Combined Informed Consent and HIPAA Authorization Guidance:

- **Study Title:** A Group-Mediated Cognitive Behavioral Resistance Exercise Intervention in Head and Neck Cancer Patients Undergoing Chemoradiation Treatment.

- **Principal Investigators:** Brian C. Focht, PhD, FACSM, CSCS; Dukagjin M. Blakaj MD, PhD

- **Sponsor:** The Ohio State University

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.

- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.

- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

- **Key Information About This Study:** This research study will recruit patients with current head and neck cancer (HNCa) that will be undergoing Chemoradiation treatment. This study is being done to evaluate the effectiveness of a resistance exercise (RE) program using a group mediated cognitive behavior (GMCB) approach, which is a group-based counseling that works on promoting lifestyle behavior change through improving self-regulatory skills, and how they might affect your HNCa symptoms, health, weight status, activity level, and everyday life. Information that is more detailed is listed later in this form.

1. Explanation of the study (Why is this study being done?):

You are invited to be in a research study. Health research studies are done to learn new ways to treat people who have similar health problems. You may or may not get any benefit from being part of the study. There may also be risks involved with being part of this research study. You are being asked to take part in this study because: 1) you have head and neck cancer (HNCa); 2) you are currently undergoing Chemoradiation therapy treatment for your HNCa. You can decide to be in this study or not. Please take your time in thinking about what the study will want you to do, and ask the study staff to explain any words or information that you do not understand. You may also take time to talk about the study with your friends and family.

This research study is being done to evaluate the effectiveness of a resistance exercise (RE) program using a group mediated cognitive behavior (GMCB) approach and how they might affect your HNCa symptoms, health, weight status, activity level, and everyday life. This study is designed to determine the feasibility of administering a RE program, using a GMCB approach, during Chemoradiation therapy in HNCa patients, as well as compare the benefits of this program with those participating in standard of care procedures to manage their HNCa symptoms over a period of 24-weeks.

2. **Number of participants in the study (How many people will take part in this study?):** A total of up to 34 people will participate in this study at Ohio State.

3. **Study procedures (What will happen if I take part in this study?):**

If you decide to be in this research study, this is what will happen. What you do in this study does not take the place of the care that you get from your doctor. All subjects for this study will be asked to complete 3 screening visit assessments at the Physical Activity and Educational Services (PAES) building on the main campus of Ohio State University during the course of the study. These assessments will be conducted during a single screening visit at each of 3 different time points: the beginning of the study (baseline), 3 months into the study (1st follow-up), and 6 months into the study (2nd follow-up).

During each of the 3 screening visit assessments conducted at the PAES building, you will be asked to fill out some forms with questions about your background, contact information, medical history, HNCa symptoms, confidence/ability to perform common daily activities, and quality of life. These forms will take about 30-40 minutes of your time to complete.

Next, during each screening visit, you will do three simple physical function assessments, including a walk task, stair climb task, and lift and carry test. You will also do two muscular strength assessments, including a one-repetition rep maximum chest press and leg extension test. These tests will take about 30-40 minutes. After these simple tests, we will measure your height and body weight and body composition. For the body composition test, you will use a DEXA that measures the amount of bone, muscle, and fat. The DEXA scan is a Dual

Energy X-ray Absorptiometry (DXA) machine. This procedure is a type of x-ray, but involves a very low dose of radiation. Radiation exposure information can be found in the risks section of this document below. The entire screening visit will take about 1.5 to 2 hours.

Following the Baseline Screening Visit, you will participate in a resistance exercise program that incorporates a group counseling component. Below is a description of what you will do in that program.

- **Resistance Exercise and GMCB Counseling:**

If you choose to participate, you will start a 24-week resistance training program. The resistance exercise (RE) component involves performing 1-3 sets of 8RM-12RM repetitions at a rating of perceived exertion ranging from 4 (Moderately Hard) to 7 (Hard) of 9 different exercises (leg press, leg extension, leg curl, chest press, lat. pull-down, overhead press, triceps extension, bicep curl, calf raises, and abdominal curl). The RE will be personalized to the individual tolerance and capacity of each HNCa patient at each session and progression of sets and reps. Load, and overall volume-load will be progressed gradually in a symptom-limited manner to address patient tolerance and preference issues. In order to implement the resistance training principles of progression and overload, when patients are able to successfully complete 2 additional repetitions on 2 consecutive sets of an exercise at the low end of the appropriate RPE range, the resistance will be increased by approximately 5% for upper body exercises and 10% for lower body exercises. A 1-2 min rest interval will be maintained between each set and exercise, and all sets will be performed in a symptom-limited manner. All exercise sessions will last approximately 1 hour in duration and you will have the option to complete these exercises at our exercise facility or at your home.

In addition to RE, patients will receive standard of care dietary counseling which will involve weekly visits with a registered dietitian nutritionist (Anna Beery, MS, RD, LD). These visits will include a 60-minute assessment at week one of treatment. RD will counsel patient on 5-6 small meals/day plan that meet recommended energy, protein and micronutrient needs. Energy requirements of 30-35 kcal/kg/day, protein requirements of 1.5-2 g protein/day and 30-35 ml/kg/day will be recommended. These will be adjusted per concurrent medical status and needs. Weekly follow up sessions lasting 15-30 minutes in duration will take place for 6 weeks or until radiation therapy completed. Weeks 1-7 routine reassessments the RD will monitor tolerance of oral diet and reassess weight, hydration status and overall nutrition needs and revise nutrition plan as needed (oral diet modifications, fluid needs and sources, etc.). High calorie, high protein soft, pureed or liquid diet information will be provided as well as how to incorporate oral medical nutrition beverages. RD will make recommendations for appropriate enteral nutrition formula and infusion schedule if patient has percutaneous endoscopic gastrostomy (PEG) tube.

Post-treatment follow up at one month after radiation completed. RD will discuss slowly advancing diet as tolerated. Liquid or pureed diet recommendations are provided and oral medical nutrition beverages as well as enteral nutrition information.

Group-based behavioral counseling, based upon Social Cognitive Theory, is a central aspect of the GMCB lifestyle intervention approach. The counseling is integrated into the RE intervention to promote: a) adoption and adherence to the RE and dietary behavior changes and participant retention and b) harness the social support of the group-dynamics to facilitate motivation for sustained health behavior change. Counseling is delivered in group-based sessions conducted following the supervised RE session, and will be held virtually with a password protection. The objective of the group-mediated counseling is to increase self-efficacy for adoption and maintenance of exercise and dietary behavior change and facilitate the successful transition from supervised to independent center-based exercise participation during the trial. The behavioral counseling focuses upon the acquisition and practice of self-regulatory skills in conjunction with a group-mediated continuous problem-solving model of behavior change to empower participants, as individuals and a group, to exert greater control over their behavior, cognitions, and environment. The behavioral counseling is designed to: a) increase health knowledge of the benefits of exercise and dietary change; b) enhance self-efficacy and positive outcome expectancies through the promotion of a series of successful experiences in changing exercise and eating behavior; and c) improve self-regulation of exercise and eating behaviors. The intervention content includes education and counseling efforts involving goal setting, self-monitoring, stimulus control, cognitive restructuring, and barrier problem-solving strategies.

To foster the practice/mastery of the emerging and/or newly acquired exercise and behavioral self-regulatory skills as well as preventing participants from becoming overly-dependent on the expertise of clinic staff to facilitate exercise and dietary behavior changes, supervised exercise decreases from 2 sessions/week in weeks 1-8 to 1 supervised sessions/week in weeks 9-12 of the intervention. During weeks 9-12, participants have the goal of completing one center-based exercise session/week independent of study staff supervision during each week. During weeks 13-24, supervised exercise and GMCB counseling booster sessions will be conducted bi-weekly (i.e., 2x/month). In addition to these supervised sessions, HNCa patients will be provided the goal of completing two individual exercise sessions each week. The HNCa patients will have free access to the PAES exercise facility, during its regular use hours, throughout the study. While the facility is supervised by trained fitness staff members during this time, the participants will have no supervisory contact with the study staff during these independent exercise sessions.

4. Duration of participation (How long will I be in the study?):

You will be in the study for about 24-weeks, or until you have completed the final, 24-week Testing Visit. You can stop participating at any time.

5. Study withdrawal (Can I stop being in the study?):

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. Description of the risks (What risks, side effects or discomforts can I expect from being in the study?):

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to the procedures we are studying include:

Risks involved with increasing your physical activity include, but are not limited to, injuries to the muscles, ligaments, tendons and joints of the body. Other risks include abnormal blood pressure, low blood sugar, fainting, dizziness, disorders of heart rhythm, and in very rare instances, heart attack, stroke, or even death (less than 1% of these serious heart problems ever occur). To help make sure that you are safe, the exercise programs in the study are led by trained Kinesiology graduate students and OSU research staff. We will check to see if you have any serious reaction to moderate physical activity at the beginning of the study. During the study we will ask you how you are feeling and if you have leg cramps, chest pain, shortness of breath, unusual tiredness, low blood pressure, too much weight loss or stomach problems. You should report any of these to the study Project Manager or your group leader. If you do have any of these problems, you will be asked to see your regular doctor for care. You then will not come back to the intervention sessions until your doctor says it is okay to do so.

The risks associated with this protocol are expected to be minimal. Participants will complete three experimental assessment visit during which measurement of all study variables will be obtained. Resistance exercise has inherent risk of minor muscular strains and sprains as well as mild discomfort initially. Additionally, Dr. Focht and members of the investigative team who are certified exercise leaders will be directly involved in conducting and supervising the completion of the strength tests and exercise sessions.

There are minimal risks associated with completing the self-report measures for this study. One possible psychological risk is that some individuals may experience some guilt or embarrassment in self-reporting low levels of motivation or intention to exercise. These kinds of questions are commonly asked in studies on lifestyle change and quality of life, and we have found that answering them does not bother most people. Your answers will be kept private. **However, you can skip any questions that you don't**

want to answer. The answers are coded to protect your privacy and kept under lock and key. Only a few people that work for the study can look at the coded answers. Safety of the participants during the strength testing will be ensured through several strategies: appropriate medical prescreening conducted by the research staff, primary care physician, and strict adherence to established testing protocols demonstrated to be safe in prior research. Collectively, the participants will be assuming no more than minimal risk in completing the assessment protocol and the minimal risk inherent to completing the assessments will be mitigated via stringent pre-test medical screening and during testing supervision.

Being in this study will take up some of your personal time. We will try to schedule your visits at convenient times for you.

Risks from the fitness testing are sore muscles, getting tired, injury, and pain. Our staff will do everything they can to keep you safe. You could fall during the walking or climbing tests, or as you exercise in the program. During testing, we will clear anything from your path that could cause you to trip or fall.

Possible problems may occur if the exercise program is performed incorrectly. These are muscle soreness, pain, swelling, making an existing joint problem worse, or stiffness. You will be taught how to exercise properly based on your particular level of strength and flexibility. Therefore, we do not expect that you will have problems. While we believe the exercise program will be safe for you to do, if your health changes during the study period, you should discuss whether you should continue to participate with your doctor.

If you participate in this study, you will be exposed to amounts of radiation above what you would normally receive in daily life. This research study involves exposure to radiation from three DXA scans. The amount of radiation exposure that you will receive from this procedure is equivalent to a uniform whole body exposure of 9 millirem or a 90 microsievert. To give you an idea about how much radiation you will get, we will compare it to the amounts that people encounter in daily life. This research gives you the same amount of radiation as you would get from living in a high altitude city such as Denver for 7 days, or taking 2 airplane flights from New York to Los Angeles. Thus, the risk of this procedure is small. Other than minimal exposure to radiation, there are no risks associated with DXA scans.

There also may be other side effects that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records,

will be made to keep your information safe. You will have the option to complete this consent in-person or online. There is a risk of a breach of confidentiality for discussing the consent online, and additionally for sending the consent form via mail or scanned copy.

7. Description of the benefits (What benefits can I expect from being in the study?):

If you agree to take part in this study, you may or may not benefit from it. However, by participating, you will help researchers and health providers better understand how to manage the health, physical activity, and dietary habits of patients with HNCa. You will receive regular body weight, strength, and body composition tests at no cost to you. Information will be given about your level of body fat and bone density. All of this information will be given to you free of charge

8. Alternatives (What other choices do I have if I do not take part in the study?):

You do not have to be in this study to get treated for your HNCa. You should talk to your doctor about all of the choices you have for treatment. You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. Additional costs to participants (What are the costs of taking part in this study?):

There are no costs to you for taking part in this study. All study costs, including any procedures related directly to the study, will be paid for by the study.

10. Description of the incentives provided (Will I be paid for taking part in this study?):

You will receive an incentive payment of a $25 gas card for completing the 3 screening visits held at baseline, 3-month, and 6-month follow-ups for a potential total compensation of $75 during the study. You will receive the gas cards either after each screening visit or as the gift cards arrive. By law, payments to subjects are considered taxable income.

11. Compensation/medical treatments for injury (What happens if I am injured because I took part in this study?):

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

If you are injured, the sponsor may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the sponsor is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call the Principal Investigator, Dr. Brian Focht at (614) 292-2165.

12. Participants' rights (What are my rights if I take part in this study?):

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

13. Future use of de-identified information and/or biospecimens (Will my de-identified information (and biospecimens) be used or shared for future research?):

In the future we will use clinical data that is de-identified for research purposes and future clinical trials.

14. Confidentiality of records (Will my study-related information be kept confidential?):

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices
- Your insurance company (if charges are billed to insurance).

15. HIPAA Authorization (HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES):

I. What information may be used and given to others?

- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Records about the exercise protocol in the study

II. Who may use and give out information about you?

- Researchers and study staff.

III. Who might get this information?

- Authorized researchers and study staff.

IV. Your information <u>may</u> be given to:

- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

16. Contact Information (Who can answer my questions about the study?):

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact **Dr. Brian C. Focht: focht.10@osu.edu** or Dr. Dukagjin M. Blakaj: **Dukagjin.Blakaj@osumc.edu**

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact Jennifer Elliot, Suite E2140, 600 Ackerman Road, Columbus, OH 43201

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Dr. Brian C. Focht, 305 Annie and John Glenn Ave Columbus, OH 43210, ph: 614-292-2165 or Dr. Dukagjin M. Blakaj 460 W 10th Ave. Columbus, OH 43212, ph: 614-293-415.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of subject	**Signature of subject**
	AM/PM
	Date and time
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
	AM/PM
Relationship to the subject	**Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es)

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time