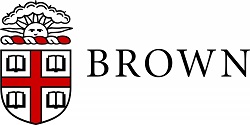
****

**Brown University**

**Institutional Animal Care and Use Committee**

**Protocol Animal Use Form**

|  |  |
| --- | --- |
| **Principal Investigator Name:** |  |
| **Principal Researcher:** |  |
| **Protocol Number\*:** |  |
| **Project Title:** |  |
| **Type of protocol**: | New  De novo (Three year renewal) for Protocol# |
| **Emergency Contact Information:** | Name:       Telephone Number: |

\*When you create a new protocol in Coeus, you will be assigned a number. Put that number in the box above.

**Veterinarian Consultation** (must consult veterinarian during protocol development)**:**

The following veterinarian has pre-reviewed this protocol. **Date:**

[Lara Helwig, DVM](mailto:lara_helwig@brown.edu)(863-5471)  [Tiffany Borjeson, DVM](mailto:Tiffany_Borjeson@brown.edu) (863-1158) [Jessica Johnston, DVM](mailto:Jessica_Johnston@brown.edu) (863-1987)

**Principal Investigator Certification**

**I certify to the following:**

* The information provided in this IACUC protocol is complete and accurate.
* This project will be conducted in accordance with the policies and procedures of Brown University regarding the care and use of laboratory animals, the USDA Animal Welfare Act and Regulations, the *Guide for the Care and Use of Laboratory Animals, 8th edition*, and any applicable federal and state laws and regulations.
* Due consideration has been given to alternatives to animal models and alternatives to procedures that may cause more than momentary or slight pain or distress to the animals.
* The proposed experiments do not represent an unnecessary duplication of previous work.
* Veterinary staff will be consulted before initiating experiments that include USDA pain category D or E procedures, as required by the Animal Welfare Act and Regulations.
* All personnel who work with animals under this protocol have received, or will receive, appropriate training in protocol procedures and animal handling methods prior to working with animals.  I will ensure that individuals not listed in this protocol do not participate in the protocol experiments.
* All listed personnel will read this protocol after it has been approved by the IACUC and before undertaking any procedures on laboratory animals.
* This protocol meets all animal use and care requirements of the funding agencies asked to support the project.
* Procedures on experimental animals described in this IACUC protocol accurately reflect those described in the funding applications and awards, if externally supported. DHHS policy requires that the institution certify to the government that the IACUC protocols are appropriately consistent with the federal grant applications.
* Approval from the IACUC will be obtained prior to making any change to the approved protocol*.*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

Signature of Principal Investigator Date

**1. Nature and Purpose of Proposed Studies**

1. **Lay Summary**

Describe the specific aims and details of animal use in non-scientific terms. The lay summary is used by community representatives on the IACUC and also may be used by Public Relations in the event of an external inquiry into the project. Define all acronyms. Only describe the use of live animals.

1. **Background and Significance** (1-4 sentences)

1. **Question being addressed** (1-4 sentences)

1. **How will the results of the study be used? Describe the relevance to human or animal**

**health, the advancement of knowledge, or the good of society** (1-4 sentences)

1. **Summarize the Specific Aims** (derived from the grant proposal/research plan)

1. **Technical Abstract**

Use the following outline to create a structured technical abstract that provides a clear and concise overview of the proposed work. It must include enough detail to allow the reviewers to understand the rational for the project, the specific objectives of the work, and the animal-related experiments that will be performed. It is not necessary to include excessive detail about the ex vivo analysis of tissues.

* Background: *Present the ideas and reasoning behind the proposed work.*
* Objective/Hypothesis: *State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.*
* Specific Aims: *State the specific aims of the study.*
* Study Design: *Briefly describe the study design including appropriate controls.*

1. **Experimental Design**

**If applicable**, please include a flowchart(s) or diagram(s) to explain the proposed animal experiments, including the study groups, treatment time points, and euthanasia time points. Begin with the arrival of animals in the facility and/or the first procedure and end with euthanasia. Note when individual animals will be used for more than one procedure. Please see the [IACUC website](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/institutional-animal-care-and-use-committee-iacuc) for examples.

**Insert diagram below**

**2. Animal Numbers**

**List all animals including strain, sex, etc.**

Please see the [IACUC Guidelines for Counting Animals Used in Research & Justification for Animal Numbers](https://www.brown.edu/research/conducting-research-brown/preparing-proposal/research-integrity/iacuc-home-page/policies-useful-links-related-forms) for more information.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Species** | **Strain** | **Sex** | **Age/**  **Type** | **# to be purchased** | **# to be born on-site (or fetuses for in utero studies)1** | **Total # to be used2** | **USDA pain category3** |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  | | | | | | | |
| **Total # of animals** | | | |  |  |  |  |

1 “# to be born on-site” includes all animals which are born on-site and fetuses used in pregnancy/in utero studies), even if they are not used for experiments or breeding

2 “Total # to used” = # to be purchased + # to be born on-site

3 Indicate the appropriate pain category based on the [USDA Pain Category Classifications and Examples](https://www.brown.edu/research/conducting-research-brown/preparing-proposal/research-integrity/ori-staff-directory/usda-pain-catagories) and the approximate number of animals in each category. If multiple procedures will be performed on an animal, the animal is placed in the category appropriate for the most painful/distressful procedure. Create separate groups in the Coeus Species/Groups tab for each different species and pain category.

**3. Description of Procedures Performed in Live Animals**

**a. Summary of procedures to be performed**

Provide a clear and concise sequential list of **all** procedures involving the use of live animals that will be easily understood by all members of the committee. Please use non-scientific terminology. **Detailed descriptions of surgical and non-surgical but potentially painful or distressful procedures are to be included in the applicable appendices.** **Complete descriptions of procedures which do not involve surgery or do not present pain or distress should be described in detail below**, including the use of any sedatives or anesthetics (e.g. use of sedation for restraint prior to imaging or EKG).

*Examples of procedures include: tail snips, surgery, tumor induction, blood collection, metabolism procedures, behavioral studies, injections of chemical/biological agents, etc. If additional procedures will be performed as part of the present protocol, please add additional items as needed.*



|  |  |  |
| --- | --- | --- |
| Procedure name: | Pain Category: | Number of Animals needed: |
|  | B  C  D  E |  |
| Brief description: | | |

|  |  |  |
| --- | --- | --- |
| Procedure name: | Pain Category: | Number of Animals needed: |
|  | B  C  D  E |  |
| Brief description: | | |

|  |  |  |
| --- | --- | --- |
| Procedure name: | Pain Category: | Number of Animals needed: |
|  | B  C  D  E |  |
| Brief description: | | |

|  |  |  |
| --- | --- | --- |
| Procedure name: | Pain Category: | Number of Animals needed: |
|  | B  C  D  E |  |
| Brief description: | | |

|  |  |  |
| --- | --- | --- |
| Procedure name: | Pain Category: | Number of Animals needed: |
|  | B  C  D  E |  |
| Brief description: | | |

To add additional procedures, you can copy and paste the table above.

*NOTE: Assign each procedure to the applicable species group(s) in the Coeus procedures tab.*

Fill out the appropriate Appendices for the following procedures:

1. [Surgical Procedures](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/iacuc/submitting-iacuc-protocol-amendment-or-continuation#iacuc)

2. [Non-Surgical Procedures](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/iacuc/submitting-iacuc-protocol-amendment-or-continuation" \l "iacuc)

3. [Hazardous Agent Use](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/iacuc/submitting-iacuc-protocol-amendment-or-continuation#iacuc)

4. [Breeding](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/iacuc/submitting-iacuc-protocol-amendment-or-continuation#iacuc)

5. [Antibody Production](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/iacuc/submitting-iacuc-protocol-amendment-or-continuation#iacuc)

**b. Collection of tissue or fluid from live animals**

Will tissue or body fluids be collected from live animals (excluding tail snips)? yes no

*If yes, complete the table below:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Species** | **Tissue or Body Fluid** | **Method of Collection** | **Amount and Frequency of Collection** | **Agents\* Administered Prior to Specimen Collection** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*\*Anesthetic, analgesic, sedative, or tranquilizer*

**4. Substances Administered to Animals** *(excluding anesthetics/analgesics)*  N/A

**a. Experimental/study agents, therapeutic drugs, chemicals**

Identify all therapeutic drugs, experimental/study agents, chemicals, or other materials administered to live animals by injection, intubation, implantation, or surface application in the appropriate tables below. **Do not include anesthetics and/or analgesics which are mentioned in either the Surgical and/or Nonsurgical Procedures appendix.**

**Species #1:**       (*Please duplicate table if agents will be administered to multiple species.)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name** | **Source** | **Pharmaceutical Grade? (*If no, justify below)*** | **1. Dose (mg/kg)**  **2. Volume**  **3. Route (e.g. ip, im, po)**  **4. Frequency (e.g. sid, bid)** | **5. Timing of administration (e.g. pre-op, intra-op, post-op)**  **6. Expected duration of effect** |
| Agent: | Brown ACF  Other (specify) | Yes  No | 1. Dose  2. Volume  3. Route  4. Frequency | 5. Timing  6. Duration |
| Agent: | Brown ACF  Other (specify) | Yes  No | 1. Dose  2. Volume  3. Route  4. Frequency | 5. Timing  6. Duration |
| Agent: | Brown ACF  Other (specify) | Yes  No | 1. Dose  2. Volume  3. Route  4. Frequency | 5. Timing  6. Duration |
| Agent: | Brown ACF  Other (specify) | Yes  No | 1. Dose  2. Volume  3. Route  4. Frequency | 5. Timing  6. Duration |

To add additional agents, you can copy and paste the table above.

**b. Justification for the use of non-pharmacological grade agents**

Federal regulations require the use of pharmaceutical-grade medications wherever possible, even for acute and non-survival procedures. All materials administered by parenteral routes, (e.g., intravenous, intramuscular, intraperitoneal and intracranial) must be sterile unless otherwise approved by the IACUC. See the [OLAW FAQ’s](http://grants.nih.gov/grants/olaw/faqs.htm#useandmgmt_4) (F4) for rationale and elaboration.

|  |  |  |
| --- | --- | --- |
| **Drug/Agent name (from table above)** | **Justification** | **Preparation(*e.g. diluents, sterilization, pH balancing, storage and labeling*)** |
|  | Pharmaceutical grade not available  Scientific necessity (specify)    Other (specify) |  |
|  | Pharmaceutical grade not available  Scientific necessity (specify)    Other (specify) |  |
|  | Pharmaceutical grade not available  Scientific necessity (specify)    Other (specify) |  |

To add additional agents, you can copy and paste the table above.

**c***.* **Biological Agents.**  N/A

If you will inject transplantable tumors, cell lines, blood products, or other biological materials into animals you must attach documentation of testing for murine pathogen viruses. The veterinarians will provide further information regarding testing requirements. Please also complete the [hazardous agent use appendix](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/iacuc/submitting-iacuc-protocol-amendment-or-continuation#iacuc).

Study Conducted at Animal Biosafety Level:  1  2

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Agent**  **Name** | **Source** | **Viral**  **testing date** | **Dose** | **Route** | **Volume** | **Diluent/**  **Media** | **Frequency**  **of injection** |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

*NOTE: If work requires Institutional Biosafety Committee (IBC) approval, IACUC approval cannot be granted until IBC approval is in place.*

**5. Animal Use Justification**

**a. Justification for the number of animals requested for each species listed above.**

Describe the strategy used to determine the number of animals required for the experiments described in this protocol. Statistical power analyses should be used to justify animal numbers whenever possible. Assistance with sample size estimation can be obtained from the [Statistical Consulting Unit](https://scu.stat.brown.edu/Home) through the [Center for Statistical Sciences](http://www.stat.brown.edu/). Please see the IACUC [Guidelines for Counting Animals Used in Research & Justification for Animal Numbers](https://www.brown.edu/research/conducting-research-brown/preparing-proposal/research-integrity/iacuc-home-page/policies-useful-links-related-forms) for more information.

**Check all that apply and provide specific answers to the associated questions**:

**Pilot study or preliminary project – Group variances unknown**

*Describe the information used to estimate how many animals are needed.*

**Group Sizes determined statistically- power analysis**

*Describe the statistical analysis used to estimate the number of animals needed (n). This is usually based on the expected size of the treatment effect, the variance associated with the measurement, and the desired statistical power.*

**Group sizes based on quantity of harvested cells or amount of tissue required**

*Describe how the amount of tissue or cells required was determined and explain how much tissue is needed based on the number of experiments you will conduct and how much tissue you expect to obtain from each animal.*

*Example: Need 10 g tissue. Can get 2 g tissue per animal = 5 animals required*

**Product testing**

*If the number of animals needed is based on FDA guidelines, provide the citation from the regulations, the IND tracking number, or relevant FDA correspondence.*

**Other**

*Please describe alternate method for sample size determination.*

**b. Justification of the Proposed Animal Model(s)**

**Are there non-animal alternatives available to accomplish your goals?**  yes  no

If yes, provide a brief narrative as to why those alternatives are not being used.

**Will you be using an established (published) animal model?**  yes  no

If yes, provide literature citations. If no, provide the rationale for development of the model? (Note: the veterinarians must be involved in all new animal model development)

**Have you used this animal model system before?**  yes  no

If yes, describe any refinements you have implemented to reduce the number of animals used or to reduce the amount of pain or distress experienced by individual animals?

**Does the proposed animal model system have the potential to negatively affect the long-term health and well-being of the study animals?** (Examples include: tumor implantation, which can lead to cachexia (wasting) and/or chronic pain; cardiac failure, which may lead to respiratory distress; arthritis, which may inhibit motion and the ability to feed.)  yes  no

*If yes, describe all anticipated negative consequences of the animal model?*

*If yes, also describe how will the animals be monitored for these outcomes?*

**6. Animal Procurement**

**a. Source(s) of animals**:

Commercial Vendor

Charles River Laboratories

Jackson Laboratories

Taconic Farms, Inc

MMMRRC

Other (specify):

Non-Commercial (e.g. academic) Source (specify)\*:

*\* All mice and rats entering Brown’s Animal Care Facilities (ACF) from a noncommercial source (such as an academic institution) will be quarantined and tested before being released for project use. Please contact the ACF Office (863-3223) for quarantine procedures and required documents.*

**7. Animal Husbandry**

* 1. **Housing Location/Facility** (Check all that apply)

BioMed Center Animal Care Facility (ACF)

Ship Street Facility

Sidney Frank Hall

Other *(specify)*:

*NOTE: Please enter all room numbers in the Procedures tab in Coeus under Procedure Locations.*

**b. Social Housing** (*Check all that apply*)

*Social animals must be housed in stable pairs or groups of compatible individuals unless they must be housed alone for experimental reasons or because of social incompatibility. If both group and single caging will be used, provide specifics in 7.f.*

Group housing  Single housing (Select single housing exception in the Coeus species tab.)

Justify the need for single housing.

**c. Food and Water:**

*If a non-standard diet will be used, provide specifics in 7.f.*

Standard diet  Non-standard diet

Food/Water Restrictions (Select appropriate exception in the Coeus species tab.)

Justify need for food/water restrictions

**d. Enrichment:**

Is it acceptable for ACF staff to provide standard enrichment as appropriate for the species (e.g. chews, toys, and nesting materials)?

Yes No

Justify if standard enrichment is not allowed.

**e. Non-Standard Husbandry**  N/A

*Describe any non-standard husbandry requirements. Animals exposed to human biological agents must be housed in an ABSL-2 room.*

*ABSL-2 housing*

*Metabolic cages*

*Special food or water (specify)*

*Altered day/night cycles (specify)*

*Altered cage change cycles (specify)*

Other *(specify)*

**f. Identification**

How will individual animals be identified? (*Check all that apply*.)

No individual identification will be used

Ear tags

Tattoos

Ear punch

Temporary marker (e.g. Sharpie)

Toe clipping *(mice < 10d only; requires IACUC approval) See the IACUC [Toe Clipping Policy](https://www.brown.edu/research/conducting-research-brown/preparing-proposal/research-integrity/iacuc-home-page/policies-useful-links-related-forms)*

Subcutaneous RFID microchip *(please describe in Procedures – question 3)*

Other method *(please describe in Procedures – question 3)*

**8. Animal Transport**

**a. Will live animals be transported outside of the animal care facility?**  Yes   No

If *“yes,” provide the procedure used to transport animals including the route and elevator(s) to be used and complete b and c below)*

**b. Will animals be transported outside of the animal care facility and then returned to their housing room?** Yes  No

*If “yes,” please justify why the procedures could not be performed within the animal facility and describe the containment measures that will be used to minimize the risk of introducing pathogenic agents from the lab back into the animal facility.*

**c. Will animals be transported outside of the animal care facility for use of equipment also used for human patients (e.g. MRI, CT scan, etc.)?**  Yes  No

**9. Emergency Treatment**

*In an emergency, animals will be treated to relieve suffering and preserve life, or if necessary, euthanized. When possible, investigators will be contacted by ACF or veterinary staff prior to diagnostic testing, therapy, or euthanasia. In the event that contact is not possible, staff will do their best to follow the parameters listed below.*

No therapeutic restrictions exist.

Do not use the following medications (e.g., corticosteroids, antihistamines, antibiotics):

**10. Humane Endpoint Criteria for Euthanasia**

**a. Monitoring of animals**

*Individuals who will be responsible for monitoring animals must be trained to assess and recognize animal pain or distress.*

i. Lab personnel who will be responsible for monitoring animals.

ii. How often will this be done?

Even though euthanasia may not be planned for a particular project, the IACUC requires establishing both humane endpoints for a project and criteria to euthanize animal(s) prior to the end of the experiment in the event that the animal’s condition falls outside the anticipated experimental parameters. Please define both the humane endpoints and criteria to euthanize animal(s) on this protocol for all animals from time of receipt to their final disposition.

The following signs of ill health will be used as euthanasia criteria:

|  |  |
| --- | --- |
| **Clinical Observation** | **Applicable to this project** |
| Clinical condition that does not respond to treatment (e.g. infected surgical site) |  |
| Delayed wound healing, dehiscence of surgical site |  |
| Difficulty in ambulation which render animal unable to access food/water |  |
| Persistent and progressive dermatitis or self-trauma |  |
| CNS signs such as tremors, seizures, circles that were not anticipated by the study plan |  |
| Anorexia >48 hours, other lesions interfering with eating or drinking |  |
| Sudden behavioral change (e.g. aggression, guarding, hiding) |  |
| Weight loss of 20% or more from baseline at the start of the experiment or as compared to age/gender/strain-matched controls |  |
| Markedly discolored urine, excessive urine, or no urine |  |
| Severe or refractory diarrhea or decreased fecal output > 48 hours |  |
| Dehydration unresponsive to oral or parental therapy |  |
| Rough hair coat, hunched posture, distended abdomen, reluctance to move, or lethargy |  |
| Respiratory signs such as labored breathing, wheezing, or copious nasal discharge |  |
| Cumulative tumor burden exceeds the IACUC-approved tumor burden |  |
| Mobility impairment due to tumor burden and/or location of tumor, regardless of tumor size |  |
| Tumor ulceration, necrosis or infection |  |
| Ascites due to tumor production which results in a 20% increase in body weight |  |
| Hemorrhage (blood loss) from any site that is estimated to be >10% total circulating blood volume |  |
| Any condition that a veterinarian (or their designee) deems serve enough to warrant euthanizing the animal and/or animals found in a moribund state |  |
| Additional humane endpoints: |  |
| Additional criteria for euthanasia: |  |

11. Disposition of Animals (*Check all that apply)*

**Euthanasia**

*Briefly describe the primary and, where applicable, secondary methods of euthanasia for each species. A secondary method is a second procedure that is used to confirm euthanasia. (Example: administration of an anesthetic as primary method followed by thoracotomy as a secondary method)*

**Primary method:**

|  |  |
| --- | --- |
| **Chemical Method** | **Physical Method** |
| CO2 inhalation per [Brown Policy](https://www.brown.edu/research/conducting-research-brown/preparing-proposal/research-integrity/iacuc-home-page/policies-useful-links-related-forms) 1 | Cervical Dislocation |
| Inhaled Anesthetics 1 | Decapitation |
| Injectable Pharmaceutical Agents 2 | Exsanguination Under Anesthesia |
| Name of Pharmaceutical Agent: | Asphyxiation |
| Immersion in MS-222 | Hypothermia (neonates only) |
| Other | Pithing |
| Describe: | |

1 Secondary method of euthanasia is required

2 If a Pharmaceutical Agent it to be used, please list in Section 4 (Substances Administered to Animals)

**Secondary Method:**

|  |  |
| --- | --- |
| Bilateral Thoracotomy | Cervical Dislocation |
| Exsanguination | Decapitation |
| Other |  |
| Describe: | |

**Methods are consistent with the current** [***AVMA Guidelines on Euthanasia***](https://www.avma.org/KB/Policies/Pages/Euthanasia-Guidelines.aspx)*.*

*Any deviation must be justified for scientific or medical reasons.*

Justify any method that is not consistent with current AVMA guidelines

**Animals will/may become moribund and die before they can be humanely euthanized**.

*Death of animals is a planned experimental endpoint (e.g. toxicity testing), or there is a likelihood that animals may/will become moribund and die (e.g. sepsis studies, organ failure studies).*

1. Provide a scientific justification,
2. Estimate how many (i.e. rate or percentage) will die at the end of the experiment, and
3. Indicate the procedures that will be used to minimize non-euthanasia deaths.

**Animals will be transferred to another protocol.**

Provide details*:*

**Other**

Provide details*:*

**12. Assurance that the Proposed Work Does not Unnecessarily Duplicate Previously Published Work on the Same Topic**

In accordance with USDA regulations, PHS [9 CFR Part 2.31 (8)] and the Animal Welfare Act, I have conducted a literature search covering the period **from       to** using the following databases and keywords.

**Keywords** *(Scientific search terms related to the proposed model)*

**Databases** *(Minimum of two required)*

      and

**I have concluded that the activities described in this protocol are not unnecessarily duplicative of previous experiments, including my own.**

*Please note: OVID, Medline and PubMed search engines use the same database. You may use one of these databases plus one other database, such as Agricola. Hyperlinks to animal welfare information web sites that may be helpful in your search for alternatives to potentially painful/distressful procedures may be found in the* [Literature Search for Alternatives *guidelines*](https://www.brown.edu/research/conducting-research-brown/preparing-proposal/research-integrity/iacuc-home-page/policies-useful-links-related-forms)*.*

**13. Search for Alternatives to Painful/Distressful Procedures**

**This study does not involve potentially painful or distressful procedures.**

**No alternatives exist. This must be documented by completing the following:**

I certify that I have reviewed the pertinent sources and have found no valid alternatives to any of the proposed procedures which may cause more than momentary pain or distress. The methods and sources used in my searches included the following databases and keywords.

Please document your searches for alternatives below. Please document separate searches for each painful or distressful procedure. A minimum of two different databases are required.

*Skin and body cavity penetrations (laparotomy, thoracotomy, craniotomy, and entry into a joint space) are examples of procedures considered to be potentially painful. Prolonged restraint and procedures that result in limited mobility, malaise, etc. are examples of procedures considered to be potentially distressful. Refer to the procedure list (item 3b, above) for a list of potentially painful/distressful procedures.*

|  |  |  |  |
| --- | --- | --- | --- |
| Procedure 1: |  | | |
| Databases searched: | Keywords used: | Years searched: | Date search was performed: |
| and |  | through |  |
| Narrative: | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| Procedure 2: |  | | |
| Databases searched: | Keywords used: | Years searched: | Date search was performed: |
| and |  | through |  |
| Narrative: | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| Procedure 3: |  | | |
| Databases searched: | Keywords used: | Years searched: | Date search was performed: |
| and |  | through |  |
| Narrative: | | | |

      To add additional searches, you can copy and paste the table above.

**Consultation with colleagues**

*Provide names, affiliations, credentials, and dates of contact. Describe the colleague’s area of expertise and why this colleague is qualified to provide an opinion on alternatives to the proposed painful/distressful procedures.*

**Other information services utilized.**

*Elaborate, providing specific information.*

**Alternatives exist, but are not appropriate for these studies.**

*Elaborate, providing specific information.*

**Study Personnel Qualifications**

To add additional personnel, add a new row by clicking the outside of the bracket [ at the top right of the table and hit enter. Then copy the information from the table and paste into the new row below.

Note: Please ensure all personnel listed here are also listed in the Study Personnel tab in Coeus.

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