

December 21, 2023

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

Wake Forest NCORP Research Base Holiday Hours

Wake Forest NCORP RB will be closed on Monday, December 25 & Tuesday, December 26, 2023 and Monday, January 1, 2024. Happy Holidays!

M<u>K</u> ESSON

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 <u>clinicalresearchservices@mckesson.com</u>.

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

You can join this meeting by clicking the link on our website

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

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 <u>NCORP@wakehealth.edu</u>

Upcoming Site Calls

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 <u>Wake NCORP website</u>. 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 <u>NCORP@wakehealth.edu</u>

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 Please email <u>7NCORP@wakehealth.edu</u> 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



DATA ALERT

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

 Ensure that all pages have the <u>patient header</u>, <u>including PID</u> and <u>page numbers</u> <u>completed</u>. 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: <u>https://wakencorp.phs.wakehealth.edu/study/wf1901-impacts/</u> for more information.

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

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 <u>cbrauninglis@cc.hawaii.edu</u>
- Courtney Chun, Clinical Research Specialist III, is the champion contact for study team members needing assistance with recruitment. Contact is cchun@cc.hawaii.edu

<u>WF-2201 - HYPOGRYPHE - Hypofractionated Radiotherapy vs Single</u> 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 <u>CTSU</u> [wakehealth.us19.list-manage.com] website.
- The *Helpful Guide* and *Training resources* are available on the <u>WAKENCORP</u> [wakehealth.us19.list-manage.com] website.

Sites interested in participating should contact <u>NCORP@wakehealth.edu</u>; 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 <u>NCORP@wakehealth.edu</u>; Attn: WF-2201.

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



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 <u>NCORP@wakeheatlh.edu</u>.

- 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.

Cancer Trials Sup	port Unit
My Account CR35P	User Access Update: CTLP-LAH & IDume Welcome Jessica Sheedy 8: (20 User
🕈 Home Protocols 🦷 Dashboar	d Rogulatory* OPEN Data Management + Auditing & Monitoring + RUMS + Delegation Log + Resources + Collaboration CLASS + Reports +
Site Registration Protocol Requir	rements Provider Association Regulatory Submission -
 Add New Submission 	
STEPS	1. Select Stes and Picocob 2. Select Submission Priority 3. Upload Document(s) 4. Review and Submit Packet
1. Select Sites and Protocols	Previous Next Discard
2. Select Submission Priority	
3. Upload Document(s)	Documents being submitted are for:
4. Review and Submit Packet	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 the
	Pick from my sites:
	Select Site
	Site(s) not in list? Search and select site(s)
	Protocols: Heipful Hint: Search by Protocol Number, Type minimum 3 characters
)	Search Protocol
	Add To Cart Reset
	📴 🧝 Selected Sites and/or Protocols
	Site Protocols
	No records were found that matched the criteria
	Message regarding submission (optional) Helpful Hint: Provide the IBB number here if it is not indicated within the approval documentation

 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.
 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 <u>https://wakencorp.phs.wakehealth.edu/study/wf2300cd-connect-</u> <u>survey/</u>

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

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non- Patients)	Target (Non- Patients)
WF-1806	M&M	177	+1	300		
WF-1901	IMPACTS	138	+2	250	0	40
WF-1805CD	HN-STAR	201	+7	350	116	140
WF-2201	HYPOGRYPHE	1		244		

Accruals as of December 20, 2023

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	57	+27	120	124	+77	240

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