

## STUDY MATTERS

**December 8, 2022** 

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

## **REDCap Update**

Due to a planned system upgrade, REDCap will be offline from 5:00PM - 7:00 PM ET on Thursday, December 22, 2022.

- Projects will not be available during the update.
- Email triggers and survey links will not work during the update.
- 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 check any data entered after 5 PM ET, December 21, 2022 to make sure it is still available.

If you have any questions or concerns, please email NCORP@wakehealth.edu

### Wake Forest NCORP RB Holiday Hours

Our office will be closed Monday, December 26th and Monday, January 2nd for the holidays.

## **Biospecimen Lab Holiday Schedule**

We will be available to receive samples now until Thursday 12/22 and 12/27-30. We will not be able to ship new kits to sites during the weeks of 12/19-23 and 12/26-30. Regular shipment of requested kits will resume 1/3/2023. Please advise your study teams for WF-1901 IMPACTS, WF-1806 M&M and WF-97415 UPBEAT (24-month samples only) to make any requests for new kits before 12/16/2022.

## **McKesson Holiday Hours**

Clinical Research Services Closed December 26, 2022 & January 2, 2023

In observance of the Christmas holiday, McKesson's Clinical Research Services will be closed **Monday**, **December 26**, **2022**. We will resume regular business hours on Tuesday, December 27, 2022.

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
   23. Orders placed prior to 2 pm ET will be delivered on Tuesday,
   December 27.
- If refrigerated or temperature-controlled product is required before the holiday, orders must be placed by Thursday, December 22 prior to 2 pm

ET. Orders placed prior to 2 pm ET will be delivered on **Friday**, **December 23**.

In observance of the New Year holiday, McKesson's Clinical Research Services will be closed **Monday**, **January 2**, **2023**. We will resume regular business hours on Tuesday, January 3, 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 New Year holiday.** 

- Only non-refrigerated product will be shipped on **Friday**, **December 30**. Orders placed prior to 2 pm ET will be delivered on **Tuesday**, **January 3**.
- If refrigerated or temperature-controlled product is required before the holiday, orders must be placed by **Thursday**, **December 29** prior to 2 pm ET. Orders placed prior to 2 pm ET will be delivered on **Friday**, **December 30**.

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 <a href="mailto:clinicalresearchservices@mckesson.com">clinicalresearchservices@mckesson.com</a>.

We appreciate the opportunity to assist you and your patients.

Kind regards,

Clinical Research Services team

**MCKESSON** 

## **Upcoming Site Calls**

If you would like to attend one of these calls, but did not receive an invitation, please email NCORP@wakehealth.edu

Click the button below the meeting to add it to your Outlook 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 <u>Wake NCORP website</u>. Click the call in the "Upcoming Events" section on the Home page or through the Calendar.

## WF1806- M&M - Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer

December 14, 2022 at 2:30pm EST. Please update your calendars.

Click here to add this WF1806-M&M meeting to your calendar

## WF1901- IMPACTS - Internet-delivered Management of Pain Among Cancer Treatment Survivors

January 11, 2022 at 2:30pm EST. Please update your calendars.

Click here to add this WF1901-IMPACTS meeting to your calendar

#### Wake Forest NCORP Research Base Website

Please visit and register on our Wake Forest NCORP Research Base website 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

Please email <a href="mailto:7NCORP@wakehealth.edu">7NCORP@wakehealth.edu</a> when shipping biospecimen samples to the NCORP Research Base Biospecimens lab (Studies WF-97415, WF-1801, and WF-1901). 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-1801 - Ramipril- A Single Arm, Pilot Study of Ramipril for Preventing Radiation-Induced Cognitive Decline in Glioblastoma (GBM) Patients

#### **NEW AMENDMENT ACTIVATION**

WF-1801 (Ramipril) Amendment 7, Protocol Version Date 10/25/2022, Release Date 11/29/2022

The WF-1801, 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 **Tuesday**, **November 29**, **2022**.

#### Changes with this amendment include:

 Addition of Non-Member Collaborator Carolinas Medical Center/Levine Cancer Institute (NC042).

#### WF-1801 Document Access:

- The protocol documents are available on the <a href="CTSU">CTSU</a> website.
- The OPEN enrollment is posted on the WAKENCORP site.

**CIRB sites** must have Amendment 7 locally implemented within 30 days of notification (posting on the CTSU website).

Sites interested in participating should contact <a href="NCORP@wakehealth.edu">NCORP@wakehealth.edu</a>, Attn: WF-1801

## WF-1802 - PCW - Influence of Primary Treatment for Prostate Cancer on Work Experience

Three strata are now full. The Higher Income AA stratum, Lower Income AA stratum and Higher Income white stratum are now full. Please make every effort to screen and approach individuals from the Lower Income white stratum. We only need 27 more to complete recruitment for this study! Many thanks for all your hard work!

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

#### **NEW AMENDMENT ACTIVATION**

WF-1806 (M&M) Amendment 7, Protocol Version Date 10/28/2022, Release Date 11/22/2022:

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 **Tuesday**, **November 22**, **2022**.

#### Changes with this amendment include:

- Addition of four Non-Member Collaborator sites from Levine Cancer Institute;
  - Carolinas Medical Center/Levine Cancer Institute (NC042)
  - Atrium Health Cabarrus/LCI-Concord (NC083)
  - Atrium Health Pineville/LCI-Pineville (NC193)
  - Atrium Health University City/LCI-University (NC154)

#### WF-1806 Document Access:

- The protocol documents are available on the <u>CTSU</u> website.
- Sites should access the <u>WAKENCORP</u> website for additional resources needed for this study.

**CIRB sites** must have Amendment 7 locally implemented within 30 days of notification (posting on the CTSU website).

For site registration guidelines please refer to the protocol document. If there are any questions regarding the WF-1806 study, please contact <a href="NCORP@wakehealth.edu">NCORP@wakehealth.edu</a>; Attn: WF-1806.

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

Please update the shipping address on all RT DICOM Image CDs to:

Dr. Greg Hundley (C/O Stacey Belton)
Wake Forest Health Sciences
Department of Internal Medicine/Cardiology
Medical Center Blvd.
Winston Salem, NC 27157-1045

Phone: (336) 713-7085

Email shipping information including date sent, method, and tracking number to <a href="McORP@wakehealth.edu">MCORP@wakehealth.edu</a> so we can ensure proper delivery.

If you would like to send these image files by file transfer or other method please contact Ricardo Peral (rperal@wakehealth.edu)

#### Accruals as of December 7, 2022

Open Studies	Name	Enrolled (Patients)	Target (Patients)	Enrolled (Non- Patients)	Target (Non- Patients)
WF-1801	RAMIPRIL	59	75		
WF-1802	PCW	228	255		
WF-1806	M&M	118	300		
WF-1901	IMPACTS	72	456	0	40
WF-1804CD	AH-HA	546	600	24	40
WF-1805CD	HN STAR	126	350	88	140

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