ANSWER ALL QUESTIONS. DO NOT LEAVE BLANKS. INDICATE N/A WHERE APPLICABLE.

**PROTOCOL #:** Click or tap here to enter text. **DATE SUBMITTED:** Click or tap to enter a date.

**AMENDMENT #:** Click or tap here to enter text.

***ORP WILL FILL IN PROTOCOL AND AMENDMENT #***

1. **ADMINISTRATIVE DATA**

**Title of Project:** Click or tap here to enter text.

**Descriptive Title of Amendment:** Click or tap here to enter text.

**Principal Investigator:** Click or tap here to enter text. **Extension:** Click or tap here to enter text.

**Emergency Number:** Click or tap here to enter text. **Email:** Click or tap here to enter text.

**Personnel (list ALL LIMR and non-LIMR personnel):  
List name and role of all personnel involved in this protocol. As part of the role, include procedures to be performed by each person and their level of experience through previous training/experience. If not previous experience, indicate who will provide training for procedure.**

|  |  |
| --- | --- |
| **Name** | **Role** |
| Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. |
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| Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. |

**Collaborators:** Click or tap here to enter text.

**Submission Type:  New Protocol  3-Year Rewrite  Amendment**

**Funding Source(s):  Grant (Grant Info Form required)  Grant Sub-award (Grant Info Form required)  
  Institutional Funds  Other-**Click or tap here to enter text.

**Funding Agency:** Click or tap here to enter text.

**Grant Title:** Click or tap here to enter text.

1. **ANIMAL REQUIREMENTS**

**List the species and number of animals for this three year period. List individual animal strains for each species in Appendix 1. MUST DESCRIBE ALL ANIMALS ASSOCIATED WITH EXPERIMENTS AND BREEDING**

|  |  |
| --- | --- |
| **Species** | **Total Number of Animals Required for Three Year Period** |
| Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. |

1. **LAY SUMMARY**

**Describe, in 200 words or less, the purpose of the study in lay language. Abbreviations and acronyms should be spelled out and explained the first time they are used. Non-scientific representatives from the community will be among the readers, therefore use of highly technical terms is not acceptable.**Click or tap here to enter text.

1. **RATIONALE FOR ANIMAL USE**

**Clearly state the rationale for involving animals in the project. Explain why this research is scientifically necessary and why the animals listed in Section B are the most appropriate species for the studies described in this form.**Click or tap here to enter text.

**Describe all animal models. If genetically modified animals are used, describe any phenotypes expected to cause pain/distress and any special treatments if necessary.**Click or tap here to enter text.

1. **STUDY OBJECTIVES – Description of Experimental Design and Animal Procedures**

**Provide a detailed description of all experimental procedures and numbers of each species that will be used. Include a sequential description of the procedures involving the use of animals and the number of each species that will be used. Justify the number of animals for each experiment by statistical analysis or by citing scientific literature.**Click or tap here to enter text.

**Define humane endpoints for each experiment, including assessment criteria. Describe the rationale for anticipated and selected endpoints. Include frequency of monitoring, how pain will be recognized, and how pain will be relieved.**Click or tap here to enter text.

1. **PROCEDURES AND SURGERY**

**Will all procedures (chronic and terminal) be performed within the Research Annex?  
 Yes   
 No – location for each procedure (including euthanasia):** Click or tap here to enter text.

**Does this protocol include a surgical procedure?  
 Yes (Appendix 3 is required)   
 No**

1. **PAIN OR DISTRESS CLASSIFICATION AND CONSIDERATION OF ALTERNATIVES**

**Pain Classification—enter the total number of animals in each category for the proposed experiments.**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **USDA Category C** | **USDA Category D** | **USDA Category E** |
|  | **NO PAIN** | **PAIN WITH RELIEF  (PAIN AND DRUGS)** | **PAIN WITHOUT RELIEF (PAIN – NO DRUGS)** |
|  | Animal subjected to no pain or distress (or momentary or slight) which do not require use of pain relieving drugs | Animals subjected to pain or distress with appropriate anesthetic, analgesic, and/or tranquilizer use or euthanasia | Animals subjected to pain or distress where appropriate anesthetic, analgesic, or tranquilizer will not be used |
| **Number of Animals** | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |

**Will more than momentary restraint be required during which animals will be awake?** Note: physical restraint is the use of manual or mechanical means to limit some or all of an animal’s normal movement for the purpose of examination, collection of samples, drug administration, therapy or experimental manipulation. The period of restraint should be the minimum required to accomplish the research objective. **Yes – provide justification and describe duration of restraint and acclimation period:** Click or tap here to enter text. **No**

**For events and procedures involving animals in USDA Category E above, scientifically justify why pain-relieving measures cannot be used. Describe the literature search conducted or scientific literature reviewed to determine there are no valid or acceptable alternatives to the procedures performed under this category.**Click or tap here to enter text.

1. **ANESTHESIA, ANALGESIA, TRANQUILIZATION, OTHER AGENTS**

**List the anesthetics, analgesics, tranquilizers, or other agents for all animal procedures in the table below.** Note: records of analgesia administration must be maintained, sterile preparations are required,\* and all substances must be used prior to their expiration date.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Event/Procedure** | **Number of Animals** | **Name & Type of Agent** | **Dose (mg/kg)** | **Volume** | **Route** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
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**Are all preparations of agents, drugs, anesthetics are prepared in a sterile\* manner?  
 Yes   
 No – explain and provide justification:** Click or tap here to enter text.

1. **Hazardous Agents, Biological Material, Animal Products for Use in Animals**

**Toxic Agents: For any agents in Section H classified as a ‘toxic agent,’ check the properties that apply in the table below. If not applicable, check this box:**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Name of Toxic Agent** | **a. Mutagen** | **b. Carcinogen** | **c. Teratogen** | **d. Select Agent?** | | | **e. Other – specify toxic properties** |
| **Not a Select Agent** | **Select Agent Used in Sub-threshold Quantities** | **Select Agent that Requires Registration/Approval\*** |
| Click or tap here to enter text. |  |  |  |  |  | \* | ► Click or tap here to enter text. |
| Click or tap here to enter text. |  |  |  |  |  | \* | ► Click or tap here to enter text. |
| Click or tap here to enter text. |  |  |  |  |  | \* | ► Click or tap here to enter text. |
| Click or tap here to enter text. |  |  |  |  |  | \* | ► Click or tap here to enter text. |
| Click or tap here to enter text. |  |  |  |  |  | \* | ► Click or tap here to enter text. |
| Click or tap here to enter text. |  |  |  |  |  | \* | ► Click or tap here to enter text. |

**\*For each ‘select agent’ that requires registration/approval, provide the following details:**

**Name of agent**

**Registered with CDC or USDA**

**Registration #**

**Registration Date**

**Expiration Date of Registration**

**Name of official who granted approval on behalf of LIMR**

**Date of approval**

**Infectious Agents: For any agents in Section H classified as an infectious agent, complete the table below. If not applicable, check this box:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name and BSL Number of Infectious Agent** | **a. ABSL Number\*** | **b. Drug Sensitivity Panel Available? (Describe)** | **c. Select Agent?** | | |
| **Not a Select Agent** | **Select Agent used in Sub-threshold quantities** | **Select Agent that Requires Registration/Approval** |
| Click or tap here to enter text. | Click or tap here to enter text. | Yes  No  Click or tap here to enter text. |  |  | \*\* |
| Click or tap here to enter text. | Click or tap here to enter text. | Yes  No  Click or tap here to enter text. |  |  | \*\* |
| Click or tap here to enter text. | Click or tap here to enter text. | Yes  No  Click or tap here to enter text. |  |  | \*\* |
| Click or tap here to enter text. | Click or tap here to enter text. | Yes  No  Click or tap here to enter text. |  |  | \*\* |
| Click or tap here to enter text. | Click or tap here to enter text. | Yes  No  Click or tap here to enter text. |  |  | \*\* |
| Click or tap here to enter text. | Click or tap here to enter text. | Yes  No  Click or tap here to enter text. |  |  | \*\* |

**\*Complete this section for agents which the ABSL # is less than the BSL # shown**

**Name of agent**

**Registered with CDC or USDA**

**Registration #**

**Registration Date**

**Expiration Date of Registration**

**Name of official who granted approval on behalf of LIMR**

**Biological Agents: For any agents in Section H classified as a biological agent, complete the table below. If not applicable, check this box:**

|  |  |
| --- | --- |
| **Name of Biological Agent** | **Screening for Infectious Agents** |
| Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. |
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| Click or tap here to enter text. | Click or tap here to enter text. |

**Radioactive Agents: For any agents in Section H classified as a radioactive agent, complete the table below. If not applicable, check this box:**

|  |  |  |
| --- | --- | --- |
| **Name of Radioactive Agent (specify the isotope)** | **Authorized Individual** | **Approving Committee or Official** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
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**Recombinant Nucleic Acid: For any agents in Section H classified as recombinant nucleic acid, complete the table below. If not applicable, check this box:**

|  |  |  |
| --- | --- | --- |
| **Name of Agent**  **that Contains Recombinant Nucleic Acid** | **Subject to the *NIH Guidelines for Research Involving Recombinant DNA Molecules*** | **Exempt** |
| Click or tap here to enter text. |  |  |
| Click or tap here to enter text. |  |  |
| Click or tap here to enter text. |  |  |
| Click or tap here to enter text. |  |  |
| Click or tap here to enter text. |  |  |
| Click or tap here to enter text. |  |  |

**Protection of Animal Facility Staff from Hazardous Materials: For all agents listed in section 1 – 5, complete part a and b below. If not applicable, check this box:**

1. **Complete the table:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of Hazardous Agent** | **Approving Committee or Official** | **Institution** | **Names of Animal Facility Staff Members at Risk** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
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1. **Detail how the staff listed in the table above have been (or will be) informed of the possible risks of exposure and have been (or will be) trained to avoid exposure to these agents.**

Click or tap here to enter text.

**Safety Procedures: For all agents listed in section 1 – 5, complete part a, b, and c below. If not applicable, check this box:**

1. **Complete the table and attach Safety Data Sheet(s):**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name of Hazardous Agent** | **Signage, Enclosure, and/or Special Equipment Required** | **Storage Method(s)** | **Major effects on humans including targeted organ(s)** | **Routes of excretion of the agent (i.e. urine, feces, saliva, exhaled air)** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
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1. **Emergency Procedures: In the event of overt personnel exposure (inhalation, ingestion, inoculation) or spills, outline the procedure to contain and resolve the incident.**

Click or tap here to enter text.

1. **Decontamination and Disposal: Outline the decontamination procedure and disposal method (including any special requirements) for the agent.**

Click or tap here to enter text.

1. **NON-PHARMACEUTICAL GRADE AGENTS**

**Will a non-pharmaceutical grade chemical, drug, or substance be used?** Refer to Policy 1.3. **Yes – complete table below. Include a separate entry for each non-pharmaceutical compound and attach supportive documentation.   
 No**

***One Table Per Compound (if more than 1 compound, add appendix 4)***

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Compound** | **Site-Route of Administration** | **Grade** | **Storage** | **Quality Control** | **Scientific Justification** | **Information about Testing Compound** | | |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | **Yes if known,**  **No if unknown** | **YES** | **NO** |
| **Purity** |  |  |
| **Formulation** |  |  |
| **Sterility** |  |  |
| **Stability** |  |  |
| **pH** |  |  |
| **Pharmacokinetics** |  |  |
| **Compatibility of Components** |  |  |
| **Side Effects** |  |  |
| **Adverse Reactions** |  |  |

**Are controlled substances used in this protocol?  
 Yes – identify the controlled substances that will be used, who will use them, and when used outside the research annex, where they will be stored (Refer to Policy 1.22 for additional details):** Click or tap here to enter text. **No**

1. **METHOD OF EUTHANASIA OR DISPOSITION OF ANIMALS AT END OF STUDY**

**Describe euthanasia procedure(s) below. Note: Ether is explosive and cannot be used as a euthanizing agent.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Method** | **Agent** | **Dose** | **Volume** |
| Overdose Anesthetic | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Euthanasia Solution | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Cervical Dislocation**+** | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Other**+** | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| CO2 - Must also indicate method of verifying death below: | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| **Thorocotomy** | **Cervical Dislocation** | **Checking for lack of heartbeat or respiration at least 15 minutes after exposure to CO2 and prior to placing animals in freezer** | **Other, specify:** Click or tap here to enter text. |

|  |  |  |
| --- | --- | --- |
| **+If Cervical Dislocation or Other as Method of Euthanasia:** | | |
| **Unconscious** | **Conscious** | **If Conscious, justification required:** Click or tap here to enter text. |

**If, at the end of the study, animals and/or tissue are to be used by another investigator, state the name, project title, and protocol number to which the animals/tissues will be transferred. Additionally, if animals and/or tissues are supplied by another investigator, indicate investigator name, project title and currently approved IACUC protocol number:** Click or tap here to enter text.

1. **DATABASE SEARCHES AND REFERENCES**

**Indicate the reference sources that you have consulted in the table below to determine if the animal species is appropriate and is the lowest phylogenetic species for conducting these studies; there are no appropriate alternatives to the use of animals to achieve the objectives of these studies; and there are no alternative procedures that may cause less pain or distress if the use of animals falls under categories D or E in Section G above.**

**What alternatives to the use of animals were considered?** Click or tap here to enter text.

**Why are these alternatives not suitable?** Click or tap here to enter text.

**Search information:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Databases/Searches** | **Frequency of Searches** | **Search Words** | **Date of Initial Search** | **Time Period Covered by Search** | **Date of Last Search** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
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**Justification if less painful/stressful alternatives for any of the painful/stressful procedures described are identified but not used:** Click or tap here to enter text.

**List experts or other investigators in the field with whom you have consulted and their area(s) of expertise:** Click or tap here to enter text.

**Provide the complete literature references that describe the methods and procedures for the use of animals in these studies and the justification for the animal models you have chosen to perform these studies:**Click or tap here to enter text.

1. **ANIMAL HOUSING, HUSBANDRY, DIET**

**Special housing includes use of biosafety, imaging, quarantine or barrier rooms, special PPE, isolation, special caging or handling requirements, specific number of animals per cage (e.g. single housing), specific location of cage in rack, or area of room, etc.**

**Select all that apply to this protocol:**

**Single Housing –** social animals should be housed in pairs or groups of compatible individuals unless they must be housed alone for experimental reasons or because of social incompatibility.

**Explain:** Click or tap here to enter text.

**Trio Breeding**

**Explain:** Click or tap here to enter text.

**Special Location and Handling –** includes use of biosafety, imaging, quarantine and/or barrier rooms, and includes special PPE and precautions.

**Explain:** Click or tap here to enter text.

**Personnel assigned to changing cages:** Click or tap here to enter text.

**Exception to Enrichment Policies** (Policies 8.5 and 8.6).

**Explain:** Click or tap here to enter text.

**Other, Explain:** Click or tap here to enter text.

**Special Husbandry Requirements –** (e.g. food on cage flooring)

**Explain:** Click or tap here to enter text.

**Special Diet Required –** include a diet and/or feeding frequency that differs from the routine feeding program, or a deviation in the method, frequency and/or fluid composition from the routing watering procedures.

**Explain:** Click or tap here to enter text.

**Personnel assigned to special requirements:** Click or tap here to enter text.

1. **PRINCIPAL INVESTIGATOR CERTIFICATION**

**As Principal Investigator, I certify that:**

* **This protocol does not unnecessarily duplicate previous experiments performed here or elsewhere.**
* **Appropriate pain-relieving drugs will be used throughout the entire study to relieve pain and distress whenever it occurs, including post-operative and post-procedural care as indicated in the protocol as applicable.**
* **Pertinent scientific literature and/or databases were searched to determine there were no acceptable alternatives to the procedures described in this protocol.**
* **I am responsible for ensuring that laboratory personnel adhere to procedures described within approved protocols; they are familiar with animal care and use responsibilities, regulations, and policies; and they are adequately trained.**
* **I will conduct my research in accordance with the LIMR Animal care Policies and Procedures Manual, Public Health Service Policy on Humane Care and Use of Laboratory Animals, the Guide for the Care and Use of Laboratory Animals, and the Animal Welfare Act.**
* **I will notify the Research Annex Supervisor of all special handling, housing, dietary and safety requirements.**
* **All modifications will be submitted to the IACUC for review prior to implementation.**
* **Documentation of training for hazardous materials must be maintained and must be available upon request as required under Policy 5.2 and 5.3, if applicable.**
* **I am responsible for reporting unexpected outcomes, complications, adverse events, including an unexpected phenotype that may affect animal well-being, morbidity or animal mortality.**
* **Addition of personnel to an approved study will require the submission of an amendment.**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Principal Investigator Signature Date**

**Appendix 1**

**Breeding Strain/Source  
All strains used on protocol (purchased and breeding strains)**

**Species:** Click or tap here to enter text.

**(list one species per page; attach additional pages as needed)**

|  |  |  |
| --- | --- | --- |
| **Model #** | **Strain\*** | **Source\*\*** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
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**\*Strain should match those described throughout the application and Appendix 2. Provide names used by vendors when ordering.  
\*\*Refer to Policy 7.1 for list approved vendors.**

**Appendix 2**

**Breeding Section**

**Complete one form for each type of breeding used in this protocol. Types of breeding include continuous, sequential or other (trio breeding).**

1. **Identify all strains involved in breeding covered under this protocol. Include Model Numbers with each strain.**

Click or tap here to enter text.

1. **Indicate if the type of breeding is a.) continuous; b.) sequential; or c.) other, e.g. trio breeding\* and describe how many females will be introduced into a single cage with each male and how long they will be housed together.**Click or tap here to enter text.
2. **Describe the breeding scheme and indicate how many animals will be used each year to maintain the colony for each strain.**Click or tap here to enter text.
3. **If breeding genetically modified animals, how will you monitor for the presence of the transgene in the animals?**Click or tap here to enter text.
4. **Indicate how animals will be marked for identification, and what will be done with the animals that are bred in excess of your needs or those that do not meet your breeding criteria. If planning to euthanize unneeded littermates, describe the method to be used and the age at which it will be carried out.**Click or tap here to enter text.
5. **At what age will weaning occur?**Click or tap here to enter text.

**\*Trio-breeding requires justification in the protocol and prior approval by the IACUC.**

**Appendix 3**

**Surgery Section**

**Complete one form for each type of surgery in this protocol.**

1. **Identify type of surgery and categorize the procedure as a.) major or minor (does not invade a body cavity or cause permanent physical handicap); and b) survival or nonsurvival surgery.**Click or tap here to enter text.
2. **Indicate if more than one surgery will be performed on the same animal. If yes, briefly describe the additional surgery and categorize as a) major or minor; and b) survival or nonsurvival.**Click or tap here to enter text.
3. **Indicate where surgery will be performed and who will perform the surgery (building/room).**Click or tap here to enter text.
4. **Indicate the number of animals that will undergo the surgical procedure at any one time.**Click or tap here to enter text.
5. **Describe the planned surgical procedure(s) in detail. Indicate if aseptic procedures will be followed. If aseptic procedures are followed, describe the technique(s), including pre-surgical preparation of the surgeon, and method for sterilizing instruments before and between surgeries. Include a description of the skin preparation, anticipated procedure duration from start of anesthesia to recovery.**Click or tap here to enter text.
6. **Describe the planned anesthesia and analgesia procedures. Describe the method of anesthesia and anesthesia monitoring. Include procedure for measuring depth of anesthesia (e.g. toe pinch or lack of corneal reflex). Indicate the person who will administer the anesthesia and provide monitoring. Indicate when the first dose of anesthesia will be administered.**Click or tap here to enter text.
7. **Describe the intra-operative monitoring plan and identify which parameters will be measured. All parameters must be evaluated prior to surgery. Include location for recovery and frequency of monitoring. Specify the signs of pain distress which will be monitored and include criteria for pain management and euthanasia. Note: observations for rodents must be recorded either on an operative and post-operative monitoring form or in a laboratory notebook. This information may be entered into a computer later. Animals must be observed at least until they regain consciousness and are able to maintain sternal posture. Refer to Policy 3.3**Click or tap here to enter text.
8. **Check the surgical apparel worn by the surgeon:  
    Disposable gown  Shoe Covers**

**Sterile gloves  Mask**

**Disposable bonnet  Other, specify:** Click or tap here to enter text.

1. **Survival surgery will conform to requirements of Rodent Survival Surgery Policy 3.3:  
    Yes  
    No – if no, describe deviation from Policy 3.3:** Click or tap here to enter text.
2. **Will animals be placed on warming pads/mats during and after surgery:  
    Yes  
    No – if no, provide justification:** Click or tap here to enter text.
3. **Describe the immediate and long-range postoperative care for animals undergoing survival surgery, including arrangements for after work hours, holidays, weekends and the names of responsible personnel. Include the frequency of observation and the pain management plan.**Click or tap here to enter text.

**Appendix 4  
Additional Pharmaceutical Compounds   
(complete if more than 1 compound is being used from question H.3. above)**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Compound** | **Site-Route of Administration** | **Grade** | **Storage** | **Quality Control** | **Scientific Justification** | **Information about Testing Compound** | | |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | **Yes if known,**  **No if unknown** | **YES** | **NO** |
| **Purity** |  |  |
| **Formulation** |  |  |
| **Sterility** |  |  |
| **Stability** |  |  |
| **pH** |  |  |
| **Pharmacokinetics** |  |  |
| **Compatibility of Components** |  |  |
| **Side Effects** |  |  |
| **Adverse Reactions** |  |  |
| **Compound** | **Site-Route of Administration** | **Grade** | **Storage** | **Quality Control** | **Scientific Justification** | **Information about Testing Compound** | | |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | **Yes if known,**  **No if unknown** | **YES** | **NO** |
| **Purity** |  |  |
| **Formulation** |  |  |
| **Sterility** |  |  |
| **Stability** |  |  |
| **pH** |  |  |
| **Pharmacokinetics** |  |  |
| **Compatibility of Components** |  |  |
| **Side Effects** |  |  |
| **Adverse Reactions** |  |  |
| **Compound** | **Site-Route of Administration** | **Grade** | **Storage** | **Quality Control** | **Scientific Justification** | **Information about Testing Compound** | | |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | **Yes if known,**  **No if unknown** | **YES** | **NO** |
| **Purity** |  |  |
| **Formulation** |  |  |
| **Sterility** |  |  |
| **Stability** |  |  |
| **pH** |  |  |
| **Pharmacokinetics** |  |  |
| **Compatibility of Components** |  |  |
| **Side Effects** |  |  |
| **Adverse Reactions** |  |  |