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## STUDY MATTERS

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**April 14, 2022**

**Wake NCORP Website:** [https://wakencorp.phs.wakehealth.edu/\[wakehealth.us19.list-manage.com\]](https://wakencorp.phs.wakehealth.edu/[wakehealth.us19.list-manage.com])

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We invite all NCORP CCDR Leads and interested site investigators and staff to save the date for a half day CCDR workshop led by investigators from the iDAPT: Implementation and Informatics P50 Center. The focus will be on building capacity to participate in implementation science CCDR studies, including information on assessing your practice readiness and engaging stakeholders. The in-person workshop will be immediately following the Wake Forest NCORP Research Base Annual Meeting on the morning of October 12<sup>th</sup>.

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

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

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### **Upcoming Site Calls**

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

April 20, 2022 at 1:00pm EDT

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

May 11, 2022 at 2:30pm EDT

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

May 17, 2022 at 1:30pm EDT

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

May 18, 2022 at 3:00pm EDT

**WF-1804CD - AH-HA - Assessing Effectiveness and Implementation of an  
EHR Tool to Assess Heart Health Among Survivors (AH-HA)**

May 19, 2022 at 11:30am EDT

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

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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).

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## Study Updates

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### **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.

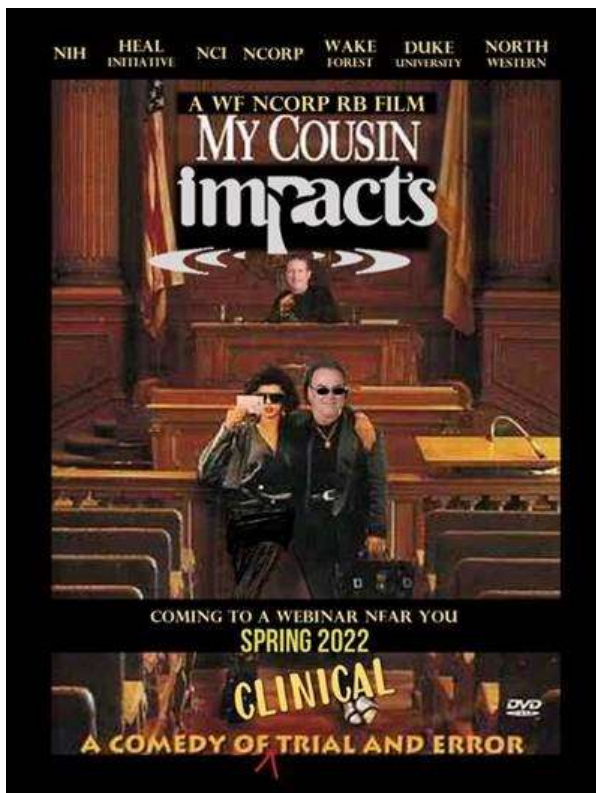
### **Document Access:**

- The protocol documents are available on the [CTSU \[wakehealth.us19.list-manage.com\]](https://wakehealth.us19.list-manage.com) website.
- An updated **Helpful Guide, Study Staff Fact Sheet, CRA Checklist, and REDCap User Guide** is available on the [WAKENCORP \[wakehealth.us19.list-manage.com\]](https://wakehealth.us19.list-manage.com) 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 \[wakehealth.us19.list-manage.com\]](https://wakehealth.us19.list-manage.com) website under DASHBOARD/VIDEOS.



## **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.

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## **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.

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Accruals as of April 13, 2022

Open Studies	Name	Enrolled (Patients)	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF 1801	Ramipril	51	75		
WF 1802	PCW	195	255		
WF 1806	M&M	78	300		
WF 1901	IMPACTS	45	456		40
WF 1804CD	AH-HA	355	600	19	40
WF 1805CD	HN STAR	62	350	69	140

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