Clinical Trial: A211601-Retrospective for A011502 patients

This is a cover page for a consent form for a clinical trial. This cover page provides the contact information for your physician and research staff.

This consent form contains important information to help you decide whether to participate in this clinical trial. Your physician and research staff will explain this trial to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family or friends.

- Being in a clinical trial is voluntary – your choice.
- If you join this clinical, you can still stop at any time.
- No one can promise that a clinical trial will help you.
- Do not join this clinical trial unless all of your questions are answered.

After reading and discussing the information in this consent form you should know:

- Why this clinical trial is being done;
- What will happen during the clinical trial;
- Any possible benefits to you;
- The possible risks to you;
- Other options you could choose instead of being in this clinical trial;
- How your personal health information will be treated during the clinical trial and after the trial is over;
- Whether being in this clinical trial could involve any cost to you; and
- What to do if you have problems or questions about this clinical trial.

Some of the hospitals that are members of Montana Cancer Consortium are Catholic health institutions and therefore uphold the Ethical and Religious Directives for Catholic Health Care Services that do not promote or condone artificial/ medically induced pregnancy prevention methods. The attached consent may contain language that is not consistent with this religious directive.

Please read this consent form carefully.

You should talk to your doctor or research coordinator about any questions or concerns you have about this study. Their contact information is listed below.

Physician Name & Phone Number:

Research Coordinator Name & Phone Number: _____

Cancer Center Address: _____

You may also contact Montana Cancer Consortium
2132 Broadwater Ave, Suite A1, Billings, MT 59102
Phone: 406-969-6060, Fax: 406-969-6070

Acknowledgement of Consent Cover Page

_____

Participant Signature Date

12.0 CONSENT FOR PATIENTS PREVIOUSLY ENROLLED TO ALLIANCE A011502

Study Title for Participants:

Testing the Effect of Aspirin on Breast Density: A companion study to Alliance Study A011502

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

Alliance A211601, "Evaluation of Mammographic Breast Density Effect of Aspirin: A companion study to Alliance Study A011502"

Overview and Key Information

What am I being asked to do?

We are asking you to take part in a research study. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

We are asking you to take part in this research study because you have breast cancer and you previously enrolled to the Alliance study A011502, "Aspirin for Breast Cancer Study" (or ABC study).

Taking part in this study is your choice.

You can choose to take part or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It's important that you have as much information as you need and that all your questions are answered. See the "Where can I get more information?" section for resources for more clinical trials and general cancer information.

Why is this study being done?

This study is being done to answer the following question:

Does taking aspirin reduce breast density?

What is the usual approach to imaging after my breast cancer diagnosis?

The usual approach for patients with breast cancer is to have annual mammograms.

What are my choices if I decide not to take part in this study?

- You may choose to have the usual approach described above.
- You may choose to take part in a different research study, if one is available.
- You may choose not to be treated for cancer.
- You may choose to only get comfort care to help relieve your symptoms and not get treated for your cancer.

What will happen if I decide to take part in this study?

If you decide to take part in this study, you will be asked to allow your clinic to send us copies of your mammograms from before the time that you enrolled to A011502, and then after 1 and 2 years after enrolling to the study. You will also be asked about your menstrual cycles, either in person or over the telephone at those same times.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

Risks

The greatest risk is the release of information from your health records. The Alliance for Clinical Trials in Oncology (or just the "Alliance") will protect your records so that your name will be kept private. The chance that this information will be given to someone else is very small.

Benefits

This study is unlikely to help you. We hope the information learned from this study will benefit other patients with breast cancer in the future.

If I decide to take part in this study, can I stop later?

Yes, you can decide to stop taking part in the study at any time.

If you decide to stop, let your study doctor know as soon as possible. If you stop, you can decide if you want to keep letting the study doctor know how you are doing.

Your 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.

Are there other reasons why I might stop being in the study?

Yes. The study doctor may take you off the study if:

- Your health changes and the study is no longer in your best interest.
- New information becomes available and the study is no longer in your best interest.
- You do not follow the study rules.
- You become pregnant while on the study.
- The study is stopped by the National Cancer Institute (NCI), Institutional Review Board (IRB), or study sponsor (Alliance). The study sponsor is the organization who oversees the study.

If you decide not to stay in the A011502 study, you will not be able to stay in this study either.

This study is conducted by the Alliance for Clinical Trials in Oncology, a national clinical research group supported by the National Cancer Institute. 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.

It is important that you understand the information in the informed consent before making your decision. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask your study doctor or nurse.

What is the purpose of this study?

This study is being done as a related study (also called a "companion study") to the Alliance A011502 clinical trial. The purpose of this study is to see if the use of aspirin causes a decrease in mammographic breast density.

The breast is composed of fat, milk glands and various other tissues, which determine how dense the breasts are. High breast density has been shown to be a strong risk factor for developing breast cancer. It is thought that decreasing breast density may decrease the risk for breast cancer. The main goal of this study is to see whether women treated with aspirin will have reduced breast density as seen on a mammogram. Breast density is determined by a mammogram, and cannot be determined by a physical exam.

There will be about 384 women taking part in this study.

What are the study groups?

In this study, all study participants who enroll at time later than when they enrolled to A011502 will follow the same procedure. If you take part in this study, you will have to complete a form that allows us to get access to your original mammograms and to make a copy of them.

We will ask the clinic that did your mammograms to send us copies of the following mammograms:

- The most recent mammogram from before the time that you started on the A011502 study.
- Mammograms closest to year 1 after you started that study.
- Mammograms closest to year 2 after you started that study.

Your name and other information will be removed from the Alliance copy, so no one will be able to tell it is yours by looking at it.

The specific breast density calculations that are made for this study will not be made available to you or your doctor. However, every mammogram report does have breast density information that is available to you and your doctor.

What exams, tests, and procedures are involved in this study?

You will follow the schedule of exams, tests, and procedures for A011502.

Your mammograms from the beginning of that study, and then 1 and 2 years after enrolling to A011502 will be sent to the Alliance. These are routine time points for getting mammograms.

You will also be asked about your menstrual cycles, either in person or over the telephone at those same times.

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

The greatest risk is the release of information from your health records. The Alliance for Clinical Trials in Oncology (or just the "Alliance") will protect your records so that your name will be kept private. The chance that this information will be given to someone else is very small.

Mammograms expose you to low-dose radiation. The dose of radiation is very low and it is felt they will not expose you to significant risk.

What are my responsibilities in this study?

If you choose to take part in this study you will need to:

- Keep your study appointments.

Do not get pregnant or breastfeed while taking part in this study. Tell your study doctor right away if you think that you have become pregnant during the study.

What are the costs of taking part in this study?

You and/or your insurance plan will need to pay for the costs of medical care you get as part of the study, just as you would if you were getting the usual care for your breast cancer. This includes your insurance co-pays and deductibles.

Talk to your insurance provider and make sure that you understand what your insurance pays for and what it doesn't pay for if you take part in this clinical trial. Also, find out if you need approval from your plan before you can take part in the study.

Ask your doctor or nurse for help finding the right person to talk to if you are unsure which costs will be billed to you or your insurance provider.

You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

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

If you are injured as a result of taking part in this study and need medical treatment, please talk with your study doctor right away about your treatment options. Contact information for your study doctor is listed on the consent cover page. The study sponsors will not pay for medical treatment for injury. Your insurance company may not be willing to pay for a study-related injury. Ask them if they will pay. If you do not have insurance, then you would need to pay for these medical costs.

If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. Agreeing to take part in this study does not mean you give up these rights.

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 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 for Clinical Trials in Oncology
- The Institutional Review Board (IRB), which is a group of people who review the research with the goal of protecting the people who take part in the study.
- The National Cancer Institute (NCI) and the groups it works with to review research.

Your study records also will be stored for future use. However, your name and other personal information will not be used. Some types of future research may include looking at your records and those of other patients to see who had side effects across many studies or comparing new study data with older study data. However, 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.

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.

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.

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.

My signature agreeing to take part in the study:

Participant Signature: _____

Date: _____

Signature of Person Obtaining Consent: _____

Date: _____

Time of consent: _____ (AM) (PM)

(Required for initial consent only)

Consent Acknowledgement Form

By signing this form I, _____ am acknowledging the following:

- I have been given adequate time to review the consent form for Clinical Trial A211601.
- My physician has answered my questions to my satisfaction at this point.
- If I have any study-related questions in the future, I will talk with my doctor, nurse, or research coordinator.
- I understand that participation in this clinical trial is optional, and that I may withdraw from the trial at any time.
- No matter what I decide to do, and whether or not I decide to participate in this study, my decision will not harm the care that I receive or my relationship with my doctor, nurses, or other healthcare provider.
- No study procedures specific for this clinical trial were performed prior to my signing this consent form.
- I have reviewed with my doctor all medications that I am currently taking, including nonprescription medications, vitamins, herbal supplements, and naturopathic preparations, to avoid possible drug interactions.
- I have been informed of the potential reproductive risks associated with treatment on this clinical trial and understand precautions must be taken to avoid pregnancy while undergoing treatment and for a period of time after the conclusion of treatment.
- While abstinence is the most effective way of preventing a pregnancy, we understand that you may consider other pregnancy prevention methods. You are encouraged to ask your study doctor or research nurse for more information about reproductive risks and pregnancy prevention methods.
- If I become pregnant or have reason to believe I might be pregnant or fathered a child while receiving treatment on this clinical trial, I will notify my doctor immediately.
- Once I am no longer receiving treatment on this clinical trial, I may discuss with my doctor when it may be safe to become pregnant or father a child.
- I have received a signed copy of the consent form for the above named clinical trial.

_____ _____
Patient Signature Date

_____ _____
Person Obtaining Consent Signature Date

Montana Cancer Consortium
Authorization (Permission) to Use or Disclose (Release) Identifiable Health Information for Research

Participant's Name: _____

Birth Date: _____

1. What is the purpose of this form?

The ALLIANCE, is an organization that does research to learn about the causes of cancer, and how to prevent and treat cancer. Researchers would like to use your health information for research. This information may include data that identifies you. Please carefully review the information below. If you agree that researchers can use your personal health information, you must sign and date this form to give them your permission.

2. What personal health information do the researchers want to use?

The researchers want to copy and use the portions of your medical record that they will need for their research. If you enter an ALLIANCE research study, information that will be used and/or released may include the following:

- the history and diagnosis of your disease;
- specific information about the treatments you received, including previous treatment(s) you may have had;
- information about other medical conditions that may affect your treatment;
- medical data, including laboratory test results, tumor measurements, CT scans, MRIs, x-rays, and pathology results;
- information on side effects (adverse events) you may experience, and how these were treated;
- long-term information about your general health status and the status of your disease;
- data that may be related to tissue and/or blood samples that may be collected from you; and
- numbers or codes that will identify you, such as your social security number, medical record number, initials, and date of birth.

You may request a blank copy of the ALLIANCE data forms from Montana Cancer Consortium to learn what information will be shared.

3. Why do the researchers want my personal health information?

Montana Cancer Consortium will collect your health information and share it with ALLIANCE if you enter a cooperative group research study, or to evaluate your eligibility for a study. ALLIANCE will use your information in the following cancer research study:

ALLIANCE A211601: Evaluation of Mammographic Breast Density Effect of Aspirin: A Companion to Alliance Study A011502

4. Who will be able to use my personal health information?

Montana Cancer Consortium will use your health information for research. As part of this research, they may give your information to the following groups taking part in the research. Montana Cancer Consortium may also permit the following groups to come in to review your original records that are kept by Montana Cancer Consortium so that they can monitor their research study**:**

- National Cancer Institute (NCI) Central Institutional Review Board (CIRB)
- the ALLIANCE Operations Center;
- the ALLIANCE Biostatistical Center;
- the Cancer Trials Support Unit (CTSU) or designees, a research group sponsored by the National Cancer Institute to provide greater access to cancer studies;
- Public Health agencies and other government agencies (including non-U.S.) as authorized or required by law;
- other people or organizations assisting with ALLIANCE research efforts. This may include drug manufacturers, drug companies that may provide partial support for the study, drug distributors, and/or their designees; and
- central laboratories, central review centers, and central reviewers. The central laboratories and review agencies may also give your health information to those groups listed in the bullets above.

5. How will information about me be kept private?

ALLIANCE will keep all patient information private to the extent possible, even though they and other federal research groups are not subject to the same federal privacy laws governing clinical centers. ALLIANCE will not release identifiable health information about you to others except as authorized by this form, or required by law. If your identifiable health information must be shared with other organizations, the privacy laws that govern those organizations would apply.

6. What happens if I do not sign this permission form?

If you do not sign this permission form, you will not be able to take part in the research study for which you are being considered.

7. If I sign this form, will I automatically be entered into the research study?

No, you cannot be entered into any research study without further discussion and separate consent. After discussion, you may decide to take part in the research study. At that time, you will be asked to sign a separate research consent form.

8. What happens if I want to withdraw my permission?

You can change your mind at any time and withdraw your permission to allow your personal health information to be used in the research. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission, no new personal health information will be used for research. However, researchers may continue to use the health information that was provided before you withdrew your permission.

If you sign this form and enter the research study, but later change your mind and withdraw your permission, you will be removed from the research study at that time.

To withdraw your permission, please contact the institution below. They will make sure your written request to withdraw your permission is processed correctly.

Montana Cancer Consortium
2132 Broadwater Ave, Suite A1
Billings, MT 59102
406-969-6060
Fax: 406-969-6070

9. How long will this permission last?

If you agree by signing this form that researchers can use your personal health information, this permission has no expiration date. However, as stated above, you can change your mind and withdraw your permission at any time.

10. What are my rights regarding access to my personal health information?

You have the right to refuse to sign this permission form. You have the right to review and/or copy records of your personal health information kept by Montana Cancer Consortium. You do not have the right to review and/or copy records kept by ALLIANCE or other researchers associated with the research study.

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Signatures

I agree that my personal health information may be used for the research purposes described in this form.

Signature of Patient: _____Date: _____

Signature of Person Obtaining Permission: _____Date: _____

Printed Name of Person Obtaining Permission: _____