



Thank you to all who joined our virtual 2020 Annual Meeting last week!

Congratulations to the Top Accruing Sites recognized below!



Cancer Control



	Community Site	Accruals
1	Metro Minnesota Community Oncology Research Consortium (MMCORC)	34
2	Upstate Carolina Consortium Community Oncology Research Program	23
3	VCU Massey Cancer Center MU NCORP	21

	Affiliate/Sub-affiliate	Accruals
1	NC004 - Cone Health Cancer Center, Greensboro, NC SC024 - Spartanburg Medical Center, Spartanburg, SC	16
2	VA010 - Virginia Commonwealth University/Massey Cancer Center, Richmond, VA	14
3	NC002 – Wake Forest Baptist Comprehensive Cancer Center, Winston-Salem, NC	12

*Data from 08/01/2019 – 07/31/2020



Cancer Control (Minority/Underserved Accruals only)



	Community Site	Accruals
1	Upstate Carolina Consortium Community Oncology Research Program	13
2	Heartland Cancer Research NCORP	9
3	Delaware/Christiana Care NCORP Metro Minnesota Community Oncology Research Consortium (MMCORC) Southeast Clinical Oncology Research Consortium (SCOR) NCORP	8

	Affiliate/Sub-affiliate	Accruals
1	SC024 - Spartanburg Medical Center, Spartanburg, SC	10
2	NC004 - Cone Health Cancer Center, Greensboro, NC	8
3	NC002 – Wake Forest Baptist Comprehensive Cancer Center, Winston-Salem, NC	5

*Data from 08/01/2019 – 07/31/2020



CCDR Accruals



	Community Site	Accruals
1	Southeast Clinical Oncology Research Consortium (SCOR) NCORP	106
2	Columbus NCORP	93
3	Metro Minnesota Community Oncology Research Consortium (MMCORC)	58

	Affiliate/Sub-affiliate	Accruals
1	NC047 - <u>Novant</u> Health Forsyth Medical Center, Winston-Salem, NC	55
2	DE028 - Helen F Graham Cancer Center, Newark, DE	36
3	IA008 - <u>Mercy</u> Medical Center - Des Moines in Des Moines, IA	31

*Data from 08/01/2019 – 07/31/2020

STUDY UPDATES:

NEW AMENDMENT

WF-1805CD HN-STAR - Amendment 2, Protocol Version Date 09/04/2020, Release Date 11/02/2020

The 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, November 2, 2020**.

Changes with this amendment include:

- Allowing virtual study visits in both study arms if the patient is already scheduled for a virtual survivorship visit or if usual care practice in the clinic includes virtual visit options.
- Implementation of remote consenting process.

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 will be available on the [CTSU](#) website on 11/02/2020.
- A WF-1805CD Helpful Guide and FAQ document are available on the [WAKENCORP](#) 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

WF-1806 M&M – *Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer, Amendment 3, Protocol Version Date 05/01/2020.*

- **Updated FAQ document, dated 11/04/2020 and posted on [WAKENCORP](#) website. Please review addition of Question #15 seen below.**
Question #15 - I have a patient who is on the Alliance A021703 trial, which compares the prognostic effect of high dose versus low dose supplemental Vitamin D. May I also enroll this patient on the M&M WF 1806 study, since Vitamin D is considered a supplement rather than an investigational agent? **Yes, co-enrollment with the A021703 is allowed.**
- If there are any question regarding the WF-1806 activation or site registration procedures, please contact NCORP@wakehealth.edu; Attn: WF-1806

WF-30917CD Telehealth – *A Stepped-Care Telehealth Approach to Treat Distress in Rural Cancer Survivors*

- The next Site Call will be November 9, 2020 at 4pm EST. If you have not received a WebEx invitation but would like to attend, please email NCORP@wakehealth.edu. **During this site call, we will be briefly discuss the changes coming in Amendment 5.**

WF-10217 WAYS - *Work Ability in Young Adult Survivors (WAYS)*

We would like to thank all sites who have participated in this study and for those who continue to screen and recruit for the remaining minority slots that we have available. **We wanted to let you know that we will be closing this study to enrollment as of December 4, 2020 unless we meet the enrollment goal before this deadline.** We still have several slots open so we encourage you to continue to recruit.

General WF NCORP RB Biospecimen Lab Management:

Shipping Address Change

The address for samples to be shipped for DNA isolation on the two studies listed below has changed. **Please request new pre-paid shipping labels by sending your Site's contact name and address to NCORP@wakehealth.edu.** If you have a sample to send before you receive your replacement labels, you may still use your current labels as we will be monitoring the other address for packages.

- WF-97116 Remember
- WF-1801 Ramipril

The new address is: WF NCORP Biospecimen Lab
Wake Forest Biotech Place
575 Patterson Avenue, Suite 240-250
Winston-Salem, NC 27101
Phone: (336) 716-2581

NOTE: Missed samples can be collected at any future clinical or study visit as it reflects a germline process that will not be affected by treatments.

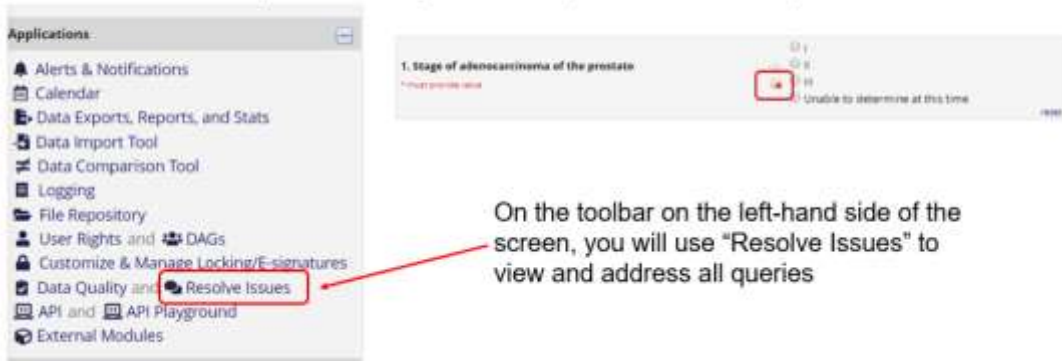
- Please request your lab kits before you run completely out of kits. This will ensure that there will be no delay in getting samples shipped to the Biospecimen Laboratory.
- Please check and record your stored Biospecimen kit expiration dates.
- Please do not ship samples on Thursday or Friday so that samples will not arrive on the weekend

General Data Management – How do I find my REDCap data queries?

For studies using REDCap data entry (WF-20817CD OASIS, WF-97415 UPBEAT, WF-1801 RAMIPRIL, WF-1802 PCW, WF-1804CD AH-HA, WF-1805CD HN-STAR, WF-1806 M&M and WF-1901 IMPACTS) please click the “Resolve Issues” link on the left side menu to check for any open data queries.

Queries in REDCap

- Queries will be opened directly in REDCap. Fields that are queried will be marked



The image shows two screenshots. On the left is the 'Applications' sidebar menu in REDCap, with 'Resolve Issues' highlighted by a red box and a red arrow pointing to it. On the right is a data entry form for '1. Stage of adenocarcinoma of the prostate'. A red box highlights a red 'X' icon in the toolbar, with a red arrow pointing to it from the text below.

On the toolbar on the left-hand side of the screen, you will use “Resolve Issues” to view and address all queries

Accruals as of October 31, 2020

Open Studies	Name	Enrolled	Target
WF 97115	Acupuncture	218	240
WF 97116	Remember	261	276
WF 97415	Upbeat	271	1000
WF 10217	Ways	207	220
WF 30917CD	Telehealth	42	90
WF 1801	Ramipril	34	75
WF 1802	PCW	85	220
WF 1804CD	AH-HA	10	624
WF 1805CD	HN-STAR	0	350
WF 1806	M&M	25	300
WF-1901	IMPACTS	0	456

Please email NCORP@wakehealth.edu with any questions you may have regarding the Bi-Weekly information.