Through the CCTS Pilot Program, we seek to ameliorate health conditions that disproportionately affect our region as represented by the CCTS Partner Network, and to develop the future clinical and translational science workforce by fostering collaboration, team science and innovative discovery.

**PROPOSALS**

**NEW THIS YEAR:** Our program invites proposals seeking to overcome barrier(s) in the conduct of research as to minimize or eliminate these issue(s) in subsequent work focused on ameliorating health condition(s) that disproportionately affect our region.

**ELIGIBILITY**

The program supports early stage investigators from any of the CCTS Partner Network institutions. Established researchers may be considered with justification of how the proposal represents a major shift in experimental approach or a new, collaborative project involving 2+ partner sites.

**FUNDING**

Applicants may request up to $60,000 (direct) with expectations of co-sponsorship.

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<th>Event</th>
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<tr>
<td>CCTS Pilot Q&amp;A Session (optional)</td>
<td>September 28, 2022 from 9-10AM CST</td>
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<td>Pre-Application Due Date</td>
<td>October 25, 2022 by 5PM</td>
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<td>Full Application Due Date</td>
<td>December 21, 2022 by 5PM</td>
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<td>Scientific Merit Review and Advisory Council</td>
<td>January – mid-February 2023</td>
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<td>NIH Review</td>
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<td>Earliest Award Start Date</td>
<td>May 1, 2023</td>
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<td>Award End Date</td>
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**LEARN MORE**

- **PILOT WEBSITE**
- **PILOT TOOLBOX**
- **Q&A SESSION**

**VISIT:** go.uab.edu/CCTSpilots  
**CONTACT:** Anne Russell, PhD, Program Manager (anneruss@uab.edu)
CCTS PARTNER NETWORK PILOT PROGRAM

Overview

Proposals
Proposals should address overcoming barrier(s) encountered in the conduct of research as to improve the efficiency and/or effectiveness of ameliorating health condition(s) that disproportionately affect our region. Research plans may lie at any point along the translational science spectrum. Projects already extramurally supported by the US federal government cannot be considered. Phase III clinical trials are not eligible. Extensions of prior research (e.g. secondary data analyses) that are aligned with the mission of this program and whose scope is non-overlapping with previously funded research plans are welcome.

Investigator Eligibility
The program supports investigators from any of the CCTS Partner Network institutions. Collaborative teams spanning multiple partner sites are encouraged but not required. 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 if the proposed aims represent a major shift from his/her scientific portfolio to date and/or the proposed work shifts prior research to another stage along the translational science spectrum. Individuals with a faculty appointment with a start date on or before the award date are eligible. Established investigators are discouraged from serving as the principal investigator on behalf of others. All projects should directly represent the ideas of the principal investigator. Investigators are not required to be US Citizens.

Application Process
This program utilizes a two-stage application process. Pre-applications are due October 25, 2022 by 5PM. Those considered meritorious will be invited to submit a full application. The ~8-week period between receiving invitation to submit a full application and submitting represents a "consultation period". During this period, the CCTS will coordinate a BERD consult and Panel for all applicants. If the application proposes to enroll human subjects, the CCTS will supply applicants with feedback about their proposal as provided by the CCTS Community Scientific Action Board (CSAB). Applicants are encouraged to initiate consults with CCTS capacities and/or additional relevant shared capacity for feedback and/or quotes before submitting full applications. Full applications (due December 21, 2022 by 5PM) are reviewed using an NIH-style review. Meritoriously reviewed applications will be notified of selection, triggering a “Just-in-Time” request for information that may be subject to QAQC review and NIH approval before funding is provided. The award period is May 1, 2023 – April 30, 2024.

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.
Pre-Application Instructions

Pre-Applications must be submitted via RED-ASSIST (https://redcap.dom.uab.edu/surveys/?s=XKRYLHKE34), which requires applicants to provide (1) a Pre-Application Proposal and (2) Other Project Information. Before submitting your application, consider visiting RED-ASSIST or review this pre-application template to better conceptualize submissions. Do not submit the template as part of your application.

Pre-Application Proposal

Pre-application proposals should be submitted as a single, flattened, PDF containing the sections below. Do not provide a PDF that utilizes bundling, portfolios, chapters, segmentation functions as they may render the file incompatible for reviewers’ consideration. Follow NIH formatting.

A. Pre-Application Research Plan (2-page maximum)
   1. Significance. Address the importance of the problem of critical barrier to progress that the proposed project addresses. Provide a clear and concise description of the central theme and goal(s) of the project.
   2. Innovation. Explain how the application challenges and seeks to shift current research, clinical practice, and/or public health 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. Address if the proposed innovation is novel to one field of research or in a broad sense.
   3. Approach. Include explicit statements of aims and corresponding hypotheses. Ensure that the proposed work systematically addresses overcoming a barrier in the conduct of research (e.g. one or more dedicated aims). Describe the overall strategy, methodology and analyses to be used to accomplish the specific aims of the project.
   4. References Cited. Provide a bibliography of all references cited. This section is not included in the 2-page maximum.

B. Human Subject Enrollment (if applicable, no page limit)
   If you plan to enroll human subjects, provide the following information as organized below.
   1. Risks to Human Subjects:
      a. Human Subjects Involvement, Characteristics and Design. Describe the study population(s) to be included in the study and the anticipated numbers of subjects for each study group. List any collaborating sites where human subjects research will be performed and describe the role(s) of those sites and collaborating investigators in performing the proposed research.
      b. Study Procedures, Materials and Potential Risks. Describe planned research procedures (interventions and interactions) involving study subjects; how research material, including biospecimens, data and/or records, will be obtained. If applicable, describe alternative treatments and procedures and rationalize the proposed approach.
   2. Adequacy of Protection Against Risks:
      a. Informed Consent and Assent. Describe the process for obtaining informed consent (e.g. who seeks it, the environment under which it is sought and method of documentation). Provide justification if a waiver for some or all of the consent is planned.
   3. Recruitment and Retention:
      a. Recruitment. Describe how you will recruit participants in your study (including planned recruitment activities)
      b. Retention. Describe how you plan to retain participants in your study (e.g. engagement strategies) or justify why retention is not needed (e.g. only one interaction).

C. NIH Biosketch
   The biosketch provided for the PI(s) must conform to the NIH Biosketch requirements. Biosketches are an opportunity to describe why you’re well suited for your role in a project. Biosketches are not required for coinvestigators, collaborators or other significant contributors.

D. Letter(s) of Support (if related to your appointment, optional)
   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.
Other Project Information
Enter the following directly into the relevant fields in RED-ASSIST.

A. Lay Summary (250 word maximum)
   This summary will not be scientifically reviewed or scored. However, a well-developed lay summary is imperative. If you are invited to submit a full application, this summary may be utilized to garner feedback from the CCTS Community Scientific Action Board (CSAB), identify reviewers for your full application and, if selected for award, may be used by the CCTS to promote your research. For guidance on how to write a lay summary, please read “10 Tips For Writing a Lay Summary.”

B. Acknowledgement of Cosponsorship
   At the pre-application stage, applicants only need to acknowledge that cosponsorship is a required (i.e. you understand that cosponsorship is a term of award). Letter(s) of Support specifying cosponsorship should not be included in the pre-application.

Consultation Period
If invited to submit a full application, the CCTS will coordinate a BERD consult and Panel for all applicants. The CCTS will also supply applicants with feedback garnered from the CCTS Community Scientific Action Board (CSAB) based on the information supplied in your pre-application. Applicants are encouraged to engage CCTS capacities (listed below) and/or engage additional relevant shared capacity, as needed, for feedback and/or quotes before submitting full applications. Applicants can engage CCTS capacities by contacting the CCTS (ccts@uab.edu, 205-934-7442). Consults and resulting feedback are intended to help sharpen the science that applicants propose. Individuals engaged during the consultation period do not review or score full applications.

- **Biostatistics, Epidemiology and Research Design (BERD)**
  The CCTS Biostatistics, Epidemiology and Research Design (BERD) unit supports a multidisciplinary team of biostatisticians, epidemiologists, and methodologists to assist investigators on study design, data collection and analysis.

- **Panel**
  A Panel, specifically a “Panel Done Quickly”, involves assembling a group of peer experts that asynchronously assess study plans and then meet as group with the applicant to provide feedback to help develop a highly compelling application.

- **Informatics**
  Informatics expertise and resources can help investigators with study design; access to summary, limited (de-identified), and fully identified data sets; innovative tools and analytic approaches to support informatics research spanning the translational science spectrum.

- **Clinical Research Support Program (CRSP)**
  CRSP can discuss, provide resources and/or assist investigators with clinical study feasibility, regulatory requirements (e.g. human subjects research protocol development, good clinical practice, IND/IDE submissions, clinicaltrials.gov registration and reporting), budgeting, research nurses and study coordination, recruitment and data collection.

- **Bionutrition Unit**
  The Bionutrition Unit enables nutrition-related research, inclusive of a Metabolic Kitchen supporting nutritional requirements for outpatient studies, facilities and equipment to support onsite nourishment and metabolic analyses, study planning and nutritional education.

- **Specimen Processing & Biorepository Unit**
  The Specimen Processing & Biorepository Unit works closely with the CRU, Phase I Clinical Trials Unit and other UAB Health System clinics to rapidly process, aliquot, store and/or ship research specimens.

- **Clinical Research Unit (CRU)**
  The CRU provides investigators with clinical space (outpatient and limited inpatient), equipment and nursing capacities frequently needed to execute clinical studies.

- **Child Health Research Unit (CHRU)**
  The CHRU provides investigators with clinical space (outpatient) and equipment essential to support pediatric clinical studies.

- **Phase I Clinical Trials Unit**
The Phase I Clinical Trials Unit is a program dedicated to providing leadership and support for the conduct of early phase (e.g. first in human) clinical trials.

- **Other Shared Resources – As applicable**
  Applicants are encouraged to use shared resources, as applicable to the proposed research.

**Full Application Instructions**

Invitations to submit a full application will contain a unique RED-ASSIST hyperlink, which must be used to submit a full application. RED-ASSIST requires applicants to provide (1) a Full Application Proposal and (2) Other Project Information. Before submitting your full application, consider visiting the RED-ASSIST you were supplied or review this full application template to better conceptualize submissions. Do not submit the template as part of your application.

**Full Application Proposal**

Full application proposals should be submitted as a single, flattened, PDF containing the sections below. Do not provide a PDF that utilizes bundling, portfolios, chapters, segmentation functions as they may render the file incompatible for reviewers’ consideration. Follow NIH formatting.

**A. Full Application Research Strategy** (4-page maximum)

1. **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 goals of project. Explain how the proposed project will improve scientific knowledge, technical capability, clinical practice, clinical services and/or interventions in one or more broad fields. If applicable, explain how the scope of work proposed builds, in a non-overlapping manner, with previously funded research.

2. **Innovation.** Explain how the application challenges and seeks to shift current research, clinical practice, and/or public health 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. Address if the proposed innovation is novel to one field of research or in a broad sense.

3. **Approach.** Include one or more statements of a specific aim(s) and corresponding hypothesis(es) that are achievable in one year. Ensure that the proposed work systematically addresses overcoming a barrier in the conduct of research (e.g. one or more dedicated aims). Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Address how the proposed work will reduce or eliminate barriers to conducting subsequent work as planned by the applicant, conducted by the field and/or across disciplines.

4. **References Cited.** Provide a bibliography of all references cited. This section is not included in the 4-page maximum.

**B. Resource Sharing Plan(s)** (1-page maximum)

Please address resource sharing plans, as applicable. This section represents a distillation of information requested via NIH’s policies related to Data Management and Sharing Plans (DMSP), Genomic Data Sharing Plans and Sharing Model Organisms. Address the resource sharing categories relevant to the proposed research. If a category is not applicable, indicate “N/A”.

1. **Resource Type.** Identify the type of resource(s) (i.e. scientific data, genomic data and/or model organism(s)) you plan to generate as part of the research. Describe which aspects of the resource(s) (e.g. raw or processed data; whole organism or vectors) and any other relevant information (e.g. metadata, study protocols, data collection instruments) will be preserved and shared.

2. **Related Tools, Software and/or Code.** Identify specialized tools are needed to support replication or reuse.

3. **Standards.** Describe any data formats, data dictionaries, data identifiers, definitions, unique identifiers or other data documentation applied to the data generated.

4. **Preservation, Access, Distribution or Reuse Considerations.** Describe how the resource(s) and related tools, software and/or code will be preserved. Describe how the resource(s) may be accessed in the future. Describe any anticipated limitation on the use of the resource(s) (e.g.
restrictions imposed by the informed consent; applicable laws, regulations, policies, or existing or anticipated agreements; controlled access). If related to model organisms, describe how risks of infection or contamination will be minimized.

5. **Timelines.** Describe the timeframe that the resource(s) will be preserved.

6. **Oversight.** Describe how compliance with the proposed plan(s) will be monitored and managed.

C. **Protection of Human Subjects** (if applicable, no page limit)

If you plan to enroll human subjects, provide the following information as organized below.

1. **Risks to Human Subjects:**
   a. **Human Subjects Involvement, Characteristics and Design.** Briefly describe the overall study design. Describe the study population(s) to be included in the study and the anticipated numbers of subjects for each study group. List any collaborating sites where human subjects research will be performed and describe the role(s) of those sites and collaborating investigators in performing the proposed research.
   b. **Study Procedures, Materials and Potential Risks.** Describe planned research procedures (interventions and interactions) involving study subjects; how research material, including biospecimens, data and/or records, will be obtained and whether any private identifiable information will be collected in the proposed research project. Describe all the potential risks to subjects associated with each study intervention, procedure or interaction, including physical, psychological, social, cultural, financial and legal risks; risks to privacy and/or confidentiality; or other risks. Discuss the risk level and the likely impact to subjects. If applicable, describe alternative treatments and procedures and rationalize the proposed approach.

2. **Adequacy of Protection Against Risks:**
   a. **Informed Consent and Assent.** Describe the process for obtaining informed consent (e.g. who seeks it, the environment under which it is sought and method of documentation). When appropriate, describe how potential adult subjects’ capacity to consent will be determined and the plans for obtaining consent from a legally authorized representative for adult subjects not able to consent. Provide justification if a waiver for some or all of the consent is planned.
   b. **Potential Benefits of the Proposed Research to Research Participants and Others.** Discuss the potential benefits of the research to research participants and others. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to research participants and others.

D. **Recruitment and Retention Plan** (if applicable, no page limit)

If you plan to enroll human subjects, provide the following information.

1. **Recruitment.** Describe how you will recruit participants in your study (including planned recruitment activities)
2. **Retention.** Describe how you plan to retain participants in your study (e.g. engagement strategies) or justify why retention is not needed (e.g. only one interaction).

E. **NIH Biosketch** (5-page maximum each)

The biosketch provided for the PI(s) must conform to the [NIH Biosketch requirements](https://grants.nih.gov/grants/guide/p Policymore.html). 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](https://www.nih.gov/PS398) to submit their budget. Allowable expenses include: personnel, supplies, inpatient / outpatient care costs and other expenses (e.g. shared resource capacities). 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 the CCTS (ccts@uab.edu) prior to submission of your full application. Unallowable expenses include: travel expenses, publication costs, alterations, and renovations. 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 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”. If the project’s budget includes a shared resource capacity(ies) (CCTS or beyond), include the name and contact information of the individual(s) that provided the quote(s).

H. Letter(s) of Support (no limit)
1. Consponsorship (required). 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. Include a formal Letter of Support from each co-sponsor that outlines each co-sponsor’s financial pledge.
2. Appointment (if applicable). Investigators with a faculty appointment starting on or before the award start date may include a Letter of Support from their Department Chair substantiating their upcoming appointment
3. Other Letters or Agreements (if applicable). Other Letter(s) of Support and related agreements may be included in the application to substantiate a collaboration, utilization of a resource, etc.

I. 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.

Other Project Information
Enter the following directly into the relevant fields in RED-ASSIST.

A. Cosponsor Names
Enter the names of the unit(s) and individual(s) providing cosponsoring Letter(s) of Support.

B. 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. External reviewers must agree to uphold confidentiality at the beginning of the review process.

C. Just-in-Time Information
Acknowledge that you understand and agree to the following: If selected for pilot funding, I understand that Just-in-Time information such as project relevant regulatory approvals/registrations (e.g. IACUC, IRB, IND/IDE, clinicaltrials.gov) and additional project attachments must be submitted to the CCTS, who will then submit the information to the NIH for review and approval. I understand that the RFA describes the Just-in-Time period and that CCTS staff will help ensure timely submission and approval. I understand that NIH Approval of Just-in-Time information may be a contingency of the pilot award.

Review Criteria
Pre-Application Review Criteria
Reviewers will first assess the scientific merit of the proposal based on significance, innovation, approach, investigator(s) and environment. Then, reviewers will consider additional criteria such as the protection of
human subjects, vertebrate animals, extramural competitiveness and budget/timeline. Finally, reviewers will assign a single overall impact score (NIH 9-point scale).

**Full Application Review Criteria**

Reviewers will score (NIH 9-point scale) each of the following aspects: significance, innovation, approach, investigator(s) and overall impact. Reviewers are empowered to consider the study timeline, protection of human subjects, vertebrate animals and extramural competitiveness as part of the overall impact score. Reviewers’ consideration of the budget, resource sharing plans and involvement of foreign organization(s) should not affect the overall impact score. Comments on all sections are welcome, as they are leveraged to provide applicants feedback and may be considered by the Scientific Review Group (SRC) when applications are evaluated for scientific and technical merit.

**Just-in-Time Information (Please read carefully)**

Akin to NIH award (e.g. R01) Just-in-Time procedures, the NIH / NCATS reviews and approves all CTSA-sponsored pilot projects that involve human subjects and/or vertebrate animals to ensure compliance with applicable federal regulations and reporting. Therefore, if your full application is selected for award, you must provide relevant regulatory approvals/registrations (e.g. IACUC, IRB, IND/IDE, clinicaltrials.gov) and additional project information. You will be asked to submit this information to the CCTS using a dynamic Just-in-Time survey (*Just-in-Time Example Survey*). Please use this example survey to assess the information you may need to supply and access templates containing NIH-derived instructions. The information you supply will be reviewed via a QAQC specialist to ensure the content and format complies with the NIH’s requirements. Then, the information is submitted, by way of the CCTS and our designated UAB signing official, to the NIH for review and approval. Since there are only ~8 weeks between award selection and award start, and NIH approval is a contingency of award, applicants are highly encouraged to develop regulatory submissions before and during review of Full Applications.

*The *Just-in-Time Example Survey* may change as NIH/NCATS updates requirements.*

**Award Administration**

**Award Notices** - Meritorious applications will receive a Notice of Selection (NoS). 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 few weeks 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 provide scientific progress reports and, if applicable, enrollment information. Templates and the deadline(s) 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
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), LHL liaisons to the CCTS.