

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 NCORP Research Base (WF NCORP 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 WF NCORP RB 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 either Cancer Control Committee (CC) or Cancer Care Delivery Research Committee (CCDR) review along with ESC and NCI review prior to grant submission. PIs are encouraged to contact the WF NCORP RB 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 RB	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.	
2	Committee Review (Cancer Control or CCDR)	WF NCORP RB proposal* + study schema *The proposal template can be found on WF NCORP RB website. https://wakencorp.phs.wakehealth.edu/	Investigators will present (10-15 min with power point slides) to the committee and receive feedback on proposal	2 nd Friday of the month, 12pm-1pm EST (CCDR) 4 th Monday of the month, 4pm – 5pm EST (CC)
3	Executive Steering Committee (ESC) Approval	NCORP proposal, study schema + study activities responsibilities description	Committee Chairs will present (10-15 min with power point slides), with time for questions and discussion	1st Wed of the month, 4-5pm EST
4	NCI Approval	NCORP proposal, study schema + study activities responsibilities description	A WF NCORP RB PI will request NCI approval to submit the grant. <u>This approval process often requires a meeting and may take several weeks.</u>	
5	Other materials	The WF NCORP RB 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 WF 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 WF NCORP RB (member of ESC or a committee) serves as a co-investigator on the grant to act as a central liaison to the WF NCORP RB team and to guide NCORP-related study approval, protocol development, and site recruitment activities.
- Please discuss support for other WF NCORP RB staff (site coordination, regulatory, etc) with the RB 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 proposal, steps 4 & 5 are as follows:

4	Concept Development	A 10-page concept following the NCI guidelines will be developed with support from the WF NCORP RB team. The WF NCORP RB will submit the approved concept to the NCI Symptom Management or CCDR Steering Committee.		
5	NCI Approval	NCORP concept	Investigators will present and respond to critiques (5-10 min with PowerPoint slides) from the committee. Successful concepts typically undergo two rounds of review prior to approval.	These committees meet 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 NCI CIRB protocol review generally take 6-8 months. The WF NCORP RB generally activates studies within 60-75 days of NCI and NCI CIRB approval.

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 Wake Forest NCORP Research Base via NCORP@wakehealth.edu.