

July 20, 2023

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

REDCap will be Offline from 9:00AM- 12:00PM ET on Saturday, July 29th

As with any upgrade, we want to include our standard reminder of a few key points which you should be aware of during this process:

- Wake Forest NCORP Research Base projects will not be accessible until REDCap is brought back online.
- Surveys invitations, Alerts/Notifications, and other system notifications will not be sent. WF NCORP RB personnel will re-trigger these if necessary.
- In the very unlikely event that a system restore is required for our server, data will be reverted to the previous day's system backup. Please take note that all data captured through the end of day (5 PM ET) on Friday, July 28th will be preserved, but any data collected thereafter may not be restored.
- Please plan any REDCap work that you may have on this day (and weekend)
 accordingly, as well as communicate this message to any appropriate members
 of your team. Stay tuned for further announcements regarding new features once
 the upgrade/maintenance is completed.

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

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. We hope to see you there!

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

You will need to book your rooms by 09/24/2023.

Book your group rate hotel for the Wake Forest NCORP Research Base Annual Meeting



Upcoming Site Calls

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 MCORP@wakehealth.edu

Wake Forest NCORP Research Base Quarterly Call

July 26, 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 Radiotherapy

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

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

August 22, 2023 at 2:30pm 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-1802 - PCW - Influence of Primary Treatment for Prostate Cancer on Work Experience

LAST CALL! This study will be closing to new patient enrollment on August 1, 2023. Please make a final push to enroll in the two open strata by the end of July. After this date, please complete remaining protocol activities with current patients. Thank you to all sites who have participated in this study.

We have the following slots available: Higher Income, AA- 1 slot available Lower Income, White- 27 slots available

You can determine the remaining slots left for any stratum by going to CTSU-OPEN>Slot Reservation>Report.

If you have any questions, please contact NCORP@wakehealth.edu

NEW AMENDMENT ACTIVATION

PCW (WF-1802) Amendment 5, PVD 05/11/2023, Release Date 7/10/2023

The WF NCORP Research Base study entitled *Influence of Primary Treatment for Prostate Cancer on Work Experience (PCW) protocol and related documents have been amended.*

The following changes were made:

Removing references to DOD from study's consent form.

WF-1802 Document Access:

- The protocol documents are available on the CTSU website.
- The FAQs and Training Attestation documents are still available on the WAKENCORP website.

If there are any questions regarding the WF-1802 activation, please contact NCORP@wakehealth.edu; Attn: WF-1802.

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



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

NEW AMENDMENT ACTIVATION

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

The WF-1806, Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer (M&M) study has been amended. The amended protocol and related documents were released on Friday, July 14, 2023.

Changes with this amendment include:

- Update to contact information for Protocol Principal Investigator Grant R. Williams, MD.
- Addition of new Co-Principal Investigator, Smith Giri, MD, MHS.
- Correction to the footnote references in the participant schedule of events section; replacing symbol b with β and replacing symbol □ with Φ.
- Changing lab location for blood sample submission to WF NCORP Biospecimen Lab. –
 See updated Helpful Guidelines info below
- Update to CTSU language based on 05/05/2023 support logistical template language document.

WF-1806 Helpful Guidelines document has been updated to version 07/05/2023 and reflects the new blood sample shipment destination below.

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

Note: The shipping destination for the CT scans is still UAB-Birmingham but the contact names and FedEx account have changed:

For Fed Ex billing, please use the following account:

Account #: 027403727

Internal Reference: WF NCORP Research Base

Ship discs to:
Ref: M&M Study
Smith Giri
C/O Abigail Tucker
ICOS, Lowder 500
1600 7th Ave South
Birmingham, AL 35233
Phone 205-638-2146

WF-1806 Document Access:

- The protocol and participant directed documents are available on the CTSU website.
- The Helpful Guidelines, FAQs, Provider Fact Sheet and Training Attestation documents are available on the WAKENCORP website.

If there are any questions regarding WF-1806 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



TRAVEL AWARDS

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 SPANISH DOCUMENTS POSTED

HYPOGRYPHE (WF-2201) Amendment 1, Protocol Version Date 01/15/2023 was posted on 03/17/2023.

The Spanish versions of the following documents that align with this amendment were posted on CTSU **Friday**, **July 7**, **2023**.

- **Recruitment Brochure** (version 02/13/23): Spanish
- Recruitment Flyer (version 02/13/23): Spanish
- Recruitment Letter (version 02/13/23): Spanish
- Study Summary (version 02/13/23): Spanish

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

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

24-Month Data Collection- Please make sure you have adequate study supplies - gift cards, lab kits, etc., and place any final orders as soon as possible.

- Please complete 24-Month data collection for all active participants on or before July 31, 2023.
- Please schedule these participants for their final in-person assessments within the protocol-specified windows if possible (e.g. participants can be scheduled 22 months from their "T1" reference dates and still be "in-window"). Early visits, prior to 22 months from T1, are acceptable if necessary.
- MRI and CPET data collection activities cannot be reimbursed if completed after July 31, 2023.
- For participants past the 24-Month Time Point (3-11 Year KCCQ and CV Event collection), please continue all follow-up data collection.

Please contact <u>NCORP@wakehealth.edu</u> for more information on participant retention strategies.

We thank you for your continued efforts on this study!

Please note the shipping address for the Biospecimen Lab for shipping serum and plasma for WF-97415-UPBEAT Cancer Treatment Participants:

UPBEAT Study
NCORP Biospecimen Lab: K. Kourman & M. Morris
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 check your kit numbers and expiration dates. Kits numbered 666 or lower will have outdated FedEx shipping labels.

- Please update shipping address or request new shipping labels by emailing NCORP@wakehealth.edu or through REDCap.
- If your tubes are expired you can request replacement tubes by emailing <u>NCORP@wakehealth.edu</u> or through REDCap.

Please do not ship samples to the Biospecimen Lab on Fridays as they will not be received on the weekend and will thaw before processing.

Accruals as of July 19, 2023

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non- Patients)	Target (Non- Patients)
WF-1801	RAMIPRIL	67		75		
WF-1802	PCW	252	+1	255		
WF-1806	M&M	149	+2	300		
WF-1901	IMPACTS	113	+4	456	0	40
WF-1805CD	HN STAR	150	+3	400	106	140
WF-2201	HYPOGRYPHE	1	+1	244		

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