Promoting Clinical Research in Southeastern NC
Request for Applications (RFA) – Deadline March 12, 2024

The **Research Advisory Council (RAC)** is an innovative, joint committee composed of research leaders from Novant Health, Novant Health New Hanover Regional Medical Center (NH-NHRMC), the University of North Carolina Health Care System (UNC Health), and the University of North Carolina at Chapel Hill School of Medicine (UNC SOM).

The RAC was established according to the Academic and Clinical Affiliation Agreement (Affiliation Agreement) implemented in connection with the Novant-NHRMC Asset Purchase Agreement. Tasked with providing opportunities for collaborative research, the RAC is sponsoring an annual pilot award project to support clinical research in the defined region through a lens of access, value, and health equity.

The RAC is focusing efforts on promoting clinical research to understand and improve relevant community health challenges such as cancer, heart disease, stroke, diabetes, primary care, COVID-19, women and children's health, substance use disorder and more. Awards will provide up to $50,000 in funding for a 12-month project period.

Note: Cancer investigators are particularly encouraged to develop collaborative projects in response to these RFAs. Cancer investigators interested in the March 2024 deadline should complete this brief form (pdf) and email Crystal.Walker@unchealth.unc.edu.

I. Purpose

Despite notable improvements gained because of technological advancements in medicine, there remains a need to advance medicine through clinical research. Historically, limited resources have been available to execute well-designed clinical trials or conduct impactful research in the community setting. While academic medical centers often have the requisite infrastructure to execute clinical trials effectively, community hospitals have generally lacked investigator support, research coordinators, data managers, software and other tools necessary to manage trials in an ethical, safe, quality and compliant manner, thereby limiting access to clinical research opportunities for patients in the region.

The purpose of this RFA is to build capacity and facilitate interventional clinical research for patients in the region. Other clinically directed research may also qualify as detailed below. We are seeking projects that can be initiated within 3 months of the award and have a strong potential to impact health through clinical research in the region. It is desirable that initial work might be expanded over time to inform subsequent grant applications to the NIH or other external funding agencies.

Examples of the types of projects appropriate for this RFA include, but are not limited to:

- Drug, device, surgical or other interventional studies
- Biobanking to promote basic and translational science activities
- Registries to better understand disease incidence, morbidity and mortality in the region
- Epidemiology

- Behavioral health interventions
- Health services research focused on improving clinical trial access and delivery in the region.
- Studies to develop methods to facilitate clinical trials in the region.

The highest impact projects would:

- Meaningfully address acute or chronic clinical needs in the local region
- Advance treatment options that lead to better health outcomes for patients
- Enhance access to clinical trials locally, minimizing the need to travel long distances to access trials
- Promote remote technologies to lessen patient burden of clinical trial participation (i.e., remote monitoring, local lab collection, e-consent, e-visits, virtual/telephonic follow-up, web-based PRO tools)
- Integrate back-office research support to reduce redundancy, increase efficiency (i.e. software, regulatory, IRB, DSMB, statistics, medical writer, grant support).

Projects should promote sustained partnerships between UNC SOM faculty investigators and local Novant Health New Hanover Regional Medical Center providers. Engagement in trial planning and execution across both the UNC and Novant Health systems is an important component. Applicants should consider relevant clinical research best practices including those of the FDA, ICH, OHRP, GCP, NIH clinical trial basics, clinicatrial.gov requirements and both UNC and local policies related to human subjects protections and clinical research.

II. Key Dates

Proposals Due	March 12, 2024
Review and Award Decision	Within 12 weeks of application deadline

III. Funding and PI Eligibility

This funding opportunity is supported by the financial commitment set forth in the Affiliation Agreement and approved by the Affiliation Executive Council.

Applications must:

(1) come from a collaborative team from Novant Health and UNC Chapel Hill with a minimum of one Co- Principal Investigator (Co-PI) from UNC SOM and one Co-PI from NH-NHRMC Novant Health Medical Group Coastal Region, and

(2) address relevant gaps in clinical trial opportunities in the coastal region defined as Bladen, Brunswick, Columbus, New Hanover and Pender counties, and

(3) include a brief letter (or email) of support from the relevant Novant Health service line or institute leader indicating general agreement with the proposed project.

Applications must identify one PI as the main contact PI with primary responsibility for the administrative aspects of the pilot award. Researchers eligible to serve as PI include permanent faculty whose appointments allow them to serve as PI on externally sponsored research projects and non-faculty such as research scientists and investigators who are eligible to apply for investigator- initiated awards and R01-level funding.

Study teams that involve residents, cross- disciplinary collaborations, and community partners are strongly encouraged. Consultation with a biostatistician in the project design and application process is recommended. No cost share ("match") is required.

IV. 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.

Primary review criterion includes (1) the likelihood for the pilot work to have a sustainable impact on patients or clinical research conduct in the targeted area, and (2) the potential to lead directly to a fundable external 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 sustainability or follow-on proposals for external funding following the pilot.

The following additional review criteria will also be considered:

1. Significance
2. Innovation
3. Existence of a genuine multidisciplinary team integral to the conduct of the research
4. Soundness of the proposed methods
5. Appropriateness of community/stakeholder engagement plan
6. Feasibility of accomplishing the stated project goals within the 12-month project period

V. Application Process

Applications must be submitted using the NC TraCS online grant portal. Once in the system scroll down to the section titled "Promoting Clinical Research in Southeastern NC" and click "Apply," or use the "quick search bar" at the top to search. 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 internal use (250 word maximum).
2. **Impact:** Briefly describe the likelihood for your project to exert a sustained, powerful influence on the research field(s) involved (50 word maximum).
3. **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)

4. **Cited References**: (No page limit)
5. **Budget**: Use PHS 398 Form Page 4 (see Section VIII "Budget Guidelines" below for more details). The total budget should not exceed $50,000.
6. **Budget Justification**: Include sufficient detail for reviewers to assess whether appropriate resources have been requested (see "Budget Guidelines" below). (No page limit)
7. **Timeline**: covering the 12-month funding period.
8. **Human Subjects:** Although Institutional Review Board (IRB) is not required at time of submission, the application should briefly describe any human 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 when possible, and comply with HIPAA. Consult with your local IRB in advance as an IRB reliance agreement may be needed to use a single IRB. Note that no funds will be released without the requisite approvals in place. (No page limit)
9. **NIH Biosketches or CVs:** for the key members of the research team.
10. **Letters of Collaboration:** A brief letter (or email) of support from the relevant Novant Health service line or institute leader indicating general agreement with the proposed project is required. Additional 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)
11. **Resubmission Summary** (if applicable): Resubmission applications should include a summary that details changes to the original application. *Applicants are limited to two submissions (an original submission and one resubmission) per application*. *The Resubmission Summary is limited* to 1-page, with 1.5 line spacing, 1-inch margins, and font no smaller than Arial 11.

VI. 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 documentation is provided, applicable contracts are fully executed (e.g. Data Use Agreement), 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, the RAC reserves the right to withdraw the award.
2. All funds should be expended by the end of the grant period. A request for carryover may be granted if reasonable to meet project needs.
3. Projects of all budget sizes up to $50,000 are encouraged. Budget should be appropriately matched to the scope of the project and divided evenly across organizations as much as possible.
4. Pilot grant funds may be budgeted for (1) research support personnel, (2) travel necessary to perform the research, (3) equipment, research supplies and core lab costs, (4) 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, Co-PI or faculty collaborators, (2) office supplies or communication costs, (3) meals or travel, including to conferences, except as required to collect data, (4) IRB fees,

(5) professional education or training, (6) manuscript preparation and submission, or (7) indirect costs.

VII. Other Guidelines

1. Prior to receiving funds, research involving human subjects must have appropriate approvals from the IRB of record. 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 research must be reviewed in accordance with the organization'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 RAC will work closely with funded projects throughout the grant period to monitor progress and provide assistance where necessary. Three-month interim progress reports and a final progress report are required. The PI must report the outcomes achieved due to the pilot award over the lifetime of the work, e.g., subsequent external funding, publications, presentations, and patents.
3. If an awardee leaves their position, they should notify the RAC for initiation of close out procedures.

VIII. Submission Instructions

Applications will be accepted only through the NC TraCS Institute online grant portal. 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 12 weeks of the deadline whether their application has been selected for funding. For further assistance, please contact Crystal Walker - Crystal.Walker@unchealth.unc.edu