

Multi-site CTSA “Carolinas Collaborative” Translational Research Pilot Program Request for Applications on use of EHR for clinical research

The CTSA hubs are the academic homes of the National Institutes of Health’s (NIH) Clinical and Translational Science Awards (CTSAs). North and South Carolina are home to 4 CTSA hubs: Duke University, the Medical University of South Carolina, the University of North Carolina at Chapel Hill, and Wake Forest University. The 4 CTSAs have partnered with Health Sciences South Carolina (HSSC) to create the [Carolinas Collaborative](#), a data resource that harmonizes the electronic health record data across the institutions to expedite clinical research and quality improvement activities.

In an effort to promote inter-institutional collaborations and to increase utilization of the Carolinas Collaborative available resources, the four CTSAs are soliciting applications for proposals that involve at least two of the Carolina CTSAs and utilize the data available from the Carolinas Collaborative to generate new knowledge and improve the quality of care delivered to patients in the Carolinas. This collaborative pilot Request for Application (RFA) is in line with the priorities of the NIH and other funders to use the electronic health records for clinical research within and across integrated delivery systems.

I. Purpose

This pilot program is designed to encourage and facilitate novel clinical and translational research that applies or accelerates discovery into testing in clinical or population settings, including implementation of effective therapies into new settings. The proposed pilot work should collect preliminary data to lead to a competitive proposal submitted to an external funding agency (NIH, AHRQ, PCORI, foundation, etc.) within one year from onset of funding. Projects must demonstrate high translational potential with a clear path to subsequent grant support for a cohort study or clinical trial. Population health improvement projects should demonstrate significant stakeholder involvement to move it into broader practice patterns, clinical guidelines, and other applications.

Carolinas Collaborative has an existing harmonized dataset, called the Carolinas Collaborative Common Data Model (CDM). This means institutions store their electronic health record data in the same format, so that clinical data queries can be run across all member sites. The Carolinas Collaborative CDM includes several common types of data (e.g., diagnosis, procedures, labs, etc.) and is available for review [here](#). Use of the Carolinas Collaborative CDM is a central component of this RFA (See Section III).

Pilot funds may be used to support the following types of translational research:

- Acquisition of preliminary data to support cohort studies and trials to test hospital or practice based research examining tests, treatments and policies.
- Collection of preliminary analyses using the medical record derived databases, statistical consultation regarding sample size and recruitment, development or validation of computable phenotypes, stakeholder engagement activities, test linkages with claims or registry data, and pilot testing of outcome measures and recruitment methods.
- Development of methods advances to improve the efficiency of recruitment and conduct of clinical trials and cohort studies, as well as methods to enhance the representation of previously under-represented populations in clinical and translational research.

Plans for or evidence of prior stakeholder engagement will be considered essential for the proposed work. Potential applicants should consult with their CTSA community engagement services regarding services available to engage patients, caregivers, providers, advocacy groups, etc. as part of the proposed work.

[This article](#) is a useful reference titled “Recommendations for Planning Pilot Studies in Clinical and Translational Research.”

This pilot award program is not meant as bridge funding or as supplementary funding for existing projects.

II. Key Dates

- RFA Released: June 18, 2018
- Informational webinar held: June 29, 2018 from 10–11am - register [here](#). The slides will be made available for anyone who cannot join this optional educational event.
- Application Submission Deadline: 5pm on August 15, 2018
- Selection of Awardees: By September 30, 2018
- Funding Period: Budget period is 12 months beginning no more than 60 days after notification of the award and ending no later than November 30, 2019.

III. Eligibility

Proposed projects must involve participation from at least two of the 4 constituent CTSA hubs. Proposals are encouraged from new teams of investigators from different disciplines. Applicants at each institution must have a full-time faculty appointment such that they could lead an external funding application.

The Carolinas Collaborative pilot grants are multi-PI grants with 2-4 PIs on each project. All site PIs share the responsibility for leading and directing the project and all communication about the grant will be sent to all the PIs. Similar to NIH multiple PI awards, each project must designate one of the PIs as the overall contact PI. That person’s name, institution and contact information should be entered where indicated on the application.

More than one proposal may be submitted per faculty member, but the faculty member is only eligible to receive one award as PI during a given funding cycle. Note that Duke faculty members may not serve as PI on more than one concurrently funded Duke CTSA Collaborative (including the Duke/UNC-Chapel Hill Collaborative) or Transformative pilot award. Currently funded Carolinas Collaborative award PIs may not apply as a PI in this round.

Interested investigators seeking collaborators at the other CTSA sites should visit the [For Researchers](#) section of the [Carolinas Collaborative website](#) and “Submit a Collaborator Request” for assistance. This should occur prior to submission so that collaborators can be identified and included in the submitted grant materials.

Preference will be given to proposed projects that exclusively utilize the Carolinas Collaborative Common Data Model (CDM) and do not require data elements outside of the Carolinas Collaborative CDM. Acquisition of data elements or types that are not in the Carolinas Collaborative CDM require greater development time at each institution and effort required will vary by site. Proposed projects that require data elements outside of the Carolinas Collaborative CDM will still be considered for

funding. Investigators can review the Carolinas Collaborative CDM [here](#) and will learn more during the Carolinas Collaborative Data Consultation (see Section IV). All proposals should include adequate funding for data extraction.

IV. Carolinas Collaborative Data Consultation

At a minimum, the overall contact PI must consult with a local Carolinas Collaborative data analyst. Data analysts can help PIs understand data availability and data quality in the Carolinas Collaborative Common Data Model (CDM) and associated costs for data extraction. The online application includes a question where the overall contact PI must list the name of the person with whom they consulted. To initiate a consult with a Carolinas Collaborative data analyst click “Submit a Consultation Request” on the “Services Consult” section of the Carolinas Collaborative website - <https://carolinascollaborative.org/researchers/>

All site PIs are encouraged to have similar consultations with local Carolinas Collaborative data analysts. This will be especially important if the proposed project requires data outside of the Common Data Model, as availability varies by site.

Interested investigators may also request counts of patients through the Carolinas Collaborative website in order to assess the feasibility of a project.

V. Funding

The research activities at each participating institution will be funded by that institution’s CTSA or through funding from the Duke Endowment, the initial funder of the Carolinas Collaborative. Each CTSA hub will fund up to \$25,000 in direct costs per project. An equal amount should be requested from each CTSA hub. Funds will not be subcontracted from one institution to the other.

Each institution will allocate up to \$75,000 for this RFA; the total number of grants funded may be greater or fewer than three depending on the number of CTSA hubs participating in each project, the project budgets, and the responsiveness and merit of the proposals.

See Section VIII for more details on allowable and non-allowable budget items. Since CTSA funds cannot be carried over from one fiscal year to the next, requests for no-cost extensions will not be approved.

VI. Review Criteria

Applications will be reviewed by a joint Study Section with representatives from the 4 CTSA hubs. Review criteria will include:

- Significance of the work
- Novelty/innovation of the research idea
- Relevance of the proposed study to translational research
- Applicants are a multidisciplinary team
- Potential for the project to lead to future external funding
- Potential for the project to impact broader practice patterns, clinical guidelines, and other applications (if applicable)
- Soundness of the proposed methods
- Feasibility of accomplishing the stated project goals within the project period

- Level of community/stakeholder engagement
- Preference will be given to projects that exclusively utilize the Carolinas Collaborative CDM and do not require data elements outside of the Carolinas Collaborative CDM

VII. Application Procedure

The sponsoring CTSA's strongly recommend involving a biostatistician and biomedical informatics faculty and staff in the application development process.

1. Proposal is submitted via UNC's online submission system. To apply

- Visit <http://bit.ly/UNCgrants>, click on "Create New User" (or log in if you already have an account). Proposals must be submitted under the Principal Investigator's name.
- The online application system is very intuitive, however a step-by-step user's guide is also available. Click here to access the [video](#).
- Select the "Carolinas Collaborative" funding opportunity and follow the instructions.

Proposal sections will be uploaded as individual PDF files. Application sections include:

- A. Scientific Abstract: The abstract summary of the proposal for use by review committee members (250 word maximum).
- B. Research Plan: The Research Plan should follow the standard NIH format: Specific Aims, Significance, Innovation, and Approach. Include where applicable clear evidence of how the proposal meets the review criteria. (5-page limit, including tables and figures. References do not count toward the 5-page limit; single line spacing, font no smaller than Arial 11, 1-inch margins.)
- C. Budget with Budget Justification using [PHS 398 Form](#) Pages 4 and 5 (combined into a single PDF without a page limit). Section VIII below provides more detail on budget preparation. The Budget Justification should include sufficient detail for reviewers to assess whether appropriate resources have been requested. Each site budget should be prepared on a separate form page but submitted together as a single PDF.
- D. Project Timeline.
- E. Human Subjects: Institutional Review Board (IRB) approval is not required prior to submission. Briefly describe any human subject issues. If human subjects are involved, provide a description of their involvement and characteristics, specific risks to subjects who participate, and protection against those risks. Describe the sources of materials that will be obtained from human subjects as part of their study participation. Provide assurance that the project will be reviewed and approved by the appropriate IRB and comply with HIPAA. We anticipate that IRB reliance procedures will be used across the sites.
- F. NIH Biosketches for key members of the research team (as a single PDF).

Data Elements Checklist: The online application includes a required checklist detailing the data elements needed for the proposed project. If data elements outside of the Carolinas Collaborative CDM are required, investigators should explain how they plan to obtain and utilize the data. A copy of the checklist is attached to this document for your reference.

VIII. Budget Guidelines

1. The budget period is for 12 months beginning between October 1 – December 1, 2018 and ending no later than November 30, 2019. Up to \$25,000 in direct costs at each institution may be requested and the amount requested from each must be equal as funds will not be subcontracted between organizations. If external tasks need to be compensated, for example

compensating external stakeholders, invoicing may be used. Funding will not be available until applicable IRB documentation is provided.

2. Budget Guidelines

A. Grant funds may be budgeted for:

- Salary support for the PI or faculty collaborators (Duke, MUSC (up to 5% per faculty utilizing the NIH cap) and Wake Forest only)
- Research support personnel
- Travel necessary to perform the research
- Data extraction costs from the Carolinas Collaborative or local clinical data warehouses
- Small equipment, research supplies and core lab costs,
- Other purposes deemed necessary for the successful execution of the proposed project

B. Grant funds may **not** be budgeted for:

- Salary support for the PI or faculty collaborators (UNC only)
- Effort for post-doctoral trainees or fellows on training grant equivalents
- Capital equipment
- Office supplies or communication costs, including printing
- Meals or travel, including to conferences, except as required to collect data
- Professional education or training
- Manuscript preparation and submission,
- Indirect costs

C. Awarded funds must be used to conduct the work proposed. All direct charges to this award must adhere to federal regulations and requirements regarding the use of CTSA funds. The CTSA hubs reserve the right to revoke funding in the event it is determined that funds were not spent in accordance with the approved proposal. The general criteria for determining allowable direct costs on federally sponsored projects is set forth in 2 CFR Part 200: Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (The Uniform Guidance).

IX. Other Guidelines

1. Prior to receiving funds, research involving human subjects must have appropriate approvals from the IRB. Either an IRB approval letter or an IRB response to a "Determination Whether Research or Similar Activities Require IRB Approval" must be submitted to the component CTSA hubs prior to funds being released. Human subjects must be reviewed in accordance with the university's general assurances and HIPAA. All personnel named on the budget page must have certification of training in the protection of human subjects prior to the start of the grant period.
2. If applicable, prior human subjects approval must also be obtained by NIH/NCATS. Awardees will be assisted with the documentation submission process.
3. If funded, all data sharing requests will need to undergo an established approval process with the Carolinas Collaborative Data Request Review Committee, and Data Use Agreements will need to be executed before data can be shared. Carolinas Collaborative staff will explain this process to awardees. Data Use Agreement templates will be available.
4. CTSA and Carolinas Collaborative staff will work closely with funded teams throughout the grant period to monitor progress and, when necessary, provide assistance. A six-month interim progress report and a final progress report will be required. We expect PIs to report over the

lifetime of the work the outcomes achieved due to the pilot award, e.g., subsequent external funding, publications, presentations and patents.

5. All publications that are the direct result of this funding must reference: "Research reported in this publication was supported by the National Center for Advancing Translational Sciences of the National Institutes of Health under Award Numbers 1UL1TR002553 (Duke), UL1TR001111 (UNC), UL1TR001421 (Wake Forest) and UL1TR001450 (MUSC). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Publications must also be registered in PubMed Central.
6. Any awardee who leaves his or her position during the project timeframe should contact their CTSA hub to discuss future plans for the project.

For questions about this RFA, please contact:

At CTSA hub:	Email address
Duke	CTSIFunding@dm.duke.edu
MUSC	cameroa@musc.edu
UNC and RTI	nctracspilots@unc.edu
Wake Forest	ltrost@wakehealth.edu

Data elements required

Please indicate the data elements that will be required for your proposed project. This checklist includes items available within the Carolinas Collaborative Common Data Model (CDM). If you require data elements outside of the CDM, there is space to note these items at the end of the list.

Note: This is a preliminary listing of the data you will need. If funded, you will be required to provide more detail by completing a formal data request.

Demographic

Age (Current)
Age (at Encounter)
Ethnicity
Race
Sex/Gender
Vital Status
Date of Birth

Diagnosis

ICD-9-CM/ICD-10-CM
Diagnosis Date
Diagnosis Modifier (e.g., Admitting, Discharge)

Encounter

Admitting Source
Diagnosis Related Group (DRG)
Discharge Disposition
Discharge Status
Encounter Type
Payor
Payor Modifier (i.e., primary, secondary)
Length of Stay
Admission Date
Discharge Date

Laboratory

Lab Tests (Labs use a coding system called LOINC. A data analyst can help identify LOINC codes for needed labs at the data request stage.)
Lab Collection Date

Medications

Ordered Medications (Medications use a coding system called RxNorm. A data analyst can help identify RxNorm codes for needed medications at the data request stage.)
Order Start Date
Order End Date

Procedure

CPT-4/HCPCS (i.e., HCPCS Level I, II)

ICD-9-CM/ICD-10-PCS
Procedure Date

Tobacco History

Smokeless Tobacco Use
Smoking Tobacco Use
Tobacco User
Tobacco Type
Tobacco Modifiers (e.g., Packs per Day, Years Used)

Vitals

Blood Pressure
 Diastolic
 Systolic
 Modifier (e.g., sitting, standing) – *May not be available across all sites.*
Body Mass Index (BMI)
Height
Weight
Vital Measurement Date

Patient Reported Outcomes (PROs)

PROMIS Measures - Note only a limited list of PROMIS measures are available in the Carolinas Collaborative CDM. Please see data dictionary for list of available PROMIS measures.

Other data elements

Although preference will be given to those projects that exclusively utilize the Carolinas Collaborative Common Data Model (CDM), certain projects may also require data elements outside of the CDM. These projects will still be considered for funding.

If you're requesting data elements outside of the CDM, the following information is required.

Indicate any other data elements that are required for your project below and briefly describe how you intend to utilize them. Provide detail about why these data are needed and provide information about data availability based on your conversations with a Carolinas Collaborative data analyst.

Character Limit: 10000