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, generally undergo Cancer Control or Cancer Care Delivery Research committee review and must undergo Executive Steering Committee (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 four months prior to planned 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 an NCORP lead and biostatistician if necessary. The proposal template can be found on the WF NCORP website.	
2	Committee Review (Cancer Control or CCDR)	NCORP proposal or draft specific aims + study schema (see proposal template)	Investigators will present (10-15 min with slides) to the committee and receive feedback on proposal	Monthly
3	Executive Steering Committee (ESC) Approval	NCORP proposal or draft specific aims, study schema + study activities responsibilities description	WF NCORP Scientific Committee chairs will present the results of the Committee review to the ESC; the presence of study PIs may be requested to answer questions	Monthly
4	NCI Approval	NCORP proposal or draft specific aims, study schema + study activities responsibilities description & budget outline	A research base PI will request NCI approval to submit the grant. A meeting with the NCI needs to take place at least 4 weeks prior to the grant due date and several documents will need to be provided at least a week before the meeting (see details below).	
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 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 when working on grant-funded projects.
- It is strongly recommended that a faculty member supported by the Wake Forest NCORP Research Base (member of ESC or a committee) serve 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, data management, etc) with the NCORP PIs and Administrator.

Materials required for NCI Review

1. Specific Aims and Schema, including a description of the rationale for the study, proposed study population and primary endpoint, and assessment of feasibility in NCORP (two pages maximum)
2. Study Timeline/Milestones (following requirements in the NOFO or RFA for which they a are responding)
3. Description of potential scientific overlap with ongoing or planned NCORP studies (Wake Forest NCORP Research Base will provide this)
4. Budget Mock-Up, Overall and by Year (Excel spreadsheet or Word table)
5. Notice of Funding Opportunity (NOFO), Request for Applications (RFA) or other funding announcements to which the grant will be submitted.

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 Wake Forest NCORP RB team. The Wake Forest NCORP RB will submit the approved concept to the NCI Symptom Management and Health-Related Quality of Life 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 meet monthly.

Estimated timelines to open a study within NCORP:

It takes approximately one year from the grant award or concept approval for studies to 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 6-8 months. The Wake Forest Research Base generally activates studies within 60-90 days of NCI approval. In accordance with these timelines, we generally will not consider sponsoring a study with a planned duration of less than 3 years.