**NOTICE OF FUNDING AWARD**

## PART 1. OVERVIEW INFORMATION

| | |
|---|---|
| Participating Organization(s) | CTSA Program at UT Southwestern |
| Funding Opportunity Title | Translational Pilot Program Grant |
| Funding Opportunity Number | CTSA-TPP-YR5-D |
| Funding Opportunity Purpose | The primary purpose of this opportunity is to engender preliminary data for extramural grant submission while tracking the success of the pilot award recipients to obtain extramural funding; and to facilitate training in the application process towards future extramural funding applications to the National Institutes of Health (NIH). |

## KEY DATES

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|---|---|
| **Announcement Date** | **October, 8 2024** |
| **Specific Aims and Video Due Date** | **November 20, 2024, by 5:00 PM:** Submit a 7 minute "TED Talk" video to CTSAProgram@UTSouthwestern.edu promoting your research proposal along with a 1 page specific aims, NIH Biosketch and CTSA Pilot Program Video Application Page. Applicants submitting from partner institutions are required to have appropriate IRB/IACUC approvals. |
| **Selection of Video Applications** | **December 10, 2024:** Twelve applicants from those who provided a "TED Talk" video application will be selected and move on to the panel presentation stage. |
| **IRB/IACUC Submission Due Date** | **December 20, 2024:** The 12 applicants selected from "TED Talk" round will require proof of IRB and/or IACUC **submission** as applicable if from UTSW. |
| **Presentation to Review Panel** | **January 21 – January 31, 2025:** Applicants selected from "TED Talk" round will present proposals to a panel of experts. **Eight finalists** will then be chosen from selected presenters and notified of their eligibility to submit a full application by no later than **February 5, 2025.** |
| **Final Application Due Date** | **March 10, 2025, by 5:00 PM:** Applicants who have been invited to apply are encouraged to apply early to allow adequate time to make corrections by the dure date if errors are found in the application during the submission process. **All appropriate human (IRB) and animal (IACUC) study approvals are required before March 10, 2025, to be eligible to submit an application.** |
| **Award announcement** | **April 14, 2025** |

**Earliest Award Start Date** **May 1, 2025**

## PART 2. FULL TEXT OF ANNOUNCEMENT

### SECTION I. FUNDING OPPORTUNITY DESCRIPTION

**Background**
The Clinical & Translational Science Award (CTSA) Program at UT Southwestern is pleased to extend an invitation to apply for a Program grant for the next award cycle. The intent of the pilot program is to attract strong applications from new investigators with novel scientific studies. Studies that involve inter-institutional and inter-disciplinary concepts are encouraged. This Funding Opportunity Announcement (FOA) is also designed to support preliminary data and provide new investigators with the opportunity to engage in a scientifically rigorous study design with enhanced focus on using the application process to develop and submit stronger proposals for extramural funding. This grant, 5UL1TR003163, is funded by the National Center for Advancing Translational Sciences (NCATS) of the NIH.

**Objectives**
The CTSA Program at UT Southwestern will provide financial support for investigators to conduct innovative clinical and translational research projects. It is anticipated that this funding mechanism will achieve the following:

- Promote and support the development and testing of novel research ideas.
- Promote and support novel translational ideas of developing investigators.
- Promote and encourage inter-institutional and inter-disciplinary collaborations.
- Assess the feasibility of new approaches to translational science that lead to extramural funding.

### SECTION II. AWARD INFORMATION

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| **Funding Instrument** | Grant: A support mechanism providing money to eligible investigators to carry out an approved inter-institutional and inter-disciplinary project or activity. |
| **Application Types Allowed** | New |
| **Award Budget** | The project budget for most awards should not exceed $50,000 direct costs. Indirect costs are not allowed. |
| **Award Budget Period** | The maximum project period is 1 year, dependent on required regulatory approvals and award date |

## SECTION III. ELIGIBILITY INFORMATION

### Eligible Applicants

The Translational Pilot Program is targeted solely to the following individuals who display the talent and personal traits associated with career success and who have identified the environmental resources and interdisciplinary collaborations required to make success likely:

- Junior faculty at the Instructor or Assistant Professor level or formal participants in the CTSA Program KL2 Scholars Program or UT Southwestern Clinical Scholars.
- Associate Professor proposing a new direction in their research. This must be a substantial shift in research direction (e.g., not just using a different model system)

The career path of the applicant and their ability to develop interdisciplinary collaborations will be considered in the selection process at par with the scientific merit of the proposed project. Applicants who are post-doctoral fellows or residents must have a mentor who will work with them on the proposed project.

### Eligible Organizations

Applications from trainees or faculty members at the following institutions will be accepted:

- University of Texas Southwest Medical Center (UTSW)
- Children's Health℠
- Parkland Health & Hospital System
- Texas A&M University College of Veterinary Medicine
- Dallas Veterans Affairs Medical Center
- Moncrief Cancer Institute
- Southern Methodist University (SMU)
- Texas Scottish Rite Hospital for Children (TSRHC)
- Texas Tech University Health Sciences Center
- University of North Texas Health Sciences Center, Fort Worth (UNTHSC)
- University of Texas at Arlington (UTA)
- University of Texas at Dallas (UTD)

### Eligible Projects

Emphasis on the development and testing of new hypothesis in the following areas:

- **Health Equity/Disparity Research** encourages complementary, multi-disciplinary research teams in areas such as: identifying inequities across populations, developing interventions to support highest level of health for all people, elucidating and quantifying biological, genetic, inflammatory, metabolic, and immunological disease processes across ethnic populations and evaluating how social determinants of health influence disease progression.
- **Translational Research** includes two areas of translation. One is the process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans. The second area of translation concerns research aimed at enhancing the adoption of best practices in the community. Cost-effectiveness of prevention and treatment strategies is also an important part of translational science.
- **Clinical Research** includes clinical trials with human subjects to test intervention safety and effectiveness, behavioral and observational studies, outcomes and health services research, and the testing and refinement of new technologies.
- **Community-Based Research** is a collaborative effort between academic researchers and non-academic based community members that aims to generate social action and positive social change through the use of multiple knowledge sources and research methods. Ideally, the research questions

originate from off-campus communities and the process involves meaningful participation by all partners in every stage of the research.

- **Health Services Research** examines how people get access to health care, how much care costs, and what happens to patients as a result of this care. The main goals of health services research are to identify the most effective ways to organize, manage, finance, and deliver high quality care; reduce medical errors; and improve patient safety.
- **Team Science** is used to refer to a collaborative approach that draws concepts and technologies from multiple fields to develop a new perspective on answering research questions or solving complex problems. While traditional single investigator driven approaches are ideal for many scientific endeavors, coordinated teams of investigators with diverse skills and knowledge may be especially helpful for studies of complex social problems with multiple causes.

**Required Registrations**
All applicants must have an eRA Commons account. Applicants should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. Obtaining an eRA Commons account can take up to 2 weeks.

## SECTION IV. APPLICATION AND SUBMISSION INFORMATION

1.) Applicants must submit:
   a. CTSA Pilot Program Video Application Page, CTSA Pilot Program Video Application Page, 1 page Specific Aims and Biosketch in one file named: **last name_co-investigator last name_TPP_2025**.
   b. 7 minute **"TED Talk" video**. The video can be recorded via your cell phone or other electronic device such as a laptop or computer. Click here for instructions on how to record a video in PowerPoint.
   c. If you are submitting from a partner institution appropriate IRB/IACUC approval is required at this stage.

   Please upload the video to either Dropbox or Google Drive. The video URL can then be shared with file in a above via e-mail to CTSAProgram@UTSouthwestern.edu. *Please note that sending the 7-minute video via e-mail will likely not work as the file will be too large to transmit. Therefore, we request that you share the file location link instead.*

   Please contact us if you experience issues or have questions please reach out directly to Victoria Lutgen Gronau <Victoria.LutgenGronau@UTSouthwestern.edu>.

   **DEADLINE 11/20/2024**

2.) The file and video will be reviewed by a committee of CTSA stakeholders and collaborators with expertise in basic, translational, and clinical research. Scoring is based on scientific merit and sustainability.

   **APPLICANTS SELECTED WILL BE NOTIFIED of DECISION to move to next stage by 12/10/24.**

   UTSW applicants selected to move forward after the "Ted Talk" round **will be required** to have human (IRB) or animal (IACUC) proposals **SUBMITTED** in order to proceed to the panel presentations.

   **DEADLINE 12/20/2024**

3.) Applicants invited to present their proposals to a panel of experts will be judged and provided with specific critique and suggestions for the proposed study. If selected to submit a full application, these suggestions must be incorporated into the research proposal application (or explain why they were not).

**PANEL PRESENTATIONS WILL BE BETWEEN JANUARY 21, 2025 AND JANUARY 31 2025. NOTICES INCLUDING TIME SLOT FOR PRESENTATION WILL BE SENT TO THOSE SELECTED NO LATER THAN 1/6/2025.**

4.) Applicants selected after the panel presentations are invited to submit a full application. At this stage, approval of human (IRB) or animal (IACUC) research as applicable is **REQUIRED**. At this step, applications submitted without approval will not be considered. Please submit all forms in one file named: **last name_co-investigator last name_TPP_APP_2025**. These full applications will go through an in-depth and robust review by at least three reviewers.

**APPLICATIONS WITH APPLICABLE IRB/IACUC APPROVAL ARE DUE 3/10/25.**

5.) Final scores are submitted to the CTSA Pilot Program Council. Priority is given to early career investigators/trainees who are in the process of achieving independence as clinical or translational researchers.

**FINAL REVIEW AND SELECTION OF AWARDEES COMPLETED ON OR BEFORE 4/14/2025.**

6.) Up to four grants will be funded, subject to award funds availability.

**EARLIEST FUNDING WILL BE 5/1/2025.**

## 1. CONTENT AND FORM OF ALL PACKAGE SUBMISSIONS

**Instructions for Submission**
Only e-mailed submissions will be accepted. Submit completed applications to CTSAProgram@UTSouthwestern.edu

**2. "TED TALK" PACKAGE (see step 1 in the previous section)**
Complete all the following forms:

- CTSA Pilot Program Video Application Page which includes a statistical approach summary
- Specific Aims (1 page)
- Biosketch
- "Ted Talk" video

**3. FULL APPLICATION PACKAGE (see step 4 in the previous section)**
Refer to the application section of this FOA - or request application documents by email at CTSAProgram@UTSouthwestern.edu

## APPLICATION COMPONENTS

**Application Forms**
Complete all the following forms as applicable. Combine into one file named: **last name_co-investigator last name_TPP_APP_2025** in the following order:

- Pilot Face Page
- Detailed Budget Page
- Budget Justification (see Budget Guidelines)
- Research Plan Components as listed

- Biosketch
- Letter of Support from Research Mentor, if applicable
- Letter of Support from Department Chair, if applicable
- F&A waiver from partnering institutions, if applicable
- IRB Approval (as applicable)
- PHS Human Subjects and Clinical Trials Information (as applicable, note: please download and open in Adobe; may be sent as a separate file)
- IACUC Approval (as applicable)

**Page Limitations**

| **Component Type** | **Page Limits** |
|---|---|
| Research Plan – Hypothesis and Specific Aims | 1 page |
| Research Plan – Background and Rationale | 1 page |
| Research Plan – Study Design and Methods including response to Areas of Improvement from the Panel Presentations | 6 pages |
| Research Plan – Multidisciplinary Team Approach | 2 pages |
| Research Plan – Next Steps | 2 pages |
| Research Plan – Literature Cited | No limit |
| Biosketch (current NIH format) | 5 pages |
| Letter of Support from Research Mentor | 2 pages |
| Letter of Support from Department | 2 pages |
| F&A Waiver from partnering institutions | 1 page |

**Research Plan**

Formatting on the Research Plan should be single spaced, ½" margin, Arial 11 font with applicant's name in header on the right-hand margin of each page and paginated in the bottom-right corner of each page. All sections of the Research Plan should be combined and submitted as a single PDF file.

- *Hypothesis and Specific Aims*
  Include only those aims which can be completed within the 1-year budget period.
- *Background and Rationale*
  Provide sufficient and properly cited source documentation of previous research related to the proposed topic of study. Define precisely why the proposed work is innovative and how it relates to the theme of the award; how it challenges current concepts or paradigms that would make extramural funding unlikely in the absence of preliminary data; how it fosters collaborations that would otherwise not take place; or how it establishes the feasibility of an idea in order to support a future grant application.
- *Study Design and Methods*
  Include a description of how the experimental approach relates to the aims and a discussion of how the data will be interpreted. The description of the research plan should provide a clear understanding of how the investigators will approach the testing of the hypotheses, sufficient detail in the execution of the experiments, and a discussion of how the data will be interpreted, specifying alternative experimental

and/or analytical provisions when pertinent. This section must include an outline of potential experimental problems and the solutions devised to overcome them, clinical significance, and a timetable for the performance of the studies. The research design and methods section should focus on the details of the study design, including patient populations and inclusion/exclusion criteria (where appropriate), methods of data collection and analysis, and must include a statistical analysis plan.

- *Multidisciplinary Team Approach*
  Describe the specific contributions of all co-investigators and collaborators and include their primary discipline and describe how each is uniquely qualified to perform in their respective roles (co-I, mentor, study coordinator, nurse, pharmacist, or other member of the translational workforce). Additionally, collaboration with a biostatistician regarding the study design and analysis is encouraged for most investigators.
- *Next Steps*
  Describe the next steps in your research project after these services have been completed. Include resources available to you to ensure success and plans for progression to extramural funding.
- *Literature cited*

**Human Subjects Research**

All proposals involving human research subjects must include the additional application requirements depending on the category of research being proposed including IRB submission (*required on December 20th, 2024*), IRB approval (*approval may NOT be pending at the time of full application submission*) and PHS Human Subjects and Clinical Trials Information (required at time of application submission). Of note, applicants submitting from partner institutions must have IRB approval at time of video submission. Please see NCATS New Projects With Human Subjects Research for further information. For information on the IRB submission process, please watch the "Introduction to IRB" course on Taleo Learn. For more information please contact UT Southwestern HRRP at 214.648.3060, hrpp@utsouthwestern.edu or visit the HRPP website.HRPP website.

| NCATS REQUIRED DOCUMENTS | Category 1[1] | | Category 2[2] | |
|---|---|---|---|---|
| STUDY CATEGORY | Clinical Trial | Greater Than Minimal Risk Study | Minimal Risk[3], Exempt 1-3; 5-8 Study | Exemption 4 |
| COMPLETE HSS SECTIONS[5] | 1-6 | 1, 2, 3.1 & 3.2 | 1, 2, 3.1 & 3.2 | 1, 3.1 & 3.2 |
| Addendum | √ | √ | √ | √ |
| Certification of IRB-Approval | √ | √ | √ or | |
| Institutional Exemption Determination | | | √ | √ |
| Biosketches for PIs and key personnel | √ | √ | | |

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|---|---|---|---|---|
| **Institutional letter attesting to completion of Human Subjects Training for PI and key personnel[4]** | √ | √ | √ | √ |
| **IRB-Approved Protocol** | √ | √ | | |
| **IRB-Approved informed consent, verbal consent transcript, assent and parental permission documents, or documentation of IRB waiver (as applicable)** | √ | √ | | |
| ***Specified NCATS Required Document PDFs should be combined and attached in HSS Sections*** | ***5.1*** | ***2.7*** ***(Study Timeline attachment box must be used to attach the Study Timeline plus the NCATS-specified documents.)*** | | |

[1]**Category 1 Human Subjects Research** that meets the NIH definition of a clinical trial. *Answered "Yes" to all the questions in HSS Section 1.4 - Clinical Trial Questionnaire.* OR Human Subjects Research study deemed Greater than Minimal Risk by IRB.

[2]**Category 2 Human Subjects Research** study deemed Minimal Risk by the IRB or study has been determined by the institution to meet the criteria for Exemptions 1-8 under 45CFR46.

[3]**All NIH-defined clinical trials are considered Category 1** research even if proposed research might otherwise be considered Minimal Risk.

[4]**Institutional letter attesting to completion of Human Subjects Training for PI and key personnel**: NIH policy (NOT-OD-00-039 & NOT-OD-01-061) requires education on the protection of human research participants for PI and all key personnel; insert signed letter.

[5]**Utilize G.500 – PHS Human Subjects and Clinical Trials Information** as a guide during the preparation of any HSS Section required for Category 1 or Category 2 Prior Approval submissions.

| **eRA HSS SECTIONS to be COMPLETED[6]** | | **Category 1[1]** | | **Category 2[2]** | |
|---|---|---|---|---|---|
| | **STUDY CATEGORY** | **Clinical Trial** | **Greater Than Minimal Risk Study** | **Minimal Risk[3], Exempt 1-3; 5-8 Study** | **Exemption 4** |
| **HSS Section 1 – Basic Information** | | | | | |
| **1.1** | Study Title | √ | √ | √ | √ |
| **1.2** | Is this Study Exempt from Federal Regulations? | √ | √ | √ | √ |
| **1.3** | Exemption Number | √ | √ | √ | √ |

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|---|---|---|---|---|---|
| **1.4** | Clinical Trial Questionnaire | √ | √ | √ | √ |
| **1.5** | Provide the ClinicalTrials.gov Identifier | √ | | | |
| **HSS Section 2 – Study Population Characteristics** | | | | | |
| **2.1** | Conditions or Focus of Study | √ | √ | √ | |
| **2.2** | Eligibility Criteria | √ | √ | √ | |
| **2.3** | Age Limits | √ | √ | √ | |
| **2.3.a** | Inclusion of Individuals Across the Lifespan | √ | √ | √ | |
| **2.4** | Inclusion of Women & Minorities | √ | √ | √ | |
| **2.5** | Recruitment and Retention Plan | √ | √ | √ | |
| **2.6** | Recruitment Status | √ | √ | √ | |
| **2.7** | Study Timeline | √ | √ | √ | |
| **2.8** | Enrollment of First Participant (Section 6.3) | √[4] | √[4] | √[4] | |
| **2.9** | Inclusion Enrollment Report(s) | √[7] | √[7] | √[7] | |
| **HSS Section 3 – Protection and Monitoring Plans** | | | | | |
| **3.1** | Protection of Human Subjects | √ | √ | √ | √ |
| **3.2** | Is this a multi-site study? | √[5] | √[5] | √[5] | √[5] |
| **3.3** | Data and Safety Monitoring Plan | √ | **Optional** | **Optional** | **Optional** |
| **3.4** | Data and Safety Monitoring Board | √ | **Optional** | **Optional** | **Optional** |
| **3.5** | Overall Structure of the Study Team | √ | **Optional** | **Optional** | **Optional** |
| **HSS Section 4 – Protocol Synopsis** | | | | | |
| **4.1** | Study Design | √ | | | |
| **4.1.a** | Detailed Description | √ | | | |
| **4.1.b** | Primary Purpose | √ | | | |
| **4.1.c** | Interventions | √ | | | |
| **4.1.d** | Study Phase | √ | | | |
| **4.1.e** | Intervention Model | √ | | | |
| **4.1.f** | Masking | √ | | | |
| **4.1.g** | Allocation | √ | | | |
| **4.2** | Outcome Measures | √ | | | |

| | | | | | |
|---|---|---|---|---|---|
| **4.3** | Statistical Design and Power | √ | | | |
| **4.4** | Subject Participation Duration | √ | | | |
| **4.5** | FDA-Regulated Intervention? (IND/IDE) | √ | | | |
| **4.7** | Dissemination Plan | √ | | | |
| **HSS Section 5 – Other Clinical Trial Attachments** | | | | | |
| **5.1** | Other Clinical Trial Attachments | √ | | | |
| **HSS Section 6 – Clinical Trial Milestone Plan[8]** | | | | | |
| **6.1** | Study Primary Completion Date | √[8] | | | |
| **6.2** | Study Final Completion Date | √[8] | | | |
| **6.3** | Enrollment and Randomization | √[8] | √[8] | √[8] | |
| **6.4** | Completion of primary endpoint data analyses | √[8] | | | |
| **6.5** | Reporting of results in ClinicalTrials.gov | √[8] | | | |
| **6.6** | Is this an applicable clinical trial under FDAAA? | √[8] | | | |

[1]**Category 1 Human Subjects Research** that meets the NIH definition of a clinical trial (*Answered "Yes" to all the questions in HSS Section 1.4 - Clinical Trial Questionnaire)* OR Human Subjects Research study deemed Greater than Minimal Risk by IRB.

[2]**Category 2 Human Subjects Research** study deemed Minimal Risk by the IRB or study has been determined by the institution to meet the criteria for Exemptions 1-8 under 45 CFR 46

[3]**All NIH-defined clinical trials are considered Category 1** research even if proposed research might otherwise be considered Minimal Risk.

[4]**Section 2.8 Enrollment of First Participant:** This field is now populated in Section 6.3 in HSS. Do not complete this field if you answered "YES" to the question "Using an Existing Data Set or Resources?" in the Inclusion Enrollment Report.

[5]**Section 3.2 Multi-site Studies**: Answer "Yes/No;" or select N/A only if: a. You answered "Yes" to "Question 1.2 Is this Study Exempt from Federal Regulations?". gvhoSee G.500 for reference.

[6]**Utilize G.500 – PHS Human Subjects and Clinical Trials Information** as a guide during the preparation of any HSS Section required for Category 1 or Category 2 Prior Approval submissions.

[7]**Section 2.9 Inclusion Enrollment Report(s)** is not required for KL2/K12 Scholar projects and Category 4 Exempt HSR ( note: If the KL2/K12 Scholar is conducting an independent clinical research that is only using KL2/K12 research funds to support the research, then the IER is required.)

[8]**Section 6.3 Anticipated Enrollment of 1st participant** is required for all prior approval submissions except Exempt Category 4. *Even though Section 6 was initially created for clinical trials, the enrollment start must be included and updated for ALL HSR projects (including exempt studies, other than category 4) before submitting the RPPR.*

For clinical trials, the other fields in Section 6 will populate when the NCT number is entered in Section 1.5 and the 'populate' button is pushed. However, this is not required for prior approval submission but must be populated within 21 days of enrollment of the first participant. *The information from clinicaltrials.gov will populate the HSS fields so ensure the clinicaltrials.gov entry is current upon HSS completion.*

**Vertebrate Animal Research**

All proposals involving animal research subjects must include the following application requirements:

1. IACUC submission by **12/20/2024**.
2. IACUC Approval Letter by full application submission **3/10/2025** *(Approvals may **not** be pending at the time the full application is submitted).*
3. If applicant is from a partnering institution full IACUC approval is required at time of video submission.
4. Vertebrae Animals Section
   See NIH Worksheet for Applications Involving Animals 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 in the table below.

For more information on the IACUC submission process, please contact the UT Southwestern IACUC at iacuc@utsouthwestern.edu or visit their website. Of note, although unlikely, it can take up to 12 weeks for approval for high-risk protocols.

| | |
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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.<br><br>**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).<br><br>**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*) |

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| **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.<br><br>**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? |

## 4. ADDITIONAL REQUIRED ATTACHMENTS

- Biosketch Forms
  Using the most current NIH form, maximum 5 pages, biosketches should be completed for the applicant PI and all Key Personnel such as Co-Investigators or Collaborators who will be working on the proposed project. Combine all biosketches as one document and attach. All biosketches must include the link to the personalized MyBibliography.

- *Letter of Support from Research Mentor*
  For applications submitted by early career investigators (i.e., post-doctoral trainees, assistant professors), attach a letter from the applicant's primary research mentor in PDF format: The letter must include all seven points. Please follow the order and include numeration as listed above. Items a – d must provide a thorough explanation or description.
  a. Describing the trainee's potential as an investigator
  b. Explaining the ability of the trainee to carry out the work as proposed
  c. Describing the environment
  d. Explaining how the study will contribute to the applicant's professional goals
  e. Stating he/she has evaluated and approved the submission of the research proposal
  f. Stating he/she will provide scientific oversight throughout the duration of the project and will be responsible for the conduct of the study and describing his/her role in the team science approach, if applicable
  g. Assuring access to resources needed to conduct the research

- *Letter of Support from Department*

Early career (i.e., post-doctoral trainees, assistant professors) applicants must submit a letter of support from his/her department chair or division chief documenting that the PI has his/her time protected, his/her salary supported to conduct the proposed research, and a commitment to return unspent funds if the project is determined to be unfeasible.

- *F&A Waiver*
  If the applicant is from a partnering institution, a letter from their institution waiving F&A in the event the applicant is awarded (contact the CTM for assistance in obtaining this letter). Indirect costs are not allowable on the pilot award.

**5. SUBMISSION DATES AND TIMES**

Part 1 Overview Information contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission.

Only e-mailed applications will be accepted. Submit completed applications to the CTSA Program Translational Pilot Program at CTSAProgram@UTSouthwestern.edu. Failure to adhere to the application and submission instructions, including page limitations and formatting, will result in the immediate rejection of the application.

**6. BUDGET GUIDELINES**

Complete the Detailed Budget template and Budget Justification of all costs in the application. Applicants must explain how all requested funds relate to the aims or goals of the proposed project.

Expenses that are allocable, allowable, reasonable and consistent should be taken into consideration when creating the budget. Refer to the NIH Grants Policy Statement on the Cost Principles for specific details.

**Approved Use of Funds**

- Personnel: Funds from this mechanism may be used for any of the following salary support: non-PI research personnel such as research nurse, technician, data entry personnel, consultants, etc. Personnel costs must also include the appropriate amount of fringes.
- Service Providers: Funds may be used to offset costs for laboratory analyses, data collection, database design/support, research coordinator services, or other services provided by core facilities on the UT Southwestern campus. A list of UTSW Service Providers is provided on the Application Forms spreadsheet. Applicants should seek consultation with proposed service providers to ensure sufficient funds are requested and that all related services are included. A price quote must be attached to the application if core service funding is requested in the budget. Price quotes are price estimates based on discussions with the core(s) of your choice. Price quotes must be generated by and come from the core facility.
- Equipment: Equipment is an article of tangible nonexpendable personal property that has a useful life of more than 1 year and an acquisition cost per unit that equals or exceeds $5,000. Equipment may be purchased only if such equipment is essential and allocable and not otherwise available for use by the applicant through a core facility on the UT Southwestern Campus. All equipment purchases must comply with the NIH Grants Policy Statement and UT Southwestern Purchasing Department requirements.
- Supplies: Funds may be used to offset materials and supplies necessary to carry out the proposed research.
- Inpatient and Outpatient Care Costs: Funds may be used to offset costs for inpatient or outpatient research visits, including hospital fees, nursing, metabolic services and meals, facility usage fees, investigational drug services, lab processing, etc.

- Other Expenses: Funds may be used to offset costs for study subject payments and expenses not included in the other budget categories.

**Non-Approved Use of Funds**

- Publication costs
- Invention, Copyright, Patent, or Licensing Costs
- Computer costs
- PI salary and fringe
- Travel & meals
- Administrative Costs, including paper, pens, notepads, and office furniture.
- Indirect costs (F&A), including subcontracts with CTSA partnering institutions. Applicants from partnering institutions should obtain a waiver for F&A from their institution as a condition of award (contact the CTSA Program at UT Southwestern or assistance in obtaining this letter).
- Other common unallowable costs, including but not limited to, advertising, IRB/IACUC costs, entertainment, membership dues, meetings/conferences, postage, printing, student costs).

NOTE: In some cases, non-approved costs may be allowed if directly related to the research and well-justified in accordance with the Cost Principles and Allowability of Costs/Activities guidelines of the NIH Grants Policy Statement. These may include costs such as computer, and books and journals. Contact the CTSA with questions on the allowability of a budget item to obtain confirmation.

Refer to the NIH Grants Policy Statement on Allowability of Costs/Activities for further guidelines.

### 7. FUNDING RESTRICTIONS

In accordance with section 479(b) of the Public Health Service Act (as amended by the Consolidated Appropriations Act, 2012, Public Law 112-74 and by the 21st Century Cures Act, 2016, Public Law 114-255), NCATS is authorized to use fiscal year 2021 funds to provide infrastructure and resources for all phases of clinical trials research but can only support clinical trials through the end of Phase IIB.

## SECTION V. APPLICATION REVIEW INFORMATION

### 1. CRITERIA

The review of applications will resemble the NIH application and review processes to develop investigator's familiarity and understanding of the scoring procedures facilitated at NIH applicable to potential extramural health-related research applications.

**OVERALL IMPACT**

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on research field(s) involved.

**SCORED REVIEW CRITERIA**

- **Significance**
  Does the project address an important problem or a critical barrier to progress in the field? Is there a strong scientific premise for the project? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
- **Investigator(s)**
  Are the PI, collaborators, and other researchers well suited to the project? If early career Investigators or new Investigators, or in the early stages of independent careers, do they have appropriate experience

and training? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project? Comment on the PI's track record and career path.

- **Innovation**
  Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed? How does the proposed research relate to the theme?
- **Approach**
  Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility, and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects? If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?
- **Environment**
  Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?
- **Sustainability**
  Does this project have potential for extramural funding?
- **Budget**
  Is the budget and justification reasonable based on the anticipated proposed research? Are there recommendations in reductions or increases in budget amount?

**ADDITIONAL REVIEW CRITERIA**

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

- **Protections for Human Subjects**
  For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials. For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the NIH Guidelines for the Review of Human Subjects.
- **Inclusion of Women, Minorities, and Children**
  When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children to determine if it is justified in terms

of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research.

- **Vertebrate Animals**
  The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 4) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for the Vertebrate Animals Section (VAS).

**ADDITIONAL REVIEW CONSIDERATIONS**

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

- **Budget and Period of Support**
  Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

**2. REVIEW AND SELECTION PROCESS**

Applications will be evaluated for scientific and technical merit.

- Invited full applications will compete for available funds with all other recommended applications submitted in response to this FOA.
- Applications will be assigned to appropriate reviewers based on scientific relevance.
- Following initial peer review, recommended applications will receive a second level of review by the PTC Scientific Review Committee. The following will be considered in making funding decisions: Scientific and technical merit of the proposed project as determined by PTC Scientific Review Committee.
- Following PTC Scientific Review Committee review, recommended applications will be reviewed by the CTM Council. The following will be considered in making funding decisions:
  - Availability of funds.
  - Relevance of the proposed project to program priorities.

**3. ANTICIPATED ANNOUNCEMENT AND AWARD DATES**

Refer to Part 1 Overview Information for key, and earliest start dates.

## SECTION VI. AWARD ADMINISTRATION INFORMATION

**Award Notices**

A formal notification in the form of a Notice of Award (NOA) will be provided to applicants for successful applications.

**Pre-Award Meeting** Attendance by the applicant, along with the Administrative and Financial contacts listed in the application, is required at a pre-award meeting with the CTSA Program Translational Pilot Program Staff. The purpose of the meeting is to ensure awardees understand and agree to their responsibilities in relation to the award.

**Distribution of Funds**

- Awardees appointed to UTSW will have funds distributed into a Chart of Accounts at UT Southwestern. The Chart of Accounts number will be provided in the Notice of Award (NOA).
- Awardees appointed to partnering institutions will be funded through a subcontract.

**Duration of Funding**
Applicants must be fully prepared to begin the project immediately upon receiving a Notice of Award. Funds must be expended by April 30, 2025.

## SECTION VII. POST-AWARD REQUIREMENTS

**Clinical Trials**
If the proposed project involves a clinical trial, the awardee will be required to promptly inform the CTM of all adverse events that are serious, unexpected, and related to participation in research. Further guidance is available at clinicaltrials.gov adverse events. In addition, all applicable clinical trials must be registered in clinicaltrials.gov. For more information, see https://utswmed.org/patient-resources/clinical-trials/.

**Translational Science Forum**
All CTSA Program supported recipients will be required to present at a future Clinical & Translational Science Forum.

**Tracking and Reporting**
Quarterly and Final Reports: All funded applicants must be committed to providing quarterly reports for the 12 months budget period and a final annual progress report at the end of the budget period. The reports provide accountability in tracking and evaluating the program's impact on recipient projects, including any additional funding, inventions, patents, or licenses, publications and other project information and data resulting from the project. Failure to provide these reports will result in forfeiture of funding and disqualification from future funding opportunities. Quarterly reports must be submitted every 3 months. The annual progress report is due 60 days after the award period. In addition, a final invention and certification statement will also be required to be submitted 60 days after the award period. Forms will be provided with the NOA or can be requested by email to the CTSAProgram@UTSouthwestern.edu

**Acknowledgement**
All publications must be registered with PubMed Central, and all Translational Program grant recipients must acknowledge the support of the CTSA Program at UT Southwestern in all publications, presentations, and posters by stating "Research reported in this publication was supported by the National Center for Advancing Translational Sciences of the National Institutes of Health under the Center for Translational Medicine's award number 1UL1TR003163-01A1. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH."

**Unspent Funds**
Any unspent funds must be returned to the Program in the event that the project is determined to be unfeasible, is not completed for any other reasons, or the funds are no longer required for the project (for example, if external support is obtained for the same project).

## SECTION VIII. PROGRAM CONTACTS

Questions may be submitted to CTSAProgram@UTSouthwestern.edu