Wake Forest
NCORP RESEARCH BASE

STUDY MATTERS

July 6, 2023

Wake NCORP 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 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

If you haven't already added the meeting to your calendar, please add them now

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-1901 IMPACTS Site Call

July 12, 2023 at 2:30pm ET. Please update your calendars.

WF-1805CD HN-STAR Site Call

July 19, 2023 at 3:00pm ET. Please update your calendars.

Wake Forest NCORP Research Base Quarterly Call

July 26, 2023 at 3:00pm ET. Please update your calendars.

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

The bi-monthly site call will be moving to the fourth Tuesday of the even numbered months; same time slot of 2:30pm ET. This will start with our next meeting on August 22nd.

The old meeting series occurred on the second Wednesday of the even numbered months. Please update 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

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- 3 slots 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

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

NEW AMENDMENT ACTIVATION

WF-1805CD Amendment 5, PVD 01/09/2023, Release Date 06/13/2023
The WF-1805CD study titled *Implementation and Effectiveness Trial of HN-STAR* has been amended. The amended protocol and related documents were released on **Tuesday, June 13, 2023.**

Changes with this amendment include:

- Updated enrolling and consenting language in Section 4.2.7 to give sites the option to complete the consent as a 1- or 2-step process.
- Updated survivor inclusion criteria 4.2.3.2 to include oropharynx and hypopharynx.
- Updated survivor exclusion criteria 4.2.3.7 to clarify remotely as via telephone or videoconference.
- Removed Information Technology Specialists from Stakeholder Inclusion Criteria, Section 4.4.3.2
- Created a new, paper version of the List of Symptoms – Designated Clinician form.
- Added flexibility in the sample size of survivors from the original planned n=350 to a range of n=298-400 total required depending on the number of participating sites ranging from at most 36 to a minimum of 20 respectively. Given the possibility of as few as 20 practices who enroll patients, we have modified the number of providers/stakeholders and primary care providers to reflect this smaller available pool as well but have not altered the maximum that can be accrued.
- Revised the Designated Clinician Interview Guides for both the Usual Care and HN-STAR Intervention Arms.
- Removed the Stakeholder (SH) Usual Care arm interview from the Interview Guides.

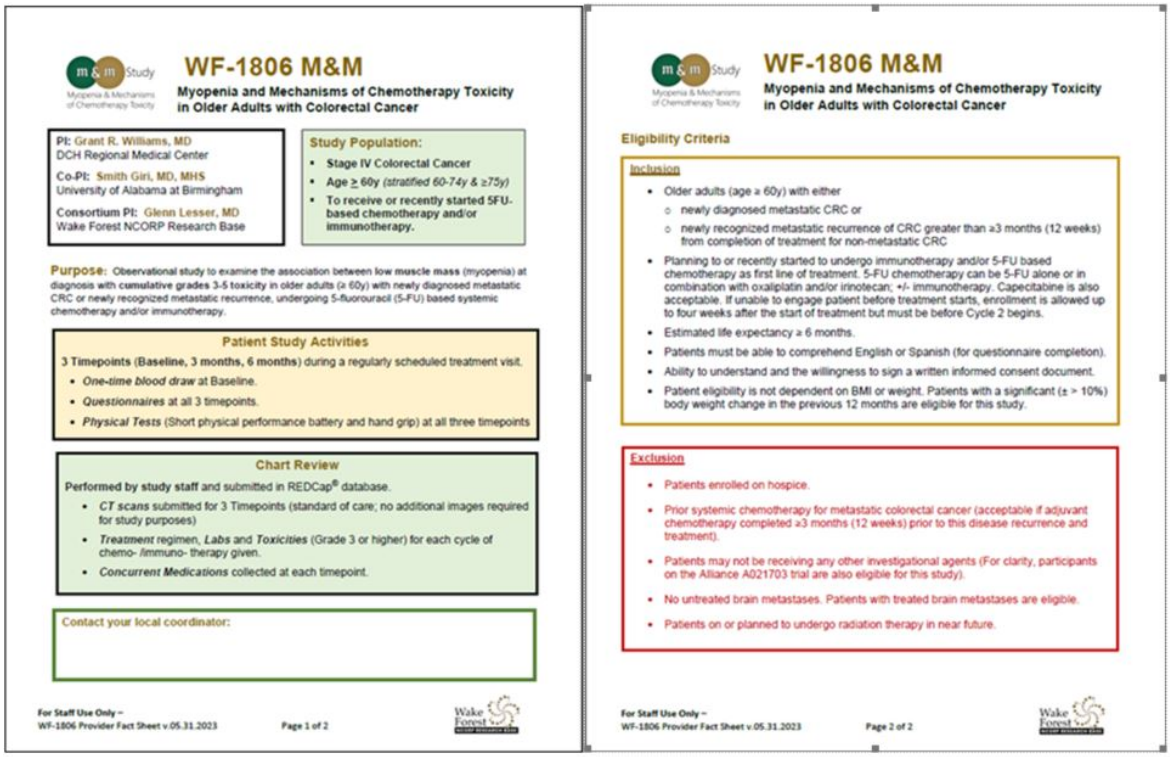
Document Access:

- The protocol documents are available on the CTSU website.
- Data collection trainings and an FAQ document are available on the WAKENCORP website.

Sites interested in participating should contact NCORP@wakehealth.edu. Attn: WF-1805CD

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

A *Provider Fact Sheet* has been created to facilitate spreading the word to your clinic providers and staff. This is a two-sided document with space for you to add your contact information. The *Provider Fact Sheet* is available for download on the Wake NCORP website **WAKENCORP [wakehealth.us19.list-manage.com]** from the WF-1806 M&M Study Page / Study Documents & Forms.



WF-1806 M&M

Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer

PI: Grant R. Williams, MD
DCH Regional Medical Center

Co-PI: Smith Giri, MD, MHS
University of Alabama at Birmingham

Consortium PI: Glenn Lesser, MD
Wake Forest NCORP Research Base

Study Population:
- **Stage IV Colorectal Cancer**
- **Age ≥ 60y** *(stratified 60-74y & ≥75y)*
- **To receive or recently started 5FU-based chemotherapy and/or immunotherapy.**

Purpose: Observational study to examine the association between low muscle mass (myopenia) at diagnosis with cumulative grades 3-5 toxicity in older adults (≥ 60y) with newly diagnosed metastatic CRC or newly recognized metastatic recurrence, undergoing 5-fluorouracil (5-FU) based systemic chemotherapy and/or immunotherapy.

Patient Study Activities

3 Timepoints (Baseline, 3 months, 6 months) during a regularly scheduled treatment visit.
- ***One-time blood draw*** at Baseline.
- ***Questionnaires*** at all 3 timepoints.
- ***Physical Tests*** (Short physical performance battery and hand grip) at all three timepoints

Chart Review

Performed by study staff and submitted in REDCap® database.
- ***CT scans*** submitted for 3 Timepoints (standard of care; no additional images required for study purposes)
- ***Treatment*** regimen, ***Labs*** and ***Toxicities*** (Grade 3 or higher) for each cycle of chemo- /immuno- therapy given.
- ***Concurrent Medications*** collected at each timepoint.

Contact your local coordinator:

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WF-1806 M&M

Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer

Eligibility Criteria

Inclusion
- Older adults (age ≥ 60y) with either
  - newly diagnosed metastatic CRC or
  - newly recognized metastatic recurrence of CRC greater than ≥3 months (12 weeks) from completion of treatment for non-metastatic CRC
- Planning to or recently started to undergo immunotherapy and/or 5-FU based chemotherapy as first line of treatment. 5-FU chemotherapy can be 5-FU alone or in combination with oxaliplatin and/or irinotecan; +/- immunotherapy. Capecitabine is also acceptable. If unable to engage patient before treatment starts, enrollment is allowed up to four weeks after the start of treatment but must be before Cycle 2 begins.
- Estimated life expectancy ≥ 6 months.
- Patients must be able to comprehend English or Spanish (for questionnaire completion).
- Ability to understand and the willingness to sign a written informed consent document.
- Patient eligibility is not dependent on BMI or weight. Patients with a significant (± > 10%) body weight change in the previous 12 months are eligible for this study.

Exclusion
- Patients enrolled on hospice.
- Prior systemic chemotherapy for metastatic colorectal cancer (acceptable if adjuvant chemotherapy completed ≥3 months (12 weeks) prior to this disease recurrence and treatment).
- Patients may not be receiving any other investigational agents (For clarity, participants on the Alliance A021703 trial are also eligible for this study).
- No untreated brain metastases. Patients with treated brain metastases are eligible.
- Patients on or planned to undergo radiation therapy in near future.

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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

HYPOGRYPHE
Investigating Hypofractionated Radiosurgery During Immunotherapy

Study Activated 3/17/2023

Primary Objective

To compare the proportion of participants experiencing Grade 2 or higher Adverse Radiation Effects (ARE) within 9 months following randomization to single fraction stereotactic radiosurgery (SSRS) vs fractionated stereotactic radiosurgery (FSRS) in patients with brain metastases >=2 cm in diameter or >=4cc in volume treated with concurrent immune checkpoint inhibitor (ICI) therapy.

Hypothesis

Reduction in Grade 2 or higher ARE from 22.5% with SSRS to 7.1% with FSRS (15.4% reduction).

Study Population

Melanoma, renal cell, non-small cell lung or breast cancer patients with brain metastases (<=15 metastases) currently receiving or planning to receive PD-1/PD-L1 targeted immune checkpoint inhibitor therapy within 30 days of SSRS/FSRS.

Contact us at NCORP@wakehealth.edu if your site is interested in the study. Also be sure to update your profile on our Wake Forest NCORP Research Base website to receive notifications for this study. Recruitment materials can be found on the CTSU website.

WF2201-HYPOGRYPHE Introductory Webinar

https://vimeo.com/806099986

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 **Tuesday, May 30**, **2023.**

- **Consent Form**, (PVD 01/15/23): Spanish
- **Post SRS Visits Patient Reported Outcomes (PROs)**, (version 01/15/23): Spanish
- **Pre-Randomization Patient Reported Outcomes (PROs)**, (version 01/15/23): Spanish

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

ADDITIONAL FUNDING

Study Activation: 03/17/2023

Funding Source and Study Component		Mandatory/ Mandatory Request or Event/ Optional	Study Specific Notes	Enter Date in OPEN ? (c)	NCORP Research Base Funding for Non-NCORP Sites (a)	NCORP Funding Amount per Patient (b) Std/HP
Federal	Base Intervention (Non-NCORP & Standard/ High Performance (HP) NCORP)	Mandatory	n/a	No	$3000	$3000/ $5000
Federal	Biospecimen – Serum, Plasma & DNA (Baseline, 9 mo) Updated 5/16/23	Optional	1	Yes	$150	$150
Federal	Biospecimen – Serum, Plasma & DNA (Clinically Indicated due to ARE Post SRS) Updated 5/16/23	Optional	1	Yes	$150	$150
Federal	Biospecimen – Tissue – H&E slides Updated 5/16/23	Optional	2	Yes	$300	$300
Total Potential Federal Funds					$3,600	$3,600/ $5,600
Other Federal	$10 Gift card to patient after completing Baseline, 2 mo & 9 mo visits	Mandatory Event	3	No	$30	$30
Total Potential Other Federal Funds					$30	$30
Total Potential Funds					$3,630	$3,630 /$5,630

General Notes:

(a) Non-NCORP institutions enrolling in NCORP trials receive the NCORP standard amount for base intervention and any federal dollar amount listed for ancillary studies, e.g., biospecimens, quality of life, etc., through the credited NCORP Research Base.

(b) The dollar value varies for standard and high performance (HP) NCORP Sites.

(c) All sites participating in a trial with components that have a payment after initial enrollment, (such as a biospecimen collection) MUST enter the collection date in the OPEN funding screen to verify compliance and verify funding. If the trial component consists of a series of submissions over time, such as a QOL study, the site only needs to enter the date the first CRF is submitted.

Study-specific notes:

1. Sites are eligible to receive federal funds for those patients who consent for optional blood biospecimen collections. See information contained in section 10.2 of the Protocol on blood biospecimen collections. Sites MUST enter the collection date in the OPEN funding screen to verify compliance and verify funding.
2. Sites are eligible to receive federal funds for those patients who consent for optional tissue biospecimen collections. See information contained in section 10.3 of the Protocol on optional tissue slide submission. Sites MUST enter the collection date in the OPEN funding screen to verify compliance and verify funding.
3. These gift cards will be purchased by the study for the patient. No funds will be given to the site directly for these events.

Study contact information

Wake Forest NCORP Research Base (NCORP@wakehealth.edu)

Study funding information

Wake Forest NCORP Research Base (NCORP@wakehealth.edu)

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 NCORP@wakehealth.edu 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 NCORP@wakehealth.edu 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 5, 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	251	+1	255		
WF-1806	M&M	147	--	300		
WF-1901	IMPACTS	109	+2	456	0	40
WF-1805CD	HN STAR	147	--	350	106	140
WF-2201	HYPOGRYPHE	0	--	244		