|  |
| --- |
| **IMPORTANT NOTE:** **Public Health Service’s (PHS) Office of Laboratory Animal Welfare (OLAW) and United States Department of Agriculture’s (USDA) Animal and Plant Health Inspection Service (APHIS) require a complete, continuing review of ongoing animal research every 3 years.**  Failure to conduct continuing review of approved animal research in a timely manner will result in *automatic expiration* of the protocol. The federal regulations do not allow a grace period. When a protocol expires, all activities involving animals must immediately cease. Use of animals without an IACUC-approved protocol in place is considered a **violation of federal regulations** that govern the use of animals in research. Such violations must be reported to the federal government and to university officials. Termination of research and research funding by the government and/or the University may occur.  **INSTRUCTIONS:** Please complete and submit this form (typed) by the IACUC-requested due date. Submit to the IACUC Coordinator or Office of Regulatory Services at [regulatoryservices@uta.edu](mailto:regulatoryservices@uta.edu). |
|  |
| **General Information** |
| **Today’s Date:** Click here to enter a date.  **Principal Investigator:** Click here to enter text.  **Dept:** Click here to enter text.  **IACUC Protocol #:** Click here to enter text.  **Protocol Title:** Click here to enter text.  **Original Approval Date:** Click here to enter a date.  **Current Funding Status and Source(s):** Click here to enter text. |
|  |
| **Section A: Protocol Status** |
| **During the past THREE years (check one option):** |
| The study was not active, and no animals were used. |
| The study was active. |
| **Future plans (check one option):** |
| The research will continue without change. I seek IACUC approval to continue this project. **[*Complete all sections of this form except Section F.*]** |
| The research will continue with change. (Procedures, Animals, PI, co-PI, etc.). I seek approval to continue this project with modification. **[*Complete all sections of this form*.]** |
| The research will not continue. Please consider this to be a Final Report and close the protocol upon completion of this review. **[*Complete Sections B, E, and G only.*]** |
|  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Section B: Progress Report** | | | | | | | |
| 1. **Please provide a progress report from the previous 3 years (avoiding jargon and specialized terminology), including your *progress toward specific aims* *and objectives* outlined in your original protocol. If there has been no activity in the past 3 years, please explain why.**   Click here to enter text.   1. **Please provide a list of any publications and presentations that have resulted from the project.** | | | | | | | |
| Click here to enter text. | | | | | | | |
| 1. **Were there any Unanticipated Events that you have not yet reported? If yes, please fill out the** [**Unanticipated Event Report Form**](https://resources.uta.edu/research/regulatory-services/animal-subjects/forms.php) **and submit to** [**regulatoryservices@uta.edu**](mailto:regulatoryservices@uta.edu)**. See** [**UTA IACUC Reporting Unanticipated Events SOP**](https://resources.uta.edu/research/regulatory-services/animal-subjects/iacuc-policies-and-procedures.php) **for more information.** | | | | | | | |
| **Yes  No** | | | | | | | |
|  | | | | | | | |
| **Section C: Objective and Significance of Research** | | | | | | | |
| 1. **Please provide justification for continuation of this research by describing the objective and significance, including the probable benefits of this work to human and/or animal health, the advancement of knowledge, or the good of society.** | | | | | | | |
| Click here to enter text. | | | | | | | |
| **Section D: The Three R’s: Reduction, Refinement, and Replacement** | | | | | | | |
| 1. **Alternatives to the use of animals should be considered and used when possible. Since the original IACUC approval of this research study, have alternatives to the use of animals become available that could be substituted to achieve your specific project aims?** | | | | | | | |
| Click here to enter text. | | | | | | | |
| 1. **(Address the following if your project involves animals in Category D or Category E; see Category descriptions under Section E.) Procedures that cause the least amount of pain or distress to the animals should be considered and used when possible. Since the original IACUC approval of this research study, have alternatives which are potentially less painful or distressful become available that could be used to achieve your specific project aims? If this study involves USDA-covered species (see USDA’s** [**definition of animal**](https://www.govinfo.gov/content/pkg/CFR-2020-title9-vol1/xml/CFR-2020-title9-vol1-part1.xml)**), you must also complete Appendix A to fulfill USDA’s requirement for a** [**literature search**](https://www.nal.usda.gov/legacy/awic/alternatives-literature-searching)**.** | | | | | | | |
| Click here to enter text. | | | | | | | |
| 1. **Activities involving animals must not unnecessarily duplicate previous experiments. Provide written assurance that the activities of this project remain in compliance with the requirement that there must be no unnecessary duplication. If you choose to include details of a literature search, please provide source, dates covered, keywords used, and number of hits.** | | | | | | | |
| Click here to enter text. | | | | | | | |
| **Section E: Animal Use Information (Attach additional copies of this table as necessary.)** | | | | | | | |
| **Section E. Part 1** | **Species:** Enter text. | | | | **Species:** Enter text. | | **Species:** Enter text. |
| **Number of Animals Used, Previous 12 Months** (Refer to the original approved protocol to determine Category C, D, or E, or review the descriptions provided below this box) | **# in Category C:** Enter text. **# in Category D:** Enter text. **# in Category E:** Enter text. | | | | **# in Category C:** Enter text. **# in Category D:** Enter text. **# in Category E:** Enter text. | | **# in Category C:** Enter text. **# in Category D:** Enter text. **# in Category E:** Enter text. |
| **Number of Animals Used, Previous 3 years** (Refer to the original approved protocol to determine Category C, D, or E, or review the descriptions provided below this box) | **# in Category C:** Enter text. **# in Category D:** Enter text. **# in Category E:** Enter text. | | | | **# in Category C:** Enter text. **# in Category D:** Enter text. **# in Category E:** Enter text. | | **# in Category C:** Enter text. **# in Category D:** Enter text. **# in Category E:** Enter text. |
| **Number of Animals Used, Total Project to Date (from original approval until present date).** Refer to the original approved protocol and your records such as previous annual or triennial reports. | **# in Category C:** Enter text. **# in Category D:** Enter text. **# in Category E:** Enter text. | | | | **# in Category C:** Enter text. **# in Category D:** Enter text. **# in Category E:** Enter text. | | **# in Category C:** Enter text. **# in Category D:** Enter text. **# in Category E:** Enter text. |
| **INSTRUCTIONS: Number of Animals Planned for Use in Project Continuation – *The number of animals starts over at the time of Triennial Review. Please enter the number of proposed animals below for the next 3-year period. If you plan to include/use animals you have leftover from the previous 3-year period, please explain in Section E Part 2.*** *If you are adding new species that were not included in your original approved protocol, please describe below in Section F, “Modification.”* | | | | | | | |
| **Number of Animals Planned for Use in Project Continuation** | **# in Category C:** Enter text. **# in Category D:** Enter text. **# in Category E:** Enter text. | | | | **# in Category C:** Enter text. **# in Category D:** Enter text. **# in Category E:** Enter text. | | **# in Category C:** Enter text. **# in Category D:** Enter text. **# in Category E:** Enter text. |
|  | | | | | | | |
| **Category C:** Animals subjected to procedures that cause no pain or distress, or procedures that cause only momentary or slight pain or distress and do not require the use of pain-relieving drugs.  **Category D:** Animals subjected to potentially painful or stressful procedures that are alleviated by appropriate anesthetics, analgesics, tranquilizers, removal from study, euthanasia or other approved methods.  **Category E:** Animals subjected to potentially painful or stressful procedures that are not alleviated by anesthetics, analgesics, tranquilizers or other approved methods. Withholding these interventions must be scientifically justified & approved by the IACUC. | | | | | | | |
|  | | | | | | | |
| **Section E. Part 2** | | | | | | | |
| 1. **Please describe your reason for selecting the species and provide justification for the number of animals requested for continuation. How did you calculate the number in each group that are required to achieve statistical significance? How did you calculate the total number you are requesting?**   Click here to enter text.   1. **Are other animals, especially a lower species, suitable for these studies?** | | | | | | | |
| Click here to enter text. | | | | | | | |
| **Section F: Modifications *(Skip this section if there are no changes currently planned for continuation of this study.)*** | | | | | | | |
| **Please check the nature of your requested change (check all that apply):** | | | | | | | |
| Change of project title | | Change of funding agency | | | | | |
| Change/addition of animal species or strain | | Change and/or addition of procedures | | | | | |
|  | | Change of PI or co-PI | | | | | |
| 1. **For each item selected above, please fully describe the change:** | | | | | | | |
| Click here to enter text. | | | | | | | |
| 1. **If requesting a new species/strain, please provide information for the following items (if N/A, proceed to Section G):** | | | | | | | |
|  | | | | | | | |
| * 1. **Number of animals requested. Specify Category C, D, or E:** | | | | | | | |
| Click here to enter text. | | | | | | | |
| 1. **A detailed description of the procedures to which the animals will be subjected:** | | | | | | | |
| Click here to enter text. | | | | | | | |
| 1. **Provide your reason for selecting the species. Are other animals, especially lower species, suitable for these studies?** | | | | | | | |
| Click here to enter text. | | | | | | | |
| 1. **Provide justification for number of animals requested. How did you calculate the number in each group that are required to achieve statistical significance? How did you calculate the total number you are requesting?** | | | | | | | |
| Click here to enter text. | | | | | | | |
| 1. **Describe your experience with the proposed animal model and manipulation:** | | | | | | | |
| Click here to enter text. | | | | | | | |
| **Section G: Assurance and Signature** | | | | | | | |
| For active and/or continuing protocols, **I certify** that the use of animals has been and/or will be in accord with U.S. Department of Agriculture Animal Welfare regulations, the Public Health Service Policy on Humane Care and Use of Laboratory Animals, the National Research Council *Guide for the Care and Use of Laboratory Animals*, and the policies established by the University of Texas at Arlington. **I further certify** that no significant change in this protocol will be implemented without prior IACUC approval.  **\*\***As principal investigator of this study, I understand that **I am responsible** for maintaining appropriate and accurate recordkeeping pertaining to the use of animals during the course of this study, and for reporting animal use numbers on an annual basis, or as requested by the IACUC. | | | | | | | |
|  | | | | | |  | |
| **Signature of Principal Investigator** | | |  |  | | **Date** | |

APPENDIX A:

[**?**](http://www-test.uta.edu/research/administration/departments/rs/animals-subjects-iacuc/iacuc-Guidance.php#appb) **Literature Search (Alternatives to animal use or procedures involving pain or distress)**

This section only needs to be completed for studies involving [USDA Covered Species](https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare/sa_awa).

The purpose of a **Literature Search** is to demonstrate the concept of the “three Rs.” The three Rs are **Reduction** in number of animals used, **Refinement** of methods to minimize pain and distress, and **Replacement** of the animal model with a non-animal model or a species phylogenetically lower.

***INSTRUCTIONS:***

*(1) Refer to guidance from* [*National Agricultural Library’s Animal Welfare Information Center (AWIC)*](https://www.nal.usda.gov/legacy/awic/alternatives-literature-searching)*.*

*(2) You must consult at least 3 sources – please see below for recommendations/samples.*

*(3) List the dates for publication year(s) covered.*

*(4) For each source, list the keywords and/or combination of keywords searched.*

*(5) Indicate the number of hits for each keyword(s).*

*If you have any questions or require assistance, please feel free to contact the IACUC at* [*regulatoryservices@uta.edu*](mailto:regulatoryservices@uta.edu)*.*

Date(s) of the Search(es):

1. Source #1:

Publication year(s) covered:       to

Keywords Searched / Number of Hits:

1. Source #2:

Publication year(s) covered:       to

Keywords Searched / Number of Hits:

1. Source #3:

Publication year(s) covered:       to

Keywords Searched / Number of Hits:

1. Additional Sources:

Attendance of colloquia or conferences (please list the date of the event(s) and the content provided):

Consultation with subject experts (please list the consultant’s name, qualifications, and date and content of the consult):

1. Search Results:

Did your search identify any known alternatives for animal use? If so, please provide scientific justification for not using the available alternatives:

Did your search identify the possibility of using a less sentient species? If so, describe why you can or cannot use them:

Did your search identify ways to reduce animal numbers? If so, please provide scientific justification for your requested number of animals:

Did your search identify any refinement techniques for minimizing animal discomfort, distress, and pain? If so, please describe why you can or cannot use these techniques:

**Literature Searches – Sources and Samples Used in Searching for Alternatives**

**SOURCES** (*You are not limited to the sources listed here*):

MEDLINE: <http://intapp.medscape.com/px/medlineapp/medline?src=Overture&OVRAW=MEDLINE&OVKEY=medline&OVMTC=standard>

AGRICOLA:

<http://agricola.nal.usda.gov/>

CAB Abstracts:

<http://www.cabi.org/datapage.asp?iDocID=165>

Center for Alternatives to Animal Testing

PubMed:

<http://www.ncbi.nlm.nih.gov/entrez/query.fcgi>

BIOSIS:

<http://www.biosis.org/>

ALTBIB:

<http://toxnet.nlm.nih.gov/altbib.html>

CRIS:

<http://cris.csrees.usda.gov/>

TOXNET:

<http://toxnet.nlm.nih.gov/>

Altweb Anesthesia/Analgesia Database:  
<http://apps1.jhsph.edu/altweb/aadb/aadb_search.cfm>

Altweb Humane Endpoints Database:  
<http://altweb.jhsph.edu/humane-endpoints.htm>

EMBASE:  
<http://www.embase.com/>

SCISEARCH:  
<http://library.dialog.com/bluesheets/html/bl0034.html>

Spaceline:  
<http://spaceline.usuhs.mil/>

PsycINFO:  
<http://www.apa.org/psycinfo/>

AWIOnline:  
[*http://www.awionline.org/SearchResultsSite/refine.aspx*](http://www.awionline.org/SearchResultsSite/refine.aspx)

DIALOG:  
<http://www.dialog.com/products/guide/science.shtml>

**SAMPLE** (*The following is a sample key word search for a teaching protocol*):

MEDLINE (1966 – 2005)

KEYWORDS: HITS:

Teaching and stereotaxic surgery 30

Computer simulation and stereotaxic surgery 81

Computer simulation and plus maze 0

Teaching and plus maze 1

CRIS (1966 – 2005)

KEYWORDS: HITS:

Teaching and physiology 46

Computer simulation and teaching 0

Teaching and stereotaxic surgery 0

Computer simulation and stereotaxic surgery 0

Computer simulation and plus maze 0

Teaching and plus maze 0

ALTBIB (1980 – present)

KEYWORDS: HITS:

Teaching and stereotaxic surgery 21

Computer simulation and stereotaxic surgery 31

Computer simulation and plus maze 95

Teaching and plus maze 85

Teaching and physiology 35

Computer simulation and teaching 16