Official Title:	Computerized Cognitive Training in Breast Cancer Survivors
NCT Number:	NCT05570604
Document Name:	Informed Consent
Document Date:	December 18, 2019

INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR

Computerized Cognitive Training in Breast Cancer Survivors

IUSCC-0625

You are invited to participate in a research study of cognitive training for the treatment of cognitive impairment for breast cancer survivors. You were selected as a possible subject because you are a breast cancer survivor. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

This study is being conducted by Dr. Diane Von Ah at Indiana University. It is funded by the Center for Enhancing Quality of Life.

STUDY PURPOSE
The purpose of this study is to evaluate whether a program offered over the web will improve concerns regarding cognitive functioning including attention and concentration, memory, or the ability to process information or problem-solve.

The study will also examine how cognitive training affects levels of a brain molecule that is linked to brain functioning called brain derived neurotropic factor (BDNF). You will be asked to donate blood to test your levels of BDNF.

NUMBER OF PEOPLE TAKING PART IN THE STUDY
If you agree to participate, you will be one of 68 subjects who will be participating in this research.

PROCEDURES FOR THE STUDY
If you choose to take part, you will have tests done throughout the study. The sections below describe the tests and procedures that will be done if you take part in this study.

Screening
If you sign this informed consent form, tests or procedures will be done either by phone or in person to find out if you can be in the study. There is the possibility that your screening and Baseline visit will occur on the same day.

You will be asked to provide information about your

- Demographics (e.g. age, birth date, education)
- Medical history (including disease information and treatment history)
- Whether you have concerns regarding the way you are able to think, remember, process information and/or solve problems.

Baseline and Follow-up Assessments:
If you are eligible to participate in the study:
You will be asked to take part in two onsite visits. These visits will be completed in a private room on either the campus of Indiana University-Purdue University Indianapolis, IU North Hospital or Eskenazi Hospital. At each visit, you will fill out a set of questionnaires about yourself, your cognitive functioning, and other symptoms you may be having. You will also be asked to complete an assessment of your cognitive functioning administered by one of our staff and provide a blood sample (3 mL or about ½ teaspoon) at each visit.

The first visit will last about 1-hour and the other visit should last about 50 minutes. Visit 1 will be done after you consent to this study. Visit 2 will be immediately after the 10-week cognitive training program (within 90 days) as described below.

Intervention

After the baseline assessment, you will be randomly assigned to one of two groups. Randomization is like the flip of a coin. Your chances of being in the two groups are equal. Both groups will be required to complete activities that will require you to attend to, learn, process and remember information. You will participate in these programs at home using your computer. If you do not own a computer, one will be provided for you for the duration of the study. Research staff will meet with you to provide specific instructions on the program you are assigned.

You will complete up to 40 hours of the assigned activity over a 10-week period. The activities in this cognitive training program will ask you to complete specific tasks that will require you to attend to, learn, process, and retrieve information to the best of your ability. You will be asked to record each activity session on a log sheet that will be provided to you and to answer questions about the program.

Once you have completed 10-week-program, you will receive a phone call from a member of the study team asking if you would be willing to participate in a phone interview. This interview will ask you questions about what you found helpful or not helpful about the training program.

RISKS OF TAKING PART IN THE STUDY

Blood Collection

You may experience bruising, bleeding, soreness or rarely, fainting of infection as a result of collection of the blood samples.

Our experienced research staff is trained and certified in phlebotomy. They will apply universal precautions when drawing blood so as to reduce the risk of infection and will take steps to minimize discomfort to subjects including application of pressure on the site following needle withdrawal.

Loss of Confidentiality:

There is a risk of loss of confidentiality. The chance that your information will be given to someone else is very small. However, every effort will be made to keep your personal information confidential.

Your name, address, phone number, and other identifying information will be taken off anything connected with your data. This would make it very difficult for any research results to be linked to you or your family. Also, people outside the study team will not have access to results about any individual person, which will help to protect your confidentiality. The files that contain any information linked to your name can only be accessed by a limited number of research staff

Psychosocial Risks:

You may feel uncomfortable answering some of the questions asked in this study. You do not have to do any study-related task that feels uncomfortable or upsetting. You have the option of stopping participation at any point during the study.

BENEFITS OF TAKING PART IN THE STUDY

If you agree to take part in this study, there may or may not be direct benefit to you. It is hoped that over time, information from this study using these samples will help researchers learn more treating cognitive impairment in cancer survivors.

ALTERNATIVES TO TAKING PART IN THE STUDY
Instead of being in this study, you have the option of not participating. Taking part in the study is voluntary.

CONFIDENTIALITY
Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and her research associates, the Indiana University Institutional Review Board or its designees, the study sponsor, Center for Enhancing Quality of Life, and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP) who may need to access your medical and/or research records.

FUTURE USE OF INFORMATION
Information and samples collected for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

COSTS
Taking part in this study will not lead to any added costs to you or your insurance company.

PAYMENT
You will receive $20 gift card for each completed visit, or up to a total of $40 at the end of the study for completing two visits. .

COMPENSATION FOR INJURY
In the event of physical injury resulting from your participation in this research, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled. If you are participating in research, which is not conducted at a medical facility, you will be responsible for seeking medical care and for the expenses associated with any care received.

CONTACTS FOR QUESTIONS OR PROBLEMS
For questions about the study or a research-related injury, contact the principal investigator, Dr. Diane Von Ah at 317-278-2827.

For questions about your rights as a research participant or to discuss problems, complaints or concerns about a research study, or to obtain information, or offer input, contact the IU Human Subjects Office at (317) 278-3458 or (800) 696-2949.

VOLUNTARY NATURE OF THIS STUDY

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this study will not affect your current or future relations with Indiana University Melvin & Bren Simon Cancer Center, Indiana University School of Medicine, or Indiana University Health.

SUBJECT'S CONSENT

In consideration of all of the above, I give my consent to participate in this research study.

I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Subject's Printed Name:_____

Subject's Signature:_____ **Date**:_____
(must be dated by the subject)

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____ **Date**:_____