



December 7, 2023

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

WF-2300CD CONNECT Survey Webinar

CONNECT

Caregiver Oncology Needs Evaluation Tool

Tuesday, December 12, 3:30-4:00pm ET

Dr. Chandysten Nightingale

Join us to learn more about this important study and the steps needed to enroll your site(s)!

Please check our website for the link to this webinar

MCKESSON

Clinical Research Services Closed December 25, 2023 & January 1, 2024

In observance of the Christmas holiday, McKesson's Clinical Research Services will be closed **Monday, December 25, 2023**. We will resume regular business hours on Tuesday, December 26, 2023.

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 Christmas holiday**.

- Only non-refrigerated product will be shipped on **Friday, December 22**. Orders placed prior to 2 pm ET will be delivered on **Tuesday, December 26**.
- If refrigerated or temperature-controlled product is required before the holiday, orders must be placed by **Thursday, December 21** prior to 2 pm ET. Orders placed prior to 2 pm ET will be delivered on **Friday, December 22**.

In observance of the New Year holiday, McKesson's Clinical Research Services will be closed **Monday, January 1, 2024**. We will resume regular business hours on Tuesday, January 2, 2024.

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 New Year holiday**.

- Only non-refrigerated product will be shipped on **Friday, December 29**. Orders placed prior to 2 pm ET will be delivered on **Tuesday, January 2**.
- If refrigerated or temperature-controlled product is required before the holiday, orders must be placed by **Thursday, December 28** prior to 2 pm ET. Orders placed prior to 2 pm ET will be delivered on **Friday, December 29**.

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.

We appreciate the opportunity to assist you and your patients.

Kind regards,

Clinical Research Services team

Strategies to Disseminate and Sustain Cancer Care Delivery Innovations Webinar

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

Dr. Kristie Foley and Dr. David Miller

Please check our website for the link to this webinar

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

If you haven't already, 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-1806- M&M- Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer

December Site Call Time Change Alert

The WF-1806 M&M Site Call scheduled for **December 26th (2:30 pm ET)** has been moved. Please delete this from your calendar.

The new meeting time is **December 12th at 3:00pm 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*****

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



BLOOD SPECIMEN SHIPPING ALERT

Some sites are still sending samples to the University of Alabama - Birmingham location. Please be aware that the shipping location changed with our last amendment, which was announced via broadcast email on 7/14/2023.

WF-1806 (M&M) Amendment 8, Protocol Version Date 05/23/2023, Release Date 07/14/2023:

- Changing lab location for blood sample submission to WF NCORP Biospecimen Lab. – See updated Helpful Guidelines.

WF-1806 Helpful Guidelines document has been updated to version 07/05/2023 and reflects the new blood sample shipment destination below. This document is available on our Wake NCORP RB website; <https://wakencorp.phs.wakehealth.edu/>.

ATTN: WF-1806 (M&M)
WF NCORP Biospecimen Lab
Bldg. A1A Lab 230 c/o Delivery on Time
Wake Forest School of Medicine
Richard Dean Bldg. Receiving Dock
391 Technology Way
Winston-Salem, NC 27101
Phone: (336) 716-2581

Please email 7NCORP@wakehealth.edu if you need replacement air bills for kits that you have in stock and be sure to include the **kit #** in your email.

If there are any questions, we are glad to help. Please contact us at NCORP@wakehealth.edu;
Attn: WF-1806.

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



NEW AMENDMENT ACTIVATION

IMPACTS (WF-1901) Amendment 7, PVD 10/05/2023 Release Date November 27, 2023

The WF NCORP Research Base study titled *Internet-delivered Management of Pain Among Cancer Treatment Survivors* has been amended.

Changes with this amendment include:

- Updated the “What are costs of taking part in this study?” section of the Patient In-Person Consent.
- Baseline activities must now be completed within 30 days of consent instead of 30 days from screening. In this context, we updated screening language in **Schedule of Events** footnote to state that participants should be rescreened if more than 30 days have passed since the patient was originally screened.
- Added “or designee” language to the following sections: 4.6, 6.1, 6.3.1, 6.4, 6.5.1 and 7.4
- Clarified use of **Informed Consent** language.
- Clarified **Case Report Form** language.
- Removed Dr. Megan Irby from Sections 4.3 and 7.4

Regulatory Requirements:

- Re-consent of patients is not required with this amendment.
- 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).
- Site Open to Enrollment (SOTE) letter from the WF NCORP RB will be provided to the site after all onboarding activities are completed.

Document Access:

- The protocol documents are available on the [CTSU](#) website.
- The current **Helpful Guide** document is available on the [WAKENCORP](#) website.

Participation:

If there are any questions about the activation process or if your site is interested in participating in this study, please contact NCORP@wakehealth.edu. Attn: WF-1901.

****DATA ALERT****

Before distributing the 7-Day Medication diary to a participant (in person or by mail):

1. Ensure that all pages have the patient header, **including PID** and page numbers completed. We recommend making a copy of the form, in case it gets lost in the mail.
2. Please complete the **Medication, Type** and **Dose/Strength** fields on the form for any medication that the participant currently is taking, using the medical record to provide a complete list of all medications. Please provide additional blank pages for medications, supplements or essential oils that the participant may need to add at home later.
3. At timepoints T3 and T4 the two typical usage questions are optional for patients. They are designated as "Staff Only". You may draw a line through them, initial and date these questions, if you prefer.

Participants will not receive payment for lost or unidentifiable diaries.

These items can be completed electronically on the PDF document or hand-written in the spaces provided prior to distribution.

Please check the Helpful Guide on our website: <https://wakencorp.phs.wakehealth.edu/study/wf1901-impacts/> for more information.

If you have question about completing these diary forms please contact NCORP@wakehealth.edu

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 Chunn, 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 \[wakehealth.us19.list-manage.com\]](https://wakehealth.us19.list-manage.com) website.
- The *Helpful Guide* and *Training resources* are available on the [WAKENCORP \[wakehealth.us19.list-manage.com\]](https://wakehealth.us19.list-manage.com) 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 STUDY ACTIVATION

CONNECT Practice Survey (WF-2300CD) Amendment 1, PVD 10/12/2023 was activated on November 13, 2023.

The WF NCORP Research Base study entitled, “*Practice Survey for Multi-site Community Oncology Planning for the CONNECT Intervention Targeting Lung Cancer Caregivers*” was activated on November 13, 2023.

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 \[wakehealth.us19.list-manage.com\]](https://wakehealth.us19.list-manage.com) website.

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

CTSU Cancer Trials Support Unit
A SERVICE OF THE NATIONAL CANCER INSTITUTE

My Account CRISP User Access Updates: CTEP-IAN & ID.me Welcome Jessica Sheedy as LPO User Your password will expire in 0 days.

Home Protocols Dashboard Regulatory OPEN Data Management Auditing & Monitoring RUMS Delegation Log Resources Collaboration CLASS Reports

Site Registration Protocol Requirements Provider Association Regulatory Submission

← Add New Submission

STEPS

1. Select Sites and Protocols
2. Select Submission Priority
3. Upload Document(s)
4. Review and Submit Packet

Previous Next Discard

Documents being submitted are for:
Specific Site(s) and Protocol(s)

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

Pick from my sites:
Select Site
 Site(s) not in list? Search and select site(s)

Protocols:
Helpful Hint: Search by Protocol Number. Type minimum 3 characters
Search Protocol

Add To Cart Reset

Selected Sites and/or Protocols	
#	Protocols
No records were found that matched the criteria	

Message regarding submission (optional)
Helpful Hint: Provide the IRB number here if it is not indicated within the approval documentation

****The Introductory Webinar from November 16 has also been posted to <https://wakencorp.phs.wakehealth.edu/study/wf2300cd-connect-survey/>**

****The next live webinar is being held Tuesday, December 12 from 3:30-4pm ET. Please see the link at the top of this document to add this to your calendar.**

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

[WF-97415 - UPBEAT - Understanding and Predicting Breast Cancer Events after Treatment](#)

Please submit any remaining MRI and CPET invoices before **December 15, 2023.**

*****Remember to continue annual follow-up contact with participants through 11 years. This follow-up includes the KCCQ Questionnaire, documentation of any cardiovascular events and SAEs as described in the study protocol.*****

Accruals as of December 6, 2023

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1806	M&M	176	--	300		
WF-1901	IMPACTS	136	+1	250	0	40
WF-1805CD	HN-STAR	194	+6	350	116	140
WF-2201	HYPOGRYPHE	1	--	244		

Open Studies	Name	Enrolled (Practice Groups)	Change in Past 2 Weeks	Target (Practice Groups)	Enrolled (CTEP IDs)	Change in Past 2 Weeks	Target (CTEP IDs)
WF-2300CD	CONNECT Survey	30	+27	120	47	+35	240

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Wake Forest NCORP Research Base
Medical Center Blvd
Winston Salem, NC 27157-0001

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