CCTS Partner Network Pilot Program

From bench to bedside, the CCTS is on a mission to improve health and health equity in communities across the deep south. By working together, we can accelerate the translation of fundamental and clinical research into improvements for human health and healthcare delivery.

Aligned with this mission, the CCTS Partner Network Pilot Program seeks to ameliorate health conditions that disproportionately affect our region as represented by the CCTS Partner Network and develop the future translational research workforce by fostering collaboration, team science and innovative discovery.

1. Overview

Key Dates

Posted Date	September 1, 2021
Pre-Application Due Date	October 25, 2021 by 5PM
Full Application Due Date (by invitation only)	December 21, 2021 by 5PM
Scientific Merit Review and Advisory Council	January – early February 2022
NIH Review	April 2022
Earliest Start Date	May 1, 2022
End Date	April 30, 2023

Application Process

This program utilizes a two-stage application process. Pre-applications will be scored using an NIH 1-9 scale by CCTS members from across the Partner Network. If invited to submit a full application, the CCTS will help applicants coordinate a BERD consult and CCTS Panels Done Quickly (PDQ) to sharpen full proposals before they are submitted. Full applications will then be reviewed internally and externally (e.g. via the CTSA External Reviewer Exchange Consortium (CEREC)). After review, selected proposals will be subject to NIH prior approval before an award can be made.

Proposals

Proposals should be set in the context of health conditions that disproportionately affect our region. Research plans may lie at any point along the translational science spectrum – from biological basis of health or disease to interventions aims at improving health of our community.

Eligibility

The program supports investigators from any of the CCTS Partner Network institutions. Collaborative teams spanning multiple partner sites are not required but encouraged. This program is primarily intended to support new investigators. Those with previous or active K-awards are encouraged to apply. Established investigators with a previous history of funding may apply, providing justification in the Declaration of Eligibility sections related to how the proposed aims represent a major shift from his/her scientific portfolio to date and/or the proposed work advances ongoing research to a later stage of translation. Individuals with a faculty appointment with a start date on or before the award date are eligible – a letter of support from the Department Chair substantiating the upcoming

appointment are welcome additions to the pre- and full-applications. Established investigators are discouraged from serving as the principal investigator on behalf of others. All projects should directly represent the ideas of the principle investigator. Projects already supported by extramural funding should not be proposed, as they cannot be considered for funding.

Funding and Cosponsorship

The CCTS has committed $180,000 to this program. Applicants may request up to $60,000 (Direct). The number of awards is contingent upon a sufficient number of meritorious applications and cosponsorship. Applicants are expected to identify at least one cosponsor. Under this cosponsorship arrangement, the CCTS will commit half of the requested funds (maximum of $30,000 Direct) and the cosponsor will commit up to half of the requested funds (maximum of $30,000 Direct). A cosponsor may include an institution, school, department, division, intramural research center, etc., or a combination thereof based at the PI's home institution. Funds from an applicant's endowment or start-up are not suitable sources of co-sponsorship.

2. Pre-Application Instructions

Pre-Application proposals are submitted as a single PDF using RED-ASSIST, a REDCap-based project designed to facilitate proposal submission and review. Project information is captured via both the pre-application proposal and the RED-ASSIST online submission form.

Pre-Application Proposal

Pre-applications should be prepared as a single PDF containing a Summary Page, Pre-Application Research Plan and NIH Biosketches as follows:

A. Summary Page (1-page maximum)

- ***Project Title***
- ***Declaration of Eligibility***
  Briefly explain (2-3 sentences) how the PI(s) meet the eligibility criteria for this funding mechanism. See "Eligibility" section for details.
- ***Project Abstract***
  Briefly explain (half-page) the proposed work's long-term objective, aims, design, outcomes and relevance to the CCTS's mission.

B. Pre-Application Research Plan (2-page maximum)

- ***Significance***
  - Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
  - Provide a clear and concise description of the central theme and research goals.
  - Please comment on how the proposed work fits the definition of Translational Research, which refers to the integration of fundamental, patient-oriented and population-based research with the goal of improving health and healthcare delivery.
- ***Innovation***
  - Explain how the application challenges and seeks to shift current research or clinical practice paradigms.

  - Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantages over existing methodologies, instrumentation or interventions.
- ***Approach***
  - Be sure to include explicit statements of aims and corresponding hypotheses.
  - Describe any strategy to establish feasibility, and address the management of any high-risk aspects of the proposed work.
  - Describe the overall strategy, methodology and analyses to be used to accomplish the specific aims of the project in a robust and unbiased manner (that is appropriate for, presumably, a feasibility-level study).* Include how the data will be collected, analyzed and interpreted as well as any resources sharing plans as appropriate.
- ***References Cited***
  - Provide a bibliography of all references cited. Use whatever format you want. This section is not included in the 2-page maximum.

C. NIH Biosketch

The biosketch provided for the PI(s) must conform to the NIH Biosketch requirements. Biosketches are not required for coinvestigators, collaborators or other significant contributors. Investigators with a faculty appointment starting on or before the award start date may append a Letter of Support from their Department Chair substantiating their upcoming appointment may be appended to their NIH Biosketch. Biosketches are an opportunity to describe why you're well suited for your role in a project.

Pre-Application Online Submission Form

Pre-applications should be submitted via RED-ASSIST. While not necessary (or accepted as part of the application package), you may download a Pre-application Online Submission Form Template for your personal use. Beyond demographic information and basic project details, the RED-ASSIST form will request:

A. Lay Summary (1,000 character maximum)

This summary will not be scientifically reviewed. For guidance on how to write a lay summary, please read "10 Tips For Writing a Lay Summary." Please include the CCTS mission relevance of your project. This summary may be utilized to identify reviewers if you are invited to submit a full application and promote your research if awarded.

B. Acknowledgement of Cosponsorship

At the pre-application stage, applicants only need to acknowledge that cosponsorship is a required. Letter(s) of Support specifying cosponsorship should not be included in the pre-application.

3. Full Application Instructions

Invitations to submit a full application will contain a unique RED-ASSIST hyperlink, which should be used to submit a full application. Project information is captured via both the full application proposal and the RED-ASSIST online submission form.

Full Application Proposal

Full applications should be prepared as a single PDF containing a Summary page, Full Application Research Strategy.

A. Summary Page (1-page maximum)

- ***Project Title***
- ***Specific Aim(s)***
  Briefly introduce the research gap and its relevance to the CCTS mission, your solution towards addressing the gap and potential outcomes. Consider reading "The Anatomy of a Specific Aims Page" as a resource while also keeping in mind that pilot projects are often feasibility-level studies (i.e. not the scope of an NIH R01).

B. Full Application Research Strategy (4-page maximum)

- ***Significance***
  - Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
  - Address the rigor of prior research that serves as the key support for the proposed project.*
  - Provide a clear and concise description of the central theme and goals of program.
  - Explain how the proposed project will improve scientific knowledge, technical capability, clinical practice, clinical services and/or interventions in one or more broad fields.
  - Please comment on how the proposed work fits the definition of Translational Research, which refers to the integration of fundamental, patient-oriented and population-based research with the goal of improving health and healthcare delivery.
- ***Innovation***
  - Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
  - Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantages over existing methodologies, instrumentation or interventions.
  - Explain any refinements, improvements, or new applications of theoretical concepts, approaches, methodologies, instrumentation or interventions.
- ***Approach***
  - Include statements of specific aims and corresponding hypothesis.
  - Describe any strategy to establish feasibility, and address the management of any high-risk aspects of the proposed work.
  - Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project in a robust and unbiased manner (that is appropriate for, presumably, a feasibility-level study). Include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.*

  - Explain how relevant biological variables are factored into research designs, analyses, and reporting in vertebrate animal and human studies. Strong justification from the scientific literature, preliminary data or other relevant considerations must be provided for applications proposing to study only one sex.*
  - Consider addressing potential problems, contingency plans and alternative strategies.
  - Provide detail regarding how this work will set the stage for future research programs and thereby extramural support.
- ***References Cited***
  - Provide a bibliography of all references cited. Use whatever format you want. This section is not included in the 4-page maximum.

C. Recruitment and Retention Plan (if applicable, no page limit)
If the proposed project requires human subject participation, please provide a Recruitment and Retention Plan. Resources that may be helpful towards developing this plan include: CCTS Clinical Research Support Program (CRSP)'s Recruitment and Retention Plan Worksheet, the NIH NIMH's Points to Consider about Recruitment and Retention While Preparing a Clinical Research Study, and NIH NCCIH's Study Accrual and Retention Plan Template

D. Authentication of Key Biological and/or Chemical Resources* (1-page maximum)
Briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies including the frequency of authentication. Key biological and/or chemical resources include cell lines, specialty chemicals, antibodies, other biologics and beyond (see examples here and here). Do not include authentication data in your plan.

E. NIH Biosketch (5-page maximum each)
The biosketch provided for the PI(s) must conform to the NIH Biosketch requirements. Biosketches are not required for coinvestigators, collaborators or other significant contributors. Investigators with a faculty appointment starting on or before the award start date may append a Letter of Support from their Department Chair substantiating their upcoming appointment may be appended to their NIH Biosketch. Biosketches are an opportunity to describe why you're well suited for your role in a project.

F. Budget (1-page maximum)
Applicants may request up to $60,000 Direct Costs, where the CCTS will commit up to half ($30,000) and a cosponsor committing up to half ($30,000). Awards are limited to 12 months in duration. Budgets are very specific to any given project and represent the financial implementation of the scientific aims. Applicants should utilize the PHS398 Form Page 4: Detailed Budget for Initial Budget Period to submit their budget. The following are a list of allowable and non-allowable costs.

- Allowable expenses may include personnel, supplies, inpatient / outpatient care costs and other expenses (e.g. core services).
- PI salary may not exceed 15% of the total direct cost budget. In the case of multiple PIs, salary of each PI may not exceed 15%.
- Additional personnel expenses (e.g. research associates) are permitted to enable the performance of outlined investigation, as needed.
- Tuition is allowable given the graduate student is among the co-investigator team according to the accounting policies of the PI's institution.

- Consultant and/or Equipment costs may be considered in unique circumstances and must be discussed with Pilot Program Leadership. Please send your requests to Anne Russell (anneruss@uab.edu) prior to submission of your full application.
- Alterations, renovations, publication costs and travel expenses are not permitted under this mechanism.
- Core services or shared expertise requires sign-off by the faculty member responsible for the service in the CCTS consultation summary document described below.
- Please do not include indirect costs in pilot project budgets. Indirect costs are part of the award at the institution's current, published rate.

G. Budget Justification (no limit)

All budget expenses must be well justified. Please download and use this Budget Justification Template or organize your budget justification as outlined by the "PHS Form Page 4: Detailed Budget for Initial Budget Period" as follows: Personnel, Consultant Costs, Equipment, Supplies, Travel (Not Applicable), Inpatient Care, Outpatient Care, Alterations and Renovations (Not Applicable), Other Expenses. Please see the NIH Guidelines for more information on what should be included in a "Detailed Budget Justification".

H. CCTS Consultation Summary (2-page maximum)

Summaries of CCTS core services/facilities are provided below. When invited to submit a full application, applicants are expected to participate in a BERD consult and CCTS PDQ Panel, which the CCTS will automatically help coordinate. Applicants can also engage expert consultation regarding regulatory considerations, informatics, clinical support(s) and other shared resources, as needed, by reaching out to the CCTS Research Commons (ccts@uab.edu, 205.934.7442). Please download and use this CCTS Consultation Summary to report consultations in your Full Application. Should core services appear in the budget, a facility representative's signature is required in the CCTS Consultation Summary.

- **CCTS Biostatistics, Epidemiology and Research Design (BERD) – Required**
  The CCTS Biostatistics, Epidemiology and Research Design (BERD) unit supports a multidisciplinary team of biostatisticians, epidemiologists, and methodologists who collaborate with researchers to serve fundamental, clinical and translational research. Services may include, but are not limited to, study design, sample size and power calculations, database design, data preparation for analysis, data analysis, graphical presentation of analysis results, interpretation of analysis results, training in statistical software, etc. Investigators are required to work with BERD to access in-person, directed consultation via walk-in clinics and / or scheduled expert consultation. CCTS Research Commons will connect you to a member of the BERD group.
- **CCTS Panels Done Quickly (PDQ) – Required**
  The CCTS is happy to assemble a group of peer experts to hone research questions, fine-tune study design and sharpen your proposal. Panels are tailored to the scientific aims of the proposal and provide important feedback to develop the most compelling application possible. CCTS Research Commons will work with you to schedule a Panel.
- **CCTS clinical supports – As applicable**
  CCTS clinical supports (Clinical Research Support Program, Clinical Research Unit/Nursing, Child Health Research Unit, Phase I Unit, Bionutrition Unit, Specimen Processing & Analytic Nexus a/o Biorepository) are committed to providing investigators and their teams a

research environment and broad range of services guided by good clinical practice. The units equip investigators with essential tools and critical resources, while providing a highly efficient and flexible infrastructure. For example, our Clinical Research Support Program (CRSP) provides a pool of trained, certified research nurses and coordinators to assist investigators with study implementation. This team is also available to advise investigators on recruitment feasibility and approach as well as regulatory requirements.

- **CCTS Informatics – As applicable**
  CCTS Informatics is committed to connecting investigators to analytic expertise across the spectrum of informatics research in support of the collection and the analysis of structured clinical and / or genomic data for clinical, translational and outcomes research from bench to bedside and back. Scientific consultation may include data mining, collection and management of information, analysis of genetic, next-generation sequencing, epigenetic, genomic, exome, transcriptome, microbiome and other '-omic' datasets, metagenomic analysis, custom software development and methodologic innovation. Services may include, but are not limited to, study design, cohort estimation, information management solutions, genomic, proteomic, and other bioinformatic /medical informatic based data analysis, display of data and results, interpretation of results, custom applications, etc.
- **Other Shared Resources – As applicable**
  Applicants are encouraged to use shared scientific facilities and research cores, which provide access to cutting-edge instrumentation, expert technical support, and scientific best practices.

I. **Cosponsorship Letters of Support** (no limit)
Applicants are expected to identify at least one cosponsor. Under this cosponsorship arrangement, the CCTS will commit half of the requested funds (maximum of $30,000 Direct) and the cosponsor will commit half of the requested funds (maximum of $30,000 Direct). A cosponsor may include an institution, school, department, division, intramural research center, etc., or a combination thereof based at the PI's home institution. Funds from an applicant's endowment or start-up are not suitable sources of co-sponsorship. As part of the Full Application, include a formal Letter of Support from each co-sponsor that outlines each co-sponsor's financial pledge.

J. **Project Timeline** (1-page maximum)
Please download and use this Project Timeline Template or create your own to define project milestones according to experimental plan**. IMPORTANT NOTE:** Regulatory approvals/registrations (e.g. IRB, IACUC, OHS, ClinicalTrials.gov) must be approved/completed prior to NIH/NCATS Prior Approval submission – details in the NIH/NCATS Prior Approval section below. Therefore, all applicants are encouraged to seek these approvals/registrations (and support via CCTS Consultations) concurrent with the submission and review of the pilot application. Execution of related administrative items (e.g. Material Transfer Agreements, Vendor Qualification, Fee for Service Agreements) in a proactive manner is also advisable.

** Denotes addressing scientific reproducibility through rigor and transparency.*

Full Application Online Submission Form

Full application proposals will be submitted to RED-ASSIST by using the unique RED-ASSIST link provided in the invitations to submit a full application. While not necessary (or accepted as part of the application package), you may download a Full Application Online Submission Form Template for your

personal use. Beyond demographic information and basic project details, this RED-ASSIST form will request:

A. **Cosponsor Names**
   Enter the names of the individuals that signed Letters of Cosponsorship
B. **NIH/NCATS Prior Approval Acknowledgement**
   Acknowledge that you understand and agree to the following: If selected for pilot funding, the proposed research must be approved by the IRB, IACUC, etc, as applicable prior to NCATS Prior Approval. Should the proposal include a clinical trial of FDA-regulated research, I understand that additional plans, letters and information will be required prior to submission to the NIH for prior approval. I understand that CCTS RFA outlines the necessary approvals prior to submission to the NIH for Prior Approval, and that program staff will work with investigators to ensure timely submissions and approvals, as necessary. If applicable, proof of any Exempt status must be provided.
C. **Acknowledgement of External Review**
   Acknowledge that you understand and agree to the following: The CCTS participates in a national CTSA External Reviewer Exchange Consortium (CEREC) to improve fairness in the scientific review process and better match applicants with feedback from experts in their respective fields. Maintaining confidentiality through the peer review process is essential to allow for the candid exchange of scientific opinions and evaluations; and to protect trade secrets, commercial or financial information, and information that is privileged or confidential. Similar to the NIH peer review process, the CCTS is committed to protecting the integrity of and maintaining confidentiality in peer review. External reviewers must agree to uphold confidentiality at the beginning of the review process.
   CEREC is comprised of Harvard Catalyst; Medical College of Wisconsin; Ohio State University; University of Alabama at Birmingham; University of Arkansas for Medical Sciences; University of California – Irvine; University of Southern California; University of Washington; Virginia Commonwealth University.

4. Review Criteria

Pre-Application Review Criteria

Pre-applications will be assigned an Impact Score (NIH 9-point scale) corresponding to the overall scientific merit of the proposal taking into account the mission alignment, investigator qualifications and likelihood of extramural competitiveness. Additional review criteria address Human Subject/Animal Protections.

- **Mission Alignment.** To be responsive to the CCTS Partner Network Pilot Program RFA, projects should be set in the context of health conditions that disproportionately affect our region with feasibility-level research plans that lie at any point along the translational science spectrum – from biological basis of health or disease to interventions aimed at improving health of our community.
- **Eligibility.** The program is primarily intended to support full-time faculty who are new investigators. Applications from established investigators with a previous history of funding will be considered if the proposal represents a major shift in science for the investigator (e.g.

moving fundamental discovery into human biology). Proposals representing a new collaborative project involving two or more CCTS Partner Sites are encouraged.

- **PI Qualifications.** Principal investigators are expected to have the necessary skills and qualifications required to lead the proposed project. This capacity is often reflected in their career development to date and their track-record of peer-reviewed publications.
- **Extramural Competitiveness.** Is it likely that successful completion of this project will provide the preliminary data that will lead to subsequent NIH (or equivalent) grant?

Full Application Review Criteria

Applications will be scored (1-9) on aspects of significance, research team, innovation, approach and overall impact. Additional review criteria address Human Subject/Animal Protections, Budget & Timeline and Extramural Competitiveness.

- **Significance.** Is the proposed research set in the context of health conditions that disproportionately affect our region with feasibility-level research plans that lie at any point along the translational science spectrum – from biological basis of health or disease to interventions aimed at improving health of our community? Will the proposed work lead to new approaches to the prevention, diagnosis and management of conditions that disproportionately impact the health of our region? Are the principles underlying the research plan translatable to one or more broad fields?
- **Investigator(s).** Are the PI, collaborator(s), and other researchers well suited to the project? If Early Stage Investigators or New Investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? Are they significantly changing research directions to be eligible for this pilot award? Are the investigators engaging in a newly established team that spanning multiple CCTS Partner Network institutions?
- **Innovation.** Does the application challenge and seek to shift current research or clinical practice paradigms? Are the concepts, approaches or methodologies, instrumentation, or interventions being refined, improved or new? Are they novel to one field of research or in a broad sense?
- **Approach.** Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aim(s) of the project? 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? Given the experience of the research team, is this feasible for the proposed time frame?
- **Overall Impact.** Upon completion of the sections above, applications receive a score (1-9) to indicate the rating of the overall scientific merit of this pilot proposal taking into account all review criteria. The score should represent a global view; an application does not need to be strong in all categories to be judged likely to have major scientific impact, and the score does not need to be a mathematical reflection of the sections above.

5. NIH / NCATS Prior Approval

NIH / NCATS (the sponsor of the CTSA Program and thus the CCTS) requires all CTSA-sponsored projects that involve human subjects and/or vertebrate animals be subject to the NIH Prior Approval to document and ensure regulatory compliance. Submission of NIH Prior Approval requires that all regulatory approvals/registrations (e.g. IRB, IACUC, OHS, ClinicalTrials.gov) must be

approved/completed prior to NIH Prior Approval. Therefore, all applicants are encouraged to seek these approvals/registrations concurrent with the submission and review of their Full Application to avoid delay and/or iterative submissions for NIH Prior Approval. The CCTS cannot extend the project period of the award in light of delays. If the NIH/NCATS declines approval, the CCTS will not be able to support the project. The CCTS will collect additional information, as needed (see below), when applicants are provided a Notice of Selection (NoS). The CCTS will then route NIH Prior Approval packages to a UAB-based, Authorized Organizational Official for their submission to NCATS prior to the pilot award start date.

Prior Approval of Human Subjects Research. The CCTS requires additional information from applicants proposing Human Subjects Research for NIH Prior Approval, including:

- NCATS Addendum
- Certification of IRB approval (including exemption determination, if applicable). NOTE: The CCTS pilot application's PI and project title should match the IRB approval's PI and project title.
- Human Subjects Study Section 1 and 3.1, 3.2 (Download this document even though it does not appear to contain content. The content appears when you open the downloaded document with Adobe.)
    - Study Title
    - Is this Study Exempt from Federal Regulations?
    - Exemption Number
    - Clinical Trial Questionnaire
    - Protection of Human Subjects
    - Is this a multi-site study?
- If a "Minimal Risk" or "Greater than Minimal Risk" study is proposed, information for Human Subjects Study Section 2 and part of Section 3 is required, including:
    - Conditions or Focus of Study
    - Eligibility Criteria
    - Age Limits
    - Inclusion of Individuals Across the Lifespan
    - Inclusion of Women, Minorities and Children
    - Recruitment and Retention Plan
    - Recruitment Status
    - Study Timeline
    - Enrollment of First Subject
    - Inclusion Enrollment Report(s)
    - And… IRB approved research protocol (i.e. IRB Human Subjects Protocol)
    - Institutional Letter attesting to completion of Human Subjects Training for PI and Key Personnel
    - Applicable consent/assent/waiver documents
- If an NIH-defined Clinical Trial study is proposed, please note that registration of the trial in ClinicialTrials.gov is required and information from ClinicalTrials.gov is pulled forward into the Human Subjects Study System. Therefore, some of the fields below may already be complete when creating the Human Subject System study record. For NIH-defined Clinical Trials, Human Subject Study Sections 3, 4 and 5 are also required, including:
    - Data and Safety Monitoring Plan

  - Data and Safety Monitoring Board?
  - Overall Structure of the Study Team
  - Brief Summary
  - Narrative Study Description
  - Primary Purpose
  - Interventions
  - Study Phase
  - Intervention Model
  - Masking
  - Allocation
  - Outcome Measures
  - Statistical Power and Design
  - Subject Participation Duration
  - FDA-Regulated Intervention? (IND/IDE)
  - Dissemination Plan
- If the proposed research requires an investigational new drug (IND) application: a letter from the FDA that includes the IND number; the approved product label, the clinical investigator brochure, as applicable.
- If the proposed research requires an investigational device exemption: a letter from the FDA that includes the IDE number; Documentation from the FDA or IRB indicating that the device involved is deemed to be non-significant risk (NSR); the approved product label or description of the device, as applicable.

Prior Approval of Research Involving Vertebrate Animals. The CCTS requires additional information from applicants proposing Vertebrate Animal Studies for NIH Prior Approval, including:

- NCATS Vertebrate Animal Checklist
- Certification of IACUC approval for the proposed research. NOTE: The CCTS pilot application's PI and project title should match the IACUC approval's PI and project title.
- A Vertebrate Animals Section
  - 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. If dogs or cats are proposed, provide the source of the animals.
  - Justifications: Provide justification that the species are appropriate. Explain why the research goals cannot be accomplished using an alternative model.
  - Minimization of Pain and Distress: Describe the interventions including analgesia, anesthesia, sedation, palliative care, and humane endpoints to minimize discomfort, distress, pain, and injury.
  - 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.

6. Award Administration

Award Notices - Meritorious applications will receive formal notice in the form of a Notice of Selection (NoS). Any costs incurred before receipt of the NoS are at the recipient's risk. Any application awarded in response to this RFA will be subject to terms and conditions listed in the NoS as well as federal requirements found on the Award Conditions and Information for NIH Grants website. Awards made to partner institutions will be amended to the existing UL1 consortium contract. No Cost Extensions (NCEs) cannot be supported through this funding mechanism.

Regulatory Approvals - All lines of investigation supported by the CCTS Pilot Program require appropriate regulatory approvals (IRB, IACUC, as applicable). These approvals must be in place in advance of human subjects and/or animal work and must remain in good standing throughout study implementation.

Project Development Teams - The CCTS will work with you to set up a Project Development Team. These teams will bring together content experts and methodologists to meet with you and to assist with project troubleshooting and progress. This panel will meet in the first week of the award period to outline all immediately urgent issues (e.g., IRB approval). The group will meet quarterly thereafter.

Career Development Enrichment - The CCTS is committed to fostering the growth of early-stage investigators and promoting competencies in translational research. To formally enhance understanding and appreciation for rigor, reproducibility, and transparency, CCTS pilot awardees must complete and pass the R2T module of Kaizen during the award year. Awardees must also attend two CCTS enrichment events. Awardees are encouraged to submit an abstract to the annual Translational Science meeting within 2 years of the beginning of the CCTS pilot award.

Progress Reports - In addition to meeting with your Project Team, you will be asked to submit scientific progress reports – a template and the deadline(s) of such reports will be provided.

Citing the CCTS - According to National Institutes of Health (NIH) grants policy, all grantees publications (including research manuscripts, press releases and other publications or documents about research) that are funded by NIH, must include a specific acknowledgment of grant support. For example - "Research reported in this [publication/press release] was supported by the National Center for Advancing Translational Research of the National Institutes of Health under award number UL1TR003096. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health."

Compliance with the NIH Public Access Policy - Award recipients are required to comply with the NIH Public Access Policy. This includes submission to PubMed Central, upon acceptance for publication, of an electronic version of a final peer-reviewed manuscript resulting from research supported in whole or in part by the NIH. The staff of Lister Hill Library (LHL) can help investigators navigate the Public Access Policy processes. For assistance, please contact Jill Deaver (jilld@uab.edu) or Kay Smith (khogan@uab.edu), LHL liaisons to the CCTS.