Title: FORCE: Focus on Reducing Dose-Limiting Toxicities in Colon Cancer with Resistance Exercise

1. Primary Objective:

To examine differences in dose reductions, dose delays and early stoppage for chemotherapy

and the total combined number of moderate and severe chemotherapy-associated toxicities

between intervention group and waitlist controls.

2. Secondary Objectives:

a. To examine specific inflammatory markers (e.g. CRP, IL-6, TNF-α receptor II [TNF-RII])

in relation to baseline MM and fat mass (FM) and examine differences in changes in inflammatory markers between intervention group and waitlist controls. Inflammatory markers and body composition will be measured pre and post intervention.

b. To examine the impact of RT induced body composition changes on the pharmacokinetics (PK) of 5-FU and oxaliplatin between baseline and 4 months of RT.

Key inclusion criteria:

• Men and women ≥18 years
• Newly diagnosed with histologically confirmed stage II-III colon cancer
• Completed curative-intent surgical resection
Currently prescribed one of the following adjuvant chemotherapy regimens: (IV 5-fluorouracil [5-FU] / leucovorin [LV], capecitabine, FOLFOX [5-FU, LV, oxaliplatin], CAPOX)

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Resistance Training to Reduce Chemotoxicity [capecitabine and oxaliplatin]

- Patients must have started chemotherapy or plan to start within 4 weeks of planned receipt of the first exercise visit. Patients enrolled at the Dana-Farber Cancer Institute must be receiving FOLFOX chemotherapy to be eligible since they will be enrolled in the pharmacokinetics sub-study (see section 2.9).
- No planned major surgery anticipated in the intervention period
- Sufficient time to heal from any major surgery to start of intervention, including colostomy reversal (port-a-cath removal excluded)
- Creatinine value <2 mg/dL
- Approval by either oncologist or surgeon to participate in trial
- Readiness (as determined by the Physical Activity Readiness Questionnaire (PAR-Q) – see Appendix 11.2.2)
  - If there are any indications that home based exercise would be unsafe based on PAR-Q the patient will not be enrolled until confirmation from the patient’s treating provider is received via email and/or phone that they are safe to exercise.
- Ability to understand and the willingness to sign a written informed consent document in English
- Willingness to be randomized