



STUDY MATTERS

January 4, 2024

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

Wake Forest NCORP Research Base Holiday Hours

Wake Forest NCORP RB will be **closed on Monday, January 15, 2024** for Martin Luther King Day.

Strategies to Disseminate and Sustain Cancer Care Delivery Innovations Webinar

**Thursday, January 25th
4-5pm ET**

Dr. Kristie Foley and Dr. David Miller

Wake Forest NCORP Research Base Accepted Abstracts

The following two abstracts were accepted for presentation at the American Association for Cancer Research Annual Meeting (in San Diego, CA from April 5-10, 2024)

1. PCW WF-1802: Sandberg JC, Dressler EV, Krane LS, et al. Employment Characteristics and Work Ability Differences by Race and Income Before Undergoing Curative Treatment for Prostate Cancer (PCW WF-1802).
2. UPBEAT WF-97415: Reding KW, Vasbinder A, O'Connell NS, et al. Biomarkers associated with Atherosclerosis-related cardiovascular dysfunction in Cancer Survivors treated with Anthracyclines

Wake Forest NCORP Research Base Website

*****If you have already registered, please update your roles on the website*****

We use this information for targeting email communications and surveys.

If you have not registered, go to:

<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.

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

Upcoming Site Calls

Please add these meetings to your 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. You must be a registered user to join from the website.

If you are having trouble joining a call or have any other issues please email NCORP@wakehealth.edu

WF-2201-HYPOGRYPHE-Hypofractionated Radiotherapy Versus Single Fraction Radiosurgery for Brain Metastasis Patients on Immunotherapy

January 9, 3:00-4:00 PM ET

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

January 10, 2:30-3:00 PM ET

*****This meeting link has changed, please update your calendars*****

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

January 17, 3:00 PM ET

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

February 27, 2:30-3:00 PM ET

Please email 7NCORP@wakehealth.edu when shipping biospecimen samples to the NCORP Research Base Biospecimens lab (Studies WF-1806, WF-1901, and WF-2201). 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-1901 - IMPACTS - Internet-delivered Management of Pain Among Cancer Treatment Survivors



IMPACTS Site to Site Mentorship Initiative

This initiative gives sites the opportunity to connect with other sites who have been successful with recruitment in IMPACTS.

- **Goal:** To promote communication that supports a positive mentorship relationship between NCORP sites.
- **Objective:** To explore potential strategies to assist sites in building confidence, recruitment awareness, and providing tips for success with IMPACTS.

Site Mentor: University of Hawaii Cancer Center

- **Christa Braun-Inglis, DNP, APRN, FNP-BC, AOCNP** is the champion contact for **providers** with questions on getting IMPACTS out to your patients. Contact is cbrauninglis@cc.hawaii.edu
- **Courtney Chun, Clinical Research Specialist III**, is the champion contact for **study team members** needing assistance with recruitment. Contact is cchun@cc.hawaii.edu

WF-2201 - HYPOGRYPHE - Hypofractionated Radiotherapy vs Single Fraction Radiosurgery for Brain Metastasis Patients on Immunotherapy



NEW AMENDMENT ACTIVATION

HYPOGRYPHE (WF-2201) Amendment 3, Protocol Version Date 10/04/2023, Release Date 12/01/2023.

The WF NCORP Research Base study entitled *Hypofractionated Radiotherapy vs Single Fraction Radiosurgery for Brain Metastasis Patients on Immunotherapy (HYPOGRYPHE)* has been amended. The amended protocol and related documents were released on December 1, 2023.

Changes with this amendment include:

- Updated inclusion criteria 4.1.8 to change Karnofsky Performance Status (KPS) to > 50.
- Updated the following sections of the protocol to remove redundant language based on the updated inclusion criteria of English or Spanish speaking only patients in Amendment 2: Section 3.0 Assessment Plan, Section 4.3, Section 7.1, Section 7.2, Section 7.5, and Section 8.2.
- Updated CTSU language.

WF-2201 Document Access:

- The protocol and participant directed documents are available on the [CTSU](#) website.
- The *Helpful Guide* and *Training resources* are available on the [WAKENCORP](#) website.

Sites interested in participating should contact NCORP@wakehealth.edu; Attn: WF-2201 and request a start-up packet. **Your site must be IROC certified to participate or be willing to become certified.** Refer to Sections 5.2, 6.2 & 6.6 of the protocol for the Protocol Specific Requirements and Site Registration and Credentialing Requirements for site participation.

Regulatory requirements to activate this study can be found in the protocol on the CTSU website.

If there are any questions regarding the WF-2201 activation, please contact NCORP@wakehealth.edu; Attn: WF-2201.

WF-2300CD - CONNECT Survey - Practice Survey for Multi-Site Community Oncology Planning for the CONNECT Intervention Targeting Lung Cancer Caregivers



Caregiver Oncology Needs Evaluation Tool

NEW AMENDMENT ACTIVATION

CONNECT Practice Survey (WF-2300CD) Amendment 2, PVD 11/29/2023 has been activated.

The WF NCORP Research Base study entitled, “*Practice Survey for Multi-site Community Oncology Planning for the CONNECT Intervention Targeting Lung Cancer Caregivers*” has been amended and released on January 02, 2024.

Changes with this Amendment include:

- Updated the practice sample size from a maximum of 120 practices to a maximum of 200 practices. Updated the maximum planned enrollment number of affiliates and sub-affiliates from a maximum of 240 to a maximum of 600.
- Updated Practice ID Email to include more detailed instructions regarding the enrollment process.

Participation:

All NCORP Administrators and CCDR Leads rostered with Wake Forest NCORP Research Base will receive the *Practice Recruitment Email*, containing a link to the *Practice Interest Form* which must be completed to initiate the start-up process and to receive your assigned *Practice ID Email*. The *Practice ID Email* is needed for 1) activation of the protocol at your site and 2) CTSU-OPEN practice site(s) registration.

- **How to Activate your Site:** Since there is no required IRB approval for this study, sites will be required to submit the *Practice ID Email* to CTSU Regulatory Office via the Regulatory Submission Portal to activate their site. Please refer to section 6.2 of the protocol for how to submit regulatory documents to CTSU. When you submit the *Practice ID Email* to the CTSU Regulatory Office, please add in the comment section the *name and CTEP ID of your site PI* for their reference.
- **Enrollment of Practice Site(s):** Sites are required to enroll all practice site(s) in CTSU-OPEN for this study. The Practice ID will be used in CTSU-OPEN during this process.

If your practice site is interested in participating in this study, contact your NCORP Administrator and/or CCDR Lead to have them complete the *Practice Interest Form*.

Document Access:

- The protocol and the NCI CIRB determination letter, stating this study is “Not Human Subjects Research” are posted on the [Wake NCORP](#) website.

If you have any questions, please contact NCORP@wakehealth.edu; Attn: **WF-2300CD**

Steps to Enroll

1. Complete Practice Interest Form. Your CCDR Lead and/or NCORP Administrator should have received this by email. If your NCORP has not received this, please email us at NCORP@wakehealth.edu.

- Group together sites that share the same providers/community resources
- If sites do not share providers/resources, then complete a separate Practice Interest Form for each site
- If you're unsure, it's best to complete separate Practice Interest Forms

2. Once the Practice Interest Form is completed, the site contact will receive a Practice ID Email.

3. The site will need to upload the Practice ID Email to CTSU Regulatory Submissions. Be sure to include the PI name and their CTEP ID in the comments section.

The screenshot displays the CTSU (Cancer Trials Support Unit) web application interface. At the top, the header includes the CTSU logo, the text "Cancer Trials Support Unit A SERVICE OF THE NATIONAL CANCER INSTITUTE", and user information: "My Account", "CRISP", "User Access Updates: CTEP-IAH & ID-ans", "Welcome Jessica Sheedy", "AS LPO User", and "Your password will expire in 0 days". A navigation menu contains links for Home, Protocols, Dashboard, Regulatory (selected), OPEN, Data Management, Auditing & Monitoring, RUMS, Delegation Log, Resources, Collaboration, CLASS, and Reports. Below the navigation, there are tabs for Site Registration, Protocol Requirements, Provider Association, and Regulatory Submission (selected). The main content area is titled "Add New Submission" and features a "STEPS" sidebar with four steps: 1. Select Sites and Protocols (active), 2. Select Submission Priority, 3. Upload Document(s), and 4. Review and Submit Packet. The main area shows "Documents being submitted are for:" with a text input field for "Specific Site(s) and Protocol(s)". Below this, there are instructions: "Select applicable Site(s) and Protocol(s). Select either an individual site and protocol or groups of sites and protocols then click the Add to Cart button. Add all necessary site and protocol selections to your cart then". There are two sections for selection: "Pick from my sites:" with a "Select Site" button and a checkbox for "Site(s) not in list? Search and select site(s)"; and "Protocols:" with a "Helpful Hint: Search by Protocol Number, Type minimum 3 characters" and a "Search Protocol" input field. At the bottom of the selection area are "Add To Cart" and "Reset" buttons. Below the selection area is a table titled "Selected Sites and/or Protocols" with columns for "Site" and "Protocols". The table currently shows "No records were found that matched the criteria". At the very bottom, there is a "Message regarding submission (optional)" section with a "Helpful Hint: Provide the IRB number here if it is not indicated within the approval documentation" and a text input field.

4. Once approved, you will enroll each of the sites listed on the Practice ID Email into OPEN, using the Practice ID. Be sure to enter the Practice ID exactly as stated.

5. Once all sites from your Practice ID Email are enrolled into OPEN, the site contact will receive their survey(s).

****The Introductory Webinars and slides from November 16 and December 12 have been posted to <https://wakencorp.phs.wakehealth.edu/study/wf2300cd-connect-survey/>**

****Be sure to update your Profile on our website to include this study so that you receive study related information.**

Accruals as of January 3, 2024

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1806	M&M	178	+1	300		
WF-1901	IMPACTS	139	+1	250	0	40
WF-1805CD	HN-STAR	206	+5	350	116	140
WF-2201	HYPOGRYPHE	2	+1	244		

Open Studies	Name	Enrolled Practice Groups	Change in Past 2 Weeks	Target Practice Groups	Enrolled CTEP IDs	Change in Past 2 Weeks	Max CTEP IDs
WF-2300CD	CONNECT Survey	99	+42	200	174	+50	600

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