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

Study Title:	Dance-Based Avenues to Advance Nonpharmacologic treatment of Chemotherapy Effects (DAANCE): Survivors (Randomized)
Principal Investigator:	Dr. Lise Worthen-Chaudhari
Sponsor:	National Institutes of Health (National Institute of Aging) & Pelotonia Foundation

- **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

The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

Physical activity has been found to improve health for some survivors. The objective of this study is to compare effect and participant satisfaction among different forms of physical activity. To do this comparison, we will randomly assign you to a specific type of physical activity with potential to improve health challenges specific to survivorship, such as neuropathy, pain, fatigue, and/or balance. We will assess how you feel and move throughout the study, then comparing how effective, satisfying, and motivational each activity is. Each type of training we offer will involve no more risk than typical whole-body fitness activity. While we cannot guarantee that any of the trainings we offer will improve your health, the

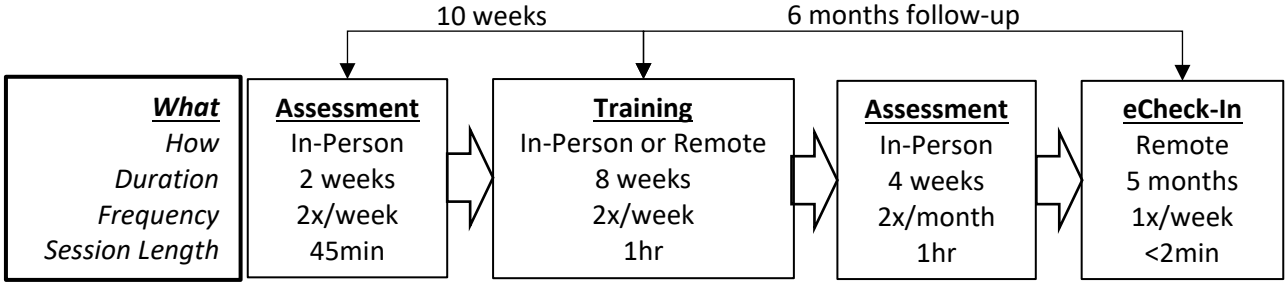
trainings will all have the potential to improve your health and to improve society's response to the challenges of survivorship.

1. Why is this study being done?
To assess the effect of different forms of physical activity – Tango dance or home exercise – on participant health, motion, satisfaction, and motivation.

2. How many people will take part in this study?
Up to 200 cancer survivors and 200 companions.

3. What will happen if I take part in this study?
You will be offered up to 16 sessions of coached physical activity: either Argentine Tango or home exercise. The training you are offered will be determined randomly (like the flip of a coin). Throughout the study we will ask you periodically for information about your health, your feedback about the activities, and any barriers to participation in the activity. Motion tests will involve balance tasks such as standing still with your eyes closed and/or navigating obstacles at your fastest speed. We may video tape your movement and/or, in an optional part of the study, ask to measure your brain activity non-invasively. Finally, we will access your medical record to obtain information about your health (e.g., age, diabetes screening results, prior reports of falls and neuropathy symptoms) and prior treatment (e.g., chemotherapy regimen, physical or occupational therapy, medications for neuropathy) in order to understand the factors influencing your neuropathy symptoms and response to the intervention. Note: if you want to learn Tango but are not randomized to that training, then you will be eligible to participate in our tango sessions after completing all other study activities.

4. How long will I be in the study?
Eight and a half months in total. The first 10 weeks will involve assessment and personalized training with our research staff; then we will follow your progress for 6 months through in-person assessment and regular personal journaling about whether you have fallen or lost your balance. The study schedule looks like this:



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?
Participants in this study should not expect to experience any more discomfort, soreness, or pain than they would after exercising outside of the research study.

7. What benefits can I expect from being in the study?
Society may benefit from the information we uncover within this research. You may experience health and wellness benefits from participation.

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 is no costs for participating in this study.

10. Will I be paid for taking part in this study?
You will receive $20 reimbursement for each in-person assessment session that does not involve activity training. There are 7 such sessions for a total $140 reimbursement for participating in this study. In addition, if we affix sensors to your skin or scalp to record your walking patterns or brain activity, you will be paid an additional $20. Five assessment sessions might use these sensor such that total possible reimbursement is $240.

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 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.

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 be used or shared for future research?
Yes, it/they may be used or shared with other researchers without your additional informed consent.

14. 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;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If we find information that significantly impacts your health, we **will** share it with you. For instance, if we find that your postural control has worsened substantially, in comparison to your baseline results, for 2+ subsequent study visits with us then we will call or ask to speak privately with you and inform you of that change.

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.

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 visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
  - Physical exams
  - Laboratory, imaging, and other test results
  - Diaries and questionnaires

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;
- Others: Representative of The National Institutes of Health including safety officers and program managers, your primary and/ or oncology-related health care providers.

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. 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 study questions, concerns, or complaints, to withdraw consent and HIPAA authorization, or if you feel you have been harmed as a result of study participation, you may contact Principle Investigator Lise Worthen-Chaudhari at phone 1-614-293-6281or email tango@osumc.edu.

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact the Health System HIPAA Privacy Officer at phone 1-614-293-4477 or address 650 Ackerman Rd Columbus, OH 43210.

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 Lise Worthen-Chaudhari at phone 1-614-293-6281or email tango@osumc.edu

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)**
	AM/PM
Relationship to the participant	**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