Clinical Trial: S1007-Addendum

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

Research Study Informed Consent Addendum Model for S1007

Step 3: Optional Specimen Submission Consent Form Addendum: Circulating Biomarker Assessment for Late Relapse in Patients with Node-Positive, Hormone-Receptor Positive, Her2-, Operable Breast Cancer (US Sites only)

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: S1007, A Phase III, Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone Receptor-Positive and HER-2 Negative Breast Cancer with Recurrence Score (RS) of 25 or Less. RxPONDER: A Clinical Trial RX for Positive Node, Endocrine Responsive Breast Cancer Metastases (NCT 01272037)

The following information should be read as an update to the original Consent form that you read and signed at the beginning of the study. Unless specifically stated below, all information contained in that original Consent Form is still true and remains in effect. Your participation continues to be voluntary. You may refuse to participate, or may withdraw your consent to participate at any time, and for any reason, without jeopardizing your future care at this institution or your relationship with your study doctor.

Overview and Key Information

When you joined the **S1007** study, SWOG (the group conducting the study) and your study doctor(s) promised to tell you about new information that might affect your participation in the trial. The following are changes that have been made to the original **S1007** study for patients in the United States.

New information

Optional sample collection that you can choose to take part in

This consent form is about an optional part of the study that you can choose to take part in. This part of the study is separate from the main **S1007** study that you are already taking part in. This optional study will not benefit your health. 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.

Taking part in this optional study is your choice. You can still take part in the main study even if you say "no" to taking part in this study. There is no penalty for saying "no." You and your insurance company will not be billed for this optional study. If you sign up for but cannot complete any of the optional study visits for any reason, you can still take part in the main study.

Optional sample collections for known laboratory studies and/or storage 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.

Why am I being asked to take part in this optional sample collection?

We are asking you to take part in an additional optional sample collection because you were enrolled to **S1007** less than 8 years ago and the breast cancer has not returned.

We are doing this part of the study because we want to help researchers understand why, for some patients, the cancer returns five or more years after initial diagnosis and treatment. This is called "late relapse." About half of breast cancers that return are late relapses. Late relapse breast cancer is hard to study because researchers need information and samples to be collected and studied long after a patient has already been treated. It is important to collect this information because changes over the years may affect how or when breast cancer returns.

Why is this optional sample collection being done?

This part of the study is being done to answer the following question:

- Is there a relationship between the presence of circulating tumor cells (a biomarker) at up to 8 years after initial diagnosis and treatment and the patient's time without cancer or time until cancer relapse (returns)?

We are doing this optional sample collection because the presence of circulating tumor cells (a biomarker) may help the researchers understand more about monitoring patients with breast cancer for relapse (whether or not the breast cancer returns). The main purpose of the research using these additional optional samples is to learn more about breast cancer and how or why breast cancer returns (relapses).

The researchers would also like to keep some of the samples for future research studies.

There will be about 890 people in the United States taking part in this optional part of the study

What will happen if I decide to take part in this additional optional sample collection?

This optional part of the **S1007** research study does not involve treatment and will not affect your ongoing follow-up or standard of care procedures.

Known future studies

If you decide to take part in this optional sample collection, your study doctors will collect blood samples at 3 additional times (a. when you agree to take part in this optional part of the study, b. 2-3 years after the initial blood collection in this optional study, and c. if the cancer returns) and a tissue sample if the cancer returns (relapses). The health information that is collected with the regular follow-up visits for the main part of the study will also be utilized for the research on circulating tumor biomarkers.

Another way to find out what will happen to you during this study is to read the chart below. Listed below are the sample collection times that will be done as part of the optional study that may not be included in the usual care (if you were not in this study).

Additional samples that will be collected and submitted for the optional circulating blood marker study and future research:

	When you agree to take part in S1007 Circulating Biomarker	**2-3 years after the first blood draw for S1007 Circulating Biomarker**	**Time of Relapse (if cancer returns)**
Blood samples (about 4.5 tablespoons of blood at each time)	X	X	X
Tissue sample			If biopsy is done

You will be asked to fast for 8 to 12 hours before each additional blood draw. Fasting means that you will not eat anything and will not drink anything except water. Before each additional blood draw, you will be asked at what time you last had some food and drank something other than water.

Some of the future research studies may use genetic tests that may identify changes in the genes in your DNA as detected in blood and/or tumor DNA. Your genes carry information about you and your family, from the color of your eyes to health conditions for which you may be at risk, such as certain kinds of cancer. Some of the research results, which may include 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.

Unknown future studies

If you choose to take part in this additional optional sample collection of blood samples at 3 additional times (described above) and a tissue sample if the cancer returns (relapses), then part of the blood samples and a sample of tissue from your relapse biopsy will be stored. Storing samples for future studies is called "biobanking." The Biobank is being run by Nationwide Children's Hospital and supported by the National Cancer Institute. 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 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 the cancer tissue, or in your normal tissue as well.

The results of the testing on the optional samples collected for known and unknown future studies will not be added to your medical records and you or your study doctor will not get the results.

What is involved in this optional sample collection?

If you agree to take part, here is what will happen next:

1. About 4.5 tablespoons of blood (7 tubes) will be collected from a vein in your arm at 3 times: when you agree to take part in this optional part of the study, 2-3 years after the

initial blood collection in this optional study, and if the cancer returns. If the cancer returns, a sample from the tissue that was collected at the time of the biopsy procedure when the cancer returned (relapse) will be sent to the biobank.

2. Part of your blood samples will be sent directly to laboratories for circulating biomarker testing. These blood samples will be kept until they are used for the circulating biomarker research and then will be destroyed.
3. Your tissue sample and part of your blood samples will be stored in the biobank. There is no limit on the length of time we will keep your samples and research information. The samples will be kept until they are used for research or destroyed.
4. Researchers can only get samples from the biobank after their research has been approved by experts. Researchers will not be given your name or contact information.
5. Some of your genetic and health information may be placed in central databases for researchers to use. The databases will not include your name or contact information.

What are the risks in this optional sample collection?

- The most common risks related to drawing blood from your arm are brief pain and maybe a bruise.
- Generally, hospitals will keep some of the tissue removed if the cancer returns (relapses). This tissue may be used to help treat cancer in the future. There is a small risk that when this tissue sample is submitted to the biobank for this optional sample collection, your tissue could be used up.
- Your medical and genetic information is unique to you. There is a risk that someone outside of the research study could get access to your study records or trace information in a database back to you. They could use that information in a way that could harm you. Researchers believe the chance that someone could access and misuse your information is very small. However, the risk may increase in the future as people find new ways of tracing information.
- In some cases, this information could be used to make it harder for you to get or keep a job and get or keep health insurance. There are laws against the misuse of genetic information, but they may not give full protection. For more information about the laws that protect you, ask your study doctor or visit: https://www.genome.gov/10002328/

How will information about me be kept private?

Your privacy is very important to the study researchers and biobank. They will make every *effor*t to protect it. Here are just a few of the steps they will take:

1. They will remove identifiers, such as your name or initials, from your sample and information. They will replace them with a code number. There will be a master list linking the code numbers to names, but they will keep it separate from the samples and information.
2. Researchers who study your sample and information will not know who you are. They also must agree that they will not try to find out who you are.
3. Your personal information will not be given to anyone unless it is required by law.

4. If research results are published, your name and other personal information will not be used.

What are the benefits to taking part in this optional sample collection?

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 to this optional sample collection?

There are no costs to you or your insurance. 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 if I change my mind about this optional sample collection?

If at any time you decide you no longer want to participate in this optional sample collection, tell your study doctor. Contact information for your study doctor is listed on the consent cover page. After you tell your study doctor, no additional optional samples or related information will be sent for this optional study. If you change your mind about additional optional sample collection, your samples that were already sent will still be used for these and future research studies unless you also tell your study doctor that you no longer want your samples to be used.

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

What if I have questions about this optional sample collection?

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.

What happens if I am injured because I took part in this optional sample collection?

If you are injured as a result of taking part in this part of the 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.

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.

Consent to take part in optional studies

When you signed the original consent form, you were asked if you would allow your samples to be kept for use in research to learn about, prevent, treat, or cure cancer.

The researchers now would like to ask you if you would like to take part in the additional sample collection described in this form for both known and unknown future studies.

Please circle your answer below to show if you would or would not like to take part in this optional study:

Blood samples for circulating biomarker study and unknown future studies

I agree that my blood samples and related health information may be used for the laboratory (circulating biomarker) study described above and I agree that my samples and related health information may be kept in a biobank for use in future health research.

YES **NO**

Tissue samples for circulating biomarker study and unknown future studies

I agree that my tissue samples and related health information may be used for the laboratory (circulating biomarker) study described above and I agree that my samples and related health information may be kept in a biobank for use in future health research.

YES **NO**

Please refer to the original consent form that you signed for the description of the use of all other optional samples that may have been or will be collected as part of already existing optional studies. The consent for the additional samples does not affect your prior consent to take part in **S1007** or previous optional studies.

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.

Patient Signature and Date

I have read this consent form addendum 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 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)

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 S1007.
- 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 SWOG, 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 a SWOG 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 SWOG 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 SWOG if you enter a cooperative group research study, or to evaluate your eligibility for a study. SWOG will use your information in the following cancer research study:

S1007: A Phase III, Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone Receptor-Positive and HER2-Negative Breast Cancer with Recurrence Score (RS) of 25 or Less. RxPONDER: A Clinical Trial Rx for Positive Node, Endocrine Responsive Breast Cancer

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 SWOG Operations Center;
- the SWOG 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 SWOG 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?

SWOG 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. SWOG 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 SWOG 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: _____