

[View this email in your browser](#)



## STUDY MATTERS

---

March 31, 2022

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

---

**Does your site want to add a CCDR study in preparation for RPPR? If so, come join HN-STAR!**

We will be hosting HN-STAR interest sessions at the times below. During these sessions, we will review the study and answer any of your study-related questions. If you would like to attend one of these sessions, please email [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu).

- Wednesday, April 6<sup>th</sup> @ 12 PM EST
-

**For Funding Opportunities Announcements Relevant to  
NCORP CCDR, click on this link:**

<https://healthcaredelivery.cancer.gov/funding/opportunities.html>

---

### **Upcoming Site Calls**

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

April 13, 2022 at 2:30pm EDT

**WF-1901 - IMPACTS - Internet Delivered Management of Pain Among Cancer  
Treatment**

May 11, 2022 at 2:30pm EDT

If you would like to attend, but did not receive an invitation, please  
email [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu)

---

**Please email [7NCORP@wakehealth.edu](mailto:7NCORP@wakehealth.edu) when  
shipping biospecimen samples. 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

#### Amendment 5, Protocol Version Date 02/28/2022 was released 03/22/2022

Changes with this amendment include:

- Removing T1 and T2 neurocognitive assessments and streamlining questionnaires to reduce patient and site burden.
- Requesting a waiver of documentation of consent to allow local NCORP site staff to obtain consent in person or remotely.
- Participants will be allowed to complete baseline questionnaire via an email link prior to the baseline visit or during the in-clinic visit.
- In addition to T2, T3 and T4, we are now providing participants with a \$25 gift card for completing the baseline (T1) assessment.

#### **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:**

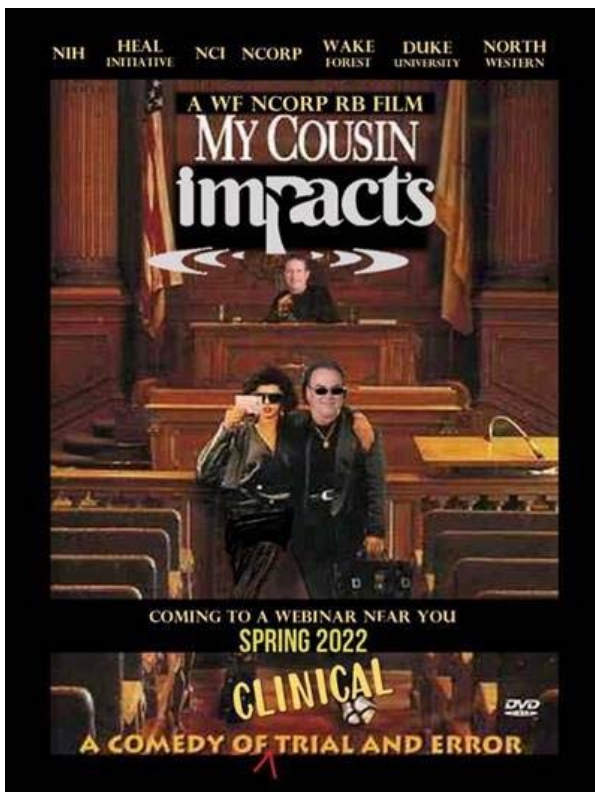
- The protocol documents are available on the [CTSU](#) website.

- An updated **Helpful Guide, Study Staff Fact Sheet, CRA Checklist, and REDCap User Guide** 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](mailto:NCORP@wakehealth.edu). Attn: WF-1901.

The recorded **WF-1901 IMPACTS Amendment #5 Introductory Webinar-2022.03.22** has been posted on the [WAKENCORP](#) website under DASHBOARD/VIDEOS.



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

### Amendment 6, Protocol Version Date 12/08/2021 was released 03/01/2022

The WF NCORP Research Base study titled *A Single Arm, Pilot Study of Ramipril for Preventing Radiation-Induced Cognitive Decline in Glioblastoma (GBM) Patients Receiving Brain Radiotherapy* (WF-1801) has been amended (Amendment 6, Protocol Version Date 12/08/2021). The amended protocol and related documents have been released as of **March 1, 2022** and are available on the [CTSU](#) website. The OPEN enrollment form will be updated and posted on the [WAKENCORP](#) site.

A brief summary of the updates with this amendment is listed below. Other changes are listed in the Summary of Changes document that is posted to CTSU.

- Exclusion criteria were updated to include Memantine, Donepezil, and/or other medications prescribed to enhance cognition.
- Inclusion criteria were updated to expand window when Ramipril is given from 21-35 days after surgery to 21-42 days after surgery.
- Sites will now be allowed to use local labs as a substitute for LabCorp to increase flexibility and decrease time required for results.
- Clarified AE/SAE reporting language.
- Temozolomide documentation was updated.
- New study flyer and patient/family brochure were created to promote the study.
- New informational sheet for PIs was created.

**Note - Limited Access Case Report Forms:** Online access to CRF 17-20 (Baseline Assessment, 6 Week Assessment, 10 Week Assessment, 22 Week Assessment) is restricted to neurocognitive test certified site personnel only and can be downloaded from the Protocol Documents page of the Wake Forest NCORP Research Base (WF NCORP RB) member website, [WAKENCORP](#). For

site staff who have questions or need to complete the neurocognitive test certification, please contact the WF NCORP RB at [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu).

**Sites interested in participating** should contact [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu), Attn: WF-1801

---

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

We are pleased to announce that we will be offering travel awards to the top two accruing sites between January 19 and July 31, 2022. Each award will cover two nights' accommodations at the Wake Forest NCORP 2022 Annual Meeting in Myrtle Beach, SC at the Marriott Grand Dunes in October.

---

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

Our Biospecimen lab is still unable to obtain the gold top 5.0 mL B&D tubes (#367986) approved in the UPBEAT Study protocol. There is still a nationwide shortage of these tubes. As a substitute, the lab will ship Red/Gray mottled 8.5 mL SST tubes (B&D #367988). Please use these 8.5 mL tubes to draw blood for serum when an unexpired gold top tube is not available. If you have current gold top tubes at your site, you may use those instead.

We will note a protocol deviation in the participant's REDCap record if these 8.5 mL tubes are used. If you use the 8.5 mL tube, please note that on the shipping log when sending the samples to the lab.

The lab will provide current gold top tubes to sites that need them as soon as they receive a new supply.

Please contact [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu) if you have any questions.

---

### Accruals as of March 30, 2022

Open Studies	Name	Enrolled (Patients)	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1801	RAMIPRIL	51	75		
WF-1802	PCW	194	255		
WF-1806	M&M	76	300		
WF-1901	IMPACTS	45	456	0	40
WF-1804CD	AH-HA	351	600	19	40
WF-1805CD	HN STAR	57	350	69	140

---

*Copyright © 2022 Wake Forest NCORP Research Base, All rights reserved.*

You were added to this email list when you were rostered to the WAKE NCORP Research Base

**Our mailing address is:**

Wake Forest NCORP Research Base  
Medical Center Blvd  
Winston Salem, NC 27157-0001

[Add us to your address book](#)

Want to change how you receive these emails?

You can [update your preferences](#) or [unsubscribe from this list](#).

