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| **STUDY MATTERS** |

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| **January 6, 2022Wake NCORP Website:**<https://wakencorp.phs.wakehealth.edu/> |

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| **NCORP BIOSPECIMEN LAB UPDATE:** ***The lab has moved!*****NEW \*REVISED\* SHIPPING ADDRESS**K. KOURMAN & M. MORRISNCORP Biospecimen LabPhone: 336-716-2581Bldg A1A Lab 230 c/o Delivery on TimeWake Forest School of MedicineRICHARD DEAN Bldg RECEIVING DOCK391 TECHNOLOGY WAYWINSTON SALEM  NC  27101New air bills will be printed and sent to sites for old kits.  New kits going out soon will have the new return address. |

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| **WF NCORP RB OFFICE CLOSURE:Our office will be closed Monday, January 17, 2022 in observance of Martin Luther King, Jr. Day.**  |

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|   **McKesson****Clinical Research ServicesClosed January 17, 2022** In observance of Martin Luther King, Jr. Day, McKesson’s Clinical Research Services will be closed **Monday, January 17, 2022.**  We will resume regular business hours on Tuesday, January 18, 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 Martin Luther King, Jr. Day.*** Only non-refrigerated product will be shipped on **Friday, January 14**. Orders placed prior to 2 pm ET will be delivered on **Monday, January 17.**
* If refrigerated or temperature-controlled product is required before the holiday, orders must be placed by **Thursday, January 13** prior to 2 pm ET.

 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 clinicalresearchservices@mckesson.com. We appreciate the opportunity to assist you and your patients. Kind regards,Clinical Research Services team |
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| **NCORP Webinar Series AnnouncementRegistration is Now Open:****[click on link below]**<https://events.cancer.gov/hdrp/ncorpccdrwebinars/registration>  Our team of Research Base, Community Site, Minority/Underserved Community Site, and NCI representatives is pleased to invite you to the final session of a three-part webinar series titled “Collaborating to Develop New Practice Randomization Trials for NCORP Cancer Care Delivery Research (CCDR).”The series has provided an opportunity to share experiences with these types of trials and strategize about how best to conduct similar trials in the future.  It is designed to be broadly applicable to NCORP members involved in CCDR, regardless of their level of engagement with practice randomized trials. The final webinar is scheduled for January 26, 2022 from 4 – 5:30pm EST. **FINAL WEBINAR****“Making the Numbers Work:  Design Considerations in NCORP CCDR Trials”**Goal:  discuss approaches to balance the design features and analysis plans of future NCORP CCDR practice-randomized trials and the reality of their conduct in NCORP CCDR.  The emphasis will be on pre-protocol approval activities. This webinar will include opportunities for attendees to interact with panelists.  Attendance is limited to those affiliated with an NCORP Site or Research Base to allow for open discussion. |

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| **For Funding Opportunities Announcements Relevant to NCORP CCDR, click on this link:**<https://healthcaredelivery.cancer.gov/funding/opportunities.html> |

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| **Upcoming Site CallsWF-1802 - PCW - Influence of Primary Treatment for Prostate Cancer on Work ExperienceJanuary 18, 2022 at 1:30pm ESTWF-1805 - HN-STAR - Implementation and Effectiveness Trial of HN-STARJanuary 19, 2022 at 3:00pm ESTWF-1804CD – AH-HA – Assessing Effectiveness and Implementation of an EHR Tool to Assess Heart Health Among SurvivorsJanuary 20, 2022 at 11:30am ESTWF-1801 - Ramipril - A Single Arm, Pilot Study of Ramipril for Preventing Radiation-Induced Cognitive Decline in Glioblastoma Patients Receiving Brain RadiotherapyJanuary 26, 2022 at 3:00pm ESTWF-1806 – M&M - Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal CancerFebruary 9, 2022 at 2:30pm ESTWF-1901 - IMPACTS - Internet-delivered Management of Pain Among Cancer Treatment SurvivorsSite Call has been moved from January 11th, 2022 to February 23, 2022at 2:30pm EST**If you would like to attend, but did not receive an invitation, please email NCORP@wakehealth.edu |

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| **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.** |

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| **Study Updates** |

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| **WF-1802 - PCW - Influence of Primary Treatment for Prostate Cancer on Work Experience****The Higher Income White stratum only has 3 remaining slots available**. Please keep this in mind when screening for participants and check the slot reservation report in CTSU-OPEN to see how many slots are available before registering. |

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| **WF-1804CD - AH-HA - Assessing Effectiveness and Implementation of an EHR Tool to Assess Heart Health Among Survivors****\*\*Last call for NCORP sites/affiliates interested in WF-1804 CD\*\***The NCI has requested that we identify all potentially interested sites for the Automated Heart Health Assessment (AH-HA) for Survivors study by Feb 1, 2022. If your NCORP site/affiliate is interested in opening this study or adding an additional affiliate, please contact the Wake Forest NCORP Research Base at NCORP@wakehealth.edu. |

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

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| ***HN-STAR (WF-1805CD) is actively looking for new sites to enroll! We have recently made significant changes that dramatically expand patient eligibility, such as allowing telehealth study visits, enabling remote consent, including patients with a history of other cancers, and  including patients up to 2 years out from treatment completion. We are happy to have individual meetings with site staff to discuss any questions and concerns about HN-STAR involvement. Please contact****NCORP@wakehealth.edu****if interested.*NEW AMENDMENT ACTIVATION****WF-1805CD Amendment 4, PVD 10/04/2021, Release Date 12/20/2021The WF NCORP Research Base study titled *Implementation and Effectiveness Trial of HN-STAR* has been amended. The amended protocol and related documents were released on Monday, December 20, 2021.Changes with this amendment include:*** Expanding eligibility criteria to include participants who are ≤24 months post-completed treatment for HNC.
* Updating and clarifying survivor inclusion criteria to include patients treated for locoregionally recurrent disease.
* Updating and clarifying survivor exclusion criteria to include evidence of prior cancer (excluding non-melanoma skin cancer) within 3 years of the designated clinic visit. Please see protocol for specific changes.
* Allowing completion of the FACT-HN portion of the **Survivor Baseline Health Assessment** up to 48 hours following the designated clinic visit
* Adding language stating the CDST should be used to guide clinical discussion and select management plans
* Removing the **Designated Clinician Acceptability & Feasibility CDST** instrument
* Adding three questions at the beginning of the **List Symptoms DC** instrument to assess Designated Clinician use of the CDST in the HN-STAR intervention arm

 **Regulatory Requirements*** 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 now available on the [CTSU [wakehealth.us19.list-manage.com]](https://urldefense.com/v3/__https%3A/wakehealth.us19.list-manage.com/track/click?u=a8dd4147fd4a4623cc1b318f8&id=4548de0148&e=5e52385a02__;!!GA8Xfdg!kT01Wf7UEkzq9RFZ79yIUSGDlx2K9EFyoAwhY3BNgYjj2-0MW9awJ2UTL5rQuFg4$) website.
* A Help Guide, data collection trainings and an FAQ document are available on the [WAKENCORP [wakehealth.us19.list-manage.com]](https://urldefense.com/v3/__https%3A/wakehealth.us19.list-manage.com/track/click?u=a8dd4147fd4a4623cc1b318f8&id=e82de75823&e=5e52385a02__;!!GA8Xfdg!kT01Wf7UEkzq9RFZ79yIUSGDlx2K9EFyoAwhY3BNgYjj2-0MW9awJ2UTL2G62RlF$) website.

**Participation**If there are any questions about the activation or if your site is interested in participating in this study, please contact NCORP@wakehealth.edu     Attn: WF-1805CD and provide the following information:* Parent CTEP ID
* Parent Institution Name
	+ Participating Site(s) (affiliates and sub-affiliates):
		- Site CTEP IDs
		- Site Names
* Principal Investigator:
	+ First and Last Name
	+ Phone Number
	+ Email Address
* Primary Point of Contact:
	+ First and Last Name
	+ Phone Number
	+ Email Address

**In accordance with Amendment #4, the following documents were updated and are available on the WAKE NCORP website:*** **Study Checklists (Usual Care and HN-STAR Arms)**
* **Data Collection Trainings (Usual Care and HN-STAR Arms)**
* **HN-STAR Tool Designated Clinician Training**
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| **WF-1806 - M&M - Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer****NEW AMENDMENT ACTIVATION** **WF-1806 (M&M) Amendment 5, Protocol Version Date 11/08/2021, Release Date 12/30/2021:** **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 Thursday, December 30th 2021.** **Changes with this amendment include:*** In addition to patients who are being treated for metastatic colorectal cancer with 5-FU, patients who are being treated with immunotherapy only are now eligible for the study.

 **WF-1806 Document Access:*** The protocol documents are available on the [CTSU](https://www.ctsu.org/Public/Default.aspx?ReturnUrl=%2f) website.
* The *Helpful Guidelines*, *FAQs*, and *Training Attestation*documents are available on the [WAKENCORP](https://wakencorp.phs.wakehealth.edu/) website.

**\*Note:  A new version of the Helpful Guidelines (v12.30.2021) for this study has been posted.** **Registration Requirements:*** 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).
* Toxicity Grading Certificates will be required for any staff member who will grade toxicities for this study.
* Physical Testing Certificate will be required for any staff member who will be administering the SPPB or HGS tests.
* Site Open to Enrollment (SOTE) letter from the WF NCORP RB will be provided to the site after all onboarding activities are completed.

 **WF-1806 Participation:**Sites interested in participating who have not started the onboarding process should contact the WF NCORP RB at NCORP@wakehealth.edu; Attn: WF-1806 and provide the following information:* Parent CTEP ID
* Parent Institution Name
	+ Participating Site(s) (affiliates and sub-affiliates):
		- Site CTEP IDs
		- Site Names
* Principal Investigator:
	+ First and Last Name
	+ Phone Number
	+ Email Address
* Primary Point of Contact:
	+ First and Last Name
	+ Phone Number
	+ Email Address

 If there are any questions regarding the WF-1806 activation or site registration procedures, please contact NCORP@wakehealth.edu; Attn: WF-1806.  |

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| **WF-97415 - UPBEAT - Understanding and Predicting Breast Cancer Events after Treatment****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](http://NCORP@wakehealth.edu/)**if you have any questions.** |

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