CCTS
Center for Clinical and Translational Science

Overview Information

Funding Opportunity Title	**CCTS Partner Network Multidisciplinary Pilot Program**
Companion Funding Opportunities	ADDA Pilot Program (uab.edu/medicine/adda/) AIMTech Pilot Program (southernresearch.org/aimtech/) CCTS Minisabbaticals (uab.edu/cctsminisabbatical) CCTS Research Vouchers (uab.edu/cctsresearchvoucher)
Funding Opportunity Purpose	Through the CCTS Partner Network Multidisciplinary 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	August 1, 2017
Open Date (Earliest Submission Date)	August 1, 2017
Letter of Intent Due Date	August 30, 2017, 5pm CT
Full Application Invitations	September 20, 2017
Full Application Due Date (invitation required)	November 10, 2017, 5pm CT
Scientific Merit Review	December – February, 2018
Advisory Council & NIH Review	March, 2018
Orientation Meeting for Awardees	March 30, 2018
Earliest Start Date	April 1, 2018
Expiration Date	September 1, 2017

*some dates may vary as a result of unanticipated delays

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Section I. Funding Opportunity Description

Purpose

The mission 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 Partner Network Multidisciplinary Pilot Program**, we seek to develop the future research workforce in a spirit that fosters collaboration, team science, and innovative discovery. The CCTS seeks letters of intent 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 (https://ncats.nih.gov/translation/spectrum). Proposals to investigate the operational principles underlying each step of the translational process are encouraged. Special consideration will be given to those projects that bring together investigators across two or more partner institutions. Priority will also be given to applications that 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-based participatory research (CBPR), 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 disproportionally affect minority and special populations represented within our region and across the nation. 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. Partners include UAB (Hub), Southern Research, Auburn, South Alabama, HudsonAlpha, LSU, University of Mississippi Medical Ctr., Pennington, Tulane, Tuscaloosa, and Tuskegee. http://www.uab.edu/ccts/partners

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 partner 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 investigators (please see NIH definition). Faculty with previous / active K-awards are eligible and are encouraged to apply. PIs must be based at any one of the 11 Partner Institutions. Staff are not eligible to serve as the PI.

This program seeks to support investigators with a full-time faculty appointment. Postdocs 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. Postdocs 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 must comment on how the proposed research represents the first effort to pursue human subjects research. They are also encouraged to apply if the application advances ongoing research to a later stage of translation. As part of the letter of intent, 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 with shared scientific interests. 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. At the Letter of Intent stage, investigators are strongly encouraged to think through potential partnerships. As part of the Full Application, investigators will be asked to list all co-sponsors in the designated application form.

Section IV. Application and Submission Information

Requesting a Letter of Intent (LOI) Application Package

This pilot program involves a two-phased application process. The Letter of Intent (LOI) is required by this mechanism. **Application packages are available upon request** -- please contact CCTS Research Commons, 205.934.7442, ccts@uab.edu). The LOI will include:

- 2-page scientific summary
- PI NIH-biosketch
- List of potential co-sponsors

Application guidelines and answers to Frequently Asked Questions (FAQs) are available on the CCTS website: http://www.uab.edu/ccts/researchcommons – click on Pilot Funding.

All proposals should represent the ideas of the Principal Investigator directly. In the designated section, please articulate at least one, and if possible, many potential co-sponsors that share scientific interests with the proposal.

Letters of Intent will be rated on the NIH 9-point scale. Highest-rated proposals will be invited to submit a full proposal.

Submission. Submit your Letter of Intent package as a single PDF to ccts@uab.edu by the date listed in Part 1. Overview Information.

Instructions for Letter of Intent (LOI) Submission

CCTS Cover Page

Please complete all sections as outlined in the Letter of Intent package, including:

- Title of Project
- Principal Investigator information
- Declaration of Eligibility

The Cover Page is a form within the application package. Applicants are discouraged from adding a separate cover letter to the application; they will not be reviewed.

NIH Biosketch (Limit: 5 pages)

The NIH Biosketch of the PI(s) must conform to the new NIH requirements (NOT-OD-15-032; Version C, OMB No. 0925-0001/0002 (Rev. 08/12)).

CCTS LOI Research Plan (Limit: 2 pages)

Please insert up to two (2) pages (excluding references) describing 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
- **Text color**: must be black (color text in figures, graphs, diagrams, charts, tables, footnotes and headings is acceptable)

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 program.
   - Articulate how this project aligns with the mission of the CCTS. Please explain how this project addresses a disparate health challenge that may affect a special population (for example, tails of the lifespan [pediatric or geriatric], a group defined by ancestry, a disease disproportionately observed in our region, etc.).
   - 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**
   - 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** (outside of 2 page limit)
   - 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.

Applicants Invited to Submit FULL Application Packages

Letters of Intent will be rated on the NIH 9-point scale. Highest-rated proposals will be invited to submit a full proposal. Full proposals will not be accepted without invitation.

Application guidelines and answers to Frequently Asked Questions (FAQs) are available on the CCTS website: http://www.uab.edu/ccts/researchcommons – click on Pilot Funding.

All proposals should represent the ideas of the Principal Investigator directly. In the designated section, please articulate at least one, and if possible, many potential co-sponsors that share scientific interests with the proposal.

Submission. Submit your FULL Application package as a single PDF to ccts@uab.edu by the date listed in Part 1. Overview Information.

Instructions for FULL Submission

CCTS Cover Page

Full application packages will be provided. Please complete all sections as outlined in the Full Application package, including:

- Title of Project
- Principal Investigator information
- Co-Sponsorship

The Cover Page is a form within the application package. Applicants are discouraged from adding a separate cover letter to the application; they will not be reviewed.

NIH Biosketch (Limit: 5 pages)

The NIH Biosketch of the PI(s) must conform to the new NIH requirements (NOT-OD-15-032; Version C, OMB No. 0925-0001/0002 (Rev. 08/12)).

Lay Summary (Limit: 2500 characters, including spaces)

Applicants need to provide a lay summary 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/

CCTS FULL Research Plan (Limit: 4 pages)

Please insert up to four (4) pages (excluding references) with 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
- **Text color**: must be black (color text in figures, graphs, diagrams, charts, tables, footnotes and headings is acceptable)
- **Rigor, Reproducibility & Transparency (R2T)**. Applicants are required to address R2T concepts in their application. Please see the CCTS R2T Resource 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.
- Articulate how this project aligns with the mission of the CCTS. Please explain how this project addresses a disparate health challenge that may affect a special population (for example, tails of the lifespan [pediatric or geriatric], a group defined by ancestry, a disease disproportionately observed in our region, etc.).
- 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**
   - Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in Item 15 (Resource Sharing Plan), 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, such as the ones noted above, 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** (outside of 4 page limit)
   - 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.

Rigor, Reproducibility & Transparency: Authentication of Reagents (Limit: 1 page)

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.

Project Timeline (See application form)

Please fill out the timeline form as provided in the application packet 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).

CCTS Consultation Summary (See application form)

Applicants invited to the second 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). Please use the consultation form in the Full Application Package to address this requirement.

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 encouraged to work with BERD to access in-person, directed consultation via walk-in clinics and / or scheduled expert consultation.

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 Clinical Services – As applicable
CCTS Clinical Services is committed to providing investigators and their teams a research environment and broad range of services guided by good clinical practice. The unit equips investigators with essential tools and critical resources, while providing a highly efficient and flexible infrastructure. In addition, our Clinical Research Support Program (CRSP) provides a pool of trained, certified research nurses and coordinators to assist you with study implementation. This team is 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.

CCTS 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 follow the format of the PHS398 Form Page 4: Detailed Budget for Initial Budget Period.

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 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, above.

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

SUPPLIES

TRAVEL

Not Applicable

INPATIENT CARE

OUTPATIENT CARE

OTHER EXPENSES

Letters of Support

Applicants are expected to identify at least one non-CCTS co-sponsor with shared scientific interests. 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. As part of the Full Application, please list all potential co-sponsors in the designated application form – include formal letters of support that reflect this commitment.

Section V. Application Review Information

Review Criteria

Letter of Intent. LOI 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.
- **Translational Research.** Translational research refers to the multidirectional and multidisciplinary integration of fundamental, patient-oriented, and population-based research, with the goal of improving the 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?
- **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.

Additional Review Considerations

Human Subject or Animal Protection. Are there any potential human subjects and/or animal protection concerns?

Budget. Is the budget appropriate for the proposed work?

Special Considerations. Proposals to investigate the operational principles underlying each step of the translational process are encouraged. Special consideration will be given to those projects that bring together investigators across two or more partner institutions. Priority will also be given to applications that 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-based participatory research (CBPR), medical device development, population health investigation or innovative approaches to promote efficiency in participant recruitment to clinical studies.

NIH / NCATS Prior Approval

NIH / NCATS (the sponsor of the CTSA Program) has initiated a new policy applicable to all CTSA-sponsored projects that involve human subjects and/or vertebrate animals. 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.
- The complete clinical research protocol (IRB HSP) and consent document. If the clinical research protocol is considered an amendment to a parent protocol, include information explaining exactly what is being supported by NCATS pilot funding. If the entire parent protocol is included in the submission, that portion which is supported by NCATS funding should be clearly labeled as such.
- If a clinical trial is proposed, product information, such as the clinical investigator brochure or package insert or description of the device shall be included. Documentation that an IND or IDE has been obtained or letter from FDA that the study is IND exempt or IDE has been waived.

- New or revised human subjects section as described in Part II of NIH competing application instructions that clearly describes risk, protections, benefits and importance of the knowledge to be gained by the revised or new activities. If the new or revised human subjects section refers to a parent protocol of which the NCATS-funded pilot project is an amendment, the information relevant to the pilot awardee's project should be clearly identified.
- Inclusion Plans for Women, Minorities, and Children, if applicable
- Targeted Enrollment Table or Inclusion Data Record (IDR), if applicable.
- Data and Safety Monitoring Plan (DSMP) and Board (DSMB), if applicable.
- Certification that the pilot awardee and any Key Personnel directly involved in the study have taken appropriate education in protection of human subjects, if not provided previously.

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:

- Provide a detailed description of the proposed use of the animals in the work outlined in the "Research Strategy" section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.
- Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.
- Provide information on the veterinary care of the animals involved.
- Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.
- Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia. If not, include a scientific justification for not following the recommendations.

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.

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.

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." 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 Lee Vucovich (lvucovi@uab.edu), LHL liaison to the CCTS.

Section VII. Agency Contacts

Application Submission Contacts

CCTS Research Commons
Center for Clinical and Translational Science
O: 205.934.7442 | ccts@uab.edu

Scientific/Research Contact

Jennifer A. Croker, PhD | Executive Administrator
Center for Clinical and Translational Science |CCTS Research Commons
O: 205.996.4478 | jcroker@uab.edu

Financial/Grants Management Contact

Richard Hines, MBA | Financial Officer
Center for Clinical and Translational Science
O: 205.934.5953 | hinesr@uab.edu

(RFA style guide borrowed from NIH for educational purposes)