



STUDY MATTERS

October 27, 2022

Wake NCORP Website: <https://wakencorp.phs.wakehealth.edu/>

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Wake Forest NCORP Research Base Annual Meeting

Many thanks to the 110 in person attendees as well as the 131 who attended virtually to make our 9th annual meeting in Myrtle Beach a great success!





***We hope to see everyone in person next year
October 2-3, 2023 in Asheville, NC!***

OPEN CALL FOR COMMITTEE MEMBERS

FINAL CALL- Action Needed by October 31

The Wake Forest NCORP Research Base is soliciting applications for NCORP Community/ M/U Community Site representatives for the Cancer Control and Cancer Care Delivery Research (CCDR) Scientific Committees and the Health Equity Core Committee.

Community site representation on all committees is being expanded. Responsibilities for members will include:

- Attend committee meetings (monthly for the scientific committees and quarterly for the Health Equity Core)
- Provide feedback about studies early and throughout the study lifecycle to improve feasibility and alignment of studies with community site priorities and provide feedback on implementation challenges
- Provide scientific/feasibility/equity review of new concepts/protocols
- Oversee active studies, including minority/underserved accrual progress

- Periodically review and make recommendations about committee priorities and activities
- Act as a liaison between NCORP community sites/investigators and the Wake Forest NCORP Research Base

We are looking for committee members who bring diversity with regards to their expertise, service within NCORP (PIs or scientific leaders, CRAs, research nursing, and Administrators), and background and populations engaged. Interested individuals should apply using the REDCap link below. The application will include a brief statement (5-10 sentences) on your prior involvement with the Wake Forest NCORP Research Base, experience with cancer control, cancer care delivery research, and/or health equity research, interest in committee service, and contributions to the diversity of the committee. You will also be asked to upload a CV or biosketch. The initial committee term will be 2 years. **The due date to apply is October 31, 2022.** Selection of committee members will take place in November and committees will begin meetings in January 2023.

Click here to

apply: <https://redcap.wakehealth.edu/redcapccc/surveys/?s=PYEDAF7EFY78J773>

**Wake Forest NCI Community Oncology Research Program
Research Base (WF NCORP RB)
Clinical Trials Boot Camp
Call for Applications**

Deadline: Friday, December 2nd, 2022 by 12pm EST

Overview: This 2.5-day Wake Forest NCI Community Oncology Research Program Research Base (WF NCORP RB) clinical trials boot camp will be held February 6 – 8, 2023 in Winston-Salem, NC. Each applicant will submit a basic trial concept (2-page max) for a Cancer Control or Cancer Care Delivery Research (CCDR) study suitable for community oncology to be fully developed during the boot camp. Protocols that are largely written before boot camp are likely not appropriate. Modeled after the AACR/ASCO Methods in Cancer Clinical Research workshop and WF Comprehensive Cancer Center boot camp for therapeutic oncology trials, the program will offer didactics related to clinical trial design, NCORP operations, feasibility and approval processes, recruitment of diverse populations, and biostatistical considerations. Lectures and discussions on how to develop protocols for inclusive and broad patient representation and participation will be led by leadership of the WF NCORP RB Health Equity Core. Boot camp lectures are mixed with intensive mentoring and feedback sessions from experienced NCORP investigators; active group participation through questions and feedback to others is expected of all participants. Additional information about the Wake Forest NCORP Research Base is available at <https://wakencorp.phs.wakehealth.edu>.

Accepted participants will work with a mentoring team comprised of boot camp faculty with expertise in clinical care, cancer care delivery and implementation science, biostatistics and study design, and research and patient advocate perspectives. Additional mentors will be incorporated as needed to meet trainee needs, i.e., radiation or surgical oncology, hematology, adolescent, and young adult (AYA) research, etc. WF NCORP RB research staff will provide additional perspectives on feasibility and multi-site implementation.

The desired outcome of the 2.5 day in-person boot camp is a final study concept ready for development into a grant or full NCORP concept proposal to submit to the NCI Cancer Control or Cancer Care Delivery Research Steering Committee. Participating mentors have extensive experience developing NCI concepts and NIH (National Institutes of Health) grants for NCORP studies and will work with each participant to decide if additional pilot data may be needed to support the concept. If so, mentors will assist in developing a plan and budget for pilot activities.

Following boot camp, participants will meet monthly with mentors and peers to develop the desired final product (NCORP study concept for Steering Committee review or NIH grant). Participants will attend and present their concepts at the WF NCORP RB Annual Meeting October 2 – 3, 2023 in Asheville, NC as the culminating experience. At the annual meeting, boot camp participants will network with national NCORP leaders,

receive feedback on their study concept from NCORP investigators, clinical research staff, and clinicians, and learn more about additional career development opportunities through this national research network.

Eligibility:

1. Doctorally trained in any oncology specialty, including medical, surgical, radiation, gynecologic, and pediatric oncology, or faculty from other departments conducting cancer clinical research. Senior fellows may also apply (letter of support from current faculty mentor for fellow applicants strongly encouraged).
 - Prioritization will be given to those new investigators (i.e., have not previously been a PI (Principal Investigator) or study chair for a WF NCORP RB study) who self-identify as members of groups underrepresented in the biomedical research enterprise (e.g., certain racial/ethnic groups, persons with disabilities, students from disadvantaged backgrounds, women, and other groups as described in the NIH Notice of Interest in Diversity) from academic institutions and/or NCORP Community and M/U Community sites.
2. The concept must focus on Cancer Control or Cancer Care Delivery Research; oncology treatment trials will not be responsive. Concepts proposing an interventional trial well-aligned with WF NCORP priorities that are feasible to open within the NCORP community oncology network (<https://ncorp.cancer.gov/about/>) are strongly encouraged. When appropriate, concepts are encouraged to include biological mechanisms, correlative science, and a focus on underserved patient populations. Priorities include:
 - Cancer Control
 - Cardiovascular complications of cancer therapy
 - Neurocognitive complications of cancer therapy
 - Additional cancer and treatment-related symptoms (e.g., fatigue, pain) and related outcomes and supportive care interventions
 - Cancer Care Delivery Research
 - Delivery of comprehensive survivorship care
 - Integrating informal or familial caregivers into cancer care
 - Integration of evidence-based care in cancer care settings

Funding: WF NCORP RB will pay for participant expenses and travel to the boot camp in Winston-Salem, provide pilot funds to collect needed pilot feasibility data (where applicable), and to attend and present their concepts at the WF NCORP RB Annual Meeting in Asheville, NC.

Additional Information: Please contact WF NCORP RB at NCORP@wakehealth.edu for more information.

Deadline: Please complete application and upload CV using this link: <https://redcap.link/enup3qd0> by **12pm EST on Friday, December 2nd, 2022.**



For Funding Opportunities Announcements Relevant to NCORP CCDR, click on this link:

<https://healthcaredelivery.cancer.gov/funding/opportunities.html>

Upcoming Site Calls

If you would like to attend one of these calls, but did not receive an invitation, please email NCORP@wakehealth.edu

Click the button below the meeting to add it to your Outlook Calendar

****Please note that your calendar may not update automatically if changes are made.
Please check these emails and our website for meeting updates.****

You can also join site calls from our [Wake NCORP website](#). Click the call in the "Upcoming Events" section on the Home page or through the Calendar.

WF1901-IMPACTS - Internet-delivered Management of Pain Among Cancer Treatment Survivors

November 9, 2022 at 2:30pm EDT. Please update your calendars.

[Click to add this WF1901-IMPACTS meeting to your calendar](#)

WF1802- PCW - Influence of Primary Treatment for Prostate Cancer on Work Experience

November 15, 2022 at 1:30pm EDT. Please update your calendars.

Click to add this WF1802-PCW meeting to your calendar

WF1805CD- HN-STAR - Implementation and Effectiveness Trial of HN-STAR

November 16, 2022 at 3:00pm EDT. Please update your calendars.

Click to add this WF1805CD-HN-STAR meeting to your calendar

WF1804CD- AH-HA - Assessing Effectiveness and Implementation of an EHR Tool to Assess Heart Health Among Survivors

November 17, 2022 at 11:30am EDT. These meetings will now be 30 minutes. Please update your calendars.

Click to add this WF1804CD-AH-HA meeting to your calendar

New Wake Forest NCORP Research Base Website

Please visit and register on our new Wake Forest NCORP Research Base website

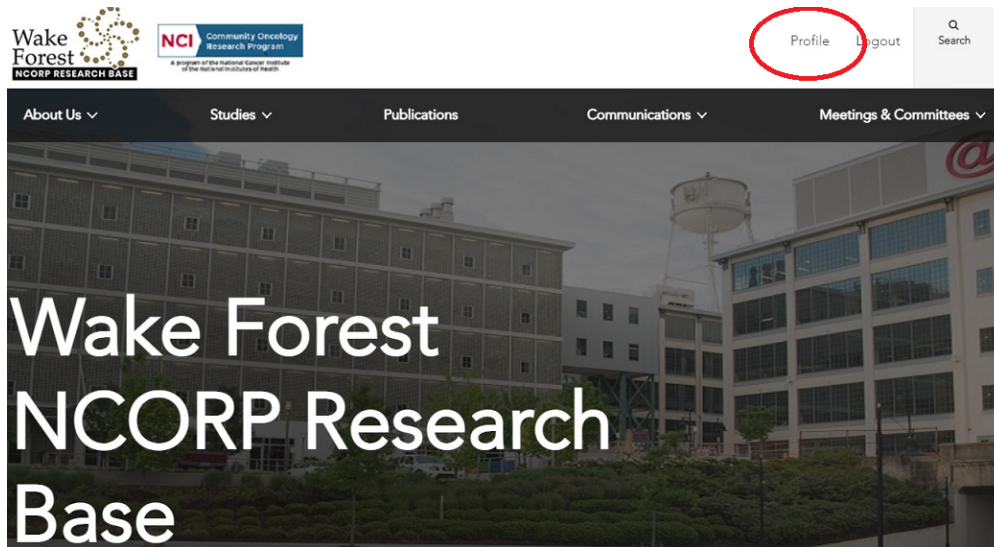
<https://wakencorp.phs.wakehealth.edu/>

Registering for an account will allow you to:

- Join site calls and other meetings from the Upcoming Events or Calendar sections
- Access study training materials
- View previous study meetings

- Download important study documents including training videos, study guides, and neurocognitive CRFs

Once registered, you must update your user profile to sign up for study-specific mailing lists and meeting announcements, indicate your NCORP Community site, add your user roles, and update your GCP for database access.



Email Preferences

NCORP

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Studies

- ☒ WF01213-RELAX
- ☒ WF01414-NAVIGATOR
- ☒ WF10217-WAYS
- ☒ WF1801-RAMIPRIL
- ☒ WF1802-PCW
- ☒ WF1803CD-CAREGIVERS
- ☒ WF1804CD-AH-HA
- ☒ WF1805CD-HN-STAR
- ☒ WF1806-M&M
- ☒ WF1901-IMPACTS
- ☒ WF20817CD-OASIS
- ☒ WF30917CD-TELEHEALTH
- ☒ WF97115-ACUPUNCTURE
- ☒ WF97116-REMEMBER
- ☒ WF97415-UPBEAT
- ☒ WF98213-PREVENT

Roles

- ☒ CCDR Lead
- ☒ Investigator
- ☒ NCORP Administrator
- ☒ CRA
- ☒ Data Management
- ☒ Regulatory
- ☒ Operations Manager
- ☒ Quality Control

GCP certificate

Upload new certificate

No file chosen

Accepted file types: jpg, png, pdf, jpeg, Max. file size: 2 MB.

If you have any questions or need assistance with registration
please email NCORP@wakehealth.edu

Please email 7NCORP@wakehealth.edu when shipping biospecimen samples to the NCORP Research Base Biospecimens lab (Studies WF-97415, WF-1801, and WF-1901). Include the FEDEX tracking number in your email so that misplaced samples can be tracked before they spoil. Please ship by "FedEx Priority Overnight" (please change this on the pre-printed shipping label if this is not selected).

Study Updates

WF-1802 - PCW - Influence of Primary Treatment for Prostate Cancer on Work Experience

Three stratas are now full. The Higher Income AA stratum, Lower Income AA stratum and Higher income white stratum are now full. Please approach individuals from the lower income white strata that needs 27 more.

WF-1804CD - AH-HA - Assessing Effectiveness and Implementation of an EHR Tool to Assess Heart Health Among Survivors

AH-HA (WF-1804CD) Amendment 6, PVD 09/28/2022, Release Date 10/27/2022

The WF NCORP Research Base study titled *Assessing Effectiveness and Implementation of an EHR Tool to Assess Heart Health Among Survivors* (WF-1804CD) has been amended (Amendment 6, Protocol Version Date 09/28/2022). Protocol documents are available on the [CTSU](#) website. Site registration requirements are listed in Protocol Section 11 and additional onboarding requirements will be provided by the Wake Forest NCORP Research Base coordinating center during onboarding. Please note this is a CIRB approved protocol. Participating sites are required to submit to the CIRB as their IRB of record.

Changes associated with this amendment include:

- Updated eligibility/inclusion criteria to allow aromatase inhibitors with or without adjuvant CDK 4/6 inhibitors such as abemaciclib.
- Added the following question to the 6 month and 1 year surveys: "On average, how many hours of sleep do you get per night?"

Note: This is a limited participation protocol and we are no longer accepting new sites. If you have any questions, please send an email to NCORP@wakehealth.edu ; Attn: WF-1804CD.

WF-1805CD - HN-STAR - Implementation and Effectiveness Trial of HN-STAR

Congratulations to Montefiore Medical Center who just opened to enrollment October 19th! Excited to have you on board!

We appreciate all the interest in the HN-STAR study following our annual meeting! Just to clarify, there is no EHR integration involved with this study. We will provide each site a tablet to run the HN-STAR website. If you have any questions regarding this study or if your site is interested in participating, please email NCORP@wakehealth.edu.

WF-1901 - IMPACTS - Internet-delivered Management of Pain Among Cancer Treatment Survivors



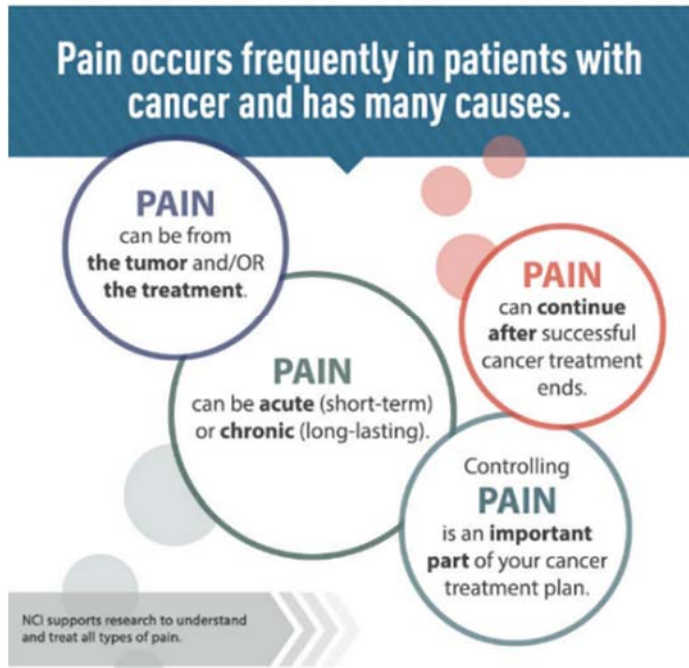
If you haven't gotten involved....Now is the time!

Welcome to the Ozarks sites in Missouri, Oklahoma and Arkansas along with MMORC sites in Maplewood Minnesota who just joined us!

We had a great response at our Annual Wake Forest NCORP Research Base Meeting.

A big THANK YOU to our NCI Leadership team for helping us get the word out!

<https://www.cancer.gov/about-cancer/treatment/clinical-trials/search/v?id=NCT04462302&r=1>



This is an important study which addresses PAIN in a novel way.

- Participants learn new methods for managing their own pain.
- Participants are not expected to stop taking their pain meds.
- Study is low burden for site coordinator and physician.
- Study is flexible with the option to do it all remotely.
- Participants who are randomized to the control arm of the study are invited to use the intervention on their own once they complete study.
- Participants receive a gift card at all 4 time-points.

Contact us at NCORP@wakehealth.edu for more information.

WF-97415 - UPBEAT - Understanding and Predicting Breast Cancer Events after Treatment

Please update the shipping address on all RT DICOM Image CDs to:

Dr. Greg Hundley (C/O Stacey Belton)
Wake Forest Health Sciences
Department of Internal Medicine/Cardiology
Medical Center Blvd.
Winston Salem, NC 27157-1045
Phone: (336) 713-7085

Email shipping information including date sent, method, and tracking number to NCORP@wakehealth.edu so we can ensure proper delivery.

If you would like to send these image files by file transfer or other method please contact Ricardo Peral (rperal@wakehealth.edu)

Accruals as of October 26, 2022

Open Studies	Name	Enrolled (Patients)	Target (Patients)	Enrolled (Non- Patients)	Target (Non- Patients)
WF-1801	RAMIPRIL	59	75		
WF-1802	PCW	228	255		
WF-1806	M&M	110	300		
WF-1901	IMPACTS	64	456	0	40
WF-1804CD	AH-HA	523	600	24	40
WF-1805CD	HN STAR	112	350	81	140

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