



## STUDY MATTERS

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November 10, 2022

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

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### Wake Forest NCORP RB Holiday Hours

Our office will be closed Thursday, November 24th and Friday, November 25th for the Thanksgiving holiday.

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### McKesson Holiday Hours

Clinical Research Services Closed November 24-25, 2022

In observance of the Thanksgiving holiday, McKesson's Clinical Research Services will be closed **Thursday, November 24, 2022 and Friday, November 25, 2022**. We will resume regular business hours on Monday, November 28, 2022.

Our regular business hours are Monday through Friday, 9 am to 6 pm ET.

Please take this information into consideration when placing your orders **prior to the Thanksgiving holiday**.

- Only non-refrigerated product will be shipped on **Wednesday, November 23**. Orders placed prior to 2 pm ET will be delivered on **Friday, November 25**.
- If refrigerated or temperature-controlled product is required before the holiday, orders must be placed by **Tuesday, November 22** prior to 2 pm ET.

Due to the influx of shipments around the holidays, carrier delays may occur. Please plan your orders accordingly.

If you have questions regarding the shipment schedule, please contact our Clinical Research Services team at 800.693.4906, or via email at [clinicalresearchservices@mckesson.com](mailto:clinicalresearchservices@mckesson.com).

We appreciate the opportunity to assist you and your patients.

Kind regards,

Clinical Research Services team

## Implementation Champions for CCDR

The Wake Forest NCORP Research Base and iDAPT will present a training for the NCORP network- "Implementation Champions for CCDR" on **November 15<sup>th</sup> from 4-5pm EST**. The training, led by Dr. Kristie Foley, will focus on identification of roles and qualities of successful study champions and strategies for building capacity to champion CCDR studies. Guided discussion will offer opportunities to share experiences across practices. Our target audience includes CCDR Leads, Key Administrators, Investigators, and Study Champions. Please register using the link below to obtain the webinar link.

**Click the link to register by 5 PM EST on November**

**14th:** [https://redcap.wakehealth.edu/redcapccc/surveys/?s=AF4F333YWJNCFYWX  
\[wakehealth.us19.list-manage.com\]](https://redcap.wakehealth.edu/redcapccc/surveys/?s=AF4F333YWJNCFYWX[wakehealth.us19.list-manage.com])

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

**Deadline: Friday, December 2<sup>nd</sup>, 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](mailto:NCORP@wakehealth.edu) for more information.

**Deadline: 12 PM EST on Friday, December 2nd, 2022**

Please complete application and upload CV using this link: <https://redcap.link/enup3qd0>



## Upcoming Site Calls

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

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

November 15, 2022 at 1:30pm EST. 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 EST. 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 17th meeting is cancelled. Please update your calendars.

### WF1801- Ramipril - A Single Arm, Pilot Study of Ramipril for Preventing Radiation-Induced Cognitive Decline in Glioblastoma (GBM) Patients Receiving Brain Radiotherapy

December 7, 2022 at 2:00pm EST. Please update your calendars.

[Click here to add this WF1801-RAMIPRIL meeting to your calendar](#)



WF1806- M&M - Myopenia and Mechanisms of Chemotherapy Toxicity in  
Older Adults with Colorectal Cancer

December 14, 2022 at 2:30pm EST. Please update your calendars.

[Click here to add this WF1806-M&M meeting to your calendar](#)

## **Wake Forest NCORP Research Base Website**

**Please visit and register on our 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.





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# Wake Forest NCORP Research Base

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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

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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](mailto:NCORP@wakehealth.edu)

Please email [7NCORP@wakehealth.edu](mailto: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).

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## Study Updates

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

**Three strata 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 stratum 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](mailto:NCORP@wakehealth.edu) ; Attn: WF-1804CD.

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

**Congratulations to MedStar Georgetown University Hospital (Lombardi Comprehensive Cancer Center) and MedStar Washington Hospital Center who just opened to enrollment November 7th! 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](mailto:NCORP@wakehealth.edu).

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

**WF-1901 IMPACTS – Additional Recruitment Resource - Physician to Physician referral letter (version 11.01.22) Now Available**

A physician referral letter was posted to our Wake Forest NCORP website <https://wakencorp.phs.wakehealth.edu/study/wf1901-impacts/> on 11/9/2022. This may be used to engage physicians in your network that could refer patients to your clinic for the IMPACTS study. Space is available to add your PI and study coordinator contact information. Look for it on the study specific page under Study Documents & Forms.

## WF-1901 (IMPACTS)

[Date]

Dear [Referring Physician],

I am writing to introduce you to **WF-1901 (IMPACTS): A parallel group randomized controlled, prospective study that examines the effect of an Internet-based PCST program on pain severity and pain interference among adult cancer survivors experiencing persistent cancer-related pain.** This study was activated on September 2020, and I am asking for your assistance enrolling patients from your practice.

Pain is one of the most common symptoms in cancer patients and is also one of the symptoms least likely to be adequately treated. Treatment guidelines state that patients should have access to behavioral pain interventions that educate them about pain and teach them skills for managing it. Pain Coping Skills Training (PCST) accomplishes these goals.

In addition to assessing the effectiveness of the internet delivered program; painTRAINER<sup>®</sup>, on pain severity and interference, IMPACTS will also explore the effects of painTRAINER<sup>®</sup> on opioid/analgesic medication use and health related quality of life when compared to the participants who are not receiving the painTRAINER<sup>®</sup> intervention.

Participants in the painTRAINER<sup>®</sup> arm will continue to receive their usual care provided by their own physician (as in the Enhanced Usual Care arm) and will receive access to the Internet-based painTRAINER<sup>®</sup> pain coping skills training program. Participants will receive printed educational materials addressing cancer pain and control and log-in instructions to access painTRAINER<sup>®</sup>. Participants will then complete the 8 painTRAINER<sup>®</sup> modules on their own (~one per week) led by the program's "virtual" coach.

Participants in the Enhanced Usual Care arm will also continue to receive their usual care provided by their own physician. They will receive printed educational materials addressing cancer pain and control. These participants will be invited to participate in the painTRAINER<sup>®</sup> program on their own following completion of all study procedures.

### Brief Study Participant Eligibility:

- Documented diagnosis of invasive cancer (Single modality therapy or any combination of surgery, radiation, and chemotherapy/drug therapy). Patients off treatment OR actively receiving anticancer therapy in an adjuvant setting, maintenance setting, or for active cancer that is felt to be stable and/or controlled and not rapidly progressive as per treating clinician
- If patient no longer receiving anticancer therapy must be  $\leq 5$  years since the completion of their anticancer therapy.
- Patients do not have to be on medications to participate. If taking analgesics, must be on a stable regimen (at least 14 days before enrollment).

*Note: Our study coordinator will screen for pain-related eligibility criteria upon referral.*

### For more information:

- ClinicalTrials.gov: <https://clinicaltrials.gov/ct2/show/NCT04462302>
- [Insert Local NCORP Site Contact Information]

Thank you for your time and interest. I would appreciate your support of this important trial.

Sincerely,

[Site Principal Investigator Name and Contact Information]



v.11.01.22

If there are any questions or if your site is interested in participating in this study, please contact [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu).

## 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](mailto: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](mailto:rperal@wakehealth.edu))

| 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      | 115                 | 300               |                         |                       |
| WF-1901      | IMPACTS  | 67                  | 456               | 0                       | 40                    |
| WF-1804CD    | AH-HA    | 533                 | 600               | 24                      | 40                    |
| WF-1805CD    | HN STAR  | 117                 | 350               | 81                      | 140                   |

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