##### **SUNY Downstate Medical Center**

**IACUC Protocol Amendment Form**

**Request to Modify an Approved Protocol**

Submission Instructions:

The completed Word document and signature page are to be sent to IACUC@Downstate.edu; please be advised that additional information may be requested to assess the impact of the proposed changes on animal welfare.

If the protocol modification is complex (e.g., addition of a surgical procedure to a protocol that does not include surgery), please contact the Office of Animal Welfare (ext. 4645) for guidance. Submission of a protocol revision may be necessary instead of completion of this amendment form.

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| **A.**  | **Protocol Information** |
| 1. | Principal Investigator:  |
| 2. | Protocol Number: |
| 3. | Title:  |
| 4. | Species: |
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| **B.**  | **Amendment Details** – Please provide a response to each item. |
| 1.  | A clear description of the relationship of the amendment to the original protocol: |
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| 2. | Addition of new procedures/experimental conditions and/or new procedure locations: * *New Procedures – Assign the proper* [*USDA Pain & Distress Category*](http://research.downstate.edu/_pdf/Guidelines-for-Assigning-Pain-and-Distress-Categories.pdf) *to each new procedure or experimental condition. List, without descriptions, the names of the new procedures/experimental condition and provide the location where each will occur.*
* *New Location Only – List the name of the existing procedure/experimental condition and add the new location.*
 |
| a. | USDA category C procedure list: Procedures/experimental conditions that have the potential for no or minimal pain and/or distress (typically do not require sedation, anesthesia or analgesia unless for the sole purpose of chemical restraint) |
|  | Name of Procedure | Location of Procedure (Building/Room) |
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| b.  | USDA category D procedure list: Procedures/experimental conditions that have the potential for more than momentary pain and/or distress, which is relieved by the use of either sedation, anesthesia, analgesia, other pharmacological support measures, and/or non-pharmacological support measures. |
|  | Name of Procedure | Location of Procedure (Building/Room) |
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| c.  | USDA category E procedure list: Procedures/experimental conditions that have the potential for more than momentary pain and/or distress, which is unrelieved. |
|  | Name of Procedure | Location of Procedure (Building/Room) |
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| 3.  | [ ] No [ ] Yes | Will any new procedure/experimental condition cause more than momentary or slight pain or distress to animals (USDA Category D or E procedures/experimental conditions)? |
|  | If “**Yes**,” provide the following information, regarding alternative procedures investigated that have less potential for pain/distress.  |
| a. | Give at least two search methods/sources (**[Altweb](http://altweb.jhsph.edu/resources/searchalt/searchaltdata.html)** provides a summary of and links to available databases; Google Scholar is not acceptable):  |
| b. | the date the search was conducted: |
| c. | keywords used in the search:  |
| d. | the date range used in the search parameters: |
| e. | [ ] No [ ] Yes | Were less painful/distressful procedures found? |
|  | If “**Yes**,” explain why they are not appropriate for this study. |
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| 4. | Procedure Description & Flow Chart (if applicable): Describe every new procedure or experimental condition in its own, self-contained paragraph. Provide sufficient detail to understand what is being done and assess the animal welfare implications. Any applicable flow charts can be included here or as a separate attachment.  |
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| 5. | List personnel who will perform new procedures:

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| Name | New Procedures individual will be responsible to perform in this study | Where and when trained in new procedures | If person is not trained, how will training be obtained? |
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| 6. | [ ] No [ ] Yes | Are you adding or changing the dose/administration of a substance (e.g., experimental, anesthetic, analgesic)?* *Note: Use of human samples, radioactive substances, infectious agents, recombinant DNA, and toxic/hazardous/carcinogenic substances requires IBC approval prior to approval of this amendment.*
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|  | If “**Yes**,” provide the following information: |
| a. |

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| Type | Substance | Dosage | Route | Frequency/ Interval | Total # of doses | [Pharma-ceutical Grade](#PharmGrade)? Yes (Y) or No (N) |
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[*Controlled Substances*](https://www.deadiversion.usdoj.gov/schedules/)*: If any of these agents is a controlled substance, complete a* [*Controlled Substance Protocol Registration Form*](http://research.downstate.edu/dcm/comparative-medicine-forms.html) *and submit to DCM (**DCM@Downstate.edu**). Do* ***not*** *submit the form to the IACUC.**Non-Pharmaceutical Grade Substances** *Investigators are expected to use pharmaceutical-grade medications whenever they are available, even in acute procedures per Federal Regulations, guidelines and policies.*
* ***A pharmaceutical-grade substance is*** *any active or inactive drug, biologic, reagent, etc., manufactured under Good Manufacturing Practices (GMP) which is approved, conditionally approved, or indexed by the Food and Drug Administration (FDA) or for which a chemical purity standard has been written or established by a recognized compendia (e.g., United States Pharmacopeia-National Formulary ([USP-NF](http://www.uspnf.com/uspnf/login)), British Pharmacopeia (*[*BP*](http://www.pharmacopoeia.co.uk/)*).*
* *A listing of pharmaceutical-grade drugs and biologics is available through the* [*FDA database*](http://www.fda.gov/Drugs/InformationOnDrugs/default.htm)*. The* [*Orange Book*](http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=orange%20book&utm_content=1) *is the reference for FDA-approved human drugs. The* [*Green Book*](http://www.fda.gov/animalveterinary/products/approvedanimaldrugproducts/default.htm) *is the reference for FDA-approved veterinary drugs. Pharmaceutical grade drugs will have a National Drug Code (an NDC) that can be found on the packaging.*
* *The use of non-pharmaceutical-grade chemical compounds in experimental animals under certain circumstances has been, and will continue to be, a necessary and acceptable component of biomedical research. OLAW and the USDA have determined that their use should be based on scientific justification, and specific review and approval by the IACUC.*
 |
| b. | If you are using a non-pharmaceutical (e.g., chemical) grade substance, provide a scientific justification for each substance in the following table:*Acceptable standard justifications include the following:* 1. *An equivalent veterinary or human pharmaceutical-grade compound does not exist or it is unavailable.*
2. *The equivalent veterinary or human pharmaceutical-grade compound is not available in the appropriate formulation or concentration required.*
3. *Although there is an equivalent veterinary or human drug available, the chemical grade is required to replicate methods from previous studies.*
4. *The equivalent veterinary or human pharmaceutical-grade compound contains preservatives or inactive ingredients which may confound the research goals of the study.*
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| Non-Pharmaceutical Grade Substance | Scientific Justification – If any of the items above (1-4) are applicable, you may copy/paste into the table or simply list the associated number(s). If none of these items apply, provide appropriate scientific justification instead. |
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|  | Describe how purity and sterility of the non-pharmaceutical grade agents listed above is documented/confirmed when (1) manufactured and (2) when manipulated on site. |
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| 7. | [ ] No [ ] Yes | Are you adding sample collection times (refer to [standard limits](http://research.downstate.edu/_pdf/iacuc/Performance-of-Repeat-rocedures-Reviewed-by-Verified-Veterinary-Consultation.pdf); request veterinary consult as needed)? |
|  | If “**Yes**,” provide the specific modifications and samples collected: |
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| 8. | [ ] No [ ] Yes | Are you adding new strain(s), breed(s), sex, or age of animal for study?  |
|  | If “**Yes**,” provide the following information: |
| a. | List new strain(s)/breed(s): |
| b. | Indicate the sex, age/weight, or other specifications: |
| c. | Indicate the preferred source(s): |
| d.  | [ ] No [ ] Yes | Are the animals or with they be genetically modified (transgenic, knock-out, etc.)? |
|  | If “**Yes**,” provide the following information: |
|  | i. | How does the genetic alteration compromise the welfare of the animals?  |
|  | ii. | Describe any special husbandry or veterinary requirements to be provided by DCM staff or laboratory staff in coordination with DCM. This includes any additional safety requirements and/or procedures, other than routine personnel protective equipment (PPE) that must be used by DCM animal care staff caring for these animals. |
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| 9. | [ ] No [ ] Yes | Are additional animals needed for the new procedures/experimental conditions? |
|  | If “**Yes**,” provide the following information: |
| a. | Total number of additional animals being requested: |
| b. | Justification of additional numbers based upon experimental design or breeding requirements.* *If the experimental sample size differs from what is described in the approved protocol, indicate the sample size, how it was determined (provide the power analysis ‘power’ and ‘alpha’ values or other information to explain how you determined the sample size), and a new or revised flow chart describing the experimental design, study groups, animal numbers, and timeline for all procedures if different from the approved protocol.*
* *RODENTS ONLY: If you are breeding, complete and append a breeding calculator to detail the number of animals needed to maintain each strain, create strains, and generate the number of experimental animals for study. Internet Explorer browser compatible link:* [*http://research.downstate.edu/\_pdf/iacuc/mouse-breeding-calculator\_DMC.pdf*](http://research.downstate.edu/_pdf/iacuc/mouse-breeding-calculator_DMC.pdf)
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| 10. | [ ] No [ ] Yes | Is single housing of social species required for experimental reasons that are not covered by the approved exceptions, detailed below? |
|  |  | *\*Social housing of social species will be the default housing arrangement. The IACUC has approved several program-wide social housing exceptions based upon animal welfare conditions, which are listed below and can be used when applicable to this protocol.** *Male breeding animals between matings*
* *Pregnant females*
* *Weaned animals when a litter contains a single male and/or female or specific genotype at the time of weaning*
* *For fasting prior to surgery or other procedures that require general anesthesia*
* *Up to 14 days for post-operative recovery and observation*
* *Lack of another socially compatible animal (e.g., aggression, health status, gender); USDA species must have this documented in their medical record.*
* *Research attrition*
 |
|  | If “**Yes**,” describe the scientific justification for non-social housing, the specific experimental groups requiring this exception, and the timeframe for which it applies: |
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| 11. | [ ] No [ ] Yes | Can all animals receive species appropriate environmental enrichment? |
|  | If “**No**,” describe the scientific justification for withholding environmental enrichment, the specific experimental groups requiring this exception, and the timeframe for which it applies: |
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| 12. | Other change details: |
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**REQUIRED SIGNATURES ARE LOCATED ON THE FOLLOWING PAGE**

**REQUIRED SIGNATURES (signatures are only needed once per submission; not with each revision during the review process prior to approval)**

1. PI Signature/Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| IACUC Approval Date: | This submission will be approved when following items are complete: |
|   | * IACUC reviewer(s) comments resolved
* Required signatures submitted
* IBC approval for all hazardous agents, when applicable
* Training requirements completed, when applicable
* Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
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