**INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)**

***CONTINUING REVIEW FORM***

PROTOCOL TITLE:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

IACUC#:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ DATE OF INITIAL APPROVAL:\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PRINCIPAL INVESTIGATOR: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

DEPARTMENT: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

CAMPUS ADDRESS:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PHONE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **RECORD OF ANIMAL USAGE**

|  |  |  |
| --- | --- | --- |
| **Species** | **Total # Approved** | **# Used to Date** |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

1. **NATURE OF THE PROTOCOL/STUDY.** (Check [ X ] all applicable items.)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| [ ] | Survival (Chronic) Study | [ ] | Prolonged Restraint | [ ] | Inducement of a Disease State |
| [ ] | Terminal (Acute) Study | [ ] | Neuromuscular Blockers | [ ] | Inducement of Behavioral Stress |
| [ ] | Multiple Surgeries | [ ] | Antibody Production | [ ] | Blood/Tissue Collection |
| [ ] | Transgenic Breeding |  |  |  |  |

1. **[USDA] PROJECT (Pain) CATEGORY [ X ]:** [ ] C [ ] D [ ] E

- - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - -

1. **PROTOCOL STATUS.** Please indicate ( X ) the status of this project.

Request Protocol Continuance

[ ] A. Active - project ongoing.

[ ] B. Currently inactive - project was initiated but is presently inactive.

[ ] C. Inactive - project never initiated but anticipated start date is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

Request Protocol Termination

[ ] D. Inactive - project never initiated.

[ ] E. Currently inactive - project initiated but project has not/will not be completed.

[ ] F. Completed - no further activities with animals will be done.

1. **FUNDING SOURCE:** Specify the funding source.
2. **PROJECT PERSONNEL.**

Have there been any personnel/ staff changes since the last IACUC approval was granted?

[ ] No

[ ] Yes

If yes, please complete the following sections (Additions/ Deletions). For additions, please submit a completed Personnel Qualification Statement with this Continuing Review Form and make arrangements with the Animal Resources center staff for inservice training on the proper care and handling of laboratory animals.

**Additions:** Name/Role/Responsibility for Project

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

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

|  |  |  |
| --- | --- | --- |
| **Deletions:** | Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Effective Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

1. **PROGRESS REPORT.** If the status of this project is 4.A. (active; project ongoing) or 4.B. (project was initiated, but is presently inactive), provide a brief update on the progress made in achieving the specific aims of the protocol.
2. **PROBLEMS/ADVERSE EVENTS.** If the status of this project is 4.A. (active; project ongoing) or 4.B. (project was initiated, but is presently inactive), describe any unanticipated adverse events, morbidity or mortality, the cause(s), if known, and how these problems were resolved. If NONE, this should be indicated.
3. **ALTERNATIVES TO ANIMAL USE.** Alternatives to the use of animals should be considered and used when possible. Since the last IACUC approval, have alternatives to the use of animals become available that could be substituted to achieve your specific project aims?
4. **ALTERNATIVES TO POTENTIALLY PAINFUL PROCEDURES.** (Address the following if your project involves USDA Category D or Category E.) Procedures that cause the least amount of pain or distress to the animals should be considered and used when possible. Since the last IACUC approval, have alternatives which are potentially less painful or distressful become available that could be used to achieve your specific project aims?
5. **DUPLICATION.** 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.
6. **FUTURE PLANS.**

[ ] No changes are planned and the project will continue as previously approved by the IACUC.

[ ] Changes are planned. Provide a full description and justification for the proposed changes. (A copy of the IACUC Protocol Amendment Form has been included for this purpose.)

[Please note that if the modifications are significant, you may be required to complete a new application. If you have questions or require assistance in making this determination, please contact the IACUC Office and/or the Attending Veterinarian.]

[ ] Other. Provide a brief explanation.

**CERTIFICATION OF THE PRINCIPAL INVESTIGATOR.** Signature certifies that the Principal Investigator understands the requirements of the PHS Policy on Humane Care and Use of Laboratory Animals, applicable USDA regulations and the Institution's policies governing the use of vertebrate animals for research, testing, teaching or demonstration purposes. Signature further certifies that the investigator will continue to conduct the project in full compliance with the aforementioned requirements.

|  |  |
| --- | --- |
| **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| Signature of the Principal Investigator | Date |

------------------------------------------------------------------------------------------------------------------ ------------------------------------------------------------------------------------------------------------------

Section 1 would be completed by the IACUC Office via database generation of the report form. The information captured in this section is considered to be basic protocol-identifying data, which may be helpful to any designated reviewer, as well as to the Committee, in their assessment. In addition, certain items, such as the pain category and nature of the protocol may prompt the IACUC to look more closely at the continuing review update.

Item 4--Protocol Status; 5--Funding Status; and 6--Project Personnel. The status of the protocol, funding source, and changes in project personnel are fairly standard questions to which the investigator is expected to provide responses.

Item 7--Progress Report. The progress in achieving the specific aims of the protocol should be described. The information in this section should be provided as an update to help the IACUC document the continued approvability of the research. For example, if 50 dogs were used and the investigator had no progress to report, in light of the specific aims of the protocol, it would be reasonable for the IACUC to request clarification. It should, however, be recognized that scientific inquiry may involve "blind alleys", and failed experiments, thus resulting in little progress in the short- versus long-term.

Item 8--Problems/Adverse Events. Any unanticipated problems or adverse events that have occurred should be reported, as well as an explanation of how these events/problems were resolved. Depending on the information provided here, this response may also need to be factored into the IACUC's assessment of the ethical cost-benefit justification.

Item 9--Alternatives to Animal Use. This section raises the question of whether any viable alternatives to use of live animals have become available since the last IACUC review.

Item 10--Alternatives to Potentially Painful Procedures. This section asks whether there are any alternatives to USDA Category D or E procedures that are potentially less painful and could be used to achieve any of the specific aims of the research. The USDA Category D and E procedures are defined as follows. Animal activities in Category D involve "procedures that may cause more than momentary or slight pain or distress" for which appropriate sedatives, analgesics, or anesthetics will be administered (12,13). Category E is similarly defined, with the exception that sedatives, analgesics, or anesthetics cannot/will not be administered due to scientific considerations/requirements (13).

Item 11--Duplication. This section requests assurance that the animal activities do not unnecessarily duplicate previous experiments, as required by USDA regulations.

Item 12--Future Plans. The investigator is asked to indicate future plans for continuation of his/her project. This would include an indication as to whether the research would continue as originally approved; or conversely, if changes are planned, an outline, description, and brief justification of the proposed changes should be provided.

Finally, the investigator is asked to sign the Continuing Review Form, which contains a certification of his/her understanding and responsibility for conduct of animal activities in accordance with the PHS Policy, USDA regulations and the institution's (IACUC) policies. Signature here also attests to the accuracy of the investigator's responses. Requiring completion of this form, at least annually, indicates to the investigator the seriousness of the IACUC's review and the importance of investigator accountability for his/her research activity; for reporting it accurately; and for justifying continuance of the research project for another year. Accordingly, the IACUC, through its designated reviewer mechanism, is also held accountable for appropriate and responsible review of the IACUC protocol file, and for continuation approval of ongoing animal research, if it is still justified.

**Method of IACUC continuing review.** All IACUC members would be provided a copy of the completed Continuing Review Form, and would have access to the corresponding IACUC protocol file on request. Any IACUC member could ask for a full committee review of the Continuing Review Form and the protocol. Utilizing the "designated reviewer" process, if none of the IACUC members requests full committee review, the IACUC Chair would then designate at least one qualified member (i.e., designated reviewer) to conduct an in-depth review of the current protocol in conjunction with the Continuing Review Form. This review would include consideration of the previously described continuing review criteria in accordance with PHS Policy IV.C. The designated reviewer would then review and be authorized to approve, require modifications in order to approve, or require full committee review of the protocol in question. By conducting such a comprehensive "de novo" review on an annual basis, using this model, there is no further PHS Policy requirement for continuing review at three-year intervals.

The way in which an institution chooses to implement the PHS Policy and USDA regulations is subject to change over time. Changes in IACUC membership may result in different perceptions and judgements regarding animal use issues. These changes may affect the outcome of continuing review, as will the evolutionary changes in protocol review forms, new regulations and guidelines, and precedents set by ongoing regulatory compliance activities, internal and external to the institution. Oki and Prentice, therefore, recommend that, in addition to the procedures outlined previously, a complete new IACUC protocol review form (i.e., new IACUC application form) be submitted if a project will extend beyond six years. There is, however, no federal requirement for resubmission of a new application for IACUC review within any time frame.

In summary, the review process and report form described in this section meet the requirements of the PHS Policy and the USDA regulations for continuing review. Use of this model for performing IACUC continuing review would rely upon yearly comprehensive "de novo" reviews for institutions desiring to comply with both sets of requirements (PHS Policy and USDA regulations).

**DISCUSSION**