The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title:	**Addressing Obesity to Reduce Cancer Risk and Health Disparities in Rural Ohio: Home-based Exercise in Rural Ohio (HERO) Study**
Principal Investigator:	**Brian C. Focht, PhD, FACSM, CSCS**
Sponsor:	American Institute for Cancer Research, National Cancer Institute

- **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
Weight loss might help reduce the risk of getting cancer. We are doing this study if people who have some extra support to change their diet and exercise habits lose weight more easily than those without it. In this study, some participants will get extra instructions and phone calls once a week for 15 weeks, while others will be given basic instructions but not support. You cannot control which group you are in. Through this small study we hope to learn if we can do something with even more people in the future.

1. Why is this study being done?

Rates for poor health behaviors and cancer are higher among adults living in rural areas than other parts of the United States (U.S.). To address these high rates, more needs to be known about how to promote healthy eating and physical activity in rural Ohio.

You are invited to be in the *HERO* (home-based exercise) study that promotes physical activity, healthy eating, and healthy weight in rural Ohio. This research study has been approved and paid for by the American Institute of Cancer Research. Researchers at The Ohio State University (OSU) are doing this research to improve health behaviors among adults living in rural Ohio. 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 reside in rural counties in Ohio; and 2) are interested in participating a research study to improve physical activity and healthy eating. 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.

The *Hero* study is being done to determine whether it is feasible and acceptable for you to complete one of two weight loss programs for 15-weeks and to examine the effect of the weight loss intervention on cancer risk factors. Subjects in this study will be randomly assigned ("like random drawings") to either a telephone-based health counselling group (30 participants) or a health education group (up to 20 participants).

2. How many people will take part in this study?

Up to 50 people living in rural Ohio will take part in the study.

3. What will happen if I take part in this study?

You have been asked to take part in the research study because you are an adult living in rural Ohio and:

- are 20-65 years old
- are able to understand and read English
- do not have physical activity or dietary restrictions
- have never been told you have cancer (except non-melanoma skin cancer)
- are not currently participating in any other weight loss intervention
- are able to walk two city blocks (about x 400 steps) comfortably
- (if female) are not pregnant, breastfeeding or less than 9 month post-partum and do not plan to become pregnant during the study
- are not planning to move away from the area during the study
- are willing to receive telephone-based counselling up to 45 minutes per week for 15 weeks
- are willing to have height, weight, body image, and bloodwork measured

<u>If you agree to take part in this study, you will be asked to do the following things:</u>

- You will complete two in-person assessments at a community center or library close to you. Every effort will be made to protect your privacy. One will take place at the beginning and one at the end of the 15-week study. Each assessment will take about one hour.

  During each session, the following activities will take place:
  - You will answer questions about you, your health, your physical activity habits and eating habits. These questions will take about 20 minutes to complete.
  - We will measure your height and body weight and body composition. For the body composition test, you will use a 3-Dimension (3D) Body Scanner machine that measures the amount of fat mass and lean mass. The scanner uses a type of camera to capture body circumference and size.
  - You will also complete bloodwork for lipids and cancer risk biomarkers. These measurements are being collected for research purposes only. To ensure the accuracy of the bloodwork, we will measure your hydration status from urine sample. If you have questions about your measurements, please contact your medical provider.
  - You will also do two simple physical function assessments, the 400 meter walk and the lift-and-carry (5 or 10 pounds) test. These tests will take about 15-minutes.
  - You will be assigned a motion sensor (ActivPAL) to wear on your right thigh for a full 7 days. You will use a motion sensor log to write down if you take the sensor off. You will be given a postage-paid envelope for returning the device by mail at the end of the week, when you are finished.
- Report any changes about your health during the study period. If you become pregnant over the course of the study, you are asked to report it to the Project Manager.
- Provide feedback on study events you attend and your experiences in the study overall.

Randomization

Following your first in-person assessment, you will be randomly assigned to one of two study programs. The process of randomly assigning you to one of two groups means that neither you nor any of the research staff (including your doctor) can choose which program you will be in. It is like "random drawings", but instead, a computer program assigns you to one of two programs.

The two possible programs include: Telephone-based health counselling (Group A) or Health education (Group B). **By signing this consent, you are showing that you are willing to be placed in either of these programs.** However, it is important that you remain in the study, regardless of the program to which you are assigned. This is how the researchers can compare the benefits of the two programs. Below is a description of what each group program will be asked to do.

Telephone-based health counselling (Group A)

If you are assigned to Group A, you will take part in a 15-week long telephone-based health counselling on healthy eating and exercise, with a primary goal to lose weight. You will be asked to do the following things:

- Each week, you will attend a 30-45 minutes counselling session with a health coach through telephone. You and the health coach will review the previous week's activity, planned weekly lessons, discuss strategies to promote physical activity, healthy eating habits, and weight loss progress.
    - Healthy eating encourages reduction in portion size and caloric and fat consumption, increase in fruit and vegetable consumption, and increase intake of whole grains.
    - Physical activity combines home-based aerobic and resistance exercises. The goal of physical activity will be to achieve 150-200 min/week aerobic physical activity and 2-3 sessions/week resistance training. Your health coach will go through the exercises with you in the first two weeks. You will receive a lifestyle modification manual with description of exercises and modifications. Online *YouTube* videos are also available as examples for proper exercise form and alternative exercise options
    - You are encouraged to participate in group messages to interact with other participants following the weekly telephone counseling, with the goal to maintain behavioral changes independently.
- You will receive a physical activity tracker (Fitbit) and a weight scale. You will learn how to use the Fitbit and will wear it during the 15-week study period. You will record weight, physical activity, and dietary intake each week.
- At the end of 15-weeks, you will complete another in-person assessment at the community center close to you.

Health education (Group B)

If you are assigned to Group B, you will be asked to do the following things:

- You will take part in a health education program with and complete two in-person assessments.
- You will receive an education brochure on physical activity and healthy eating.
- You will have access to online *YouTube* videos as examples for proper exercise form.
- You are encouraged to self-monitor weight, dietary intake, and physical activity each week.
- You will receive a physical activity tracker (Fitbit) and the lifestyle modification manual (same as the one Group A receives) at the end of the study.

4. How long will I be in the study?

You will be in the study for 15 weeks. You will complete weekly telephone sessions or until you have completed the final, 15-week assessment. You can stop participating at any time.

5. 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. 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:

Although you will be meeting with research staff for two in-person assessments, these visits will not include supervised exercises. We will encourage you to follow your independent exercise and feel it is necessary to report the modest risk associated with exercise. 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 promoted in the study will follow guidelines and safety recommendations for physical activity set by the American College of Sports Medicine and your doctor (if needed). We will check to see if you have any serious reaction to moderate physical activity at the beginning of the study. You should report any adverse symptoms to the study Project Manager or your health coach. 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 exercise until your doctor says it is okay to do so.

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 declines during the study period, you should discuss whether you should continue to participate with your doctor.

If you take medicines to control your blood pressure, there is a chance that you may feel light-headed or dizzy from a drop in blood pressure. This is called ***hypotension***. To reduce your risk of developing hypotension, your doctors will want to keep track of your blood pressure levels. If you develop hypotension, you will contact your regular doctor to talk about your blood pressure medication.

If you take medicines to control your blood sugar, and suddenly exercise much longer and harder than usual, or fast, there is a chance that you may feel weak, light-headed, or dizzy, from a drop in blood sugar. This is called ***hypoglycemia***. If you are taking medicine to lower your blood sugar, you will be asked to check your blood sugar before and after exercise. Also, if you develop hypoglycemia and are taking blood sugar lowering medication, you will contact your regular doctor to talk about changing your blood sugar medication.

Potential health problems may occur if the weight loss program is followed incorrectly. Fast weight loss or eating fewer than 1000 calories per day, especially over a long period of time, can make you feel tired and leave your body without the nutrients it needs for proper health. Failure to cut back on food intake as recommended may lead to weight gain and worsen your health conditions. You will be taught how much food to eat based on your starting weight and current guidelines for healthy weight loss, so we do not expect any health problems. While we believe that the combined exercise and weight loss program will be safe for you, if your health does change during the study period, you should discuss whether you should continue to participate with your doctor.

This research study involves using blood to evaluate your lipids and other disease risk factors (some inflammatory biomarkers). We will use both finger stick (the one used to test blood sugar) and regular venipuncture (the one used in regular check-ups) to collect blood. Both procedures are commonly used when you have a doctor's visit. For the regular venipuncture blood samples, we will need 50 mL at each assessment (about 4 tablespoons). There are minor risks associated with venipuncture (taking blood from a vein) including mild discomfort or bruising. Less commonly, a small clot, swelling of the vein, infection, or bleeding may occur at the site of puncture.

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 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.

Some of the forms you fill out ask questions that are personal, such as about your confidence, feelings, and other aspects of your health. 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.

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

A Data Safety and Monitoring Committee, or a separate group of experts, will be reviewing the information that we collect from this research throughout the study. Should we learn of any new information about the risk in participating in this study, or other studies like this one, we will contact you to discuss it with you. Presently, the researchers conducting this study are not aware of any risks, or future risks other than those listed above.

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.

7. 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. You may gain awareness of healthy eating and physical activity behaviors. By participating, you will help researchers better understand how to manage the health, physical activity, and dietary habits of adults living in rural areas like yourself. You will receive regular body weight, body composition, and blood tests at no cost to you. Information will be given about your level of body fat, lipids, and other disease risk factors. All of this information will be given to you free of charge. You will also receive important information about the role of exercise, diet and weight loss, and lifestyle change on your health.

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

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. 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. Will I be paid for taking part in this study?

You will receive an incentive payment of $25 for completing each in-person assessment (up to a total of $50). By law, payments to participants are considered taxable income.

11. 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 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. 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. 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.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

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 research participants.

13. Will my de-identified information and bio-specimens be used or shared for future research?

As mentioned above, we will protect the confidentiality of your protected health information. Specifically, we will de-identify your information that only use your study ID and remove specific information (e.g., names, birthdate, phone number, email address) that could identify you from the data set. Only authorized people (i.e., our study team) have access to the master records with your protected health information.

The de-identified information may be used or shared with other researchers without your additional informed consent.

14. Will my study-related information be kept confidential?

If we find information that significantly impacts your health (e.g. lipid profiles from blood work that are beyond the normal ranges), we **will** share it with you (by telephone, email or mail).

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;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

Certificate of Confidentiality: The NIH has issued a Certificate of Confidentiality for this study. This Certificate provides extra protection for you and your study information, documents, or samples (blood, tissue, etc.). The Certificates are issued so that we cannot be required to disclose any identifiable, sensitive information collected about you as a part of this study in a lawsuit or legal proceeding. We are also prevented from releasing your study information without your consent. This is a layer of protection over and above the already existing protections in place for you and your information, documents, or samples.

However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, the Agency that is funding this study requests the information, or if the FDA tells us to release this information. We may also use your information to conduct other scientific research as allowed by federal regulations.

Study information that has health implications may be placed in your medical record where authorized employees may see the information. Further, authorized requests for your records (medical record release for continuity of care) may result in research-related information being released.

Please talk to your study team, or contact the Office of Responsible Research Practices at 614-688-8641, if you have questions.

You may also visit the NIH website at https://grants.nih.gov/policy/humansubjects/coc.htm to learn more.

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

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

- Past and present medical records;

- Research records;
- Records about phone calls made as part of this research;
- Records about your study sessions; and
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual.

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

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office record; and
- Others: American Institute for Cancer Research, The National Institutes of Health: National Cancer Institute, and Data and Safety Monitoring Board

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

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- 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 (email either the primary investigator, Dr. Brian Focht: focht.10@osu.edu or the project manager, Xiaochen Zhang: Xiaochen.zhang2@osumc.edu). 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. 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; phone: 614-292-2165

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact *HIPAA Privacy Manager, OSU Medical Center, 140 Doan Hall, 410 W 10th Ave, Columbus, OH 43210. (phone):293-4477.*

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 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, phone: 614-292-2165

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 participant	**Signature of participant** **AM/PM** **Date and time**
Printed name of person authorized to consent for participant (when applicable)	**Signature of person authorized to consent for participant (when applicable)**
Relationship to the participant	**AM/PM** **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) - *May be left blank if not required by the IRB*

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