The UNC Center for Health Equity Research (CHER) and the North Carolina Translational and Clinical Sciences (NC TraCS) Institute's Integrating Special Populations (ISP) component are pleased to jointly sponsor this special call for pilot project applications. CHER is committed to health equity, innovation and translational research, and ISP is dedicated to increasing the participation of under-represented groups in research.

I. Purpose

The purpose of this RFA is to facilitate research that promotes health equity for groups who have traditionally been under-represented in health research or excluded altogether (e.g., people who live in rural areas, populations with low socioeconomic status, people with disabilities, adolescents, older adults, the LGBTQ community, African Americans, Native Americans, Asian Americans, and Latinos). We are seeking projects that can be completed within 12 months and have strong potential to inform subsequent grant applications to the NIH or other funding agencies.

Because UNC-CH institutional funds are being used to support this RFA, all projects must include a PI or Co-PI from UNC-CH. Projects may include co-investigators or collaborators from NC TraCS partner institutions: RTI International, North Carolina A&T State University, and NC State University.

Applicants should clearly state how their proposed project is designed to further health equity. Projects must also focus on one of the following populations: African Americans, Native Americans, Asian Americans, Latinos, adolescents, older adults, the LGBTQ community, people with disabilities, rural populations, or populations with low socioeconomic status. Examples of the types of projects appropriate for this special RFA include, but are not limited to:

- Projects that address health disparities in one or more of the populations listed above
- Projects that test mechanisms of social determinants of health
- Projects that test epigenetic mechanisms of health disparities
- Projects that demonstrate use of tools to enhance ethically-informed participation of under-represented research participants
- Testing and evaluation of existing resources designed for recruiting and retaining under-represented populations
- Methods and strategies for increasing the inclusion of under-represented populations in research
- Use of mobile and web-based tools for research participation
- Pilot strategies for recruiting under-represented populations through the Carolina Data Warehouse
- Projects that explicitly address barriers to research participation
- Development and testing of novel tools, materials, etc. to improve diverse recruitment
- Developing and testing tailored messaging to improve research participation
- Developing, testing, and disseminating interventions to achieve health and healthcare equity in one or more of the populations listed above
- Adapting existing-evidence based interventions in one or more of the populations listed above
- Testing novel implementation strategies and contexts on evidence-based guidelines
II. Key Dates

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<tr>
<th>Event</th>
<th>Date</th>
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<tr>
<td>Complete required consultation (with 250 word abstract) with CHER and TraCS ISP</td>
<td>By March 1, 2019</td>
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<tr>
<td>Proposals Due</td>
<td>March 26, 2019</td>
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<td>Award Decision</td>
<td>Within 9 weeks of application deadline</td>
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<td>Mid-term Progress Report (instructions to follow)</td>
<td>6 months after grant begins</td>
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<td>Final Progress Report</td>
<td>1 month after grant period completed</td>
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III. PI Eligibility and Requirements

UNC-CH researchers whose appointments allow them to serve as PI on externally sponsored research projects are eligible to apply as PI. This generally means permanent faculty (not adjunct appointments) and includes those with non-faculty appointments like “research scientist” and investigators from research institutes and centers who are eligible to apply for investigator-initiated awards and R01-level funding. Applications may also include collaborators or co-investigators from NC TraCS’ partner institutions; please contact Mary Beth Cassely to discuss guidelines for expending pilot funds at other institutions, and for other questions regarding investigator eligibility.

Applications with multiple PIs (“co-Pis”) must identify one PI as the main contact PI, with primary responsibility for the administrative aspects of the pilot award.

NC TraCS encourages applications from junior investigators. Senior faculty PIs (Associate Professor and above) may apply; however, they must demonstrate a departure from a previous research direction, and this new direction must be clearly evident in the application.

All applicants must complete a consultation with a faculty expert from CHER and/or ISP prior to submitting their application. Request for a coordinated consultation can be made by sending an email with a project abstract (250 words) to Abigail Haydon, ISP Program Manager at NC TraCS.

IV. Pilot Funding Requirements

If the application involves research at multiple institutions, the budget from each institution should be approximately equal, or else the budget justification should explain why this is unfeasible. In general, research activities at each institution should be funded by that institution. Funds cannot be subcontracted from one institution to the other. All funds must be expended within one year of the project start date.

Pilot grant awards are not meant as bridge funds or as supplementary funding for existing grants. NC TraCS cannot fund pilot grants where the research is conducted outside the United States. More information is available in the Pilot Program FAQ.

V. Use of NC TraCS and CHER Services

NC TraCS offers members a variety of research services and expertise, and applicants are encouraged to utilize those services in pilot grant applications where appropriate. A full list of NC TraCS services can be found here. NC TraCS services that require the investigator to contribute to the cost of the service should be consulted prior to submission to ensure that the application budget includes accurate information. Applicants are not required to use NC TraCS services in their pilot projects. NC TraCS Research Navigators are available to offer general advice and assistance with applications prior to submission. Click here to schedule a consultation (choose “Proposal Development” from the main menu). We strongly encourage awardees to become an Associate of the Center for Healthy Equity Research. For information about this process, please click here.
VI. Review Criteria

Applications should be presented in a clear and logical fashion, make a convincing case for the significance of the work, and describe the proposed methods in sufficient detail so that an adequate evaluation of the application can be made.

The primary review criterion is that the pilot work has the potential to lead directly to a fundable external proposal for disparities research, to be written and led by the pilot study PI and submitted to NIH, CDC, or other comparable federal agency within a year following completion of the pilot project. Pilot proposals that are not part of a longer-term vision for a specific research effort will not be considered responsive to this funding call. The research effort (meaning, the pilot project and the full research proposal to follow) must be designed to generate new knowledge relevant to translation of disparities research to clinical or community settings. Therefore, pilot projects are intended to generate preliminary data to provide proof of concept and/or address issues of feasibility for a planned larger research proposal. Preliminary data are not required for the pilot proposal but some specific evidence that the work has merit scientifically and that the proposed effort is feasible within the timeframe and funding level of the pilot program is required. It is strongly encouraged that the pilot proposal includes specific plans regarding the proposal for federal funding following the pilot work. The pilot project can target primary, secondary, or tertiary prevention or clinical care, and can use whatever study design is appropriate to address the aims of the project.

The following review criteria will be considered:

1. Relevance of the proposed study to disparity populations and health equity
2. Significance of the work
3. Novelty/innovation of the research idea
4. Soundness of the proposed methods
5. Feasibility of accomplishing the stated project goals within the 12-month study period
6. Potential for the project to lead to future external funding
7. PI status as a new investigator

VII. Application Procedure

NC TraCS very strongly recommends involving a biostatistician in the application development process. The online application form will ask for the name of the biostatistician who consulted on the application.

For investigators without access to a biostatistician, biostatistical support can be obtained through the NC TraCS Biostatistics Service by completing the “Request a Consult” form. For cancer-related research, please contact the Lineberger Comprehensive Cancer Center for biostatistical support (email LCCC_BIOS@med.unc.edu).

For any questions, email nctracs@unc.edu or call 919-966-6022 or 866-705-4931.

Applications must be submitted using the online system: Foundant. Scroll down to the section titled “CHER/ISP Joint Pilot” and click “Apply.” Application sections (except the Abstract) will be uploaded as individual PDF files. The application sections are:

1. Scientific Abstract: A summary of the application for use by NC TraCS and CHER (250 word maximum).
2. Research Plan: The Research Plan should include Specific Aims, Significance, Innovation, and Approach. For studies enrolling human subjects, include engagement and recruitment plans either in this section or in the Human Subjects section (number 7 below). Include where applicable clear evidence of how the application meets the review criteria. 1.5 line spacing, font Arial 11 pt., and 1-inch margins all around. (5 page limit, including tables and figures. References do not count towards the page limit.)
3. Cited References (No page limit)
4. **Budget:** Use [PHS 398 Form Page 4](#) (see Section VIII “Budget Guidelines” below for more details). The total budget should not exceed $50,000.

5. **Budget Justification:** Include sufficient detail for reviewers to assess whether appropriate resources have been requested (see “Budget Guidelines” below). (No page limit)

6. **Timeline** covering the 12-month funding period.

7. **Human and/or Animal Subjects:** Although Institutional Review Board (IRB) and/or Institutional Animal Care & Use Committee (IACUC) approval is not required at time of submission, the application should briefly describe any human and/or animal subject issues. If human subjects will be involved in the research, provide a description of their involvement and characteristics, study procedures, materials used in the research, potential risks to subjects, the process for recruitment and informed consent, and protection against risks. Provide assurance that the project will be reviewed and approved by an IRB, use a single IRB if the project is multicenter, and comply with HIPAA. NC TraCS pilot awards with investigators from multiple institutions will receive assistance from NC TraCS Regulatory Service in navigating through IRB and IACUC approvals pathways including making use of reliance agreements where possible. If vertebrate animals will be used, provide a description of the proposed use of the animals in the work outlined and procedures for ensuring that discomfort, distress, pain and injury will be limited. Provide assurance that the project will be reviewed and approved by an IACUC. Note that no funds will be released without the requisite approvals in place. (No page limit)

8. **NIH Biosketches** for the key members of the research team.

9. **Letters of Collaboration** (if applicable): Applications with a single PI who is **not** from one of the NC TraCS partner institutions (UNC-CH, NC A&T, RTI or NC State) must include a Letter of Collaboration from their NC TraCS partner institution faculty co-investigator. In addition, Letters of Collaboration may be included if they clearly state a commitment of resources required for the project’s success, for example biobank samples being made available to the investigator. Generic or non-specific letters of support are not required or encouraged. (No page limit)

10. **Resubmission Summary** (if applicable): Resubmission applications should include a summary that details changes to the original application. Include the names of any NC TraCS advisors consulted for the resubmission. Applicants are limited to one resubmission per application. If an investigator substantially changes and improves an application following two unsuccessful NC TraCS pilot submissions, he/she should consult with an NC TraCS Research Navigator to determine whether the changes/improvements warrant submission as a new application. (3-page limit).

11. **NIH Summary Statement** (if applicable): Applications that reference an external grant review relevant to the research should include the complete grant Summary Statement.

**VIII. Budget Guidelines**

1. The pilot grant budget covers expenditures of up to $50,000 for a 12-month period. The budget period will begin when applicable IRB/IACUC documentation is provided to NC TraCS and the PI indicates everything is in place for the project to begin. If the PI is not ready to start within 4 months of notification of funding, NC TraCS reserves the right to withdraw the award. The expectation is that all funds will be expended by the end of the grant period. At the end of the 12-month project period, any unexpended funds will be retained by NC TraCS and/or returned to the matching entity.

2. Projects of all budget sizes are encouraged. Budget should be appropriately matched to the scope of the project.

3. For most projects, one budget for the total project should be submitted. The budgets should be combined into one PDF for uploading. Note the total budget should not exceed $50,000.

4. Pilot grant funds may be budgeted for (1) research support personnel, (2) use of NC TraCS services, including, where applicable, salary support for NC TraCS biostatisticians, biomedical informaticians or other experts, (3) travel necessary to perform the research, (4) equipment, research supplies and core lab costs, or (5) other purposes deemed necessary for the successful execution of the proposed project.

5. Pilot grant funds **may not be budgeted for** (1) salary support for the PI or faculty collaborators, (2) office supplies or communication costs, (3) meals or travel, including to conferences, except as required to collect
data, (4) UNC-CH IRB fees, (5) professional education or training, (6) manuscript preparation and submission, or (7) indirect costs.

6. Expenditures for services outside of UNC-CH will only be allowed if the equivalent service is not available in-house, and such an expenditure will require thorough justification.

IX. Other Guidelines

1. Prior to receiving funds, research involving human subjects must have appropriate approvals from the UNC-CH IRB, and research involving animals must have the appropriate IACUC approval. Either an IRB approval letter or an IRB response to a “Determination Whether Research or Similar Activities Require IRB Approval” must be submitted to NC TraCS. Human subjects or animal research must be reviewed in accordance with the university’s general assurances and HIPAA. In addition, if the research involves human subjects, 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. The NC TraCS Institute is funded through a CTSA grant from NIH’s National Center for Advancing Translational Sciences (NCATS). NCATS requires that they review and approve all NC TraCS pilot grants involving human subjects research prior to funds being released. If your application is funded and involves human subjects research, NC TraCS will require additional documentation to send to NCATS. NCATS generally completes their review in less than 30 days.

3. NC TraCS staff will work closely with funded projects throughout the grant period to monitor progress and provide assistance where necessary. A 6-month interim progress report and a final progress report are required. NC TraCS expects the PI to report the outcomes achieved due to the pilot award over the lifetime of the work, e.g., subsequent external funding, publications, presentations and patents, and to acknowledge NC TraCS research support where appropriate.

4. If an awardee leaves their position, they should contact NC TraCS to initiate close-out procedures.

X. Submission Instructions

Applications will be accepted only through the online system: Foundant. Applications are due by 5:00pm on the due date. After submitting the application, applicants will receive email confirmation that the application was received. Applicants will be notified by email within 9 weeks of the deadline whether their application has been selected for funding. Partner institutions may have internal submission approval processes that should be completed prior to the NC TraCS submission deadline.