Novant-UNC Research Capacity Building Grants

Request for Applications (RFA) – Deadline December 7, 2024, 11:59 PM EST

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 has sponsored several annual pilot award projects to support clinical research in the defined region through a lens of access, value, and health equity.

With an explicit focus on building sustainable and high impact research teams focused on Coastal health concerns and populations, the RAC established the "Research Capacity Building Grants" of up to $500,000 total expenditures over 2-3 years.
Note for the purposes of this document the terms "Coast" and "Coastal" refer to five North Carolina counties: New Hanover, Bladen, Brunswick, Columbus and Pender.

The aim of the UNC/NH-NHRMC partnership is to foster collaboration and the development of research between both institutions. As such, there is an expectation that RAC funding supports meaningful research focused on the 5-county service area in coastal Southeastern NC. RAC-funded grants must be co-led by co-principal investigators from both organizations with an expectation that the research be impactful to patients in the coastal region. Ideally, your project focuses on coastal populations; however, we understand that there may be broad applicability statewide and beyond. With that in mind, we require investigators to recruit at least half of the research subjects from the coastal region. Applicants must describe their recruitment plan or relevant data sources to show a preference for coastal NC participation and impact. If the project is funded by RAC, and enrollment or data resources to support coastal impact are insufficient, funding and in-kind support from the RAC will be paused until the issues are resolved.

The methods, processes, experiences and data generated by these grants should enable future proposals to external funding agencies. Such proposals should be submitted through a UNC School of Medicine Department or Center, or if initiated through Novant Health, through appropriate research and medical group channels.

For assistance with this funding opportunity, including assistance in identifying collaborators please contact Crystal Walker - Crystal.Walker@unchealth.unc.edu

I. Purpose

Despite notable improvements gained through technological advancements in medicine, there remains a need to advance medicine and improve health outcomes through clinical research with a greater focus on reducing health disparities and promoting health equity. 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 and health equity focused research effectively, community hospitals and clinics have generally lacked investigator support,

research coordinators, data managers, software and other tools necessary to manage such studies in an ethical, safe, quality and compliant manner, thereby limiting access to research opportunities for patients in the region. Through the partnership, the RAC aims to mitigate these barriers for investigators and participants in the Coastal region.

The purpose of this RFA is to build capacity and facilitate human subjects research in the Coastal region. We are seeking projects that can be initiated within 3 months of award and have a strong potential to impact the health of the Coastal community. It is desirable that the Research Capacity Building Grants should leave a legacy of a vibrant sustainable research program at the Coast and explicit description of how that vision will be achieved is a requirement for a successful application.

The Novant-UNC partnership in Wilmington presents the opportunity for synergistic collaboration of one of the country's premier research universities with a large integrated health care system in a unique community with substantial health challenges. To build partnerships to facilitate capacity for clinical and health equity focused research in the Wilmington area, we encourage engagement of UNC investigators with clinical programs interested in participation in research at the coast. These "Research Capacity Building Grants," with up to $500,000 total expenditures over 2-3 years, will attract the attention of both clinicians and investigators in Chapel Hill and the coast. Ideas that might be responsive to such an RFA might include:

- The opportunity to further develop the pediatric research program at the UNC practice in Wilmington and NHRMC.
- The opportunity to develop a research program in association with the recently opened dedicated stroke unit.
- The desire to conduct a large interventional study in oncology at the coast to address barriers to routine collaboration and demonstrate the value of UNC-coastal collaboration to stakeholders.
- Developing a research ready network of clinical practice sites at the coast that can be quickly engaged in available research grants and contracts, such as PCORI funding opportunities.
- Partnering with the Michael Jordan Family Clinic to address health concerns of the population served.

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 research support from NHRMC and UNC to reduce redundancy, increase efficiency (i.e., software, regulatory, IRB, DSMB, statistics, medical writer, grant support).

Projects should promote a sustainable research team and sustainable research effort at the Coast and partnership between UNC SOM faculty and 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/Novant Health and local policies related to human subjects protections and clinical research.

II. Key Dates

Proposals Due	December 7, 2024, 11:59 PM EST
Review and Award Decision	Within 12 weeks of application deadline

III. Funding and PI Eligibility

This funding opportunity is supported from the financial commitment set forth in the Affiliation Agreement and approved by the Affiliation Executive Committee.
Applications must:

- 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; (or other local investigator approved in advance by NH-NHRMC coastal region leadership);
- address relevant gaps in research capacity and clinical needs in the coastal region defined as New Hanover, Bladen, Brunswick, Columbus and Pender counties;
- contain a clear statement of vision, deliverables, timelines and quarterly milestones to move a human subjects research program towards a successful self-sustaining program with substantial enrollment of participants. Milestones will be tracked and programs that encounter substantial difficulties or delays may be terminated based on the judgement of the RAC;
- leave a high-impact, self-sustaining research program at the coast;
- incorporate formal feasibility assessment (e.g., adequate staff, financial resources, participant availability, equipment, facilities as well as a regulatory path) through the Novant Health - NHRMC Research Office and the UNC Clinical Research Office; [Please note that these letters may identify barriers to successful completion of the project which can be addressed in the research plan.]
- include a formal letter of support from the relevant UNC and Novant Health service line or facility leader indicating general agreement with the proposed project;
- include a letter of support from administrative leaders responsible for the facilities, personnel and committed cost share (as applicable) involved in the proposal;
- provide a detailed budget and justification -- projects which will require ongoing programmatic support beyond the funding period of the award from Novant Health, UNC or the partnership cannot be supported through this mechanism;
- provide a sustainability plan documenting how the program will be sustained or grow after the period of support is completed;
- suggest at least one potential reviewer for the proposal qualified by both relevant clinical and research experience and residing or employed in the five county Coastal region – avoiding conflicts of interests defined by direct reporting

relationships or recent (5 year) collaboration in the form of publications or grant submissions.

*The UNC co-principal investigator must have a documented primary appointment in the UNC SOM. Participation of co-investigators from other schools at UNC is encouraged.

Applications must identify one PI as the main contact PI with primary responsibility for the administrative aspects of the 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.

Investigators may want to engage resources and services from the NC Translational and Clinical Sciences Institute (TraCS) in preparation of applications. These resources are broadly applicable and include expertise in biostatistics, regulatory affairs, community engagement, recruitment and others as detailed in the website, To receive in depth consultation may require 2-3 months, so teams will need to plan appropriately. If TraCS resources/services are required for the conduct of the study, if funded, a budget and letter of support should be requested from the service/resource manager.

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 work to have a sustainable impact on patients and clinical or health equity 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 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 program is required. It is strongly encouraged that the proposal includes specific plans regarding sustainability or follow-on proposals for external funding following the completion of the project.

Optimal projects would align with one or more of the goals of the Novant Health-UNC affiliation: access, equity, talent and value.

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 24-month project period and appropriate and significant milestones
7. Appropriate framing and methods to ensure that the research will promote health equity and reduce health disparities

V. Application Process

Applications must be submitted using the NC TraCS online grant portal. Once in the system scroll down to the section titled "Novant-UNC Research Capacity Building Grants" 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 (100 word maximum).

3. **Research Plan:** The Research Plan should include Specific Aims, Significance, Innovation, and Approach.
   a) For studies enrolling human subjects, include engagement and recruitment plans either in this section or in the Human Subjects section (#8 below). There is an expectation that RAC funding supports meaningful research focused on the 5-county service area in coastal Southeastern NC. We understand that there may be broad applicability statewide and beyond. Nevertheless, we require investigators to recruit at least half of research subjects from the coastal region. Applicants must describe their recruitment plan or relevant data sources to show a preference for coastal NC participation and impact. If the project is funded by RAC, and enrollment or data resources to support coastal impact are insufficient, funding and in-kind support from the RAC will be paused until the issues are resolved.
   b) Include, where applicable, clear evidence of how the application meets the review criteria.
   c) Formatting requirements: 1.5 line spacing, font Arial 11 pt., and 1-inch margins all around. (10-page limit, including tables and figures. References do not count towards the page limit).
4. **Response to previous Review**: If you previously submitted an application to the RAC Research Capacity Building Program, outline how the revised application addresses reviewer critiques. (2 pages maximum).

5. **Cited References** (No page limit).

6. **Budget**: Use PHS 398 Form Page 4 and Form Page 5 which can be accessed here. See Section VI "Budget Guidelines" below for more details. The total budget should not exceed $500,000 over two years.

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

8. **Timeline**: Describe key activities and milestones for the 24-36 month funding period. This should include quarterly milestones. Go/no-go decision points for critical milestones are highly recommended. (2 pages maximum)

9. **Sustainability Plan:** Describe in detail how the project will provide for collaborations, processes, resources and/or facilities that will support and reduce barriers to human subjects research at the Coast. The plan should provide a clear vision and potential resources to sustain research efforts beyond the period of funding. (2 pages maximum)

10. **Health Equity Plan:** Describe how the methods and processes developed and investigations proposed will reduces the inequities often present in human subjects research programs and how the proposed effort will promote equitable health care delivery and reduce disparities in health outcomes. (2 page maximum)

11. **Human Subjects**: Although Institutional Review Board (IRB) approval 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. Description of efforts to ensure inclusive research practices and enrollment reflective of the population affected by the conditions investigated in the region is required. 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)

12. **NIH Biosketches or CVs:** for the key members of the research team.

13. **Letters of Collaboration/Support:** Four brief letters of support are required:
- from the relevant Novant Health service line or institute leader indicating agreement with the proposed project.
- formal feasibility assessment through the Novant Health - NHRMC Research Office;
- formal feasibility assessment from the UNC Clinical Research Office;
- include a letter of support from administrative leaders responsible for the facilities, personnel and committed cost share (as relevant) involved in the proposal.

[Please note that these letters may identify barriers to successful completion of the project which can be addressed in the research plan.]

Additional Letters of Collaboration/Support may be included if they clearly state a commitment of resources or effort 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 encouraged. (No page limit; letters must be combined into 1 pdf for upload).

VI. Budget Guidelines

1. The capacity building grant budget covers expenditures of up to $500,000 for a 24-month period. The budget period will begin when applicable IRB review documentation is provided, applicable contracts are fully executed (e.g., Data Use Agreement), and the Co-PIs provide documentation that 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 for up to 12 months.

3. Projects of all budget sizes up to $500,000 are encouraged. Budget should be appropriately matched to the scope of the project and divided evenly across organizations as possible.

4. Capacity building 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. Grant funds **may not be budgeted for**

a) office supplies or communication costs,
b) meals or travel, including to conferences, except as required to collect data,
c) IRB fees,
d) professional education or training,
e) manuscript preparation and submission (other than journal publication fees up to $5000), or
f) 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 both organizations' 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. A RAC Project Manager 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 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.
    a) Apply to RAC to transfer responsibilities to a similarly qualified investigator at the institution or
    b) Close the study if the study cannot be completed without a replacement co-PI.

4. The methods, processes, experiences and data generated by these grants should enable future proposals to external funding agencies. Such proposals should be submitted through a UNC School of Medicine Department or Center, or if initiating through Novant Health, through appropriate research and medical group channels.

VIII. Submission Instructions

Applications will be accepted only through the NC TraCS Institute online grant portal. Applications are due by 11:59 PM on the due date (December 7, 2024). 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 assistance with the application submission system please contact Mary Beth Cassely – mbcassely@med.unc.edu.

For assistance with this funding opportunity please contact Crystal Walker - Crystal.Walker@unchealth.unc.edu