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STUDY MATTERS

March 17, 2022

Wake NCORP Website: <https://wakencorp.phs.wakehealth.edu/wakehealth.us19.list-manage.com>

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.

- Monday, March 28th @ 4 PM EST

- Wednesday, April 6th @ 12 PM EST

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

<https://healthcaresdelivery.cancer.gov/funding/opportunities.html>
[\[wakehealth.us19.list-manage.com\]](https://wakehealth.us19.list-manage.com)

Roster Management in RUMS

As a reminder, Roster Update Management System (RUMS) was made available in June 2019 for the Wake Forest NCORP Research Base. Individuals with the Administrator or RUMS Manager role on the WAKE roster may add and withdraw person roles at their site. [Individuals requiring access to the WAKE roster will need to request the Administrator or RUMS Manager roles by email NCORP@wakehealth.edu, or using the request primary role action icon in RUMS prior to making other roster updates.](#) Instructions for making roster updates are available under the Help Topics on the RUMS toolbar.

Upcoming Site Calls

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

Receiving Brain Radiotherapy

March 23, 2022 at 3:00pm EDT

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

April 13, 2022 at 2:30pm EDT

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

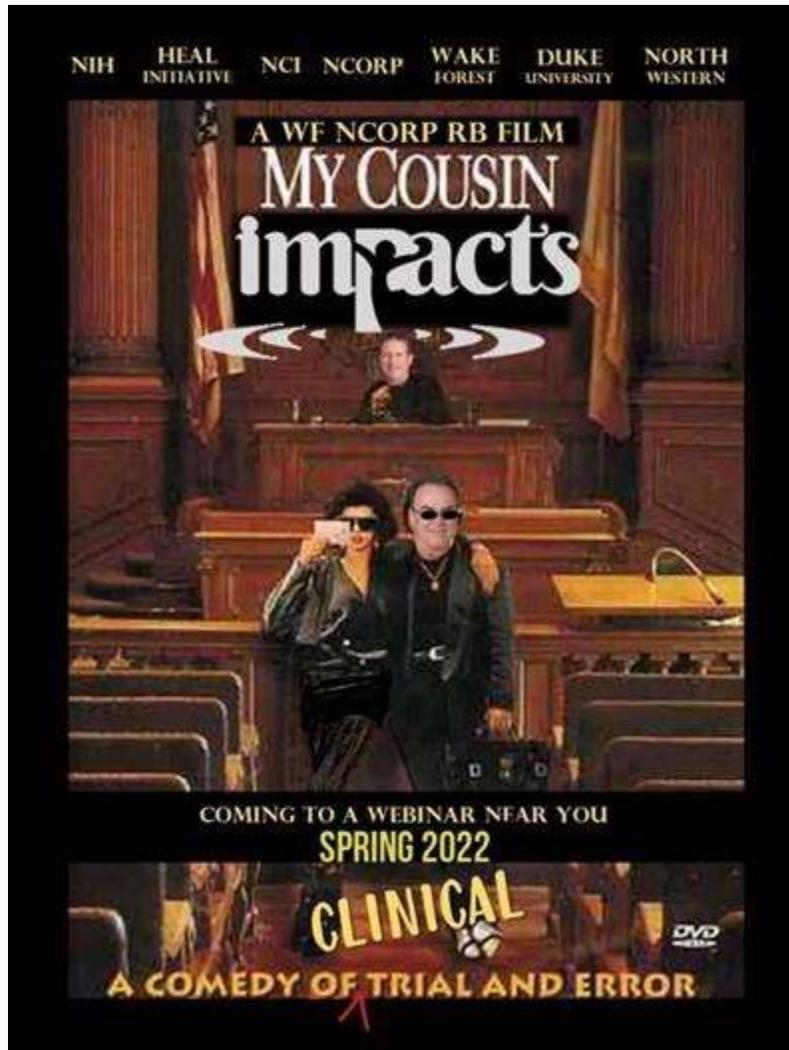
Please email 7NCORP@wakehealth.edu when shipping biospecimen samples. Include the FEDEX tracking number in your email so that misplaced samples can be tracked before they spoil.

Study Updates

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

We will host a webinar to introduce **WF-1901 IMPACTS Amendment #5** on **March 22nd, 2:00pm ET**. Please join us! If you have not received an email invitation, please contact us at NCORP@wakehealth.edu

Click the link for a sneak peek: <https://youtu.be/971-VC0qF80>
[\[wakehealth.us19.list-manage.com\]](http://wakehealth.us19.list-manage.com)



[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 \[wakehealth.us19.list-manage.com\]](https://wakehealth.us19.list-manage.com) website. The OPEN enrollment form will be updated and posted on the [WAKENCORP \[wakehealth.us19.list-manage.com\]](https://wakehealth.us19.list-manage.com) 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 \[wakehealth.us19.list-manage.com\]](https://wakehealth.us19.list-manage.com). For site staff who have questions or need to complete the neurocognitive test certification, please contact the WF NCORP RB at NCORP@wakehealth.edu.

Sites interested in participating should contact 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-1806 - M&M - Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer

Starting March 1, 2022, win M&M's in the mail! These will go to:

- The first site to enroll a participant each month

- The site who enrolls the most participants between bi-monthly site calls



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

*****Please Resume Neurocognitive Testing*****

Our license to use the copyrighted Neurocognitive Tests that are part of the Baseline, 3-Month, 12-Month, and 24-Month study procedures has been renewed. You can resume downloading and administration of these tests on the following Case Report Forms:

- CRF20 - Baseline Visit Neurocognitive Testing
- CRF21 - 3-Month Visit Neurocognitive Testing
- CRF22 - 12-Month Visit Neurocognitive Testing
- CRF23 - 24 Month Visit Neurocognitive Testing

Thank you for your help with this brief delay.

Biospecimen Samples

When shipping Serum, Plasma, and DNA samples to the Biospecimen Lab,

please change the Express Package Service selection from "FedEx Standard Overnight" to "FedEx Priority Overnight"

Several samples have been arriving late to our Biospecimen lab due to delays encountered through FedEx shipping.

As always, please do not ship samples for the WF97415-UPBEAT study on Friday as they will not be processed at the lab until the following Monday. Samples that thaw to room temperature are no longer evaluable.

New kits received from the Biospecimen Lab will have the correct shipping service indicated.

Please contact NCORP@wakehealth.edu if you have any questions.

Accruals as of March 16, 2022

| Open Studies | Name | Enrolled (Patients) | Target (Patients) | Enrolled (Non-Patients) | Target (Non-Patients) |
|--------------|----------|---------------------|-------------------|-------------------------|-----------------------|
| WF-1801 | RAMIPRIL | 50 | 75 | | |
| WF-1802 | PCW | 189 | 255 | | |
| WF-1806 | M&M | 75 | 300 | | |
| WF-1901 | IMPACTS | 43 | 456 | 0 | 40 |
| WF-1804CD | AH-HA | 335 | 600 | 19 | 40 |
| WF-1805CD | HN STAR | 52 | 350 | 69 | 140 |

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Our mailing address is:

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Medical Center Blvd
Winston Salem, NC 27157-0001

[Add us to your address book \[wakehealth.us19.list-manage.com\]](mailto:wakehealth.us19.list-manage.com)

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