Form: UCC/MRF2021.06.01



Universidad Central del Caribe

MODIFICATION REQUEST FORM

Institutional Animal Care and Use Committee (IACUC)

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MODIFICATION REQUEST FORM

Instructions for filling out this form

- This form is required to request changes to an approved IACUC protocol.
- Any changes requested cannot be implemented prior to the IACUC's review and approval.
- This form must be submitted via email to zilka.rios@uccaribe.edu or betzaida.torres@uccaribe.edu. Other modification requests will be sent to the Committee for review. The IACUC can request at any time that a new protocol be submitted if they determine that too many modifications have been made to the original protocol application making it unclear.
- A new protocol application must be submitted to incorporate the following changes:
 - Changing the species used
 - Adding procedures that do not logically relate to the specific aims of the original protocol
 - A proposed major change in the scientific aims of the original protocol application
 - Switching from non-survival to a survival surgery
 - Switching from single to multiple major survival surgeries (major surgery opens a body cavity)
 - Method of Euthanasia

When submitting a new protocol application for any of the above mentioned changes, please reference your current IACUC protocol number and explain the changes you have added. This will assist the IACUC administrative staff in increasing the efficiency of your protocol review.

- Requesting more than a 25% increase in animals can be submitted for review; however, the IACUC requires that in most cases, requests above 25% will require a new protocol application. This 25% will be for time for approval of the original protocol application.
- The electronic form of this application is available at http://www.uccaribe.edu/research/?page_id=3576 and has to be submitted via e-mail at least two months before our scheduled meetings of IACUC. IACUC approval needs to be obtained prior to beginning the research project. Hardcopy applications will not be processed.
- If you have any questions regarding this form, please contact Prof. Zilka Rios, President of IACUC office, at (787) 799-3001 extension 2082.

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MODIFICATION REQUEST FORM

| | - Commonts | _ |
|----|------------|---------------|
| -6 | = Comments | = Attachments |

| A. P | rotocol Information | |
|-------------|---|--|
| 1 | Principal Investigator | |
| | Principal Investigator #2 (if applicable) | |
| 2 | Approved Protocol Number | |
| 3 | Protocol Title | |
| 4 | Phone Number | |
| 5 | E-mail Address | |

| B. Modification Information (only complete sections which apply to the changes you are requesting) | | | | | |
|--|----------------|------------------------|--------------------------|---------|------------------|
| 6 | Addition or de | eletion of an investig | ator YES | NO | |
| | Name | Position title | E-mail | Phone # | Add or delete |
| | | | | | |
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| T 1' | | . 1 1 | al protocol from a Unive | | 110 1 |

Indicate if the person is listed on an animal protocol from a Universidad Central del Caribe or an Institution other than the Universidad Central del Caribe.

If any of the personnel added to this protocol are listed on animal protocols outside the Universidad Central del Caribe, please indicate the University or Institute for each person. The purpose of this question is to identify individuals who travel between different animal facilities and, therefore, may provide for potential cross-trafficking of infectious organisms.

| C. Pi | rotocol Title Change or | Additional Protocol Title | YES | NO |
|-------|--|--|-----------------|------------------|
| • | require an additional ti ving Laboratory Animal | tle, you must complete App Use Form | lication for Pi | rotocol Approval |
| 7 | Previous title | | | |
| 8 | New title to replace the previous title | | | |
| 9 | Please state why these cl | hanges are requested | | |
| | | | | |
| | | | | |
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| D. An | esthetic/Analgesic Cha | nges YES | NO |
|---------|---|---------------------------|--|
| See: R | ecommendations for Ase | ptic Technique, Anesthesi | ia, Analgesia and Post-Operative |
| Care fo | or Rodent Surgery | 基 | |
| Pr | roposed Anesthetic | Dose (mg/kg) | Route |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| 10 | Please explain why you | are adding/changing the | anesthetic/analgesic. |
| | | | |
| 11 | Please indicate how you identify the person in cl | | veness of the anesthetic/analgesic and |
| | | | |

| E. Ch | hange in Euthanasia YES | NO |
|---------|---|---|
| 12 | Previous Method of Euthanasia | |
| 13 | Proposed Method of Euthanasia | |
| Is this | s method by approved euthanasia met | hods AVMA Guidelines 2020 edition? |
| For m | nore information, please visit: | |
| https: | ://www.avma.org/sites/default/files/202 | 20-01/2020-Euthanasia-Final-1-17-20.pdf |
| | | Ħ |
| 14 | Please explain why this change is nec | eessary. |
| | | |
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| | | |

| 15 | Please describe the change in surgical procedure or addit | tional surgical | procedure |
|----|--|-----------------|-----------------|
| | | | |
| | | | |
| | | | |
| 16 | Why is this change needed? | | |
| 10 | The state of the s | | |
| | | | |
| | | | |
| 17 | Will this change require additional animals? | YES | NO |
| 18 | Will anesthetics/analgesics be given? | YES | NO |
| | If yes, section D must be completed | | |
| 19 | Please describe any expected and/or potential complications and how you will a | | wer must includ |
| | the frequency of these complications and now you will a | ddress them. | |
| | | | |
| | | | |
| 19 | the frequency of these complications and how you will a | | wei III |

| G. R | equesting an Increase in An | imal Numbers | YES | NO |
|--------|--|----------------------------------|-------------|---------------------------------------|
| | Strain | Number of Additiona Requested | | % Increase from the original protocol |
| | | | | |
| | | | | |
| 20 | Please explain the need for appropriate. The IACUC ge protocol application; howe | enerally requires that i | ncreases ab | • |
| | | | | |
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| | | | | |
| Н. А | Non-Surgical Procedure | YES | NO | |
| 21 | Please describe the change | or additional procedure |). | |
| | | | | |
| Please | provide justification (s). | | | |
| | | | | |
| | | | | |

| I. Cha | anges in Animal Strain | YES | NO | | |
|--------|------------------------------|------------------|-------|----|--|
| 22 | Species Used: | | | | |
| 23 | Previous Strain Used: | | | | |
| 24 | Proposed Strain: | | | | |
| 25 | Will this change require add | itional animals' | ? YES | NO | |
| 26 | Please state why this change | is necessary. | | | |
| | | | | | |
| | | | | | |
| | | | | | |
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| J. Spe | ecial Housing Requests | YES | NO | | |
|--------|------------------------------|------------------|-------------------|---------------|--|
| 27 | Please explain in detail you | r request for sp | pecial housing co | nsiderations. | |
| | | | | | |
| | | | | | |
| | | | | | |
| 20 | XXII (1 1 | 0 | | | |
| 28 | Why are these changes nece | essary? | | | |
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| | | | | | |
| | | | | | |
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| K. Ch | nange in Husbandry Procedures YES NO |
|-------|---|
| 29 | Please explain in detail the changes you are requesting regarding animal husbandry: |
| | |
| | |
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| | |
| 30 | Why are these changes necessary? |
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| L. Mo | dify or Add New Tests or Agents | YES | NO | | | | |
|--|--|--------------|-------|-----------|-----------------------|--|--|
| The authorization of the corresponding committee representative is previously necessary. | | | | | | | |
| Please list which drug or agent(s) you wish to add to your protocol: | | Dose (kg/mg) | Route | Frequency | Duration of treatment | | |
| 31 | Biological: (administration of nucleotides, human or animal origin cell, body fluids, recombinant DNA, RNA, infectious agents, and other biological hazards to the animals) Tumor Lines/Body: (administration of any genetically modified tissues, cells, viruses, or vectors into animals) | | | | | | |
| 33 | Radioisotopes or ionizing radiation | | | | | | |
| 34 | Hazardous Chemicals | | | | | | |
| 35 | Antibiotics | | | | | | |
| 36 | Why are these changes requested? | | | | | | |
| | | | | | | | |
| 37 | Will this change require additional ani | mals? | YES | NO | - | | |
| 38 | Describe any expected or potential co You must also describe the frequenc complication when it occurs. | - | • | | | | |
| | | | | | | | |

| M. Ot | ther Changes that Logically Relate to the Specific Aims of the Original Protocol eation YES NO |
|-------|--|
| 39 | List other changes that need to be made to the IACUC application that is not addressed above and explain why these changes are needed. |
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N. PRINCIPAL INVESTIGATOR CERTIFICATION.

Your electronic signature response on this protocol form certifies your agreement to the following terms.

- I certify that the methods described here will be used, and the researcher will amend this modification request as needed to reduce animal discomfort and pain when techniques are identified.
- I certify conduct will be in accordance with the PHS Policy, Guide for the Care and Use of Laboratory Animals, DEA regulations, and IACUC Policies. When there is a change in the Animal Regulatory Agency regulations, the IACUC will notify the Principal Investigator so they can request a Protocol Modification to comply with the change if needed.
- I certify that the described animal use **does not duplicate previous or existing studies** or is intended to verify previous research.
- I certify that the description of the research as provided in this application is complete and accurate.
- I certify that I will submit any changes to this description to the IACUC for written IACUC approval prior to implementing any changes.
- I understand non-expired drugs and biomedical supplies will be used.
- I understand that complete animal husbandry and procedural/surgical/testing records will be maintained.
- I understand that in the event that I cannot be contacted, any animal that shows evidence of distress, illness or pain, emergency care, including euthanasia if necessary, will be taken care by the veterinary medical staff.
- I understand the personnel is certified, adequately trained and experienced. All training has a maximum duration of three years.
- I ensure that I will inform any recipient (not listed in section B) of any hazard associated with the use of animal body fluids or tissue derived from the studies described in this protocol.
- I certify all activities undertaken as part of this proposal have been fully described in this application. Only activities listed on approved IACUC protocols will be conducted by the investigator, co-investigator, or staff. The research will be suspended at any time the work fails to comply with the PHS, or IACUC policy. The institution is required to report instances of noncompliance to funding agencies, and the public health service. These reports become a matter of public record through the agency websites.

| I understand absolutely no | research may | begin or impler | nented until | final IACUC |
|----------------------------|--------------|-----------------|--------------|-------------|
| approval is granted. | | | | |

| | mm/dd/yyyy |
|---------------------------|------------|
| Today's Date (mm/dd/yyyy) | |
| Signature: | |
| | |

MODIFICATION REQUEST FOR OFFICIAL USE OF IACUC MEMBERS

Your determination does not decide the action of this request.

This information will be evaluated and presented at the IACUC meeting to make a final decision on its approval.

| decision on its approval. | | |
|--|--|--|
| Member of IACUC (name): | | |
| Principal Investigator: | | |
| # of Protocol: | | |
| ACTION: | | |
| • Approved: | | |
| • Approved with suggestions (Please, write the suggestions below): | | |
| • More information is required (please, specify what kind of information below): | | |
| • Not approved (Please, specify the reasons below): | | |
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