**NCATS CTSA PROGRAM INSTRUCTIONS FOR SUBMITTING PRIOR APPROVAL REQUESTS FOR PLANNED RESEARCH INVOLVING LIVE VERTEBRATE ANIMALS**

Requests for prior approval of planned research involving live vertebrate animals conducted through NCATS UL1 pilot studies and KL2 scholar projects must be submitted in writing to NCATS at least 30 days before the proposed implementation of research involving live vertebrate animals. Documentation must be submitted by an Authorized Organization Representative (AOR) ([NIH Grants Policy Statement, chapter 8.1.3](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.1_changes_in_project_and_budget.htm#Requests)). This requirement applies to:

1. Studies to be conducted by KL2 scholars, if supported by NCATS funding, and
2. UL1 pilot studies supported by NCATS funding or by voluntary committed cost share.

Prior approval requests should include this checklist and should be submitted to the appropriate NCATS Grants Management Specialist via e-mail, with a copy to the appropriate NCATS Program Official. E-mailed requests should include the complete grant number in the subject line. The Vertebrate Animals Section and the IACUC approval documents must be attached to the e-mail request as individual files (either PDF or Word documents) and follow the naming convention below:

"**CTSA hub\_InvestigatorLastNameFirstInitial\_ProtocolShortTitle\_VAS\_YYYYMMDD**"

**"CTSA hub\_InvestigatorLastNameFirstInitial\_ProtocolShortTitle\_IACUC\_YYYYMMDD"**

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| --- | --- |
| **Type of Proposed Research** | **Pilot Study  KL2 Project** |
| **CTSA Institution** |  |
| **CTSA Grant #** |  |
| **Animal Welfare Assurance # (required for approval)** |  |
| **IACUC Approval Included? (required for approval)** | **Yes** |
| **Vertebrate Animals Section Included? (see below for checklist)** | **Yes** |
| **Title of Proposed DO Research Protocol**  **(\*Title must match the title submitted to the IACUC for approval)** |  |
| **Title and PI of Parent Research Protocol (if proposed DO research is ancillary to another research protocol)** |  |
| **PI Name on the IACUC-Approved Research Protocol** |  |
| **Name of Pilot Study Investigator or KL2 Scholar** |  |
| **Contact Information for Pilot Study Investigator or KL2 Scholar** |  |
| **Name of Authorized Organizational Representative (AOR)** |  |
| **Contact Information for AOR** |  |
| **NCATS Grants Management Specialist** |  |
| **NCATS Program Official** |  |
| **Date Submitted to NCATS** |  |

**REQUIRED Vertebrate Animals Section**:

Prior approval requests involving live vertebrate animals must address the criteria (#1-4) below. See [NIH Worksheet for Applications Involving Animals](https://grants.nih.gov/grants/olaw/VASchecklist.pdf) for guidance and an **example** of a Vertebrate Animals Section. The instructions and checklist are provided to assist applicants in ensuring that all elements of their Vertebrate Animals Section are addressed:

|  |  |
| --- | --- |
| **1. Description of Procedures:**  Provide a concise description of the proposed procedures to be used that involve live vertebrate animals in the work outlined in the Research Strategy section. Identify the species, strains, ages, sex, and total number of animals by species to be used in the proposed work. If dogs or cats are proposed, provide the source of the animals.  **Are the following addressed for all species?** | |
|  | Species |
|  | Strains |
|  | Ages |
|  | Sex |
|  | Total number of animals by species |
|  | Concise description of proposed procedures on live animals (i.e., sufficient information for evaluation) |
|  | Source, only if dogs or cats are proposed |
| **2. Justifications:** Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).  **Are justifications provided?** | |
|  | Choice of species is appropriate for proposed research |
|  | Why research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, *in vitro*) |
| **3. Minimization of Pain and Distress:** Describe the interventions including analgesia, anesthesia, sedation, palliative care, and humane endpoints to minimize discomfort, distress, pain, and injury.  **Are interventions to minimize discomfort, distress, pain, and injury described? (Examples below)** | |
|  | Circumstances relevant to the proposed work, when animals may experience discomfort, distress, pain, or injury |
|  | Procedures to alleviate discomfort, distress, pain, or injury |
|  | Identify (by name or class) any tranquilizers, analgesics, anesthetics, and other treatments (e.g., antibiotics) and describe their use |
|  | Provisions for palliative care or housing that may be necessary after experimental procedures |
|  | Plans for post-surgical care, if survival surgeries are proposed |
|  | Indicators for humane experimental endpoints, if relevant |
| **4. Method of Euthanasia:** Provide a justification for methods of euthanasia that are not consistent with the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If answer is “No” to the question “Is method consistent with AVMA guidelines?”, describe the method and provide scientific justification in the text field provided. | |
|  | If answer is “No” to the question “Is method consistent with AVMA guidelines?”, is the method described and a scientific justification provided? |