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

Any new study involving vertebrate animal subjects that was not peer reviewed in the competing application must be submitted for prior approval.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/UM1 pilot studies, UM1 Element E studies and KL2/K12 scholar projects 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) with a copy to the assigned Grants Management Specialist (GMS) and Program Officer (PO).

The request should be submitted via email including “Prior Approval of VA Research, Complete Grant Number, CTSA hub, InvestigatorLastNameFirstInitial, and ProtocolShortTitle” **in the subject line**. This requirement applies to:

1. Studies to be conducted by KL2/K12 scholars, if supported by NCATS funding, and
2. UL1/UM1 pilot and UM1 Element E studies supported by NCATS funding or by voluntary committed cost share.

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).
* Special requirements for element E as indicated below (**\***) when applicable.

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** | **UL1/UM1Pilot Study  UM1 Element E Study**  **KL2/K12 Project** |
| **Total budget to be supported with NCATS funds.**  *List a line-item budget for each specific aspect to be supported with NCATS funds (list supplies, services, and personnel costs).*  *Please note:*  *1. For Element E budget may not be less than $125,000 and must not exceed $500,000 in direct costs.*  *2. KL2/K12 Scholar salaries should not be included in the budget.* |  |
| Special requirements for element E, please see below (\*) | **☐ Yes ☐ No** |
| **CTSA Institution** |  |
| **CTSA Grant #** |  |
| **Animal Welfare Assurance # (required for approval)** |  |
| **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** (PI name for the prior-approval submitted research must match the PI name submitted to the IACUC for approval) |  |
| **Name of Pilot Study or Element E Investigator or KL2/K12 Scholar** |  |
| **Contact Information for Pilot Study/Element E Investigator or KL2/K12 Scholar** |  |
| **Name of Authorized Organizational Representative (AOR)** |  |
| **Contact Information for AOR** |  |
| **Institutional QA/QC Key Personnel** |  |
| **NCATS Grants Management Specialist** |  |
| **NCATS Program Official** |  |
| **Date form completed (MMDDYYYY)** |  |

**\*For UM1 Element E:** Projects that have not undergone NIH peer review must provide a full description of the project, not to exceed 6 pages. Describe:

1. The overall focus of the CTS Research Program.
2. Specific Aims, rationale, and approach to the selection of the proposed CTS research project(s); and how the project(s) will provide generalizable innovations or insights that increase the overall efficiency or effectiveness of translation.
3. A plan for dissemination of successful projects; include a proposed impact statement should the project ultimately be successful.

**REQUIRED Vertebrate Animals Section**:

Prior approval requests involving live vertebrate animals must address the criteria (#1-4) below. See [Vertebrate Animals Section | OLAW (nih.gov)](https://olaw.nih.gov/guidance/vertebrate-animal-section.htm) 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:

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| --- | --- |
| **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? |