Subject's Name _____
Subject's Medical Record # _____
IRB# Pro00009858
MCC# 17089
Date Consent Signed _____

Informed Consent to Participate in Research and Authorization to Collect, Use and Share Your Health Information

Moffitt Cancer Center/University of South Florida
Information to Consider Before Taking Part in This Research Study

Doctors and researchers at Moffitt Cancer Center study diseases and other health problems people may have. Our goal is to try to find better ways to help treat these health problems. To do this, we need the help of people who are willing to take part in a research study.

We are asking you to take part in a research study called:
Pilot Clinical Trial of COGNUTRIN in Breast Cancer Survivors

The person who is in charge of this research study is **Nagi Kumar, PhD, RD, FADA**. This person is called the Principal Investigator. However, other research staff may be involved and can act on behalf of the person in charge.

The research will be conducted at:

H. Lee Moffitt Cancer Center & Research Institute, Inc.
(Moffitt Cancer Center)
12902 Magnolia Drive
Tampa, FL 33612

This research is being sponsored by The Gateway for Cancer Research.

Why are you being asked to take part?

One of the most common adverse effects reported by breast cancer patients after treatment is "chemobrain". This is the term used to describe the mental cloudiness (i.e., thinking and memory problems) that patients sometimes notice during and after chemotherapy. Chemobrain might last a short time, or it might go on for years.

The purpose of this study is to examine the safety and effect of COGNUTRIN, a nutritional supplement, on memory and concentration tasks in breast cancer survivors following chemotherapy. COGNUTRIN includes fatty acids (Lovaza®) and blueberry extracts (Vitablue). Our goal is to treat or lessen the late effects of cancer treatment on thinking ability. Lovaza® is currently approved for the treatment of patients with very high triglycerides (hypertriglyceridemia).

COGNUTRIN is an investigational drug. An investigational drug is a drug that is being tested and is not approved for sale in the United States by the U.S. Food and Drug Administration (FDA). In addition, this study will compare COGNUTRIN with a placebo to see if taking COGNUTRIN is better than taking a placebo. A placebo is a pill that looks like COGNUTRIN but has no drug or other active ingredient in it.

We are asking you to take part in this research study because you are a woman between the ages of 30 and 70, have been diagnosed with stage I-IIIB breast cancer, and have completed treatment with chemotherapy, + or - radiation, within the last 6 months (+/- 7 days).

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What will happen during this study?

Before you can start the study, the study doctor or study staff will talk to you about the study. You must sign this form before any study procedures can be done.

Screening:

- You will be asked about your medical history, current medical condition, and other medications that you are taking.
- You will have a limited physical exam.
  NOTE: The limited physical exam can be done at either screening or baseline.
- Your ability to think, learn and remember will be evaluated using a variety of tests.
- A sample of blood from your arm will be collected in 5 small tubes each holding about 1 tablespoon of blood. Three (3) of the tubes collected will be used to make sure that your organs (like your liver, heart, and kidneys) are functioning normally and to make sure that you can participate safely in this study. The other two (2) tubes will be used to measure biomarkers of inflammation and oxidative stress.
- A 2-day Food Record Recall will be given to you to complete and return at your baseline visit.

Baseline / Randomization:

- We will collect your 2-day Food Record Recall.
- You will be asked about any changes in medications.
- You will be asked to complete a demographic questionnaire. You will also be asked to complete several questionnaires that look at your general well-being. These will include exercise, depression, fatigue and a personal assessment of your ability to think, learn and remember.
- Anthropometric measurements (such as height, weight, BMI, waist, and hip circumference) will be taken.
  You will undergo MRI scanning. An MRI uses powerful magnets and radio waves to make pictures of body tissues and structure. You will have a structural and a resting-state functional MRI.of your brain. A structural MRI examines the physical structure of the brain, while a resting-state functional MRI looks at brain activity while you are resting. The MRI will be done at University Diagnostic Institute (UDI).

If you meet all eligibility criteria, you will be randomized to one of two study groups:

- COGNUTRIN
- Placebo

We use a placebo to make sure that it really is the study medicine that is making a difference in your condition. The placebo does not have anything in it that would normally help or harm most people.

Sometimes people seem to feel better just because they are given something that looks like medicine. We want to make sure that the COGNUTRIN we are testing really works. We need

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to have some people take the placebo and some people take COGNUTRIN. That way we can compare how well COGNUTRIN works to how well the placebo works.

You have an equal chance (like flipping a coin) of being in either of the study groups. Neither you nor the study doctor will be able to pick which study group you are in. You will not know and the study doctor will not know which study group you are in, but the study doctor can find out if it is necessary to know for your health. If this happens, the study doctor may not be able to tell you which study group you were in until everyone finishes the study.

You will be provided with:

- Two bottles containing Lovaza (or placebo) and one bottle containing VitaBlue (or placebo). You will be asked to take 2 capsules of Lovaza (or placebo) two times a day and 2 capsules of VitaBlue (or placebo) three times a day. On the days of study visits, we ask that you take the study drug within 4 hours of your visit. You will be given instructions about how to take the study drug. You will take the study drug for 3 months. You are the only one who should take the study drug. You should make sure that no one else takes it.
- Multivitamin – You will be asked to start taking the multivitamin daily with your evening meal. You should not take any other nutritional supplements while you are in this study.
- Study Agent Intake and Symptom Log
- A 2-day Food Record Recall

You will be asked to limit your intake of the following foods to 2 - 3 servings per week (4 oz. per serving) while you are in this study:

- Walnuts
- Flaxseed Oil
- Canola Oil
- Fish Oils
- Fatty Fish
- Salmon
- Trout
- Mackerel
- Herring
- Sardines
- Pilchards
- Kipper
- Eel
- Whitebait
- Tuna (fresh)
- Anchovies
- Swordfish
- Bloater
- Cacha
- Carp
- Hilsa
- Jack fish
- Katla
- Orange roughy
- Pangas

You will also be asked to limit your daily intake of the following berries to **1 cup total of all berries per day** while you are in this study:

- Blueberries
- Blackberries
- Chokeberries
- Black Currants
- Elderberries
- Black Raspberries

Weeks 3, 7, and 11:

- You will be contacted and reminded to complete a 2-Day Food Record Recall and bring your remaining study drug, Study Agent Intake and Symptom Log, and 2-day Food Record Recall to your next study visit.

Weeks 4 and 8:

- We will collect your remaining study drug, Study Agent Intake and Symptom Log, and 2-day Food Record Recall when you come in for your week 4 and week 8 visits.

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- We will ask you about any changes in medications and review any adverse events.
- A sample of blood from your arm will be collected in 3 small tubes each holding about 1 tablespoon of blood. The blood will be used to make sure that that the study agent is safe.
- We will provide you with a new one-month supply of study drug and multivitamin. A new 2-day Food Record Recall and Study Agent Intake and Symptom Log will also be given to you to complete.

Week 12 (End of Treatment):

- Your remaining study drug, Study Agent Intake and Symptom Log, and 2-day Food Record Recall will be collected at your week 12 visit.
- We will ask you about any changes in medications and review any adverse events.
- Anthropometric measurements (such as height, weight, BMI, waist, and hip circumference) will be taken.
- You will complete several questionnaires that look at your general well-being. These will include exercise, depression, fatigue and a personal assessment of your ability to think, learn and remember.
- A sample of your blood from your arm will be collected in 5 small tubes each holding about 1 tablespoon of blood. Three (3) of the tubes collected will be used to make sure that that the study agent is safe. The other two (2) tubes will be used to measure biomarkers of inflammation and oxidative stress.
- You will have a limited physical exam.
- You will undergo MRI scanning. The MRI will be done at University Diagnostic Institute (UDI).

Post-intervention Follow-up (7 days after stopping study agent):

- You will be contacted by telephone 7 days after stopping the study agent and asked if you have had any problems since stopping the study agent.
- We will ask you about any changes in medications.

If you are interested, The Gateway for Cancer Research would like permission to communicate with you regarding your experience and any other information you would like to share regarding the treatments you received while participating in this clinical trial.

Please check one of the lines below. Please note that giving The Gateway for Cancer Research permission to communicate with you is completely optional and will not affect your participation in the rest of this study.

____ I give permission for The Gateway for Cancer Research to communicate with me.

____ I do NOT give permission for The Gateway for Cancer Research to communicate with me.

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How long will you be asked to stay in this study?

You will be asked to spend about 3 months in this study. You will need to come for 5 study visits in all – screening, baseline, 4 weeks, 8 weeks, and 12 weeks. All visits will take place at Moffitt Cancer Center and University Diagnostic Institute (UDI) and will last approximately 2-3 hours. The follow-up phone call will take approximately 10 minutes.

How many people will take part in this study?

Approximately 40 people will take part in this study at Moffitt Cancer Center.

What other choices do you have if you do not participate?

You do not have to be in this study to get help for your decreased ability to think, learn and remember. The study doctor will talk to you about other things you can do to possibly improve your ability to think, learn and remember, including the important risks and benefits. Your participation in this study is voluntary. You can decide not to be in the study and you can change your mind about being in the study at any time. There will be no penalty to you, and you won't lose any benefits. Your regular medical care at Moffitt Cancer Center will not change if you decide not to be in the study.

Will you be paid for taking part in this study?

We will pay you $50 for each of the 5 study visits (screening, baseline, 4 weeks, 8 weeks, and 12 weeks) for transportation costs that you may incur during the time you volunteer while being in this study. This will be paid to you by check, which will be mailed to your home after each visit. If you complete all five study visits, you will receive a total of $250. If you are traveling more than 100 miles from your home to reach the research site, you will receive an additional $30 for the transportation costs that you may incur.

The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

Will it cost anything to be in this study?

You and/or your insurance company will be financially responsible for hospital inpatient, outpatient and follow-up visits that would normally or routinely occur in the management of your disease. Inpatient and outpatient visits could include charges for treatments, medications, physician visits, laboratory tests and procedures. You and /or your insurance company will be responsible for paying for the charges which are considered routine, since you would have received these services even if you were not participating in this study.

You will be responsible for any costs not covered by your insurance company, including deductibles, co-payments and all out-of-pocket expenses.

You and/or your insurance company will not be responsible for paying for the following testing and procedures that are specifically required for this research study and are not considered part of the routine management of your disease, if these procedures are performed at Moffitt Cancer Center and University Diagnostic Institute (UDI).

- Screening Visit: CBC, CMP, PT, aPTT, LDL, Study Clinic Visit

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- Baseline Visit: MRI Brain
- Week 4 and Week 8: CBC, CMP, PT, aPTT, LDL
- Week 12: CBC, CMP, PT, aPTT, LDL, MRI Brain, Study Clinic Visit

During your participation in this study, we will provide you with the study drugs COGNUTRIN, containing VitaBlue (VDF FutureCeuticals) & Lovaza (GSK), and a multivitamin mineral at no additional charge to you.

What are the potential benefits if you take part in this study?

The study drug may help your ability to think, learn and remember, but there is no guarantee that being in this study will help you. Your ability to think, learn and remember might not get better or may even get worse while you are in this study. You may get placebo, which means you will not be receiving active drug. Information from this study might help researchers to come up with new tests or medications to help others in the future.

What are the risks if you take part in this study?

The study drug might not help.

Right now we do not know for sure if COGNUTRIN will help. If it does not help, your condition/disease may get worse.

There may be side effects.

You may have problems because of the study drug used in this study. These problems are called side effects. Some side effects are just bothersome. Others could harm you. There may be some side effects that we don't know about yet. The research might involve risks to you that are currently unforeseeable. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the study drug. In some cases, side effects can be serious, long lasting, or may never go away. There may also be the risk of death.

The risks to participants of this study are those associated with blood draws, MRI (magnetic resonance imaging test that uses powerful magnets and radio waves to make pictures of body tissues and structure), and study drug.

- **Blood draw:** Risks associated with blood draw are minimal. However, it is possible to have infection or bleeding or bruising at the needle site. To minimize risk, the site will be cleaned before drawing blood, pressure will be applied until the bleeding stops and a sterile dressing will be used to cover the puncture site.
- **MRI/fMRI:** For most people, there is no danger associated with having an MRI scan. However, there may be some risk of psychological distress (i.e., anxiety, claustrophobia) caused by the confining environment of the scanner (MRI). If you have claustrophobia, you cannot be in this study. In addition, an MRI could be very dangerous if you have certain objects or devices implanted in your body, such as a pacemaker, insulin pump, ear implant, joint replacement, permanent dentures, or shrapnel. You must tell the study doctor about any objects that you know are implanted or imbedded in your body.
- **VitaBlue:** VitaBlue is made from Wild Blueberry Extract. There is evidence to suggest

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that blueberry can occasionally cause a food allergy in sensitive individuals.

- **Lovaza:** In previous studies with Lovaza, the most commonly reported side effects were feeling of fullness, fatty stools, nausea, and abdominal pain.

Risks and side effects related to Lovaza include:

Possible Risk/Side Effect	**How often is it expected to occur?**	**How serious will it be?**	**Will it go away?**
Gastrointestinal Upset (diarrhea, abdominal bloating, abdominal pain)	Common	Can be treated	Yes – once dose is stopped
Decreased Blood Pressure	Occasionally	Can be treated	Yes – once dose is stopped
Increase in bleeding time	Occasionally	Can be treated	Yes – once dose is stopped
Mild elevation of liver function tests	Rarely	It will not impact your overall health	Yes – once dose is stopped
Chest Pain	Rarely	Can be treated	Yes – once dose is stopped
Flu like symptoms	Rarely	Can be treated	Yes – once dose is stopped
Infection	Rarely	Can be treated	Yes – once dose is stopped
Change in sense of taste	Rarely	Can be treated	Yes – once dose is stopped

There is always a chance that any medical treatment may cause you some discomfort or harm and the study drug/procedures in this study are no different. We will do everything possible to keep you from being harmed. You should talk to your study doctor when you experience any side effects that you have while taking part in the study.

It is not uncommon for the medical treatment that you would receive as your standard care to also cause problems. However, these adverse effects will be communicated to you, specific to the treatment you receive.

We will tell you as soon as we can, if we find out more information about the side effects that are caused by COGNUTRIN. During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about your willingness to be in this study. We will notify you as soon as possible if such information becomes available.

Is there any risk to your unborn children if you take part in this study?
If you are pregnant, you may not participate in this study, because there may be risks to you and your unborn baby. Breastfeeding (nursing) mothers will not be included in this study, since it is not known whether the drugs in this study will be passed on to the baby in mother's milk. If you are currently breastfeeding and wish to continue, your study doctor may

recommend another treatment.

If you are a female of childbearing potential (able to become pregnant), you will be given a pregnancy test at no cost to you before beginning any study treatment.

Tell one of the study doctors right away if:

- You are pregnant.
- You get pregnant.
- You are breastfeeding.

There may be risks to your unborn children that we don't know about ahead of time; they are unforeseeable.

If you take part in this study, you must use an effective birth control method as discussed with your study doctor.

Examples of birth control methods include:

- Oral birth control pills
- Birth control patch
- Implanted (injectable contraceptive hormones or mechanical products such as intrauterine device)
- Barrier methods (diaphragm, condoms, spermicidal)
- Tubal ligation or vasectomy
- Abstinence (no sexual intercourse)

You should discuss the method of birth control which is best for you to use both during study treatment and for a period of time after treatment.

You should tell your study doctor immediately if you become pregnant.

The long-term effects of the study drug on fertility are unknown. This means that it is unknown if treatment with these medications will affect your ability to have children in the future. If we find COGNUTRIN might harm your fertility, we will notify you as soon as possible.

What if you get sick or hurt while you are in the study?

If you need emergency care:

- **Call 911 or go to your nearest emergency room right away.** Moffitt Cancer Center **does not** have an emergency room or the facilities to provide emergency care.

If you do NOT need emergency care:

- Call or go to your regular doctor. It is important that you tell your regular doctor that you are participating in a research study. If possible, take a copy of this consent form with you when you go.

If you experience an adverse event or unanticipated problem, call Nagi Kumar, PhD, RD, at (813) 745-6885.

Moffitt Cancer Center Injury Statement

If you believe you have been injured as a result of your participation in this study or if you have

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questions about your rights as a person who is taking part in a research study, you may call the Moffitt Cancer Center Risk Manager at 813-745-4219. Florida law (Statute 768.28) limits the liability of Moffitt Cancer Center. Moffitt Cancer Center cannot pay for lost wages, disability, or discomfort. A copy of this statute is available upon request at 813-745-1869. This statute provides that damages are available only to the extent that negligent conduct of a Moffitt Cancer Center employee caused your injuries. The damages available in this situation are limited by law. The Moffitt Cancer Center and investigators have made no provision for monetary compensation in the event of physical illness or injury resulting from this study.

Be aware that your health care payer/insurer might not cover the costs of study-related injuries or illnesses.

The use and disclosure of your personal health information

We understand that information about you and your health is personal, and we are committed to protecting the privacy of that information. Because of this commitment, we must obtain your written authorization before we use or disclose your information for this study.

Research at the Moffitt Cancer Center may be undertaken jointly with the University of South Florida or other persons or entities under an organized health care arrangement. By signing this form, you are permitting researchers at Moffitt Cancer Center to use personal health information for research purposes within its organized health care arrangements. You are also allowing the Moffitt Cancer Center to disclose your personal health information to outside organizations or individuals that participate in this study. We may publish what we find out from this study. If we do, we will not let anyone know your name. We will not publish anything that would let people know who you are.

If you do not agree to the use and disclosure described above, you cannot be in the study.

Who will disclose, receive, and/or use your information?

Federal law says we must keep your study records private. We will keep the records of this study private by keeping them in a locked area or on a secure computer. To do this research, the following people and/or organization(s) will be allowed to disclose, use, and receive your information, but they may only use and disclose the information to the other parties on this list, to you or your personal representative, or as permitted by law:

- Every research site for this study, including the Moffitt Cancer Center, and each site's study team, research staff and medical staff;
- Any person who provides services or oversight responsibilities in connection with this study;
- Every member of the Moffitt Cancer Center workforce who provides services in connection with this study;
- The person who is responsible for the study nationwide or worldwide (study chairperson);
- Any laboratories and other individuals and organizations that use your health information in connection with this study;
- Any sponsor of the study, including the following sponsors: The Gateway for Cancer Research;

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- Any federal, state, or local governmental agency that regulates the study (such as the Food and Drug Administration (FDA), Florida Department of Health (FDH), the U.S. Department of Health & Human Services (DHHS), and Office for Human Research Protections (OHRP));
- Other government agencies in this or other countries;
- The designated Protocol Review and Monitoring Committees, Institutional Review Boards, Privacy Boards, Data and Safety Monitoring Board and their related staff that have oversight responsibilities for this study;
- The National Cancer Institute in evaluating the ongoing research of the Moffitt Cancer Center as a Comprehensive Cancer Center.

The organizations and people listed above may employ or pay various consultants and companies to help them understand, analyze and conduct this study. All of these people may not be known now, but if you would like to have more specific information about this at any time during the study, you may ask the study doctor and your questions will be answered.

Moffitt Cancer Center cannot guarantee the privacy of your information, or block further use or distribution, after the information has left the Moffitt Cancer Center. Others listed above may further disclose your information, and may no longer be covered by federal privacy regulations.

If all information that does or can identify you is removed from your records, the remaining information will no longer be subject to this authorization and may be used or shared for other purposes.

You might have the right to see and copy your health records related to this research. You might not be able to see or copy some of your records until after all participants finish the study. If it is necessary for your care, your records will be provided to you or your regular doctor.

What information will be used or disclosed?
By signing below, you authorize the use and disclosure of your entire study record and any medical or other records held by Moffitt Cancer Center, including, but not limited to, HIV/AIDS, mental health, substance abuse or genetic information. The purpose for the uses and disclosures you are authorizing is to conduct the study explained to you during the informed consent and research authorization process and to ensure that the information relating to that study is available to all parties who may need it for research purposes.

Your authorization to use your health information will never expire unless and until you expressly revoke it in writing to the investigator on the first page of this form. If you revoke your authorization, you will not be able to continue in the study.

By signing this form, you authorize the use and/or disclosure of your protected health information described above. Your information may also be used as necessary for your research-related treatment, to collect payment for your research-related treatment (when applicable), and to run the business operations of the Moffitt Cancer Center.

Any data collected prior to your letter will continue to be used as necessary to preserve the integrity of the study, however no additional information will be collected after you withdraw your authorization.

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You will receive a signed copy of this form.

What happens if you decide not to take part in this study?

You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study to please the study doctor or the research staff. **If you decide not to take part:**

- You will not be in trouble or lose any rights you normally have.
- You will still have the same health care benefits.
- You can still get your regular treatments from your regular doctor.

You can decide after signing this informed consent document that you no longer want to take part in this study. We will keep you informed of any new developments which might affect your willingness to continue to participate in the study. However, you can decide you want to stop taking part in the study for any reason at any time. If you decide you want to stop taking part in the study, tell the study staff as soon as you can.

We will tell you how to stop safely. We will tell you if there are any dangers if you stop suddenly.

- If you decide to stop early, we will require final lab testing to assure safety.

Are there reasons we might remove you from the study later on?

Even if you want to stay in the study, there may be reasons we will need to take you out of it. Your study doctor has the right to take you out of the study at any time with or without your agreement. Your participation may be ended without your consent for different reasons, including the following.

- If the study doctor believes, for any reason, that it is in your best interest.
- If at any time while you are taking the study drug the study doctor discovers that your health has worsened.
- If you develop side effects that the study doctor considers unacceptable.
- If you refuse to take the study drug or return for follow-up as recommended by your study doctor, or do not follow the study doctor's instructions.
- If you refuse to have tests that are needed to determine whether the study drug is safe and effective.
- If you require treatment with drugs that are not allowed on this study.
- If other causes prevent you from continuing in this study.
- If the Sponsor decides to end the study.

You can get the answers to your questions, concerns, or complaints.

If you have any questions, concerns or complaints about this study, call Nagi Kumar, PhD, at (813) 745-6885.

If you have questions about your rights as a research patient at Moffitt Cancer Center, call the Division of Research Compliance in the Corporate Compliance Department at The Moffitt

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Cancer Center at (813) 745-1869.

If you have questions about your rights as a participant in this study, general questions, or have complaints, concerns or issues you want to discuss with someone outside the research, call the USF IRB at (813) 974-5638.

WHERE CAN I GET MORE INFORMATION?
You may call the National Cancer Institute's (NCI) Information Service at: 1-800-4-CANCER (1-800-422-6237).

Visit the NCI's Websites at:

- CancerTrials: comprehensive clinical trial information at: http://cancertrials.nci.nih.gov
- CancerNet: accurate cancer information including PDQ at: http://cancernet.nci.nih.gov

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

Statement Of Participation in Research and Authorization for the Collection, Use and Disclosure of Health Information

It is up to you to decide whether you want to take part in this study. If you want to take part, please read the statements below and sign the form if the statements are true. A representative of the Moffitt Cancer Center must answer your questions completely before providing this form to you. You or your personal representative should read this form and understand it before signing below.

I freely give my consent to take part in this study and authorize that my health information as agreed above, be collected/disclosed in this study. I understand that by signing this form I am agreeing to take part in research. I have received a copy of this form to take with me.

_____ _____
Signature of Person Taking Part in Study Date

_____
Printed Name of Person Taking Part in Study

Statement of Person Obtaining Informed Consent / Research Authorization

I attest that the participant named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

_____ _____
Signature of Person Explaining Informed Consent / Research Authorization Date

_____
Printed Name of Person Explaining Informed Consent / Research Authorization

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Consent to store blood samples for future research

We are asking you to allow us to store samples of your blood for use in the future. These samples may be used for a variety of purposes, but those purposes will be related to breast cancer and/or cognition.

This means that we will store some of the blood samples taken at screening and week 12 for later testing. This will not increase the time it takes to complete the blood draw.

We may use these samples to help us:

- Learn more about breast cancer and/or cognition.
- Learn how COGNUTRIN works.
- Find new ways to help improve cognition in breast cancer patients following chemotherapy.

You can decide if you want us to store and use your samples in the future.

You do not have to agree to this in order to take part in the study that has been previously explained to you.

Please initial one of the lines below:

____ I agree for my blood samples to be stored for future research studies related to breast cancer and/or cognition.

____ I DO NOT agree for my blood samples to be stored for future research studies related to breast cancer and/or cognition.