



STUDY MATTERS
September 14, 2023

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

Wake Forest NCORP RB Annual Meeting

The 2023 Wake Forest NCORP RB Annual Meeting will be held **October 16-17, 2023** at the Renaissance Hotel in Asheville, NC.

Click here to register:

<https://northwestahec.wakehealth.edu/courses-and-events/72044/10th-annual-wake-forest-ncorp-research-base>

- Once you click on the registration link, you will land on the Northwest AHEC face page.
- If you do not have an account, you will need to create one at this time using the "Create Account" located in the banner at the top right.
- Once you have created an account, go back to the home page of the Meeting.
- A gray "Register" button is located on the left side of the page. Click on this button and you will be asked to sign in.

Your registration options are either in-person or virtual.

If you plan to attend the Health Equity Core Committee Luncheon, please register for that as well.

If you plan on attending virtually, you must register as Virtual in order to receive the WebEx invite link to join the Annual Meeting.

Our keynote speaker this year will be **Ruben Mesa, MD, FACP** who is the Executive Director of the NCI Comprehensive Cancer Center based at Wake Forest Baptist. Dr. Mesa is an international expert in hematologic cancers, who has dedicated his life's work to research and drug development for myeloproliferative neoplasms (MPN). He is a funded investigator of the NCI on several projects in MPN and has been appointed to the NCI Clinical Trial Advisory Committee. In addition to Dr. Mesa's extensive MPN research and clinical practice, he is passionate about advancing cancer health equity and increasing minority patients' participation in cancer clinical trials. He will be speaking on "Diverse Cancer Clinical Trials: Good Care – Good Science."

A block of rooms has been reserved with a group rate of \$269 per night beginning October 15 – October 18.

*****Rooms must be booked by 09/24/2023 to receive this rate.*****

Click here to book your room:

<https://www.marriott.com/event-reservations/reservation-link.mi?id=1669236799969&key=GRP&app=resvlink>



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

September 20, 2023 at 3:00pm ET. Please update your calendars.

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

October 4, 2023 at 2:00pm ET. Please update your calendars.

Please email 7NCORP@wakehealth.edu when shipping biospecimen samples to the NCORP Research Base Biospecimens lab (Studies WF-97415, WF-1801, 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-1805CD - HN-STAR - Implementation and Effectiveness Trial of HN-STAR



TRAVEL AWARDS- ONE DAY LEFT!

Available for the **2023** Wake Forest NCORP RB Annual Meeting

We are pleased to announce that we will be offering travel awards to the **first 4 sites who enroll 4 patients to the HN-STAR study between July 20, 2023 and September 15, 2023**. Awards are worth up to \$1,000 to cover travel and hotel expenses at the Renaissance Hotel in Asheville, NC.

Please contact NCORP@wakehealth.edu Attn: WF-1805CD if you have any questions.

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



NEW AMENDMENT ACTIVATION

IMPACTS (WF-1901) Amendment 6, PVD 04/24/2023 Release Date September 11, 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:

- Changed the accrual number from 456 to 250.
- Updated Patient Inclusion Criteria 4.1.2 by removing the following language: “that is felt to be stable and/or controlled and not rapidly progressive as per treating clinician judgement at the time of screening” as well as included clarity to anticancer therapy language.
- Reactivated the patient in-person consent and updated exam, test and procedure language to mirror the consent script.
- NEW Recruitment Video
 - This video is designed to enhance patient engagement and a link is now available on CTSU in the Video Submission Form. A link is also available on the study page under the Patient Recruitment Materials section of the Wake NCORP website. Please feel free to use this tool to engage patients in IMPACTS.

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.

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** assisting with recruitment. Contact is cchun@cc.hawaii.edu

TRAVEL AWARDS- FIVE DAYS LEFT!

Available for the **2023** Wake Forest NCORP RB Annual Meeting

We are pleased to announce that we will be offering travel awards to sites who **enroll 5 patients to the IMPACTS study between June 19, 2023 and September 19, 2023**. Awards are worth up to \$1,000 to cover travel and hotel expenses at the Renaissance Hotel in Asheville, NC.

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

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



NEW AMENDMENT ACTIVATION

HYPOGRYPHE (WF-2201) Amendment 2, Protocol Version Date 08/03/2023, Release Date 09/14/2023.

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 September 14, 2023.

Changes with this amendment include:

- Pushing Unacceptable Deviation from >10 days to >14 days after MRI for treatment planning.
- Adding Non-Member Collaborator Carolinas Medical Center/Levine Cancer Institute (NC042) to the protocol document.
- Updating Dr. Corbin A. Helis, MD organization's information.
- Removing Co-Investigator/ Neuropsychology Chair Tiffany L. Cummings.
- Adding inclusion criteria that states study is only available for English and Spanish speakers.

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. Please refer to your study start-up packet details to begin this process if you are interested in participating in this new study.

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

The study team has received additional funding to complete any remaining 24-Month study procedures through October 1, 2023. Please try to schedule any missing activities as soon as possible.

*****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 September 13, 2023

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1801	RAMIPRIL	70	+2	75		
WF-1806	M&M	161	+1	300		
WF-1901	IMPACTS	122	+3	250	0	40
WF-1805CD	HN-STAR	165	+2	350	107	140
WF-2201	HYPOGRYPHE	1	--	244		

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