

Study Title for Study Participants: Breast Cancer Weight Loss Study (BWEL Study)

Official Study Title for Internet Search on <http://www.ClinicalTrials.gov>:

Randomized Phase III Trial Evaluating the Role of Weight Loss in Adjuvant Treatment of Overweight and Obese Women with Early Breast Cancer

This study is conducted by the Alliance for Clinical Trials in Oncology, a national clinical research group supported by the National Cancer Institute. **This study has public funding from the National Cancer Institute (NCI), part of the National Institutes of Health (NIH) in the United States Department of Health and Human Services.** The Alliance is made up of cancer doctors, health professionals, and laboratory researchers, whose goal is to develop better treatments for cancer, to prevent cancer, to reduce side effects from cancer, and to improve the quality of life of cancer patients.

What is the usual approach to my breast cancer?

Breast cancer is usually treated with surgery, chemotherapy, radiation and/or medications that lower or block the hormone estrogen. Although many doctors may recommend that obese and overweight patients lose weight, eat a healthy diet and get regular exercise after being diagnosed with breast cancer, these things are not a routine part of breast cancer treatment at this time.

What are my other choices if I do not take part in this study?

If you decide not to take part in this study, you have other choices. For example:

- you may choose to have the usual approach to your cancer described above
- you may choose to take part in a different study, if one is available
- you may take part in a weight loss program on your own, outside of this study

Why is this study being done?

This study is being done to see if losing weight may help prevent breast cancer from coming back (recurring). Previous studies have found that women who are overweight or obese when their breast cancer is found (diagnosed) have a greater risk of their breast cancer recurring, as compared to women who were thinner when their cancer was diagnosed. At this time we do not know whether or not losing weight will reduce the risk of breast cancer returning. This study seeks to determine whether or not the higher risk for breast cancer recurrence in women who are overweight or obese when they are diagnosed with breast cancer could be reduced or eliminated if weight is lost. It is important to note that we do not know how much weight would need to be lost to lower the risk of breast cancer recurrence, or whether this strategy would work for all women. This study will help to show us whether weight loss programs should be a part of breast cancer treatment.

There will be about 3136 women taking part in this study.

What are the study groups?

This study has two study groups.

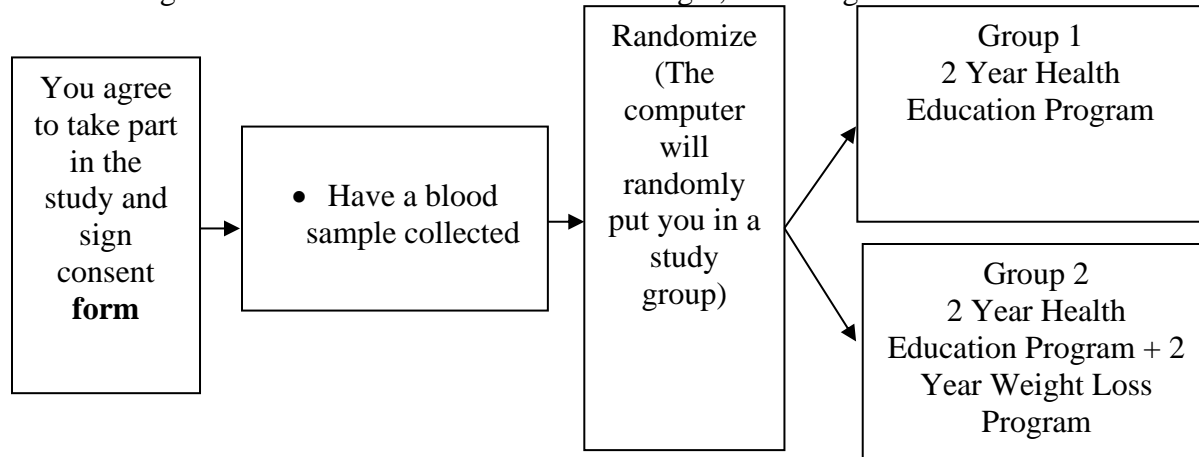
- Group 1 will get a Health Education program that is designed to give women more information about their breast cancer, as well as general information about their general health. Women who are assigned to this group will receive a cookbook, a subscription to a Health magazine, and mailings 2-4 times per year of educational materials and materials to support a healthy lifestyle (like water bottles for exercise). Women will also receive a study newsletter quarterly, and will be able to take part in webinars or teleconferences twice per year that provide information about new updates in breast cancer. Finally, they will get greeting cards on the anniversary of joining the study, holidays, etc.
- Group 2 will get the Health Education program described above and will also get a 2-year weight loss program. This program will be designed to help women lose about 10% of their starting weight by decreasing the calories they eat and by increasing their exercise.
 - Exercise goals will increase slowly over the study, with an overall goal of getting all women exercising at least 150 minutes per week over time.
 - The weight loss program will be provided through a series of 42 telephone calls over 2 years. Each call will take about 30 minutes. Telephone calls will occur weekly for the first 12 weeks of the study, every other week for the rest of the first year, then monthly during the second year of the weight loss program.
 - Each woman will be assigned a health coach who will work with her over the 2-year program.
 - Women will need to track the food they eat and the exercise they do each day, especially in the early stages of the program. This will take approximately 15-20 minutes per day.
 - Coaches will track progress using computer programs to help set goals over the 2-year program.

Women in the weight loss group will also receive:

- A weight loss workbook (available in print and on line)
- An activity sensor (such as a FitBit) to help keep track of exercise
- A journal and access to a study website to track diet, weight and exercise
- A scale, food scale and measuring cups (if needed)
- Optional text messages to help women meet exercise and diet goals
- Optional pre-packaged shakes, bars or portion-controlled entrees to replace meals

A computer will by chance assign you to one of study groups described above. This is called randomization. This is done by chance because no one knows if one study group is better or worse than the others.

Another way to find out what will happen to you during this study is to read the chart below. Start reading at the left side and read across to the right, following the lines and arrows.



How long will I be in this study?

You will receive the health education program with or without the weight loss program for 2 years. After you finish the health education/weight loss programs, your doctor will continue to watch you for side effects and follow your condition for 8 years as part of your normal breast cancer follow up.

Since this is a weight loss study and involves exercise, you must be able to walk at least 2 blocks. If at any point during the study, you become injured or develop a medical condition that makes you unable to exercise or walk, you should let the study doctor know. You may continue to participate in the study as long as you get approval from your study doctor.

You should not plan to become pregnant within the first two years of the study when you are completing the health/weight loss programs. Check with the study doctor about what types of birth control, or pregnancy prevention, to use while in this study. If you become pregnant, it is important to let the study doctor know. You may still continue to participate in the study as long as you have approval from your OB/GYN and study doctor.

What extra tests and procedures will I have if I take part in this study?

Most of the exams, tests, and procedures you will have are part of the usual approach for your cancer. However, there are some extra measurements and tests that you will need to have if you take part in this study.

Before you begin the study:

You will need to have the following to find out if you can be in the study:

- Height and weight measurements

If these measurements show that you can take part in the study, and you choose to take part, then you will need the following extra tests and assessments. They are not part of the usual approach for your type of cancer.

You will need to have the following before you begin the weight loss/health education program:

- Height and weight measurements
- Measurement of the distance around your waist and hips
- Completion of a questionnaire that will ask about fatigue and quality of life, demographic information (race, education, income, etc.), smoking and alcohol use, health problems, medications you are taking, menstrual history, employment information (whether you are working and what kind of work you do, if so), and about your thoughts on the questionnaire itself. It will take about 20 minutes to complete the survey. You may skip any question that makes you uncomfortable. However, you must provide information about your menstrual history and race/ethnicity in order to participate in the study.
- Collection of about 2-3 tablespoons of blood before you begin the weight loss/health education program. This sample is required in order for you to take part in this study because the research on the sample is an important part of the study. These blood samples will be collected at your local treatment center after you have not had anything to eat or drink for at least 12 hours. The blood samples will be used to test how the weight loss program affects a number of markers that have been linked to breast cancer, such as hormones involved in the way your body turns the food you eat into energy, markers of inflammation, and other blood markers linked to cancer. This research will allow investigators to learn which patients gain the most benefit from weight loss programs.

Blood collection is usually a very low risk procedure. There is a small risk of bleeding, bruising, infection, inflammation, blood clot or discomfort at the site of the blood collection. Attention will be taken to apply pressure following the procedure to reduce bleeding. You may feel dizzy or faint when blood is being withdrawn. We will ask you to lie down for a few minutes until any dizziness passes.

If any additional blood is left over after the tests are performed, then the remaining sample will be stored for future use in a “biobank.” Biobanking will be discussed in the “ADDITIONAL STUDIES” section. The remaining sample will only be saved for future use if you provide your consent by circling “yes” under question #2.

Your privacy is very important and the researchers will make every effort to protect it. Your test results will be identified by a unique code and the list that links the code to your name will be kept separate from your sample and health information.

Given that there is currently no information that would affect your clinical care that is being tested through these blood samples, these results will not be available to you or to your study doctor. However, at the completion of the trial, overall study findings will be shared with study participants and their doctors.

During the study (for 10 years after you are assigned to a study group):

- Weight measurements every 6 months for 3 years, then once per year
- Measurement of the distance around your waist and hips every 6 months for 3 years, then once per year
- Completion of a questionnaire about medications you are taking and other health problems you have developed every 6 months for 3 years, then once per year. It will take about 10 minutes to complete the questionnaire.
- Collection of about 2-3 tablespoons of blood at 6 and 24 months after you are assigned to a study group. This sample is required in order for you to take part in this study, just like the blood samples that were taken before you started the program(s). These blood samples will be collected at your local treatment center after you have not had anything to eat or drink for at least 12 hours.

During this study you should not participate in another clinical trial that is testing a weight loss or physical activity program. You are welcome to take part in any type of program that you would like to that is not a part of a clinical trial, like dieting on your own or joining a gym or exercise class, regardless of whether you are assigned to Group 1 or Group 2.

What possible risks can I expect from taking part in this study?

If you choose to take part in this study, there is a risk that:

- You may lose time at work or home and spend more time in the hospital or doctor's office than usual
- You may be asked sensitive or private questions which you normally do not discuss
- Weight loss may be shown to not improve survival rates from breast cancer
- If you are assigned to the group that receives the weight loss program, 5-10% of the coaching phone calls will be recorded and reviewed by study staff to ensure that the program is being provided in the same way to all study participants. These recordings will be destroyed after the study is completed and will be kept in password protected files, but there is a small chance that someone could access them.
- All participants in this study receive a complimentary subscription to a health magazine. You will be given an option of several magazines from which you can choose. You can also opt to not receive a magazine. Your mailing address will be shared with the magazine as part of the subscription process, but the magazine will not be given any of your health information. You may opt not to receive the magazine if you wish.
- There is a risk someone could get access to the personal information in your medical records or other information researchers have kept about you. Someone might be able to trace this information back to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.

There is also a risk that you could have side effects from the weight loss intervention. These side effects are usually very mild. For example, you might experience sore muscles from exercising. You might also experience some gas or bloating as a result of making changes to your diet, like eating more fruits and vegetables.

Here are important points about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, others could last a longer time

Here are important points about how you and the study doctor can make side effects less of a problem:

- Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
- The study doctor may be able to treat some side effects.

Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.

What possible benefits can I expect from taking part in this study?

It is not possible to know at this time if adding a weight loss program to the usual treatment for breast cancer will reduce the risk of your breast cancer coming back. However, losing weight has been shown in many studies to have other benefits, such as lowering the risk of diabetes, heart problems and other medical conditions. This study will also help researchers learn things that will help people in the future.

Can I stop taking part in this study?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study rules
- If the study is stopped by the sponsor, IRB or FDA.

What are my rights in this study?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

For questions about your rights while in this study, call the Operations Office of the National Cancer Institute (NCI) Central Institutional Review Board (CIRB) at 888-657-3711.

What are the costs of taking part in this study?

The weight loss and health education programs will be supplied at no charge while you take part in this study. It is possible that the programs may be discontinued before you finish them if the study is stopped early. Although not likely, if this occurs, your study doctor will talk to you about your options.

You and/or your health plan/insurance company will need to pay for all of the other costs of treating your cancer while in this study, including the cost of tests, procedures, or medicines to manage any side effects, unless you are told that certain tests are supplied at no charge. Before you decide to be in the study, you should check with your health plan or insurance company to find out exactly what they will pay for.

You will not be paid for taking part in this study.

What happens if I am injured or hurt because I took part in this study?

If you are injured or hurt as a result of taking part in this study and need medical treatment, please tell your study doctor. Contact information for your study doctor is listed on the consent cover page. The study sponsors will not offer to pay for medical treatment for injury. Your insurance company may not be willing to pay for study-related injury. If you have no insurance, you would be responsible for any costs.

If you feel this injury was a result of medical error, you keep all your legal rights to receive payment for this even though you are in a study.

No funds have been set aside to compensate you in the event of injury.

Who will see my medical information?

Your privacy is very important to us. The study doctors will make every effort to protect it. The study doctors have a privacy permit to help protect your records if there is a court case. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are.

Some of your health information, such as your response to cancer treatment, results of study tests, and medicines you took, will be kept by the study sponsor in a central research database. However, your name and contact information will not be put in the database. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

There are organizations that may look at or receive copies of some of the information in your study records. Your health information in the research database also may be shared with these organizations. They must keep your information private, unless required by law to give it to another group.

Some of these organizations are:

- Montana Cancer Consortium
- The Alliance and other organizations from the National Clinical Trials Network that take part in this study
- The Dana-Farber Cancer Institute
- The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
- The Food and Drug Administration and the groups it works with to review research
- The National Cancer Institute and the groups it works with to review research
- The NCI's National Clinical Trials Network and the groups it works with to review research, including the Imaging and Radiation Oncology Core (IROC)

For this study, your information, including your personal information and contact information, will be shared with the Alliance for Clinical Trials in Oncology, the group that is conducting this study. Your information will also be shared with the investigators and staff running the BWEL Call Center at the Dana-Farber Cancer Institute. In both of these places, your information will be kept stored in password-protected databases and/or in locked filing cabinets.

In addition to storing data in the study database, data from studies that are publicly funded may also be shared broadly for future research with protections for your privacy. The goal of this data sharing is to make more research possible that may improve people's health. Your study records may be stored and shared for future use in public databases. However, your name and other personal information will not be used.

Some types of future research may include looking at your information and information from other patients to see who had side effects across many studies or comparing new study data with older study data. However, right now we don't know what research may be done in the future using your information. This means that:

- You will not be asked if you agree to take part in the specific future research studies using your health information.
- You and your study doctor will not be told when or what type of research will be done.

- You will not get reports or other information about any research that is done using your information.

There are laws that protect your genetic information. However, there is a risk that someone could get access to your genetic information and identify you by name. In some cases, employers could use your genetic information to decide whether to hire or fire you. The study doctors believe the risk of this happening is very small. However, the risk may increase in the future as people find new ways of tracing information. For more information about the laws that protect you, ask your study doctor.

Where can I get more information?

You may visit the NCI Web site at <http://cancer.gov/> for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

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.

Who can answer my questions about this study?

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact information for your study doctor is listed on the consent cover page.

ADDITIONAL STUDIES SECTION:

This section is about optional studies you can choose to take part in

This part of the consent form is about optional studies that you can choose to take part in. You will not get health benefits from any of these studies. The researchers leading this optional study hope the results will help other people with cancer in the future.

The results will not be added to your medical records and you or your study doctor will not know the results.

You will not be billed for these optional studies. You can still take part in the main study even if you say “no” to any or all of these studies. If you sign up for but cannot complete any of the studies for any reason, you can still take part in the main study.

Circle your choice of “yes” or “no” for each of the following studies.

Optional Imaging Study (A011401-IM1)

The researchers conducting this study are interested in learning about body composition, which means how much of the body is adipose, or fatty, tissue and how much of the body is lean, or muscle, tissue. Some research suggests that body composition could influence the risk of developing breast cancer or the risk of breast cancer recurring once it has been treated.

For this optional study, researchers are asking for permission to collect CT scans of the stomach area or PET-CT scans that you may have had when you were diagnosed with breast cancer or afterward. They will then use these scans to estimate body composition and see how body composition is linked to body weight, changes in body weight, other health issues and breast cancer recurrence rates.

If you choose to take part in this study, the images from the CT or PET scans that you may have had in the past will be sent to an Alliance central image library. The study team will also record your weight at the time that the scan was done. If you agree to allow these images to be sent to the image library, any information that may identify you, such as your initials, will be removed.

Please note: You will not need to undergo any additional scans if you agree to take part in this optional study. If you never had a scan done, you will not participate in this study.

1) Please circle your answer: I choose to take part in the imaging study.

YES

NO

Optional Sample Collections for Additional Laboratory Studies and Biobanking for Possible Future Studies

Researchers are trying to learn more about cancer and other health problems using blood and tissue samples from people who take part in clinical trials. By studying these samples, researchers hope to find new ways to prevent, detect, treat, or cure diseases.

Some of these studies may be about how genes affect health and disease. Other studies may look at how genes affect a person's response to treatment. Genes carry information about traits that are found in you and your family. Examples of traits are the color of your eyes, having curly or straight hair, and certain health conditions that are passed down in families. Some of the studies may lead to new products, such as drugs or tests for diseases.

Known future studies

If you choose to take part in this optional study, researchers will collect an extra blood sample and a sample of breast tumor tissue from a previous biopsy or surgery for research on the effect of the weight loss program on additional blood markers, and to look at how markers in breast tumor tissue relate to the effects of the weight loss program. Participating in this optional study will not require that you undergo an additional biopsy or blood draw.

Unknown future studies

If you choose to take part in this optional study, any extra blood or tissue that is left over after the planned studies have been performed will be collected and stored. Storing samples for future studies is called “biobanking.” The biobank is being run by the Alliance for Clinical Trials in Oncology and is supported by the NCI. This is a publicly funded study. Samples from publicly funded studies are required to be shared as broadly as possible. However, we will protect your privacy. The goal of this is to make more research possible that may improve people’s health.

The biobank is a public research resource. It has controlled access. This means that researchers who want to get samples and data from it must submit a specific research request. The request identifies who they are and what their planned research project is. Before getting the samples and data, the researchers must agree to keep the data private, only use it for their planned research project, and never use it to try to identify you.

Right now, we don’t know what research may be done in the future using your blood and tissue samples. This means that:

- You will not be asked if you agree to take part in the future research studies.
- You and your study doctor will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your samples.

Unknown future research studies may include sequencing of all or part of your DNA. This is called genomic sequencing. Sequencing allows researchers to identify your genetic code. Changes in your genetic code may just be in your tumor tissue. These are called somatic changes. Changes may also be in your normal tissue and passed down through your family. For example, these genetic changes may be passed down to your children in the same way that eye and hair color are passed down. These are called germline changes. If only tumor tissue is sequenced, we will not know if a genetic change in your tumor is also in your normal tissue. This is why sometimes both normal tissue and tumor tissue are sequenced. This helps researchers understand if a genetic change happened only in your cancer tissue, or in your normal tissue as well.

You will be asked for permission to collect these extra samples and to store any extra samples. You can agree to one or both of these things. You will still be allowed to participate in the main study whether you agree to participate in these optional parts of the study or not.

WHAT IS INVOLVED?

If you agree to take part in the additional sample collection and/or the biobanking, here is what will happen next:

- 1) If you agree to provide additional blood samples and a sample from your breast tumor, about 2 teaspoons of blood will be collected from a vein in your arm and a sample from the tissue that was collected at the time of your surgery will be sent to the Biobank. Health-related information will also be sent to use in research. A new biopsy or surgery will not be required.
- 2) If you agree to have left over samples sent to the Biobank, all left over blood and tumor samples will be sent to the BioBank for future research.
- 3) Samples will be stored in the Biobank, along with samples from other people who take part. The samples will be kept until they are used up.
- 4) Qualified researchers can submit a request to use the materials stored in the Biobanks. A science committee at the clinical trials organization, and/or the National Cancer Institute, will review each request. There will also be an ethics review to ensure that the request is necessary and proper. Researchers will not be given your name or any other information that could directly identify you. Some related health information may be sent to the researcher.
- 5) Neither you nor your study doctor will be notified when research will be conducted or given reports or other information about any research that is done using your samples.
- 6) Some of your genetic and health information may be placed in central databases that may be public, along with information from many other people. Information that could directly identify you will not be included.

WHAT ARE THE POSSIBLE RISKS?

- 1) There is a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.
- 2) There is a risk that someone could trace the information in a central database back to you. Even without your name or other identifiers, your genetic information is unique to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information.
- 3) In some cases, this information could be used to make it harder for you to get or keep a job or insurance. There are laws against the misuse of genetic information, but they may not give full protection. There can also be a risk in knowing genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a study. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.

HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE?

Your privacy is very important to the researchers and they will make every effort to protect it.

Here are just a few of the steps they will take:

- 1) When your sample(s) is sent to the researchers, no information identifying you (such as your name) will be sent. Samples will be identified by a unique code only.

- 2) The list that links the unique code to your name will be kept separate from your sample and health information. Any Biobank and the Alliance staff with access to the list must sign an agreement to keep your identity confidential.
- 3) Researchers to whom the Alliance sends your sample and information will not know who you are. They must also sign an agreement that they will not try to find out who you are.
- 4) Information that identifies you will not be given to anyone, unless required by law.
- 5) If research results are published, your name and other personal information will not be used.

WHAT ARE THE POSSIBLE BENEFITS?

You will not benefit from taking part. The researchers, using the samples from you and others, might make discoveries that could help people in the future.

ARE THERE ANY COSTS OR PAYMENTS?

There are no costs to you or your insurance. You will not be paid for taking part. If any of the research leads to new tests, drugs, or other commercial products, you will not share in any profits.

WHAT IF I CHANGE MY MIND?

If you decide you no longer want your samples to be used, you can call the study doctor who will let the researchers know. Contact information for your study doctor is listed on the consent cover page. Then, any sample that remains in the bank will no longer be used and related health information will no longer be collected. Samples or related information that have already been given to or used by researchers will not be returned.

WHAT IF I HAVE MORE QUESTIONS?

If you have questions about the use of your samples for research, contact the study doctor. Contact information for your study doctor is listed on the consent cover page.

Please circle your answer to show whether or not you would like to take part in each option

SAMPLES FOR THE LABORATORY STUDIES:

- 2) I agree to have an additional blood sample collected and to have a sample from my breast biopsy or surgery sent to the researchers from this study. I agree that my specimen sample(s) and related information may be used for the laboratory study(ies) described above.

YES

NO

SAMPLES FOR FUTURE RESEARCH STUDIES:

- 3) My samples and related information may be kept in a Biobank for use in future health research.

YES NO

- 4) I agree that my study doctor, or their representative, may contact me or my physician to see if I wish to participate in other research in the future.

YES NO

This is the end of the section about optional studies.

My Signature Agreeing to Take Part in the Main Study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed copy of this form. I agree to take part in the main study and any additional studies where I circled 'yes'.

Participant Signature: _____

Date: _____

Signature of Person Obtaining Consent: _____

Date: _____

Time of consent: _____ (AM) (PM)

(Required for initial consent only)