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 now home to 4 CTSA hubs: Duke University, the Medical University of South Carolina, the University of North Carolina at Chapel Hill-RTI partnership, and Wake Forest University. The four 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 awareness of the Carolinas Collaborative, the four CTSAs are soliciting applications for proposals that involve at least two of the Carolina CTSAs and utilize 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. 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. Projects must use the component EHR data warehouses from at least two of the 4 Carolinas CTSAs.

The individual CTSAs, in collaboration with Health Sciences South Carolina (HSSC), will assist funded awardees in data harmonization activities across the multiple sites using tools including i2b2 and SHRINE. For information regarding these tools, applicants should consult the biomedical informatics services at their respective CTSA hubs.

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

II. Key Dates

- RFA Released: January 8, 2016
- Application Submission Deadline: 5pm on February 17, 2016
- Selection of Awardees: April 1, 2016
- Funding Period: Budget period is 12 months beginning no more than 60 days after notification of the award and ending no later than May 31, 2017.

III. Eligibility

Proposed projects must involve participation from at least two of the 4 constituent CTSA hubs. Projects that involve more hubs will be viewed more favorably, although scientific promise will be the most important criterion for the study section. 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, or appointment as a research scientist if at RTI.

More than one proposal may be submitted per faculty member acting as PI, 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.

Resources for identifying potential collaborators at CTSA hubs:

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<thead>
<tr>
<th>Collaborators at:</th>
<th>Electronic Tool</th>
<th>Contact for help identifying collaborators:</th>
</tr>
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<tbody>
<tr>
<td>Duke</td>
<td><a href="http://reachnc-community.pure.elsevier.com/">http://reachnc-community.pure.elsevier.com/</a></td>
<td><a href="mailto:dtripilots@dm.duke.edu">dtripilots@dm.duke.edu</a></td>
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<tr>
<td>MUSC</td>
<td><a href="https://profiles.healthsciencessc.org/profiles/search/">https://profiles.healthsciencessc.org/profiles/search/</a></td>
<td><a href="mailto:denmarks@musc.edu">denmarks@musc.edu</a></td>
</tr>
<tr>
<td>UNC and RTI</td>
<td><a href="http://reachnc-community.pure.elsevier.com/">http://reachnc-community.pure.elsevier.com/</a></td>
<td><a href="mailto:nctracs@unc.edu">nctracs@unc.edu</a></td>
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<tr>
<td>Wake Forest</td>
<td><a href="http://profiles.tsi.wakehealth.edu">http://profiles.tsi.wakehealth.edu</a></td>
<td><a href="mailto:BRSA@wakehealth.edu">BRSA@wakehealth.edu</a></td>
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IV. Funding

The research activities at each participating institution will be funded by that institution’s CTSA. Each CTSA hub will each fund up to $25,000 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 $50,000 for this RFA; the total number of grants funded may be more than two depending on the number of CTSA hubs participating in each project and the project budgets.

See Section VII. 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.
V. 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

VI. 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

- The online application system is very intuitive, however a step-by-step user’s guide is also available. Click here to see the video or read the document.
- Select the “2016 Carolinas Collaborative Pilot Grants” 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 VI below provides more detail on budget preparation. The Budget Justification should include sufficient detail for reviewers to assess whether appropriate resources have been requested. Site budgets should be prepared on separate form pages but submitted together as a single PDF.
D. Proposal 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).

VII. Budget Guidelines

1. The budget period is for 12 months beginning between April 1 –June 1, 2016 and ending no later than May 31, 2017. 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 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
      • Small equipment, research supplies and core lab costs, or
      • 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
      • Computers or audiovisual equipment
      • Manuscript preparation and submission, or
      • 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).

VIII. 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. CTSA and HSSC 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.

3. 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 UL1TR001117 (Duke), UL1TR001111 (UNC/RTI), ULTR001421 (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.

4. Any awardee who leaves his or her position should contact their CTSA hub to discuss future plans for the project.

Who to contact with general questions about this RFA:

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<thead>
<tr>
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<th>Contact for RFA questions</th>
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<td>Duke</td>
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