Parts 1, 2, 3), the Public Health Service Policy on Humane Care and Use of Laboratory Animals, the National Research Council Guide for the Care and Use of Laboratory Animals, and the policies established by Rosalind Franklin University. I further certify that the use of animals is not unnecessarily duplicative. I accept responsibility that all personnel working on the project will adhere to the regulations regarding the humane treatment of laboratory animals and will be properly trained for their responsibilities on protocol studies. I will obtain approval prior to instituting any other significant changes in the project. I understand that the approval is not final until I receive notification of such in writing, and that the IACUC can require changes to the protocol. I understand that approval of the animal protocol is for a maximum of three years from the date of IACUC approval of the original submission, contingent upon filing and approval of annual renewal applications, and that approval of the significant changes submitted on this form will not change the expiration date of the protocol.*

**Before submitting an electronic copy of this application, click on the attestation box below and enter your name and today’s date. After checking the attestation box, please save a copy of this application form and send the signed/attested form as a Word file to** **IACUC@rosalindfranklin.edu****. Also, send one printed hard copy of the application to the IACUC office via campus mail.**

**Principal Investigator**

I certify by checking the attestation line below that the information provided in this application is complete and accurate. I also pledge that I will agree and abide by the Assurances stated above.

\_\_\_ Attestation of Principal Investigator

**Name of PI (typed): Date:**

**………………………………………………………………………………………………………**

**Final Review and Approval by the Institutional Animal Care and Use Committee:**

 Name: Monica M. Oblinger, Ph.D. (Chair)

 Signature: Date: