**Required Documentation for Addendum to the** **Animal Use Application Form**

Please ensure you have the following documents and that the instructions for the modification type are followed before submitting them to the Molecular Sciences Research Center’s Institutional Animal Care and Use Committee (MSRC’s IACUC).

[ ]  **Addendum to the Animal Use Application form (*Addendum*).** Follow the instructions on the next page to fill out this form. A transmittal letter is not required.

[ ]  **Minor Modification or** [ ]  **Major Modification.** For definitions, read the instructions on the next page.

[ ]  **Copy of the Original *Protocol* with the Incorporated Modification as Explained in the Instructions.** Follow the instructions on modifying the original *Protocol* on the next page. Be organized and as clear as possible.

[ ]  **Evidence that a modification to the Institutional Biosafety Committee (IBC) has been requested, approved, or is in the process of being applied if it is required.** If the modifications alter any safety procedures approved by the IBC, you must notify the IBC and request approval. An email to the MSRC’s IBC notifying that the IBC associated with the IACUC’s *Protocol* must be modified counts as evidence.

[ ]  **Signatures:** The investigator submitting the proposal, the principal investigator, and the attending veterinarian must sign the *Addendum* before submission.

Don’t hesitate to contact the MSRC’s IACUC (iacuc.msrc@upr.edu) if you have any questions regarding completing the form.

**Disclaimer**:

The function of the Institutional Animal Care and Use Committee (IACUC) is to ensure the rights of animals to be treated humanely, that researchers follow the guidelines and instructions for which they have obtained permission, and that the scientific value acquired justifies the cost of subjecting them to an animal to adverse conditions. The IACUC does not perform logistical, monetary, or administrative functions of the Vivarium or the MSRC.

The approval of the Addendum to the Animal Use Application (*Addendum*) does not guarantee space in the MSRC’s Animal Vivarium. If you are requesting a location change, you must communicate your intention to submit a modification of your *Protocol* to the director of the Vivarium or the designated key personnel before filling out this document. The Vivarium’s director or key personnel must certify that the facility has the necessary resources and capabilities to support the proposed study adequately.

The IACUC frequently inspects sites where animal procedures occur. These areas encompass a range of activities, including survival and non-survival surgeries, physiological and pharmacological procedures, body fluid retrieval, and behavioral testing. The IACUC members reserve the right to interview any personnel working with animals in those areas without previous announcement. ***A knowledge deficit in any personnel could result in the Protocol’s pause, personnel retraining or exclusion, or Protocol’s cancellation***.

Confidential commercial or trade secret information may not need to be included in the Modification to the Animal Use Application or the *Protocol*.

Any suggestions for this *Addendum* could be submitted to the iacuc.msrc@upr.edu.

Consult the MSRC’s Attending Veterinarian, Dr. Marilyn Arce (marcevet08@gmail.com), or the IACUC’s Chair, Dr. José E. Lizardi Ortiz (iacuc.msrc@upr.edu), for questions.

**Instructions**:

You must read the following instructions before completing the *Addendum*.

**Note**: *To have the privilege of performing experiments on live animals, you need to request permission from the IACUC and the Institutional Biosafety Committee (IBC). The IACUC will only review the housing, handling, euthanasia, and any procedure or condition executed on live animals****. Keep in mind that all sections to be filled out in this form only refer to live animals, not dead corpses or material derived from them****. If you request a modification that involves changes in handling and procedures on such material, it must be reported to the IBC.* Visit the [MSRC’s IBC](https://cicim.upr.edu/institutional-biosafety-committee-ibc/) website for more information about how to amend the IBC protocol associated with your animal *Protocol*.

1. Before completing the *Addendum*, the Principal investigator (PI) and the authorized personnel to complete this form (*Delegate*) must read the “Standard Operating Procedure for the Review Process of the Animal Use Application or *Protocol*” to understand the reviewing process of modifications to the *Protocol*.
2. Before any modification to the original *Protocol* can begin, the *Addendum* must be submitted to and approved by the MSRC’s IACUC. Modifications approval is not guaranteed upon submission.
3. Investigators working with animals must follow The Guide for the Care and Use of Laboratory Animals (*The Guide*) and the Public Health Service (PHS) Policy. If you plan to apply for modifications that depart from or differ from what is stipulated in *The Guide*, scientific justification and approval from the IACUC full committee or a designated reviewer are required. The *Protocol* should conform with the MSRC's Animal Welfare Assurance.
4. The Principal Investigator (PI) could delegate the modification design, preparation, and submission to an appropriate investigator. The PI must be included in any written communication and notified of any event in any non-written communication. However, the PI must read, understand, and approve (sign) the *Addendum*. The *Delegate* cannot sign the form on behalf of the PI. ***Non-fulfillment of this statute could delay the modification approval or the Protocol's cancellation.***
5. To report the addition or removal of investigators to the *Protocol,* download and fill out the *Personnel Modification Form* on the [MSRC’s website](https://cicim.upr.edu/institutional-animal-care-and-use-committee/). Changes in the personnel do not require the *Addendum*.
6. Minor modifications strictly include changes in [1] the timeframe, [2] housing or experiment location, [3] analgesics, anesthetics, and procedures equivalent to the ones approved in the original Protocol, and [4] the number of animals. Read section **4. Minor Modification** for a better description. Any other changes are considered major modifications. Before completing this form, we recommend talking with the attending veterinarian.
7. Fill out one *Addendum* per *Protocol* to be modified. All applicants must provide the *Protocol* number in the “**IACUC Protocol No.**” section on Page 1 (top right corner) and complete sections **1. General Information** and **2. Changes**.
8. For major modifications provide a complete amendment copy of the original *Protocol*. Provide as much information as possible for *Protocol* clarity, including tables, figures, references, or websites. The *Protocol* must also include a surgical health record template if new surgeries are requested. The MSRC’s IACUC conducts site inspections at least twice a year at locations where survival surgeries are performed. During these inspections, the post-operative records must be readily available.

*An Addendum with major modifications will be stringently reviewed as it was for your original Protocol by the IACUC full committee or a designated reviewer*.

Highlight the addition in yellow (e.g., cervical dislocation) and highlight/strikethrough any deletions (e.g., ~~CO2 affixation~~). Be organized and clear; instead of using highlighting/strikethrough in many words or sentences in a paragraph, rewrite the whole paragraph and highlight/strikethrough the paragraphs.

If the proposed modifications alter any safety procedures approved by the IBC, you must notify the IBC and request approval.

1. For minor modifications, fill out section **4. Minor Modification** and provide a copy of the updated *Protocol* as explained above.
2. If the changes to the *Protocol* include minor and major modifications, submit it as a **Major Modification**.
3. The application will not be evaluated unless all the necessary information is provided. If a question does not apply to your study, please type N/A. The PI or the delegate may be contacted for more information.
4. Before submission, this form and the updated version of the *Protocol* must be sent to the Attending Veterinarian, Dr. Marylin Arce (marcevet08@gmail.com), for a preliminary review. No modification form will be accepted for revision without this preliminary review. Only send a copy of this form and the updated *Protocol*. Other documents described on the front page are not required.

If the veterinarian makes any recommendations, you could schedule an appointment to discuss these modifications with the veterinarian if you have any concerns about your experiments.

1. After the Attending Veterinarian’s review, compile all the required information on the front page and submit the *Addendum* to the MSRC’s IACUC email (iacuc.msrc@upr.edu).
2. Ensure that before implementing the modifications, all personnel associated with this study have received a copy, read, and understand the approved version of this *Addendum*.

**202X–XXXX**

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| A logo with orange letters  Description automatically generated | Addendum to the Animal Use Application | **IACUC Protocol No.** |

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| 1. GENERAL INFORMATION
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Name of Principal Investigator:

Name of the Delegate (if applicable):

# Title of Project:

Principal Investigator e-mail:

Delegate email (if applicable):

Principal Investigator Telephone Number:

Modification Type: [ ]  **MAJOR MODIFICATION** **[ ]**  **MINOR MODIFICATION**

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| 1. **CHANGES**
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| 1. Briefly describe the requested changes to be applied to the current *Protocol*.
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| 1. Explain the reasons for the requested changes in the current *Protocol*.
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| If changes are required for Animal Procedures, Surgery, or Euthanasia, please describe how they are done and why you need to change them. Also, explain how the changes might affect the Objective of the *Protocol*. |

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| 1. **MAJOR MODIFICATIONS**
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| If you are applying for major modifications, update the approved IACUC *Protocol* by incorporating the changes in the original *Protocol* (Word document). Highlight the addition in yellow (e.g., cervical dislocation) and highlight/strikethrough any deletions (e.g., ~~CO~~~~2~~ ~~affixation~~).Be organized and clear; instead of using highlighting/strikethrough in many words or sentences in a paragraph, rewrite the whole paragraph. Revise every applicable section of the protocol that reflects the proposed changes.If the proposed modifications alter any safety procedures approved by the IBC, you must notify the IBC and request approval. **Major modifications require revision by the IACUC’s full committee or a designated reviewer**. |
| *Consult the veterinarian before submitting a Major Modification*. |

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| 1. **MINOR MODIFICATIONS**
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| If you are applying for minor modifications, fill out the following questions and provide an updated version of the original *Protocol*. Minor modifications are not reviewed by the IACUC’s full committee or a designated reviewer. Please provide a brief explanation for each modification. Submit a **Major Modification** if you need to incorporate minor and major modifications in a *Protocol*. |
| *Consult the veterinarian before submitting a Minor Modification*. |

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| 1. Are you requesting a change in the *Protocol*‘s timeframe?
 | [ ]  **Yes** [ ]  **No** |
| You could ask that the study duration be extended or shortened if the change does not affect animal welfare. |
| *If* ***Yes****, explain why you need a new timeframe.* |

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| 1. Are you requesting a change in housing location or where the experiments will be performed?
 | [ ]  **Yes** [ ]  **No** |
| The new location must be an IACUC-approved location. If the IACUC has not approved the area, an inspection is required by the veterinary and at least one designated member of the IACUC. |
| *If* ***Yes****, explain why a new location is required.* |

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| 1. Are you requesting a change in anesthetics or analgesics?
 | [ ]  **Yes** [ ]  **No** |
| Substituting drugs or dosages with equivalent agents is allowed as long as the veterinarian approves them. |
| *If* ***Yes****, explain why the approved anesthesia or analgesia procedures need to be changed.* |

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| 1. Are you requesting a minor change in any procedures?
 | [ ]  **Yes** [ ]  **No** |
| Minor changes in procedures that are equivalent to the originally proposed and do not increase pain or distress are allowed (e.g., blood draw via tail vein to saphenous vein). |
| *If* ***Yes****, state which procedures and why you need to change them.* |

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| 1. Are you requesting small changes in the animal number?
 | [ ]  **Yes** [ ]  **No** |
| A change in the number of animals per procedure is permitted, provided it does not exceed by more than 10% the number justified in the original *Protocol*. If more animals are required, request a Major Modification. |
| *If* ***Yes****, explain why below and fill out the table below.* |

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| Additional Animals |
| Species | USDA Pain Category | Approved Animal Number | Additional Animal Requested | Total |
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| 1. **SIGNATURES**
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**Principal Investigator**:

By signing this document, I,  , certifies the accuracy and completeness of the information provided in this *Protocol*. I am responsible for ensuring the personnel performing this study (including myself) have read the complete *Protocol* and follow *the Guide*, PHS policy, MSRC’s Vivarium Safety Manual, the standard operating procedures (SOPs), and applicable institutional, state, and federal regulations.

I am aware that any modification of this study as described here requires prior approval by the IACUC. ***Deviation from this Protocol could result in the Protocol’s pause, personnel retraining or exclusion, or Protocol’s cancellation***.

Signature: Date:

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| **Delegate *(If applicable)***Name:      Signature: Date:       |
| **Attending Veterinarian**Name:      Signature: Date:       |
| **Certification of Final Approval by IACUC Chair**Name:      Signature: Date:       |