

## **eACUC Protocol Guide**

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### **I. Study Identification**

- 1.0 Protocol Title: Must match the grant/project title exactly if this is a funded study.
- 2.0 PI: Automatically entered; only indicate a Co-Investigator if they are named on the funded study.
- 3.0 Emergency Contact: This should be someone who works with the animals and has access to the facility.
- 4.0 Contact Person: Receives emails on the status of protocols, both during review and post-approval.

### **II. Study Identification, continued**

#### **Study Identification, continued**

**1.0**

**\* Is this a Three Year De Novo from a paper Protocol?** ☒ Yes ☐ No [Clear](#)

**1.a**

**\* Please attach the currently approved version of the ASP if it is not in the eACUC system:**

[None]

**1.b**

**Please attach a Progress Report:**

[None]

**2.0**

**\* Is this a Competitive Renewal?**

☒ Yes ☐ No [Clear](#)

**2.a**

**Please attach the currently approved version of the ASP if it is not in the eACUC system:**

[None]

**2.b**

**Please select the currently approved version of the ASP if it is in the eACUC system:**

1.0 Is this a Three Year De Novo form a paper Protocol?: Only select “Yes” to this field if you are renewing this study from a PAPER protocol, previously approved at Northwestern. If you are creating a submission for de novo review that already exists in the eACUC system, use that protocol’s workspace in eACUC to create the de novo.

1.a Upload a Word or PDF version of the old protocol here.

1.b Attach a progress report that describes what you have completed in the past three years on the protocol and how the next three years will continue the work. (Remember that for Click-to-Click de novos, the progress report is in the “addendum” form.)

2.0 Is this a Competitive Renewal?

2.a If the Competitive Renewal is in Word/PDF form, please attach it here.

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2.b If the Competitive Renewal is already in eACUC/Click, select it here.

### **III. Funding Source**

1.0 Please select the funding source: Select appropriate funding source here. Internal funds are classified as “Department.” If “Other” is selected, specify the funding source in the corresponding text box.

### **IV. Funding Information: For externally funded studies.**

#### **Funding Information**

1.0 \* **Grant Number:**

2.0 \* **Start Date:**



3.0 \* **End Date:**



1.0 Grant Number: Enter the grant number here. If you are creating a protocol to apply for a grant, you may enter “Pending” until the number is released to you.

2.0 Start Date: Enter the start date of the grant.

3.0 End Date: Enter the end date of the grant (not protocol approval period). If your grant is currently pending, you can approximate these dates until you have more information.

### **V. Departmentally/Internally funded studies**

#### **Department Information**

Please indicate the Department and Department Funding Chart of Account for this research.

1.0 \* **Funding Department:**

2.0 \* **Funding Department Chart of Account:**

1.0 Funding Department: For internally funded studies, enter the Department providing funding.

2.0 Funding Department Chart of Account: Provide the chart string that will supply funding.

**This page does not populate unless you select “Department” for the funding source.**

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### **VI. Summary of Research**

- 1.0 Lay Summary: Briefly describe your work using language without technical jargon that can be easily understood by the public at large (an 8<sup>th</sup> grade reading level). Using the narrative or abstract of your NIH grant is not appropriate.

**Your description should include the following:**

**A. the purpose (goal) of this research;**

**B. the intended use of animals in this research; and**

**C. how your research is linked to the advancement of a larger body of knowledge (i.e., what do you hope to learn?)**

- 2.0 Aims & Significance: Briefly describe the scientific aims and significance of your experiments. For funded projects, the grant abstract or specific aims section(s) may be used.

### **VII. Experimental Groups**

#### **Overview:**

- 1) Experimental Groups are defined as a cohort of animals undergoing the same set of procedures.
  - a. All animals in the group should be undergoing all of the procedures or alternate sets of the procedures listed in the procedure table.
  - b. If animals are undergoing alternate procedures that fall into multiple Pain Categories, the group should be divided into multiple experimental groups. For example, experimental animals undergo a surgical procedure (USDA Pain Category D) while controls animals do not (USDA Pain Category C).
  - c. In some cases, experiments require animal use in more than one Pain Category. A common example is bone marrow transplantation experiments. In these experiments, donor animals would fall in USDA Pain Category C if they are just being euthanized for bone marrow harvest while the recipient animals would fall in USDA Pain Category D because they have undergone irradiation and bone marrow transplantation. Recipients and donors therefore must be accounted for in separate experimental groups.
- 2) Breeding (and Colony Maintenance) Group: Special Experimental Group used to account for in-house breeding and offspring that are not utilized in other experimental groups.
  - a. Because breeders are not typically undergoing any other experimental procedures, they require their own experimental group.
  - b. The procedures for this experimental group typically include the following procedure types:
    - i. Breeding
    - ii. Identification (Ear tagging, notching, tattooing, etc.)
    - iii. Tail Biopsy (Classified as an AAP procedure type OR Tail Biopsy procedure type, which includes Identification)
    - iv. Euthanasia

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### 3) Experimental Group Information

## Experimental Group Information

1.0

\* **Group Name:**

Xenograft Mice

2.0

**Description** - Please relate this experimental group back to the scientific goals/specific aims of the study outlined in the Summary of Research (Aims & Significance, 2.0):

Mice in this experimental group will directly test the hypothesis of Aim 1 from our R01 grant.

3.0

\* **Species:**

Mice

4.0

\* **Total Number of Animals:**

355

5.0

\* **USDA Pain Category:**

Category Description

- ☐ B Animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery, but not yet used for such purposes.
- ☐ C Procedures that may result in only slight or momentary pain such as routine injections, blood collections, or other minor procedures are included in this category
- ☒ D Animals have the potential to experience pain/discomfort, but the necessary drugs to alleviate the symptoms are provided.
- ☐ E These procedures cause more than minimal or transient pain and/or distress but cannot be performed using anesthetics, analgesics or tranquilizers without adversely affecting the study

Clear

6.0

\* **Order By:**

1

1.0 Experimental Group Name: Give each group a brief, unique name.

2.0 Description: This section is used to link the experimental group to the Aims as defined in the Aims & Significance (Question 2.0 on Summary of Research page). Do not provide experimental or procedural details here – this should be an overview that links the group back to **the Aims**.

3.0 Species: Select appropriate species for the group. You will only be able to select procedures that correspond to the species you select here (i.e. you cannot select a rat procedure on the next page if you select "mice" here).

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- 4.0 Total Number of Animals: Indicate the total number of animals for this group. This number should match the total in Question 3.0 Numbers of Animals Justification on the following page (Procedures and Animal Numbers).
- 5.0 USDA Pain Category: Select the appropriate pain category for the group. The level selected should be based on the highest level procedure within the Experimental Group. **If you select Pain Category E, you will be required to justify the reasoning for selecting that Pain Category in text box 5.1.**
- 6.0 Order By: Specify an integer (number) for ordering of the various Experimental Groups on the main Experimental Groups page (1 will be at the top, 2 will be underneath 1, etc.).

### 4) Procedures and Animal Numbers

#### 1.0 Procedures:

Add ProcedureWrapper

#### 1.0 \* Procedure:

| Name  | Species Type |  |
|---|--------------|--|
| <input type="radio"/> Breeding                                | Mice         | Breeding   |
| <input checked="" type="radio"/> CO2 Euthanasia               | Mice         | Euthanasia   |
| <input type="radio"/> Isoflurane Anesthesia                   | Mice         | Anesthetic Regimen (e.g., surgery, restraint, imaging) |
| <input type="radio"/> Neonatal Euthanasia                     | Mice         | Euthanasia   |
| <input type="radio"/> Tail Biopsy - Mice Under 24 Days of Age | Mice         | AAP  |
| <input type="radio"/> Thoracotomy/Perfusion                   | Mice         | Surgery: Non-Survival                                  |
| Clear   |              |  |

#### 2.0 \* Execution Order:

3

- a. Procedures should be listed in the order in which they will be performed (list an “Execution Order” after clicking “Add” and selecting the appropriate procedure, see above screenshot).
- b. If a procedure in the experiment is repeated, list it only once, in the order it will first be performed. Use 4.0, Sequence and Timing, to indicate that the procedure is repeated.
- c. Do not list anesthesia procedure for surgeries or blood collection in the table as they are already embedded in the surgical/blood collection procedures.
- d. For non-surgical procedures that require anesthesia, list the anesthesia procedure before the procedure requiring anesthesia.
- e. Every procedure list should end with a euthanasia procedure or non-survival surgery.

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- 2.0 Multiple Survival Surgery Justification: This should only be filled in if multiple survival surgeries are used within an Experimental Group. This does NOT include a secondary surgery that is non-survival.
- 2.1 Will multiple MAJOR survival surgeries be performed on the same animal? If "Yes," provide the combination of major surgeries, justification for major surgeries, and timeline of surgical procedures in text box 2.3.
- 2.2 Will other combinations of multiple survival surgeries be performed on the same animal? If a combination of major/minor or minor/minor survival surgeries will be performed, mark "Yes" to this question.
- 2.3 Indicate what combination of surgeries you will perform, justification for multiple major survival surgeries, and the length of time between surgeries (with additional justification if it is less than 30 days): Include a description of multiple survival surgeries here, including a timeline of surgeries and justification for both multiple major surgeries and surgeries that occur less than 30 days apart, if applicable.

### **3.0 Number of Animals Justification**

- a. You must justify the total number of animals requested (Question 4.0 on previous page). The total here and on previous page must match.
- b. The N for each group should be based on sound statistical principles using a power analysis or clear reference to previous studies showing the number is appropriate for the variance in the measured variables.
- c. Show how the total number of animals was calculated (e.g. number of animals/group X variables/treatments X replicates).

### **4.0 Sequence and Timing of Procedures**: Using the Procedure Names from the table in Question 1.0, describe the order in which the procedures are performed and the interval between procedures (or provide a timeline).

- a. It is acceptable to attach a document (Question 5.0) to show the sequence and timing graphically.
- b. Do not provide experimental details in this section. All details should be found in the relevant procedures.
- c. Do not provide drug dosages in this section unless it is relevant to establishing the sequence and timing.

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### VIII. Indicate Procedure Personnel for this Protocol

#### Indicate Procedure Personnel for this Protocol

Lab members indicated in the PI Lab as qualified to perform these procedures have defaulted in below. To modify the personnel for THIS protocol, click Update on the specific procedure(s) below. To modify the default procedure personnel in the PI Lab, execute the Edit Lab Members activity in the PI Lab workspace.

| Procedure                       | Procedure Category | Procedure Lab Training  | Personnel Species (for this protocol) |
|---------------------------------|--------------------|---|---------------------------------------|
| <a href="#">Update</a> Breeding | Breeding           | The PI and/or other experienced, senior laboratory staff will train new lab members until they are deemed competent enough to perform the procedure on their own. New lab members will also complete all relevant institutional training courses. | Mice                                  |

Click “Update” beside each procedure to attach personnel who have been trained and will perform said procedures (see above screenshot).

In order to populate staff member names for selection, lab members must be added in the PI Library first, much like substances and procedures, via the “Edit Lab Members” link in the PI Library.

Procedures must be added to the Experimental Groups page first, before they will appear on the Define Procedure Personnel page.

Attaching procedures to personnel in the PI Library will automatically carry personnel with them when they are used in the protocol, however this process is not retroactive. So, if you attach personnel to a procedure in the PI Library after adding that procedure to the protocol, you will have to manually update the procedure on this page to include the personnel.

It is generally most convenient to complete this page of the protocol after completing the Experimental Groups page.

### IX. Genetically Modified Animals

1.0 Do your animals have a known genetic mutation?: Respond “Yes” if you are working with spontaneous mutants including immunodeficient models such as nudes or SCIDS.

2.0 Will your studies involve knockin/knockout or transgenic animals?: Respond “Yes” if you are working with transgenics on this protocol.

2.1 Genetically Modified Animals: List each strain separately in the table provided, whether it is newly created, and the source of the strain.

2.2 Discuss any known health problems.

2.3 Describe frequency of monitoring. Only use the term “daily” if animals are monitored by lab staff seven days a week. For weekdays, indicate monitoring will be performed Monday-Friday.

2.4 Indicate the proposed methods to alleviate any pain and distress caused by the phenotype.

2.5 Indicate the duration of survival for genetically modified animals or transgenics.

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### **X. Identification of Background Strain(s)**

- 1.0 Only list the background strains or stocks here, not each individual genetic modification. This page is intended to be more general, while the Genetically Modified Animals page is more specific.

### **XI. Animal Housing and Use**

- 1.0 Animal Housing: Click "Add" to add housing information for each species and housing level that applies to the protocol. For containment housing, you must provide justification for the use of containment in the text box.

For satellite housing, complete a satellite request form and attach it to this section of the protocol. Even approved satellite locations must have a form attached to each protocol.

For rooms inside CCM facilities, specific room numbers are not required. It is sufficient to specify AHR for Animal Holding Room or specify Procedure Room.

- 2.0 [PI Managed Sanitization of Laboratory Equipment](#) (Use Internet Explorer to view this document): Email a completed SOP to [acuc@northwestern.edu](mailto:acuc@northwestern.edu).

- 3.0 Animal Use: Organize procedures by room (i.e. check off all procedures that occur in a particular location then specify room).

**Be sure to account for all procedures on the protocol.**

When filing amendments that include new or amendment procedures, be sure to update the location where that procedure will be performed.



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### 1.a \* Planned Procedures:

| Name   | Species |
|--|---------|
| <input type="checkbox"/> Breeding - Mice               | Mice    |
| <input checked="" type="checkbox"/> Euthanasia - Mice  | Mice    |
| <input checked="" type="checkbox"/> Tail Biopsy - Mice | Mice    |

### 1.b \* Building:

| Campus                                   | Name                      |
|--|---------------------------|
| <input checked="" type="radio"/> Chicago | Lurie                     |
| <input type="radio"/> Chicago            | Lurie Children's Hospital |
| <input type="radio"/> Chicago            | McGaw/Olson               |
| <input type="radio"/> Chicago            | Morton                    |
| <input type="radio"/> Chicago            | Searle                    |
| <input type="radio"/> Chicago            | Tarry                     |
| <input type="radio"/> Chicago            | Ward                      |
| <input type="radio"/> Evanston           | Cook                      |
| <input type="radio"/> Evanston           | F. Searle                 |
| <input type="radio"/> Evanston           | Ford                      |
| <input type="radio"/> Evanston           | Hogan                     |
| <input type="radio"/> Evanston           | Pancoe                    |
| <input type="radio"/> Evanston           | Silverman Hall            |
| <input type="radio"/> Evanston           | Tech                      |
| Clear                                    |                           |

### 1.c \* Room:

Group procedures according to what room they will be performed in. Labs may enter "CCM Procedure Room" for facility rooms. Make sure all procedures are accounted for in this section, even if they are performed in the facility procedure rooms. Do not add Euthanasia as a procedure to any housing areas.

## XII. Animal Care Exceptions

Review all the policies below before answering. If "Yes" is selected to any exception, a justification will need to be provided in the text box for approval.

Policies 1-3 are found on the [IACUC Website](#). Policy 4 is found on the [CCM Website](#) under "Veterinary Services." You must use Internet Explorer to view these documents.

- 1.0 Animal Enrichment and Social Housing Program Policy
- 2.0 Animal Enrichment and Social Housing Program Policy
- 3.0 Mouse Breeding and Housing Density Policy ("Yes" if weaning after 21 days of age)

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### 4.0 Rodent Standard of Care Policy

## **XIII. Federal Assurances**

1.0 Why are animals needed for this study? : Indicate why animals are needed as opposed to other data collection systems.

2.0 Indicate why you have chosen each species: Indicate the reasoning for choosing a particular species of study.

## **XIV. Consideration of Alternatives**

### **Procedure:**

### **Date of search:**



### **Years covered by search:**

### **Database(s) searched:**

### **Keywords used:**

If animals are subjected to pain or distress at USDA pain category D or E by means other than a specific procedure (such as a debilitating phenotype), the “Procedure” field in the literature search can be left blank so that only the keywords may be searched. Monitoring/Supportive Care procedures for conditions such as this can also be inserted as the “procedure” in the literature search.

The keywords “alternative” and the species name (i.e. “mouse”) must be included in this search.

## **XV. Consideration of Duplication**

The purpose of this literature search is to demonstrate that the work proposed in this protocol has not previously been performed and published. Keywords for this duplication search should include those that you would commonly use to find articles in your field of research.

- a. Avoid using specific procedure names.
- b. Do not use the keyword “alternative.”

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### **XVI. Protocol Attachments**

Attach a complete copy of the grant or grant application. You may remove any information related to salaries or budget.

### **XVII. Study Personnel**

In order to have rights as a PI Proxy (editing the protocol and submitting amendments), personnel names **MUST** be added to the “PI Proxies” list on this page. Adding a lab member to the PI Proxy list in the PI Library will auto-populate all included names to future protocols, but this is not retroactive. To add new personnel to the PI Proxy list on pre-approved protocols, an amendment must be submitted to the IACUC.

#### **2.0 Associated Personnel**

Only add administrative personnel who need view-only rights to this section.

#### **3.0 Animal Ordering / Key Personnel**

In the first list, indicate lab members who are able to order animals.

In the second list, indicate lab members to receive notifications that animals have been ordered.

### **XVIII. Administration of Substances Summary**

This list is auto-populated from the substances that are embedded within the procedures used on the Experimental Groups page. If a substance is not attached to a procedure, it will not appear here. If a substance is attached to a procedure, but the procedure is not used on the Experimental Groups page, it will not appear here. If the procedure is displayed on this page, but the corresponding substances are not, then you will need to add those substances to the table within the procedure. All substances administered to any animal in the ASP should appear on this page.

To view substance information that is procedure-specific, click on “More Detail,” as seen in the **red box** below. (To edit this information, click on the procedure it is used in, such as “Euthanasia – Mice” on the right hand side of the screenshot below.) This also displays hazardous and pharmaceutical grade information for the substance, but it cannot be edited from the “More Detail” link. (To edit this information, see below.)

To view and edit the information included within a substance itself (hazard information, pharmaceutical grade information), click on the substance name, as seen in the **blue box**.

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Adjuvants are not entered as substances and only included in the procedure type  
“Immunizations/Use of Adjuvants.”

### Administration of Substances Summary

#### 1.0 Substance Dosage Info:

| More Detail | Substance      | Type       | Hazard? | Pharmaceutical Grade? | Species | Procedure         |
|-------------|----------------|------------|---------|-----------------------|---------|-------------------|
| More Detail | Carbon Dioxide | Euthanasia | no      | yes                   | Mice    | Euthanasia - Mice |
| More Detail | Isoflurane     | Anesthetic | no      | yes                   | Mice    | Euthanasia - Mice |
| More Detail | Pentobarbital  | Euthanasia | no      | yes                   | Mice    | Euthanasia - Mice |

#### 2.0 Adjuvants(if applicable):

| Type of Adjuvant              | Initial Dose | Subsequent Injections | Route And Location of Injections | Number of injection sites and volume per injection | Number of immunizations |
|-------------------------------|--------------|-----------------------|----------------------------------|--|-------------------------|
| There are no items to display |              |                       |                                  |  |                         |

## XIX. Hazardous Substances

Substances will only appear on this page if marked “Yes” as a hazard within the substance itself. If you are unsure whether a substance is hazardous or not, please refer to the MSDS or contact the Office of Research Safety.

For substances classified as Biological/Infectious agents or Cell line/serum products, please note the following:

Each PI must complete an rDNA registration in NSIS if using recombinant DNA in animal studies. Viral vectors and other genetically modified biological hazardous agents must be registered with and approved by the Institutional Biosafety Committee (IBC) before any animal procedure may be performed. Your current work must be described in the animal protocol as well as reflected in your recombinant DNA registration. It is strongly recommended that you submit your rDNA registration to the IBC before you submit your final Animal Study Protocol (ASP). Please note that the work in the rDNA registration must also be included in the ASP therefore you should continue to complete this section and then complete your rDNA registration. If you have any questions about this process or need assistance with your rDNA registration, please contact Iwona Spath in the Office for Research Safety ([i-spath@northwestern.edu](mailto:i-spath@northwestern.edu); (847)-491-5581).