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Special Broadcast
August 3, 2022

The distribution of this special broadcast is provided to notify members of recent updates to events, website updates, and protocol specific information.

NEW AMENDMENT ACTIVATION

WF-1806 (M&M) Amendment 6, Protocol Version Date 06/24/2022, Release Date 08/03/2022:

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 Wednesday, August 3, 2022.

Changes with this amendment include:

- Updated inclusion criteria to allow enrollment through the first month of chemotherapy.
- Updated inclusion and exclusion criteria to decrease allowable time since previous chemotherapy treatment from ≥ 12 months to ≥ 3 months (12 weeks).

WF-1806 Document Access:

- The protocol documents are available on the [CTSU](#) website.
- The *Helpful Guidelines*, *FAQs*, and *Training Attestation* documents are available on the [WAKENCORP](#) website.

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):
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- 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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