THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

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To: Claudio Battaglini
Exercise and Sport Science

From: Biomedical IRB

Approval Date: 3/20/2017
Expiration Date of Approval: 3/12/2018
RE: Notice of IRB Approval by Full Board Review
Submission Type: Initial
Study #: 16-3284

Study Title: LCCC1630: Get REAL and HEEL Research Program

This submission has been approved by the IRB for the period indicated.

Study Description:

Purpose: The UNC Get REAL & HEEL (GR&H) program has provided after treatment support for women with a breast cancer diagnosis since 2006. The 16-week program includes an individualized training program and the opportunity to continue working out in the GR&H facilities at the conclusion of the 16-week program. The purpose of this protocol is to implement a research agenda at GR&H that will examine the efficacy of the program. The primary aim of this study is a pre-post test of the impact of the GR&H program (standardized combination of aerobic and resistance training) on VO2peak. The secondary aims of this study are to evaluate quality of life as well as cardiorespiratory function (vascular health, mitochondria function), physical function (muscular strength, body composition), cognition, balance, and patient-reported outcomes (fatigue, depression, anxiety, quality of life). Exploratory aims are focused on evaluating the impact of exercise on biomarkers: (1) aging - $p16^{INK4a}$, (2) immune cell function - total leukocyte count, T and natural killer cells, monocytes, and neutrophils count and activity, and (3) circulating pro- and anti-inflammatory cytokines.

Participants: Patients will be eligible for this study if they have histologically confirmed early stage (non-metastatic) breast cancer and have recently (within 1 year) completed their initial treatment (they may continue to be on endocrine treatment). 75 patients will be recruited in the first 2 years.

Procedures (methods): This is a one-arm intervention study to evaluate the impact of a 16-week exercise rehabilitation program (Get REAL & HEEL Breast Cancer Exercise Rehabilitation Program) for breast cancer survivors. Each year, the study will enroll three different cohorts of approximately 20-25 patients who will complete the 16-week program. Recruitment will be continuous throughout the year. Everyone on the wait list for more than 8 weeks will have a Baseline assessment twice – once when they are recruited but wait-listed (W1) and a second time at the start of their GR&H session/exercise training (B1). Those on the wait list less than 8 weeks will have only one baseline assessment at the beginning of their session (B1). The assessments are exactly the same each time. All participants will undergo a post-intervention assessment after they complete their 16-week exercise training. Further follow-up assessments will be conducted at 6, 12, 24, 36, 48, and 60 months (+/- 4 weeks for each time point) after the training intervention.

Regulatory and other findings:

The IRB has determined that the study-specific rationale provided by the investigator is sufficient to justify a

limited waiver of HIPAA authorization to identify potential subjects for recruitment into this research study, as allowed under 45 CFR 164.512. This temporary waiver provides access to protected health information (PHI) to confirm eligibility and facilitate initial contact, after which consent and HIPAA authorization will be sought when applicable. Access and use is limited to the minimum amount of PHI necessary to review eligibility criteria and to contact potential subjects.

Investigator's Responsibilities:

Federal regulations require that all research be reviewed at least annually. It is the Principal Investigator's responsibility to submit for renewal and obtain approval before the expiration date. You may not continue any research activity beyond the expiration date without IRB approval. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.

Your approved consent forms and other documents are available online at http://apps.research.unc.edu/irb/index.cfm?event=home.dashboard.irbStudyManagement&irb_id=16-3284.

You are required to obtain IRB approval for any changes to any aspect of this study before they can be implemented. Any unanticipated problem involving risks to subjects or others (including adverse events reportable under UNC-Chapel Hill policy) should be reported to the IRB using the web portal at http://irbis.unc.edu.

Please be aware that approval may still be required from other relevant authorities or "gatekeepers" (e.g., school principals, facility directors, custodians of records).

The current data security level determination is Level III. Any changes in the data security level need to be discussed with the relevant IT official. If data security level II and III, consult with your IT official to develop a data security plan. Data security is ultimately the responsibility of the Principal Investigator.

This study was reviewed in accordance with federal regulations governing human subjects research, including those found at 45 CFR 46 (Common Rule), 45 CFR 164 (HIPAA), 21 CFR 50 & 56 (FDA), and 40 CFR 26 (EPA), where applicable.

CC:
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