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

Any new study involving animal subjects that was not reviewed in the competing application, must be submitted for prior approval. Requests for prior approval of planned research involving live vertebrate animals conducted through NCATS UL1 pilot studies,KL2 scholar projects, and TL1 projects (if the protocol is not covered under the mentor’s grant) must be submitted in writing to NCATS no later than 30-days prior to 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)) to [[NCATSPriorApprovalRequest@mail.nih.gov](mailto:NCATSPriorApprovalRequest@mail.nih.gov)](mailto:NCATSPriorApprovalRequest@mail.nih.gov) with a copy to the assigned GMS and PO. The request should be submitted via email including “Prior Approval of VA Research, Complete Grant Number, CTSA hub, InvestigatorLastNameFisrtInitial and ProtocoShortTitle” in the subject line. This requirement applies to:

1. Studies to be conducted by KL2 scholars, if supported by NCATS funding,
2. UL1 pilot studies supported by NCATS funding or by voluntary committed cost share, and
3. Studies to be conducted by TL1 trainees (if the protocol is not covered under the mentor’s grant) supported by NCATS funding.

Complete prior approval requests should include at minimum:

* this checklist,
* the Vertebrate Animals Section, and
* the IACUC approval documents as individual files (either PDF or Word documents).

Follow the naming convention below:

**“CTSA hub\_InvestigatorLastNameFirstInitial\_ProtocolShortTitle\_Checklist\_YYYYMMDD”**

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

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

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| --- | --- |
| **Type of Proposed Research** | **Pilot Study  KL2 Project  TL1 Project** |
| **Total budget to be supported with NCATS funds**  *(KL2 Scholar salaries should not be included in the budget).* |  |
| **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 Research Protocol**  **(\*Title must match the title submitted to the IACUC for approval)** |  |
| **Title and PI of Parent Research Protocol (if proposed research is ancillary to another research protocol)** |  |
| **PI Name on the IACUC-Approved Research Protocol** |  |
| **Name of Pilot Study Investigator or KL2 Scholar or TL1 Trainee** |  |
| **Contact Information for Pilot Study Investigator or KL2 Scholar or TL1 Trainee** |  |
| **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? |