



STUDY MATTERS

May 12, 2022

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

New Wake Forest NCORP Research Base Website

We are pleased to announce our new Wake Forest NCORP Research Base website

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

Please use this site to learn more about the Wake Forest NCORP Research Base, find out about upcoming meetings, and view important announcements.

You will need to register for a new account even if you had access to our previous site

Registering for an account will allow you to:

- Sign up for study-specific mailing lists

- Join site calls and other meetings from the Upcoming Events section
- Access study training materials
- View previous study meetings
- Download important study documents including training videos, study guides, and neurocognitive CRFs

Please click on the document link below to view registration instructions:

[Registration Instructions](#)

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

WF NCORP RB Quarterly Call

Has been rescheduled from May 11th
to June 15th at 4pm EDT

Please make the change to your calendar.

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

NCI Requirement: NCORP Program Site Level Attributes Survey for CCDR Studies

The enrolling affiliate/sub affiliate will complete the NCORP Program Site Level Attributes Survey and submit it to the CTSU Regulatory Office using the Regulatory Submission Portal located in the Regulatory section of the CTSU website. The form will collect various attributes about the enrolling affiliate/sub affiliate. All of the questions on the form must be complete and the distribution for the analytic cases question must equal 100%. (See form for directions). The form

must be received and complete for site registration approval in RSS. The NCORP Program Site Level Attributes Survey requirement is submitted once for participation on all NCORP CCDR trials, but will expire two years after it is received. NCORP sites will need to resubmit the NCORP Program Site Level Attributes Survey to the CTSU in order to continue to enroll to CCDR trials. Please refer to your protocol for details about this requirement.

#	Title	File Date	Format	Post D
1	Identity and Access Management (IAM) Registration Page	Not Applicable	Web Link	08-Sep-
2	Cancer Information Service (CIS)	Not Applicable	Web Link	05-Apr-
3	Cancer Therapy Evaluation Program (CTEP)	Not Applicable	Web Link	05-Apr-
4	Education and Training for Health Professionals	Not Applicable	Web Link	12-Nov-
5	NCI Community Oncology Research Program (NCORP) Information	Not Applicable	Web Link	06-Apr-
6	NCI Investigators Resources	Not Applicable	Web Link	23-Mar-
7	NCI Main Site (Cancer.gov)	Not Applicable	Web Link	05-Apr-
8	NCI's NCTN Guidelines	Not Applicable	Web Link	06-Apr-
9	NCI's Publications Locator	Not Applicable	Web Link	23-Mar-
10	NCORP Program Site Level Attributes Survey	21-Dec-2020	PDF	22-Dec-
11	NCORP Resource: HRSA List of Critical Access Hospitals as of 3/27/20	31-Mar-2020	EXCEL	08-Apr-
12	NCORP Resource: HRSA List of Rural Health Clinics as of 3/27/20	31-Mar-2020	EXCEL	08-Apr-
13	Protecting Human Research Participants Training	Not Applicable	Web Link	13-Feb-
14	Public Research Contact Information	03-Aug-2018	PDF	27-Sep-
15	Registration and Credentialing Repository (RCR)	Not Applicable	Web Link	08-Sep-

2022 Landscape Assessment

The 2022 Landscape Assessment is available to all NCORP sites through June 24th. We encourage all sites to roster and submit their data as soon as possible. For any questions about rostering or survey submissions, please email us at NCORP@wakehealth.edu. A PDF copy of the survey is available on the new Wake NCORP Website under Studies > Landscape > Study Documents & Forms.

Mark Your Calendar: CCDR Workshop

We invite all NCORP CCDR Leads and interested site investigators and staff to save the date for a half day CCDR workshop led by investigators from the iDAPT: Implementation and Informatics P50 Center. The focus will be on building capacity to participate in implementation science CCDR studies, including information on assessing your practice readiness and engaging stakeholders. The in-person workshop will be immediately following the Wake Forest NCORP Research Base Annual Meeting on the morning of October 12th. Interested participants can email NCORP@wakehealth.edu to indicate their preliminary interest and receive more information when available.

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

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

Upcoming Site Calls

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

May 17, 2022 at 1:30pm EDT

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

May 18, 2022 at 3:00pm EDT

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

May 19, 2022 at 11:30am EDT

WF-1801 - Ramipril - A Single Arm, Pilot Study of Ramipril for Preventing Radiation-Induced Cognitive Decline in Glioblastoma (GBM) Patients Receiving Brain Radiotherapy

June 1, 2022 at 2:00pm EDT

WF-1806 - M&M - Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer

June 8, 2022 at 2:30pm EDT

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

You can also join site calls from our website. Click the call in the "Upcoming Events" section on the Home page or through the Calendar in the "About Us" section

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

Amendment 5, Protocol Version Date 02/10/2022 was released 04/26/2022

Changes associated with this amendment include:

- Updated the list of items to be pulled from the Electronic Health Record at AH-HA intervention sites at 1 year post tool activation
- Clarification that the AH-HA tool can be used with appropriate non-participants seen by trained providers
- Changed the Provider Key informant interview guide

WF-1806 - M&M - Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer

An updated *Helpful Guidelines*, version 05/06/2022, is available on the WAKENCORP website. The **CRA Training** section has been updated to include instructions aligned with new website format.

Please contact NCORP@wakehealth.edu; Attn: WF-1806, if you have questions.

WF-1901 - IMPACTS - Internet Delivered Management of Pain Among Cancer Treatment

An updated *Helpful Guide*, version 05/05/2022, is available on the WAKENCORP website. The **Training** section has been updated to include instructions aligned

with new website format.

Please contact NCORP@wakehealth.edu; Attn: WF-1901, if you have questions.

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

We are pleased to announce that we will be offering travel awards to the top two accruing sites between January 19 and July 31, 2022. Each award will cover two nights' accommodations at the Wake Forest NCORP 2022 Annual Meeting in Myrtle Beach, SC at the Marriott Grand Dunes in October.

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

UPBEAT (WF-97415) Amendment 7, PVD 04/08/2022, Release Date 05/04/2022

The WF NCORP Research Base study titled *Understanding and Predicting Breast Cancer Events after Treatment (UPBEAT)* has been amended.

The study closed to enrollment on July 30, 2021. The following changes were made with this amendment:

- Corrected language in protocol regarding the length of time study participants will be followed.
- Added language regarding sample collection to Appendix B Lab Guidelines and updated address for the NCORP Biospecimen lab.

Regulatory Requirements

- All sites are required to use the NCI CIRB as their IRB of record per the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research (NPT-OD-17-076).

Document Access:

- The protocol documents are available on the [CTSU](#) website.
- The limited access Neurocognitive test booklets are available on the [WAKENCORP](#) website.

If there are any questions, please contact NCORP@wakehealth.edu. Attn: WF-97415.

Accruals as of May 11, 2022

Open Studies	Name	Enrolled (Patients)	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1801	RAMIPRIL	52	75		
WF-1802	PCW	203	255		
WF-1806	M&M	82	300		
WF-1901	IMPACTS	49	456	0	40
WF-1804CD	AH-HA	381	600	20	40
WF-1805CD	HN STAR	70	350	69	140

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