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Version 8

March 18, 2016

*For Office of Research Use*

Logged Date:

Initials:

Modification #:

**DREXEL UNIVERSITY COLLEGE OF MEDICINE**

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| LOGO_Drexel | **DREXEL UNIVERSITY**  Assurance # A3222-01  USDA Registration # 23R-0180  **IACUC AMENDMENT FORM** |

Please type all responses. Handwritten responses will be returned to the applicant.

1.1 Project Title (The title must exactly match the grant title):

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|  |

Sponsor:

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1.2 Principal Investigator

Name

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Department

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Protocol Number

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E-mail address

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Telephone Number

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1.3 Protocol Information

Species

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1. Please provide a brief explanation / rationale for the amendment request.

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| An updated Drexel IACUC Aseptic Technique description has determined that the following steps must be taken for aseptic technique prior to surgery.  [\*\*\*PI please review the policy and insert your specific details for aseptic prep to meet the minimum standards of the description (mostly described on page 3).  Your description should include these 3 main points: method of hair removal from the surgical site, selection of suitable skin disinfectant, and that the alternating scrub (ending with alcohol as the last substance on the skin before incision) is completed 3 times. Any deviations from the Policy should be scientifically justified.] |

2. Does this amendment request involve a change in number of animals, or in procedures, agents, or drugs used? If yes, continue with question 3. If not, skip to question 9.

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| Yes |

3. How many animals were approved in your original protocol?

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| 4. Does this amendment involve additional animals beyond those approved in the original protocol? | Yes |  |  | No | x |

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| If yes, how many new animals are requested? |  |  |

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| --- | --- | --- | --- | --- | --- |
| Does this amendment involve use of animals in ways such that the original number justification would not apply? For example, different procedures, or new pilot studies? | Yes |  |  | No | x |

If yes to either question, please explain in detail why new additional animals are needed and/or justify the numbers used for new or different procedures by (a) citing references to similar studies, (b) describing a power analysis, or (c) stating that amendment involves new animals but similar procedures to the original study and that the justification is the same. Refer to “[Justification of Animal Numbers](http://www.drexel.edu/~/media/Files/research/administration/financial%20compliance/regulatory/IACUC/Policy_for_Animal_Numbers.ashx?la=en)” at the IACUC Website for further guidance.

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| 5. Does this protocol involve any animals exposed to higher levels of pain or distress than they would have been in the original protocol, even if they were not additional to the total number?Please see the [IACUC Policy for Assigning Pain and Distress Categories to IACUC Protocols](http://www.drexel.edu/~/media/Files/research/administration/financial%20compliance/regulatory/IACUC/IACUC%20Policy%20Assigning%20Pain%20Distress%20Category%202016.ashx?la=en). | Yes |  |  | No | x |

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| If yes indicate the new pain level. Explain in detail and justify the change. | **C** (former Drexel A) |  | **D** (former Drexel B) |  | **E** (former Drexel C) |  |

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| 6. Are there any changes to pharmaceutical agents or drugs in this amendment? | Yes |  |  | No | x |

If yes, describe the changes. For new drugs or pharmaceutical agents, please provide the same details as provided for comparable substances the original IACUC Application -- dose, number of uses, method of injection, etc. If pharmaceutical grade of new drug or agent is not available, please describe preparation, sterilization, and storage of the new compound. Note if there are any side effects and whether any of the drugs or agents would be considered hazardous. For drugs already in the protocol, but used in different ways in the amendment, please explain the changes.

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| 7. Are there any new (or changed) procedures or surgeries in this amendment? | Yes |  |  | No | x |

If yes, provide the details as requested in the original IACUC application items 21 (non-surgical procedures), 22 (survival surgery), and/or 23 (postoperative care), as appropriate.

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| 8. Are there any other changes involving animal care or handling (such as in method of euthanasia, special care required, or keeping animals in non-ULAR facilities)? | Yes | x |  | No |  |

If yes, please explain.

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| Changing/clarifying the aseptic technique description to be in compliance with the Drexel IACUC standard for aseptic technique. |

9. Indicate any other changes in the protocol. Explain, as appropriate. For changes in personnel, please refer to the Office of Research website for the [Addition of Personnel Form](http://www.drexel.edu/~/media/Files/research/administration/financial%20compliance/regulatory/IACUC/IACUC_addition_personnel.ashx?la=en).

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| N/A |

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| --- | --- | --- | --- |
| Principal Investigator’s Signature |  | Date: |  |

Return the completed form to:

[iacuc@drexel.edu](mailto:iacuc@drexel.edu)

For courier, interoffice mail or hand delivery:

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