Research Collaborations with the Wake Forest NCORP Research Base

We welcome partnerships with investigators interested in multi-site clinical research through the NCI Community Oncology Research Program (NCORP). Many of our studies have extramural funding to support investigator time and research costs, but this is not required; the Wake Forest Research Base (RB) internally funds studies as well. While a substantial amount of lead-time is required to open studies through this research network, the large number of sites, robust infrastructure, and central IRB result in substantial efficiencies after study activation. The Wake Forest NCORP Research Base does not charge investigators for services; however, investigators with extramural funding are encouraged to reinvest in the infrastructure when possible.

Extramural Funding

It generally takes several months to acquire all of the necessary approvals for a grant submission that proposes to use NCORP resources. All submissions, including resubmissions, must undergo ESC and NCI review prior to grant submission. PIs are encouraged to contact the Wake Forest NCORP Research Base as early as possible in the grant planning process. It is generally not possible to complete this process if it begins less than three months prior to submission. Prior studies have received support from the NCI, NHLBI, ACS, and DOD. Non-NIH funders (e.g., ACS, DOD) may have some additional review steps.

For NIH proposals:

Steps		Materials Needed	Description	Meeting Schedule
1	Notify WF NCORP	Email + draft specific aims or abstract, if available	Email ncorp@wakehealth.edu; NCORP PIs will assign to a committee, identify a NCORP lead and biostatistician if necessary. The prospectus template can found on WF NCORP website.	
2	Committee Review (Cancer Control or CCDR)	NCORP prospectus or draft specific aims + study schema	Investigators will present (10-15 min with power point slides) to the committee and receive feedback on proposal	Last Tues of the month, 10-11am ET (CCDR)
3	Executive Steering Committee (ESC) Approval	NCORP prospectus or draft specific aims, study schema + study activities responsibilities description	Investigators will present (10-15 min with power point slides), with time for questions and discussion	1st Wed of the month, 3-5pm ET
4	NCI Approval	NCORP prospectus or draft specific aims, study schema + study activities responsibilities description	A research base PI will request NCI approval to submit the grant. This approval process often requires a meeting and may take several weeks.	
5	Other materials	The WF NCORP team will provide a letter of support for the RB PIs and solicit letters of support from NCORP community sites. Additional text is available for facilities and other grant sections. Preliminary data can be provided from prior studies, Landscape assessments, and potentially collected from sites (if there is sufficient time).		

Grant personnel

- A Wake Forest NCORP RB biostatistician must be the primary biostatistician for the primary analysis (please see the Biostatistics Support Policy). This identified biostatistician should generally receive grant support.
- It is strongly recommended that a faculty member supported by the Wake Forest NCORP Research Base (member of ESC or a committee) serves as a co-investigator on the grant to act as a central liaison to the NCORP team and to guide NCORP-related study approval, protocol development, and site recruitment activities.
- Please discuss support for other NCORP staff (site coordination, regulatory, etc) with the NCORP PIs.

Non-Funded Proposals: The Wake Forest NCORP Research Base internally funds a select number of proposals. Steps 1 – 3 from above are still followed. Once ESC has approved the prospectus, steps 4 & 5 are as follows:

4	Concept Development	A 6 page concept following the NCI guidelines will be developed with support from the Wake Forest RB team. The Wake Forest RB will submit the approved concept to the NCI Cancer Control or CCDR Steering Committee.		
5	NCI Approval	NCORP concept	Investigators will present and respond to critiques (5-10 min with power point slides) from the committee. Successful concepts typically undergo two rounds of review prior to approval.	These committees meeting monthly.

Estimated timelines to open a study within NCORP:

It takes approximately one year for studies to be open to accruals within NCORP. A full protocol (including all forms and consents) must be submitted to the NCI within 90 days of receipt of a notice of award or approval of a concept by an NCI Steering Committee. NCI and CIRB protocol review generally take 4-6 months. The Wake Forest Research Base generally activates studies within 45-60 days of NCI approval.

Please find the Brief Study Proposal Template on the next page.

Wake Forest NCORP Research Base Brief Study Proposal Template

1. Title Page
    - Title of Study
    - Date of Document
    - Principal Investigator (Institution), Co-investigators (Institutions)
    - PI's address, phone, fax and email address
    - PI Research Base affiliation (if any)
    - **Cancer Control** or **Cancer Care Delivery Research** (circle one)
      NCORP definitions available here: https://ncorp.cancer.gov/research/
2. Schema: one-page diagram providing an overview of the study design. It should include (if available): Sample size, Study population, Stratification factors, Study design (randomization, case control, observational), Specific intervention (if applicable), and Data collection timepoints
3. Study rationale (1-2 paragraphs)
4. How study will further science in cancer prevention or significance of study for clinical practice or future research (1 paragraph)
5. Primary and secondary study objectives
6. Primary and secondary outcomes
7. Brief description of eligibility or targeted population
8. Funding obtained or being pursued for study, if any

Study proposals should be no more than 2 pages in length and submitted to the Wake Forest NCORP Research Base via NCORP@wakehealth.edu.