**ARIZONA STATE UNIVERSITY**

**Institutional Animal Care and Use Committee**

***REQUEST FOR CHANGES TO AN APPROVED PROTOCOL***

Protocol No.

Title:

Principal Investigator:       Email Address:

If not PI, whom should we contact for questions related to this amendment:       Email Address:

[ ] Funded [ ] Unfunded

**Requested Change (check all that apply):**

[ ]  New procedures to be performed – complete Part A, and Part B, Appendix 1 and/or 2 as applicable, and sign assurance.

[ ]  New species and or an increase in the number of animals to be used – complete Part A and sign assurance.

[ ]  New location of housing or procedures – complete Part A and sign assurance.

[ ]  New personnel – complete Part C and sign assurance.

[ ]  Other (includes changes in dosages, funding, etc.) – complete Part A and sign assurance.

**A. DESCRIPTION OF REQUESTED CHANGE**

*For new procedures or additional animals that are USDA-covered species (all mammals and birds EXCEPT mice, rats, and birds bred for research)*, list the **Category of Pain:**

*For new procedures or additional animals that are not USDA-covered species,* will there be the potential to involve more than slight or momentary pain or distress that will NOT be relieved with anesthetics, analgesics, tranquilizer drugs, or other methods for relieving pain or distress (e.g., negative conditioning, unrelieved post-surgical pain, death without euthanasia)? [ ]  No [ ] Yes

If yes, describe and justify:

*If you are adding a procedure that could create pain or distress*, you need to include a **literature search** for alternatives.

*If you are adding new chemicals and other potential hazards, complete* ***Part B***

*If you are adding a new survival surgery,* submit a surgical checklist.

*If you are requesting an increase in animal numbers*, provide justification with supportive statistics.

*If you are adding additional funding sources,* provide the grant agency, grant title and ASU proposal or award number.

Describe the changes you are requesting.

**B. CHEMICALS AND OTHER POTENTIAL HAZARDS**

***(If you answer yes to any of the following questions, this information may be forwarded to another oversight unit to aid you in assuring safe practices. Approval by these units or additional training may be required prior to using any of these materials)***

1. **Will you be using on animals any drugs or chemicals that are new to the protocol?**

**[ ]** No. Proceed to section B.2

[ ]  Yes. For each new drug or chemical, list the agent, dose, route, purpose, and grade in the table below:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Agent** | **Dose** | **Route** | **Purpose** | **Frequency** | **Pharmaceutical****grade (Y/N)?** | **Is this a DEA controlled substance (Y/N)?** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

1. **For each new drug or chemical that is not pharmaceutical grade:**
2. **Indicate whether no pharmaceutical grade equivalent exists or provide scientific justification for using the non-pharmaceutical grade product.**

1. **Provide the source and vendor item number (if there is one) for each non-pharmaceutical grade product even if there is no pharmaceutical alternative.**

1. **Describe the means by which you ensure the purity, sterility, and pH of each non-pharmaceutical product are compatible with use in live animals.**

**If there is any uncertainty about the proposed product or its properties, the IACUC may require you to inform the DACT veterinary team prior to first using each non-pharmaceutical grade compound to assess the possibility of negative effects on the animal.**

1. **Does this request include any new transgenic, knockout, or knock-in animals?**

**[ ]** No. Proceed to section B.3

[ ]  Yes. List the new strains, any special care needs, and any expected clinical signs that are associated with the strain. Transgenic animals need to be covered by an IBC disclosure.

1. **Does this request include any new use of biohazardous agents in animals (microorganisms, microbial toxins, recombinant DNA)?**

**[ ]** No. Proceed to section B.4

[ ]  Yes. List the new agents, as well as concentration, dose, and route if applicable.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Agent**  | **Concentration** | **Dose** | **Route** | **ADMIN. USE ONLY** |
| **ABSL** | **IBC # if Req’d** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

1. **Does this request include any new use of irradiation or radiological material in animals?**

**[ ]**  No. Proceed to section C

[ ]  Yes. List the agent, dose, route, and purpose in the table below:

|  |  |  |  |
| --- | --- | --- | --- |
| **Agent** | **Dose** | **Route** | **Purpose** |
|  |  |  |  |
|  |  |  |  |

**a. Provide the date of Radiation Safety Committee approval:**

**C. ADDITIONAL PERSONNEL**

All personnel who work with animals are required to have animal care training within the last four years. ASU IACUC training modules can be completed at <https://asu.co1.qualtrics.com/jfe/form/SV_b2b2XRXRRs1309f>. Personnel are required to have Level III training certification on file with the IACUC office in order to perform procedures independently (without supervision). Training can be received from DACT staff or PIs can have a member of their lab approved by DACT to be a Certified Trainer who can then train others. Simply being Level III certified does not allow the training of others. See the IACUC web site (<https://researchintegrity.asu.edu/animals/training>) for more information on training and Level III forms.

**\* Procedures other than husbandry, handling, or behavioral testing MUST be performed under supervision unless the person is Level III certified to conduct the procedure independently. Certification can only be provided by the DACT veterinary team or someone the team has authorized as a trainer.  Personnel are not Level III certified until the IACUC has reviewed and approved the Level III training documentation.  The PI is responsible for ensuring that personnel who are not Level III certified are supervised at all times.**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Name** | **Title** | **ASURITE** **name** | What activities will each person perform on live animals **ONLY** while under direct supervision? | Which of these activities will each person be involved in without supervision? ***Behavioral testing may require additional training verification, depending on the tasks.*** | What additional activities will each person be allowed to perform **independently** (including appropriate Level 3 certification\*) at the time of protocol submission? | **Species with which individual will have direct contact (“all” or list species) \*** | **IACUC****USE ONLY** **Training and OHSP confirmation** |
|       |       |       |       | [ ]  Husbandry[ ]  Handling[ ]  Behavioral Tasks |  |       |  |
|       |       |       |       | [ ]  Husbandry[ ]  Handling[ ]  Behavioral Tasks |  |       |  |

Identify any trainers who have been authorized by the DACT Veterinary Team to certify lab personnel. For each individual, describe the individual’s training and years of experience with all listed species and procedures they will be conducting under this protocol. For procedures for which they are not yet trained, but will likely be trained to do during the activity period of this protocol, provide a description of who will provide such training:

**D. ASSURANCE**

As Principal Investigator of this protocol, I assure that all procedures will be conducted as described in this request for changes and that personnel will receive appropriate additional training prior to conducting any new procedures that are not listed above. I understand that I have primary responsibility for the management of my project in accordance with federal, state, university, and sponsor requirements. I take full responsibility and accountability for what happens while this protocol is active.

SIGNED:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator Date

 **For IACUC use only:**

 [ ]  Administratively approved - Approving administrator:       Date of approval:

 [ ]  Administratively handled by VCV - Veterinarian providing verification:       Date of verification:

 Sources used for verification:

 [ ]  Approved by Designated Review – Designated reviewer:       Date of approval:

 [ ]  Approved by Full Committee Review – Primary reviewer:       Date of approval: