



Center for Clinical and Translational Science

Overview Information

Funding Opportunity Title	CCTS Interdisciplinary Network Pilot Program
Companion Funding Opportunities	CCTS Minisabbaticals (uab.edu/cctsminisabbatical) CCTS Research Vouchers (uab.edu/cctsresearchvoucher) CCTS Radiology Pilot Research Initiative (uab.edu/medicine/radiology/ccts-radiology-pilot-research-initiative)
Funding Opportunity Purpose	Through the CCTS Interdisciplinary Network Pilot Program, we seek to develop the future research workforce in a spirit that fosters collaboration, team science, and innovative discovery.

Key Dates*

Posted Date	July 11, 2018
Open Date (Earliest Submission Date)	July 11, 2018
Pre-Application Due Date	August 15, 2018, 5pm CT
Full Application Invitations	September 11, 2018
Full Application Due Date (invitation required)	October 31, 2018, 5pm CT
Scientific Merit Review	November, 2018 – January, 2019
Advisory Council & NIH Review	February, 2019
Orientation Meeting for Awardees	March 30, 2019
Earliest Start Date	April 1, 2019
Expiration Date	August 16, 2018

*some dates may vary as a result of unanticipated delays

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Section I. Funding Opportunity Description

Purpose

The vision of the Center for Clinical and Translational Science (CCTS) is to reduce disparities in diseases disproportionately represented within the Deep South as we accelerate discovery to improve human health. Through the **CCTS Interdisciplinary Network Pilot Program**, we seek to develop the future research workforce in a spirit that fosters collaboration, team science, and innovative discovery. The CCTS seeks proposals that address scientific questions consistent with the Center's mission at any "stage of research along the path from the biological basis of health and disease to interventions that improve the health of individuals and the public" as described in NCATS' Translational Science Spectrum. **Special Considerations:** Special consideration will be given to those projects that bring together investigators across two or more partner institutions. Proposals to investigate the operational principles underlying each step of the translational process are encouraged. Priority will also be given to applications that address scientific questions of particular importance to the health of our communities, including health disparities, health challenges across the life course (premature birth, pediatrics, geriatrics, etc.), health literacy and/or numeracy, and environmental factors related to health, as well as applications that involve Community Engaged Research, population health investigation, medical device development, or innovative approaches to promote efficiency in participant recruitment to clinical studies.

The CCTS serves a region and a population heavily burdened with cardiometabolic, vascular, and cancer-related diseases. The **vision of the CCTS** is to ameliorate disparities in these and other conditions that disproportionately affect minority and special populations represented within the Deep South. The **CCTS Mission** defines the concept of 'health disparities' more broadly than "vulnerable groups" or "underserved populations". The Center characterizes such differences in health and health outcomes by considering multiple dimensions, including ancestry (race, ethnicity), biology (genetic admixture), geography (urban, rural), age (young, aged), or socioeconomics (education, income). **To be responsive to the CCTS Pilot Program's RFA, projects should be set in the context of health conditions that disproportionately affect our region based on one or more of these considerations. The study design may, but is not required to, compare two dimensions. A project may also attempt to better understand the biologic mechanism that may influence such differential outcomes.**

Background

The CCTS Partner Network crosses institutional boundaries to improve human health and health care delivery. This innovative partnership provides the foundation for addressing health disparities through collaborative research and training efforts. Regional partners are working together to facilitate and promote unique opportunities, including (but not limited to) drug discovery and development, genomics, advanced magnetic resonance imaging, population health and outcomes research. CCTS Partner Institutions include University of Alabama at Birmingham (Hub), Southern Research, Auburn University, University of South Alabama, HudsonAlpha Institute for Biotechnology, Louisiana State University Health Science Center, University of Mississippi, Pennington Biomedical Research Center, University of Alabama (Tuscaloosa), and Tuskegee University.

Section II. Award Information

Funding Instrument	Pilot Grant
Application Types Allowed	New
Funds Available and Anticipated Number of Awards	The CCTS has committed \$180,000 to this program. The number of awards is contingent upon a sufficient number of meritorious applications and non-CCTS matching funds.
Award Budget	Applicants may request up to \$60,000 Direct Costs with the CCTS Hub committing up to half.
Award Project Period	The maximum project period is 12 months.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Individuals (Program Director/Principal Investigator)

This program is primarily intended to support **full-time faculty who are early stage investigators** (please see [NIH definition](#)). Faculty with previous / active K-awards are eligible and are encouraged to apply. PIs must be based at one of the CCTS Partner Network institutions. Staff are not eligible to serve as the PI.

This program seeks to support investigators with a full-time faculty appointment. Postdoctoral Fellows may be eligible if a faculty appointment at a Partner Institution is on the horizon, with a start date on or before the listed award date – as part of the application, the investigator should include a letter from the Department Chair reflecting such. Established investigators are discouraged to serve as the PI for proposals on behalf of Postdoctoral Fellows. All projects should directly represent the ideas of the listed Principal Investigator. Postdoctoral Fellows may be part of the scientific team, but it is presently not advisable that they be positioned as Co-PI of the project.

Applications will also be accepted from established investigators with a previous history of funding with justification of eligibility. More established investigators are eligible if the proposed research represents a major shift from his/her scientific portfolio to date. They are also encouraged to apply if the application advances ongoing research to a later stage of translation. By providing an Eligibility Statement within the Pre-Application, more established PIs have the opportunity to comment on how the proposed aims represent a major shift from his/her scientific portfolio to date.

Co-Sponsorship

Applicants are expected to identify at least one non-CCTS co-sponsor to provide a 1:1 match for funds provided by the CCTS Hub. A co-sponsor may include an institution, a school, a department, a division, a University-wide Interdisciplinary 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 a suitable source of co-sponsorship. At the Pre-Application stage, investigators are strongly encouraged to think through potential co-sponsorships. Applicants will be required to acknowledge the need for co-sponsorship during the Pre-Application submission process. If invited to submit a Full Application, investigators will be asked to submit a Letter of Support from each co-sponsor that outlines each co-sponsor's financial pledge.

Section IV. Application and Submission Information

Phase One: Pre-Application

This pilot program involves a two-phased application process: a Pre-Application and a Full Application. A Pre-Application is *required* by this mechanism.

This funding announcement will serve as the instructions and guidelines for both Pre-Application and Full Application submissions.

All proposals should represent the ideas of the Principal Investigator directly.

Submission. Pre-Applications will be submitted through an online REDCap form, which can be found on the CCTS Pilot Program website: <http://www.uab.edu/ccts/research-commons/funding-opportunities/pilot-program>. **Chrome is the preferred browser for this REDCap submission form.** Submit Pre-applications by the date listed in Key Dates*.

Pre-applications will be scored on the NIH 9-point scale. Highest-scored proposals will be invited to submit a Full Application.

Instructions for Pre-Application Submission

Online Submission Form

A link to online submission form can be found on the CCTS website: <http://www.uab.edu/ccts/research-commons/funding-opportunities/pilot-program>. Within the online submission form, you can download the Pre-Application and prepare your responses and attachments prior to completing and submitting the online Pre-Application. Instructions for completing the form and returning to it at a later date (before submission) are contained within the form's "Instructions" section.

Please complete all sections of the online submission form, including:

- Principal Investigator(s)
- Project Details

Within the online submission form, you will be asked to upload a single PDF containing the following documents (in the order listed below):

- Declaration of Eligibility
- Statement on CCTS Vision/Mission Alignment
- Research Plan

- NIH biosketch for PI(s) only

Applicants are discouraged from adding a cover letter to the single PDF file; they will not be reviewed.

Principal Investigator(s)

Please be prepared to provide the following information for project PI(s) in the online submission form: first name, last name, degrees, institution, school, department, division, rank, phone number, email, gender, race, ethnicity, diversity status. For more information about diversity status, please see [“Revised: Notice of NIH’s Interest in Diversity.”](#)

Project Details

Please be prepared to enter the following information in the online submission form:

- Project title
- Indication as to whether or not the project meets any special considerations for this funding mechanism (see Section I. Funding Opportunity Description).

Declaration of Eligibility

Please briefly explain (2-3 sentences) how the PI(s) meet the eligibility criteria for this funding mechanism (see Section III. Eligibility Information).

Statement on CCTS Vision/Mission Alignment

Please briefly explain (up to 20 lines) how your project aligns with the vision and/or mission of the CCTS (see Section I. Funding Opportunity Description).

Pre- Application Research Plan

- **Font size:** must be 11 points or larger (smaller text in figures, graphs, diagrams and charts is acceptable as long as it is legible when the page is viewed at 100%)
- **Type density:** must be no more than 15 characters per linear inch (including characters and spaces)
- **Line spacing:** must be no more than six lines per vertical inch
- **Margins:** Provide at least one-half inch margins (top, bottom, left, and right) for all pages. No applicant-supplied information can appear in the margins.
- **Text color:** must be black (color text in figures, graphs, diagrams, charts, tables, footnotes and headings is acceptable)
- **Page Limit:** 2 pages (references are not subject to page limits)

This section should be organized as follows:

1. SIGNIFICANCE

- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
- Please provide a clear and concise description of the central theme and goals of the research.
- Please comment on how the proposed work fits the definition of Translational Research. Translational research refers to the multidirectional and multidisciplinary integration of fundamental, patient-oriented, and population-based research, with the goal of improving health and health care delivery.

2. INNOVATION

- Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- Describe any refinements to or novel theoretical concepts, approaches or methodologies, Instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.

3. APPROACH

- Be sure to include explicit statements of aims and corresponding hypotheses.

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.

4. REFERENCES CITED

- Provide a bibliography of all references cited. Each reference must include the names of all authors, the article and journal title, book title, volume number, page numbers, and year of publication.
- References are outside of page limit.

NIH Biosketch

The biosketch provided for the PI(s) must conform to the [NIH Biosketch requirements](#).

Acknowledgement of Co-Sponsorship

Within the online Pre-Application submission form, applicants are required to acknowledge the need for co-sponsorship by entering their name under a statement of Acknowledgement. This serves as an electronic signature.

Phase Two: Full Application

Full proposals will not be accepted without invitation.

This funding announcement will serve as the instructions and guidelines for Full Application submissions.

All proposals should represent the ideas of the Principal Investigator directly.

Submission. Full Applications will be submitted through an online REDCap form, shared with investigators invited to submit Full Applications only. **Chrome is the preferred browser for this REDCap submission form.** Submit Full Applications by the date listed in Key Dates*.

Instructions for Full Application Submission

Online Submission Form

The online submission form will be shared with those invited to submit Full Applications. Within the online submission form, you may download the Full Application and prepare your responses and attachments prior to completing and submitting the online Full Application. Instructions for completing the form and returning to it at a later date are contained within the form's "Instructions" section.

Please complete all sections of the online submission form, including:

- Principal Investigator(s)
- Project Details
- Lay Summary

Within the online submission form, you will be asked to upload a single PDF containing the following documents (in the order listed below):

- Statement on CCTS Vision/Mission Alignment
- Research Strategy
- Authentication of Key Biological and/or Chemical Resources
- NIH biosketch for PI(s) and Co-I(s)
- Budget
- Budget Justification
- Project Timeline
- Co-Sponsorship Letter(s) of Support
- CCTS Consultation Summary

Applicants are discouraged from adding a cover letter to the single PDF file; they will not be reviewed.

Principal Investigator(s)

Please be prepared to provide the following information for project PI(s) in the online submission form: first name, last name, degrees, institution, school, department, division, rank, phone number, email, gender, race, ethnicity, diversity status. For more information about diversity status, please see "[Revised: Notice of NIH's Interest in Diversity](#)."

Project Details

Please be prepared to enter the following information in the online submission form:

- Project Title
- A Yes/No answer to the following questions:
 - Will the project involve human subjects research? If yes, does your study meet the [NIH's definition of a clinical trial?](#)
 - Will the project involve animal models research?
 - Will the project involve FDA-regulated research?
- Indication as to whether or not the project will meet any special considerations for this funding mechanism (see Section I. Funding Opportunity Description).

Lay Summary

Applicants need to provide a lay summary (2500 character limit including spaces) of the research plan that is targeted to a general, non-scientific audience. The text should be easily readable, minimizing jargon, acronyms, complex grammatical structures or complicated concepts. The applicant should use everyday words and positive phrasing. These summaries will be used as part of a community-based (non-scientific) review. For additional guidance, please see:

<http://www.acmedsci.ac.uk/more/news/10-tips-for-writing-a-lay-summary/>

Statement on CCTS Vision/Mission Alignment

Please briefly explain (up to 20 lines) how your project aligns with the vision and/or mission of the CCTS (see Section I. Funding Opportunity Description).

Full Application Research Strategy

Please submit an expanded description of the experimental plan.

- **Font size:** must be 11 points or larger (smaller text in figures, graphs, diagrams and charts is acceptable as long as it is legible when the page is viewed at 100%)
- **Type density:** must be no more than 15 characters per linear inch (including characters and spaces)
- **Line spacing:** must be no more than six lines per vertical inch
- **Margins:** Provide at least one-half inch margins (top, bottom, left, and right) for all pages. No applicant-supplied information can appear in the margins.
- **Text color:** must be black (color text in figures, graphs, diagrams, charts, tables, footnotes and headings is acceptable)
- **Page Limit:** 4 pages (references are not subject to page limits)
- **Rigor, Reproducibility & Transparency (R2T).** Applicants are required to address R2T concepts in their application. Please see the [CCTS Rigor and Reproducibility in Research](#) page for guidance.

This section should be organized as follows:

1. SIGNIFICANCE

- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
- *Rigor, Reproducibility & Transparency.* Describe the general strengths and weaknesses of the prior research being cited as crucial to support the application. Consider discussing the rigor of previous experimental designs, as well as the incorporation of relevant biological variables and authentication of key resources.
- Please provide a clear and concise description of the central theme and goals of the program.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

- Please comment on how the proposed work fits the definition of Translational Research. Translational research refers to the multidirectional and multidisciplinary integration of fundamental, patient-oriented, and population-based research, with the goal of improving health and health care delivery.

2. 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 advantage over existing methodologies, instrumentation, or interventions.
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

3. APPROACH

- Be sure to include explicit statements of aims and corresponding hypotheses.
- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
- Describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work. Please comment on how this work will set the stage for future, extramural support.
- *Rigor, Reproducibility & Transparency*: Emphasize how the experimental design and methods proposed will achieve robust and unbiased results.
- *Rigor, Reproducibility & Transparency*: 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.

4. REFERENCES CITED

- Provide a bibliography of all references cited. Each reference must include the names of all authors, the article and journal title, book title, volume number, page numbers, and year of publication.
- References are outside of page limit.

Authentication of Key Biological and/or Chemical Resources

The authentication plan should state in one (1) page or less how you will authenticate key resources, including the frequency, as needed for your research. Briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies -- Key biological and/or chemical resources include, but are not limited to, cell lines, specialty chemicals, antibodies and other biologics. Do not include authentication data in your plan.

NIH Biosketch

The biosketch provided for the PI(s) must conform to the [NIH Biosketch requirements](#).

Budget and Justification

Applicants may request up to \$60,000 Direct Costs with the CCTS Hub committing up to half. Co-sponsoring funds are expected to match CCTS funds. Awards are limited to 12 months in duration. Applicants should utilize the [PHS398 Form Page 4: Detailed Budget for Initial Budget Period](#) to submit their budget. This form can be downloaded from the Full Application online submission form.

Budgets are very specific to any given project and represent the financial implementation of the scientific aims.

- Allowable expenses may include personnel, supplies, inpatient / outpatient care costs, and other expenses.
- 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.
- Alterations, Renovations, publication costs and travel expenses are not permitted under this mechanism.
- Consultant Costs and / or Equipment may be considered in unique circumstances and must be discussed with Pilot Program Leadership (Dr. Stuart Frank (sjfrank@uab.edu) or Dr. Kent Keyser (ktkeyser@uab.edu)) in advance of the submission.

- Pilot projects are not required to budget indirect costs; they will be part of the award.

Core Services. Budgeting of any core service or shared expertise requires sign-off by that facility – please see CCTS Consultation Summary, below.

Justification. All budget expenses should be well justified. Please see the [NIH Guidelines](#) for more information on what should be included in a detailed budget justification. Pilot projects are not required to budget indirect costs (though they will be part of the award at the institution’s current, published rate). The Budget Justification should be organized as follows. If funding is not requested in any particular category, please indicate “Not Applicable.”

PERSONNEL

CONSULTANT COSTS

Not Applicable.

EQUIPMENT

Not Applicable.

SUPPLIES

TRAVEL

Not Applicable.

INPATIENT CARE

OUTPATIENT CARE

ALTERATIONS AND RENOVATIONS

OTHER EXPENSES

Project Timeline

The Project Timeline template can be downloaded from the online submission form. Please fill out the timeline template to define the proposed timeframe for project milestones according to the experimental plan. Please be sure to describe time needed to attain regulatory approvals, to create any data collection or management tools, to recruit subjects and complete interventions, to execute experiments according to the specific aims and any other milestones specific to your project. Please also include plans for presenting related abstracts at national meetings as well as goals for manuscript submission(s) and extramural grant application(s).

Co-Sponsorship Letters of Support

Applicants are expected to identify at least one non-CCTS co-sponsor to provide a 1:1 match for funds provided by the CCTS Hub. A co-sponsor may include an institution, a school, a department, a division, a University-wide Interdisciplinary 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 a suitable source 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.

CCTS Consultation Summary

The CCTS Consultation Summary form can be downloaded from the Full Application online submission form. Applicants invited to the Full Application phase will be expected to engage expert consultation specific to the proposed aims and related to project design, regulatory considerations and other discipline-specific issues that have bearing on the study

design. Budgeting of any core service or shared expertise requires sign-off by that facility. Please connect with these groups through CCTS Research Commons (ccts@uab.edu; 205.934.7442).

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 – 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.

Acknowledgement of External Review

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 throughout 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. Before submitting a Full Application, investigators will be asked to acknowledge that proposals will undergo external scientific peer review.

*CEREC is comprised of: Harvard Catalyst; Medical College of Wisconsin; Ohio State University; University of Alabama - Birmingham; University of Arkansas for Medical Sciences; University of California - Irvine; University of Southern California; University of Washington; Virginia Commonwealth University.

Section V. Application Review Information

Review Criteria

Pre-Application. Pre-applications will be assigned an Impact Score (NIH 9-point scale) corresponding to the overall scientific merit of this pilot proposal taking into account the proposed project, approach and investigator qualifications. Applications will also be assessed on the four aspects below:

- **Mission Alignment.** The CCTS Mission is to reduce disparities in diseases disproportionately represented within the Deep South as we accelerate discovery to improve human health. In addition to “vulnerable groups” or

“underserved populations, the CCTS characterizes such ‘health disparities’ by considering multiple dimensions, including ancestry (race, ethnicity), biology (genetic admixture), geography (urban, rural), age (young, aged), or socioeconomics (education, income). *To be responsive to the CCTS Pilot Program’s RFA, projects should be set in the context of health conditions that disproportionately affect our region based on one or more of these considerations. The study design may, but is not required to, compare two dimensions. A project may also attempt to better understand the biologic mechanism that may influence such differential outcomes.*

- **Special Considerations:** Special consideration will be given to those projects that bring together investigators across two or more partner institutions, investigate the operational principles underlying each step of the translational process, address scientific questions of particular importance to the health of our communities, including health disparities and health challenges across the life course, as well as applications that involve Community Engaged Research, population health investigation, medical device development or innovative approaches to promote efficiency in participant recruitment to clinical studies.
- **Translational Research.** Translational research refers to the multidirectional and multidisciplinary integration of fundamental, patient-oriented, and population-based research, with the goal of improving health and health care delivery.
- **Eligibility.** This 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, especially if that shift involves moving fundamental discovery into human biology.
- **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.
- **Scientific Competitiveness.** Is it likely that successful completion of this project will provide preliminary data that will lead to a subsequent NIH (or equivalent) grant?

Full Applications. Applications will be scored (1-9) on aspects of research team, scientific approach and significance as well as overall impact.

- **Assessment of Investigator and the Research Team.** 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?
- **Assessment of Approach.** Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims 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?
- **Assessment of Relevance and Significance.** The purpose of the CCTS Multidisciplinary Partner Network Pilot Program is to support outstanding research that will lead to new approaches to the prevention, diagnosis, and management of disparities or conditions that disproportionately impact the health of our region. How well does this proposal address the purpose of the program? Does it make a significant contribution to translational science? Does this project merit any special considerations?
- **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.
- **Budget.** Is the budget appropriate for the proposed work?
- **Human Subjects or Animal Protection.** Are there any potential human subjects and/or animal protection concerns?

NIH / NCATS Prior Approval

NIH / NCATS (the sponsor of the CTSA Program and thus the CCTS) has a policy applicable to all CTSA-sponsored projects that involve human subjects and/or vertebrate animals. Full pilot applications identified by comprehensive review as meritorious for funding will be subject to NIH prior approval. Documentation for this federal review will be collected from applicants and submitted in advance of the pilot award date listed in Part 1. Overview Information. If the NIH/NCATS declines such approval, the CCTS will not be able to support the project. Applicants are strongly encouraged to fulfill the

NIH requirements thoroughly to avoid iterative submissions in response to NIH questions or concerns. The CCTS cannot extend the project period of the award in light of such delays.

The NIH requires prior approval of all pilot projects based on a discrete set of documentation as outlined below:

Prior Approval of Research Involving Human Subjects. Requests for prior approval of planned research involving human subjects must be submitted in writing via the CCTS Research Commons to NCATS before the proposed implementation of research involving human subjects. Documentation must be submitted by an Authorized Organizational Official and must include the following:

- Name of the grantee of the parent award, the name of the individual who is receiving the pilot award, the pilot awardee's telephone number, email address, and NIH Biosketch.
- Certification that IRB approval has been obtained for the proposed research.
- A summary (<500 words) of the pilot study being supported by NCATS pilot funding.
- The complete research protocol (IRB HSP) and applicable consent/assent/waiver documents.
- If the research protocol is considered an amendment or sub-study to a parent protocol, include a summary of the parent protocol with an explanation of how the NCATS-supported amendment or sub-study connects to it. If the entire parent protocol is included in the submission, that portion which is supported by NCATS funding should be clearly labeled as such.
- Inclusion Plans for Women, Minorities, and Children.
- Targeted Enrollment Table or Inclusion Data Record (IDR), if applicable.
- Certification that the pilot awardee and any Key Personnel directly involved in human subjects research have taken appropriate education in protection of human subjects.
- For clinical trials, a Data and Safety Monitoring Plan (DSMP) and Board (DSMB), as applicable, and confirmation that Key Personnel directly involved in the study have taken appropriate education in Good Clinical Practice.
- 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.
- A line item budget for the proposed research.

Prior Approval of Research Involving Vertebrate Animals. Requests for prior approval of planned research involving live vertebrate animals, including animals obtained or euthanized for tissue harvest and generation of custom antibodies, must be submitted in writing via the CCTS Research Commons to NCATS before the proposed implementation of research involving human subjects. The criteria in the VAS must be addressed for work proposed at every performance site – this is the site (institution) where procedures with animals will be performed. If the applicant institution is not the site where animal work will be performed or if the work will be performed at several sites, these performance sites must be identified. Documentation must be submitted by an Authorized Organizational Official and must include the following:

- Name of the grantee of the parent award, the name of the individual who is receiving the pilot award, the pilot awardee's telephone number, email address, and NIH Biosketch.
- Certification that IACUC approval has been obtained for the proposed research.
- 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 in the proposed work. If dogs or cats are proposed, provide the source of the animals.
 - 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).
 - 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. 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.

Anticipated Announcement and Award Dates

Please refer to Part 1. Overview for dates for peer review, advisory council review, and earliest start date. Section II. Award information summarizes funds available and anticipated number of awards.

Section VI. Award Administration Information

Award Notices

Meritorious applications will receive formal notice in the form of a Notice of Grant Award (NOGA) provided to the applicant. Any costs incurred before receipt of the NOGA are at the recipient's risk. Any application awarded in response to this RFA will be subject to terms and conditions listed in the NOGA as well as federal requirements found on the [Award Conditions and Information for NIH Grants](#) website. Awards made to partner institutions outside of UAB will be amended to the existing UL1 consortium contract.

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 and to chart a pathway to accomplishing such (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. Qualifying opportunities include the monthly CCTS Forum, the monthly Training Interdisciplinary & Emerging Research Scholars (TIERS) meetings or bi-weekly Case Studies in Mentoring sessions. Awardees must submit an abstract to the annual Translational Science meeting within 2 years of the beginning of the CCTS pilot award.

Reporting

Progress Reports. In addition to meeting with your Project Team, you will be asked to submit scientific progress reports and a year-end report detailing the results, products and next-steps of your research – a template will be provided as will the deadline(s) for such reports.

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 UL1TR001417. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." If the publication, press release, etc. was supported by more than one grant, please reference all relevant grant numbers.

Compliance with the NIH Public Access Policy: Award recipients are required to comply with the NIH Public Access Policy (<http://www.uab.edu/ccts/training-academy/library-tools>). 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 Kay Smith (khogan@uab.edu), LHL liaison to the CCTS.

Section VII. Agency Contacts

Application Submission Contacts

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(RFA style guide borrowed from NIH for educational purposes)